A critical analysis of the reform of the pharmaceutical sector in Iran, with specific reference to the regulatory framework

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A Critical Analysis of the Reform of the Pharmaceutical Sector in Iran, with Specific Reference to the Regulatory Framework

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March 2018
I certify that the work presented in this thesis is, to the best of my knowledge and belief, original, except as acknowledged in the text, and that the material has not been submitted, either in whole or in part, for a degree at this or any other university.

I acknowledge that I have read and understood the University's rules, requirements, procedures and policy relating to my higher degree research award and to my thesis. I certify that I have complied with the rules, requirements, procedures, and policy of the University (as they may be from time to time).

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Abstract

This thesis examines the theoretical and empirical case for reform of Iran's pharmaceutical sector, based on the responsive regulatory and human rights approach. It outlines a conceptual regulatory framework that integrates previous Iranian pharmaceutical regulatory strategies by highlighting the need to interweave the different economic, political and legal aspects of the regulatory system. The thesis emphasises the role of cooperative governance and the far-reaching concern for public health in moving towards reforming the pharmaceutical sector in Iran. It also examines the issues that either hinder or facilitate the implementation of reforms and discusses how an understanding of the context and capacity of the pharmaceutical industry is critical to delivering change in the regulatory regime. This research supports the view that a mass, private pharmaceutical sector in Iran is not, necessarily, more profitable, accountable, or effective than the public pharmaceutical sector. It argues that mass privatisation implemented in economic isolation simply cannot deliver the much-needed panacea for the pharmaceutical industry's woes because it will increase the price and decrease the accessibility of medicines for Iranian citizens. Since the institutional fundamentals to support or regulate private activities are entirely missing in Iran, rapid privatisation of the pharmaceutical sector cannot avoid regulatory capture, and corporate governance may decrease and lead to a loss of ultimate control over the privatisation process and its prescribed goals. The speed of privatisation should then be coordinated with the gradual strengthening of institutional infrastructure. This research thus recommends applying a combination of the old government-planned system and modern market-oriented forces, which can be achieved by adopting responsive pharmaceutical regulations and increasing the participation of non-governmental actors. To counter the ills associated with privatisation, it is still possible for the Iranian Government to achieve gradual and partial privatisation, while still retaining a centralised ownership base, in order to meet the development goals indicated in Iran's 20-year National Vision Plan (2005 –2025).
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Abbreviations

CESCR – Committee on Economic, Social, and Cultural Rights

EU – European Union

GATT – General Agreement on Tariffs and Trades

GDP – Gross Domestic Product

ICESCR – International Covenant on Economic, Social, and Cultural Rights

IP – Intellectual Property

IPRs – Intellectual Property Rights

IMF – International Monetary Fund

NGOs – Non-governmental Organizations

OECD – Organization for Economic Cooperation and Development

TRIPs – Trade-Related Aspects of Intellectual Property Rights

UDHR – Universal Declaration of Human Rights

UN – United Nations

UNDP – United Nations Development Program

US – United States

WHO – World Health Organization

WTO – World Trade Organization
Chapter 1 – Introduction

1.1 Research Context

In recent years, a significant number of developing countries with transitional economies have implemented policies aimed at reforming their economic and regulatory structure. In so doing, the privatisation of pharmaceutical systems has been used as a method to enhance the performance of the public sector, cut the budget deficit and increase economic growth. Some scholars are of the view that because of the poor performance of public enterprises, which pursue political objectives vs. efficiency maximisation, privatisation of pharmaceutical regulation is inevitable, particularly in developing countries irrespective of their political or legal systems.

An essential claim for privatisation is that the transfer of ownership from public to private hands will conclusively lead to an improvement in economic efficiency and, hence, financial performance. In recent years, the trend has been towards the privatisation of pharmaceutical strategies, a process that requires reforming national legislation. Proponents of privatisation justify the necessity of pharmaceutical sector privatisation in a globalised economy by noting the fact that economic globalisation causes legal changes in both domestic and international arenas. The economic globalisation demonstrated through changes in international trade, national political culture, the scientific standard-setting and intellectual property rights (IPRs) in pharmaceutical development, the impact of industrial innovation strategies on

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1 The pharmaceutical industry discovers, develops, produces, and markets pharmaceuticals for use as medications. Pharmaceutical companies may deal in generic or brand medications and medical devices. For more, see John Abraham, H. Lawton Smith and Helen Lawton Smith, Regulation of the Pharmaceutical Industry (Springer, 2003). Transition is a process during which a country shifts from a planned economy to market economy. Lídia Csizmadia and Erik Strøjer Madsen, 'The Transition Economy of Hungary between 1990 and 2004' (2008), p 1.


regulatory practices’ confidentiality and public responsibility of regulators, patent protection, and pharmaceutical pricing have resulted in new concerns for countries developing pharmaceutical regulations. In this regard, the World Trade Organization (WTO’s) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) has particularly affected international and national pharmaceutical regulation. TRIPs is an attempt to reduce gaps in the way Intellectual Property Rights (IPRs) – including those in the pharmaceutical area – are protected around the world and to bring them under common international rules.

Undeniably, the requirement for large volumes of commerce to achieve greater levels of growth and development remains the primary motivation behind developing countries’ interests in participating in the multilateral trade system. However, such global economic unification and the implications of the TRIPs Agreement’s provision on pharmaceutical patents have caused concern in developing countries. In tension with the objective of development is the related requirement to abdicate government freedom to follow policies assumed to encourage innovative domestic activity in a manner that conflicts with the pre-TRIPs Agreement. Intellectual property (IP), as preserved in the TRIPs Agreement, directly involves a critical and persistent demand by developing countries; that is, the freedom to use trans-national technology flows to achieve socio-economic goals.

Developing countries may stagnate if they upset the balance between the IP rights regime and the level of economic development. Therefore, for developing countries to implement and abide by the TRIPs Agreement, pharmaceutical IPRs must align with existing economic and regulatory structures to promote domestic technological

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4 The WTO is a 151-member organisation which acts as a forum where countries can reach agreement on lowering tariffs on foreign trade. The major role of the WTO is to create an enabling environment for businesses which provide goods and services to conduct commerce freely. World Trade Organization, What is the WTO? https://www.wto.org/english/whatwto_e/whatis_e/whatis_e.htm (last access: 23/01/2017). TRIPs agreement is an international agreement administered by the WTO that sets down minimum standards for many forms of IP regulation as applied to nationals of other WTO Members. World Trade Organization, Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, Morocco, 15 April 1994.


8 Ibid.
innovation and capital development. In other words, without an accurate and well-organized property system, free-market capitalism, a secure economic atmosphere for investment and protection of corporate interests it is improbable that IP, in and of itself, has the potential to transform developing countries into the pharmaceutical providers these countries hope to become. Consequently, the likely success of TRIPs Agreement enforcement, and of IPRs in general, will depend on the degree to which each developing country has implemented reforms that are to some extent consistent with free market principles.

The emphasis is on the inherent conflict that exists between the public health objective of access to affordable, high-quality essential medicines and the pharmaceutical industry’s policy objective of developing a thriving, profitable pharmaceutical industry. By considering the TRIPs Agreement as an integral part of the WTO’s system, there is debate surrounding the possibility of pursuing the traditional governing strategies (i.e., a centralised pharmaceutical regulatory system) within the TRIPs Agreement regime. From one perspective, argue that considering medicine to be an industrial commodity may put the health of patients at risk. They base their assertions on the recognition of citizens’ right to health by preventing, treating and controlling disease, and by ensuring access to health facilities, goods and medical services.

Access to medicines is fundamental to the realisation of human rights. Since the pharmaceutical sector is an integral part of the health care system, the World Health Organization (WHO), as a guardian of the public interest of health, has paid significant attention to the accessibility of medicines. From the 1978 Alma-Ata Declaration to the current announcement of the Sustainable Development Goals, WHO has attempted to improve health in developing countries through a focus on

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9 See generally: John Abraham and Helen Lawton Smith, Regulation of the Pharmaceutical Industry (Palgrave Macmillan, 2003).

10 Gana, above n 7, p 737.

11 Paul Cook and Martin Minogue, ‘Waiting for Privatization in Developing Countries: Towards the Integration of Economic and Non-Economic Explanations’ (1990) 10(4) Public Administration and Development 389, p 393.


Chapter 1 – Introduction

disease-oriented programs. Improving access to medicines is one of the United Nations (UN) Sustainable Development Goals (Goal 3) to save millions of people from diseases by boosting economic growth and social development and ensure healthy lives and promote well-being for all at all ages. This is mostly because without equitable access to medicines for priority diseases—especially for HIV/AIDS, tuberculosis and malaria—the fundamental right to health cannot be fulfilled. WHO, as the ‘Health for All’ paradigm’s main sponsor, has not been traditionally supportive of pharmaceutical sector privatisation in developing countries. WHO has also been attempting to regulate pharmaceutical regulation in the WHO Member States, urging governments to consider the human right to health as one of the central concerns in the national health debate. To make the interconnectedness of the right to health with pharmaceutical accessibility more transparent, the concept of essential medicines—introduced and developed by WHO—has become the decisive factor interrelating the human rights area with the commercial sphere.

Nonetheless, the global pharmaceutical market is quite competitive. Influential research postulates that, from an economic point of view, manufacturing of medicines makes sense only in larger, middle-income countries with a significant domestic market, solid regulation and sufficient technological know-how. However, in political reality, decision-makers find simply exposing their national industry to global market forces a difficult proposition. That difficulty leads to a range of direct and indirect measures aimed at protecting the national pharmaceutical industry. Some of these measures are more problematic in terms of public health than others. For example, any double-standard or low standard in enforcing quality directly affects medicine efficacy and safety and therefore health outcomes. Accepting higher prices for medicines than the open market would mean that the sick


and vulnerable cross-subsidise a business sector that otherwise might not be competitive. Consequently, a sound industrial policy should focus on policy measures that place the burden on the general taxpayer.

Most countries with a significant pharmaceutical industry today would likely want to maintain this industry in the long-run, and at the same time achieve the world standard in medicine quality. The latter is essential for having the option to export to an increasing number of markets, which is a necessary part of a long-term business plan for many companies, particularly where they do not have sufficiently large domestic markets. National governments usually combine short-term measures (e.g., subsidies, price concessions and regulatory tolerance) with long-term strategies that include fixed deadlines for achieving regulatory benchmarks spread over a period of several years. Reliable and comprehensive pharmaceutical strategies can promote health by increasing access to essential medicines, improving their safety and enhancing their rational use. Accordingly, a pragmatic approach to reconciling public health and industrial policy based on the preceding considerations should always start with an agreement on the long-term objectives.

However, since the pharmaceutical sector is still heavily regulated in many developing countries, mismanaged, decentralised pharmaceutical systems and uneven reforms in many transitional countries may introduce instability into health-related organisations, thereby increasing opportunities for corruption in the pharmaceutical sector. The appropriate governmental interventions can be implemented by fighting against systemic corruption and unethical practices in these countries, along with improving transparency to enhance the standard of the national health sector and pharmaceutical industry. Therefore, by introducing the pharmaceutical guidelines, WHO seeks to assist and encourage its Member States to make their pharmaceutical sector strategies more purpose-oriented.

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19 Ibid, p 117.
20 Ibid, p 115.
Privatisation of the Pharmaceutical Regulatory System: The Case of Iran

A noticeable direct or indirect presence of government in different financial sectors, including manufacturing and services, has been a characteristic of Iran’s financial sector. However, Iran’s economy is currently at a crossroads. Three decades after the Islamic Revolution (1979), Iranian policy-makers, who assumed responsibility for managing the national pharmaceutical system in the 1980s, modified their policies. Therefore, in compliance with the recommendations prescribed by the World Bank and the International Monetary Fund (IMF), the Iranian authorities have started a national plan for establishing a more relaxed and market-based pharmaceutical market.

The most prominent policy agenda introduced during that time was the pharmaceutical privatisation strategy to distance the government from direct involvement in business through:

- improving the operational efficiency of private pharmaceutical enterprises and their contribution to the national economy;
- reducing the financial/budgetary burden on the government; and
- allowing the government to concentrate public resources on its role as a provider of essential public health.

In so far as the Iranian Government’s quest is consistent with the above primary objectives, the pharmaceutical reform intends to ensure that pharmaceutical privatisation meets the following secondary targets:

- to create a more market-oriented economy;
- to secure enhanced access to foreign markets, capital and technology;
- to promote the development of the capital market, and

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23 Structural Adjustment Programs’Structural Adjustment Programs consist of loans provided by the IMF and the World Bank to countries that experienced economic crises. For more see: William Easterly, IMF and World Bank Structural Adjustment Programs and Poverty in Managing Currency Crises in Emerging Markets (University of Chicago Press, 2003) 361.

However, public ownership structures are central to privatisation decisions in Iran and, despite implementation of the national scheme for privatisation of the industry, the majority of the local pharmaceutical market is still in the hands of semi-governmental organisations. For political and economic reasons, after the Revolution Iran restricted foreign investors to minority equity participation, which has excluded the country from a source of new capital, markets and technology. The government is still the main actor in the national economy and the centralised regulatory system of Iran is heavily controlled by the government. The broad authority of the central government and weak economic indicators (and further distortions caused because of Western economic sanctions) have constrained Iran, forcing it to reconsider its growth forecast. There is also no clear distinction between the public and private sectors in Iran's national economy in general, and in its pharmaceutical industry in particular. Therefore, even though private pharmaceutical companies have gained more market share in Iran in recent years, their share in the local pharmaceutical market is still low. In such circumstances, the government has delegated some authorities to other government bodies or semi-governmental entities which are, directly or indirectly, supported by the central government. The decision of the government to transfer some authorities and financial sources to these entities has led to decentralisation of some major industries including the pharmaceutical industry in Iran.

What is worth clarifying here is that, while the state-oriented economy of Iran restricts economic competition in the country, the Iranian Government aims to call such a reform privatisation. Such changes cannot be defined as privatisation because privatisation only may occur where there is a competitive economic atmosphere in which the strong private sector can contribute to the economic activities and growth of a country.

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competitions. The effect that privatisation could have on the already non-existent wealth dynamics\textsuperscript{29} explains why implementing privatisation policy has been slow in Iran. Since any objective in policy-making must be ‘SMART’ – that is, Specific, Measurable, Realistic, and Time-bound\textsuperscript{30} – the most recent 2017 IMF Country Report reveals that the implementation of pharmaceutical reform in Iran has not been systematic and efficient and, so far, has not translated into significant improvements – neither in private sector improvement or in productivity\textsuperscript{31} It can be argued that, had there been reasonable and fundamental preparations taken before launching the economic policy reform, Iran’s economic reform process could have been carried out in a more effective manner and yielded improved results than have been achieved. In fact, what is termed privatisation of industries in Iran is not the actual privatisation, but it is decentralisation. In this thesis, since privatisation is used as in the literal sense (not in the Iranian sense which is decentralisation), the thesis seeks to analyse the implications for privatisation in the event of the Iranian Government deciding to privatise the major sectors, including the pharmaceutical sector. The thesis also argues that according to the current economic, political and structural situation of Iran, adopting a rapid approach towards policy reform will not be an effective option for Iran and leads to policy failure. All the issues reviewed above make Iran’s pharmaceutical privatisation experience even more worthwhile to evaluate.

1.3 Literature Review

There is a significant amount of literature on the subject of privatisation. Many of these studies have a narrow, but deep, evaluation approach of privatisation and focus on one or only a few aspects, for example, pharmaceutical regulation and the type of privatisation strategy used in each country,\textsuperscript{32} the level of production or the efficiency

\textsuperscript{29} An intuitive system which equips entrepreneurs with links to the growth stages in business, giving clarity on leadership succession and links to country, industry and lifestyle trends, giving clarity on when winning formulas become losing formulas by providing essential formulas for step-by-step actions to reach wealth. See: Travis J. Lybbert et al, ‘Stochastic Wealth Dynamics and Risk Management among a Poor Population’ (2004) 114(498) The Economic Journal 750.


\textsuperscript{31} International Monetary Fund, ‘The Islamic Republic of Iran, Selected Issues, Report No. 17/63’ (2017), p 40.

of private enterprises. While the rapid extensions by the government to rate and entry regulations in the pharmaceutical sector have been followed by regulatory control, relatively little research assesses the behaviour and performance of the governmental agencies.

The conceptual basis for government intervention lies in market imperfections caused by costly and inexact information about the consequences of economic decisions. A substantial amount of theoretical research into externalities (a result of an industrial/commercial activity which affects other parties involved without being reflected in market prices), information costs, product quality, consumer misperceptions and moral hazards underlies a general case for government intervention in the pharmaceutical area. Public interest theory is usually applied to explain regulation as an aim for economic efficiency. Furthermore, it can be necessary to correct undesirable market results for reasons other than economics, for example, considerations of justice, motives or ethical principles. Such disparate regulatory activities are pursued to protect parties to private market transactions from making decisions that are not profitable.

However, empirical relevance of market imperfections has proved difficult to document because the information that is needed to measure it cannot be easily inferred from market transactions. Deciding on the instruments to be used and the ability of government regulatory agencies to deal with the given issues efficiently is still a matter of debate. It is debatable why regulation, rather than a change in the institutions (e.g., for financing, health or pharmaceutical care), is necessary.

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35 The notion of public interest can be described as the best possible allocation of scarce resources for individual and collective goods. See: Bronwen Morgan and Karen Yeung, An Introduction to Law and Regulation; Text and Materials, Cambridge University Press (2007).


38 Some of the relevant research includes: Anthony E. Boardman and Aidan R. Vining, 'Ownership and Performance in Competitive Environments: A Comparison of the Performance of Private, Mixed, and State-Owned Enterprises' (1989) 32 JL & Econ. 1, Jean-Jacques Laffont and Jean...
reviewing the available studies, the two main alternatives to public governance in the pharmaceutical area emerge, including an approach that advocates the role of private management and another that recommends a cooperative public–private model.

1.3.1 Private Management Model

Privatisation means greater reliance on society’s private institutions (e.g., the marketplace and its participants, voluntary associations, social services, health, and education) and less dependence on government to satisfy people’s needs. Emanuél Savas defines privatisation as the act of reducing the role of government or increasing the role of the private institution of society in meeting people’s needs. In privatisation, either the government eliminates direct control, ownership of the function and the delivery of services (full privatisation), or it preserves some influence by holding stock in the privatised company. The intention in all such arrangements is that the regular production and delivery of goods and services will be left to private operators, and thus the market and the government’s involvement will be regulatory.

As a reform strategy, privatisation is based on a market-to-market system, in which the policy-makers should evaluate the applicability of the policy and then, gradually, start deregulation of the market. In this strategy, as Morgan and Yeung argue, the need for administrative management and public decision-making are replaced by market competition as a mechanism for achieving coordination and advancing public
goals. This is because, in the absence of a competitive market to monitor the monopolistic institutions, handing over government entities to the private/semi-government sector is simply a transfer of monopoly from the government to the private/semi-government sector.

Based on a survey of literature supporting private management, there is ample evidence of the regulatory failures when governments cannot entirely relinquish their responsibilities, and when an organisational problem requires an official response. By examining the valuation of corporations, some studies claim that private pharmaceutical companies perform better than public and mixed-ownership pharmaceutical companies. According to the findings of these studies, corporate value with small government shareholdings decreases with the fraction of government shareholding but rises when the government is a significant shareholder. Accordingly, private pharmaceutical companies are significantly more profitable than public enterprises and have lower levels of liability and fewer labour-intensive production processes than do their governmental counterparts.

There is also a link between ownership and company-specific rates of productivity growth, which differs in public and private pharmaceutical enterprises, and such a causal relationship goes from ownership to productivity, and not vice versa. Based on this view, a 'partial' change from government ownership to private ownership has little effect on the long-term productivity growth, the benefits are based on 'full' privatisation of the company. The change from complete government ownership to private ownership in the 'long-run' would increase productivity growth and reduce costs, and these differences are not affected by the degree of market competition or regulation. In fact, the 'short-term' effects of changes from the government to private ownership on productivity and costs remain vague. Also, in regard to the

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44 See generally: Morgan and Yeung, above n 35.
49 Ibid.
performance of private and public pharmaceutical enterprises in transitional economies, the literature review reveals that the average effect of privatisation is that it works, that is, private pharmaceutical enterprises perform better than their peer public companies.\textsuperscript{50}

In accordance with the available empirical results of privatisation in developing countries, there is little evidence that private pharmaceutical sectors experience weak or unstable performance.\textsuperscript{51} In other words, private enterprises operate better than public enterprises with high income per capita and for companies whose governments surrender voting control.\textsuperscript{52} According to this extant research, privatised pharmaceutical companies in most developing countries are more profitable, can increase their real sales and investment spending, and improve their efficiency.\textsuperscript{53} Privatisation also enhances the financial and operating performance of companies, and this advancement is the result of valuable improvements in production efficiency and continuous effort.\textsuperscript{54}

However, the success of the privatisation program in a country depends on the strength of the markets within that country, and vice versa.\textsuperscript{55} The developing government’s real intent in privatising a public enterprise can be measured by examining its recent record, or probable actions, concerning structural reform.\textsuperscript{56} Structural adjustment has become an integral part of the development strategy for

\textsuperscript{50} Although they show that while privatisation improves performance, the effect is limited to certain measures of performance and in cases where the public enterprises are sold to outside owners. Roman Frydman et al, 'When Does Privatization Work? The Impact of Private Ownership on Corporate Performance in the Transition Economies' (1999) Quarterly journal of economics 1153


\textsuperscript{53} Djankov and Murrell, above n 51 51.


\textsuperscript{56} For example, in the absence of other reforms that affect the pattern of relative prices in the economy and increase competition, the privatised enterprise still faces the same prices as the public enterprises before it. Privatisation by itself will not change the nature of the market in which the company operates, and the environment which shapes its pricing decisions. Nicolas Van De Walle, 'Privatization in Developing Countries: A Review of the Issues' (1989) 17(5) World Development. 601.
many countries. However, it usually takes longer than originally anticipated. Webb and Sharif take the view that some reforms should be implemented quickly, whereas some others may need more time.57

According to the World Bank:

Gradualism may sometimes be justified when reform faces particularly large economic uncertainties. And by nature, some reforms take longer than others. However, swift actions bring the benefits of reform more quickly. Speed also makes sense if the political opportunity for reform is unlikely to last. Gradualism may not be feasible for economies in acute crisis or governments with limited credibility.58

Thus, there are two general arguments in this regard. One group of scholars suggests that rapid reform is more sustainable politically because it can 'head off the formation of interest groups,'59 and as Fisher and Gelb stipulate:

A slower pace may lead to prolonged uncertainty and a longer period of poor performance, during which opposition forces can be formed to block the reform process. A rapid approach in which markets are liberalised even before adequate preparation avoids the danger of delay but raises the potential for chaos.60

According to this view, rapid, decisive reform is more credible.61 Active monetary policy reform, for example, requires rapid implementation of policies that are consistent, transparent and nondiscretionary. A rapid approach preceded by the announcement of a comprehensive reform plan shows the determination and commitment of the government to improve. For privatisation reform, a rapid approach provides a critical scale for the privatised companies to be efficient.62 Moreover, rapid change avoids the distortions, intertemporal speculation and

57 Steven B. Webb and Karim Shariff, 'Designing and Implementing Adjustment Programs' (World Bank, 1990), p 81.
60 Ibid, p 104.
61 Jeffrey Sachs and David Lipton, 'Poland’s Economic Reform' (1990) 69(3) Foreign Affairs 47.
hoarding of goods often induced by gradual or partial price reform and corruption.\textsuperscript{63} A rapid approach to privatisation also cuts subsidies to the public sector sufficiently to force public sector workers to reallocate to the private sector. Sachs and Woo, using a three-sector labour allocation model with substantial subsidies to governmental workers, show that only a big cut in grants forces public sector workers to shift to the private sector, invigorating the economy.\textsuperscript{64} According to their argument, in a country without excess labour, small cuts in subsidies or partial reform will not lead to labour reallocation and, as such, the non-government sector will not grow.\textsuperscript{65}

On the other hand, the most persuasive argument for gradualism is its avoidance of excess, and its not too steep reduction in living standards\textsuperscript{66} and too great a cost to the government budget.\textsuperscript{67} Rapid reform is not economically necessary unless macroeconomic imbalances are severe.\textsuperscript{68} In that way, gradual change is also more sustainable politically.\textsuperscript{69} A gradual approach that works at the margin removes constraints on market behaviour and permits experimentation.\textsuperscript{70} Even partial reform can promote productivity in an industry.\textsuperscript{71} By allowing trial and error and mid-course adjustment, progressive improvement is particularly appropriate when results are uncertain, as in intergovernmental fiscal relations, large-scale privatisation and other reforms of property rights.\textsuperscript{72} Poor source conditions also call for a gradualist approach to the privatisation of major public enterprises.\textsuperscript{73} However, while rapid

\begin{itemize}
\item Ibid.
\item Gelb, Jefferson and Singh, above n 68.
\item World Bank, above n 2323.
\item Wang, above n 66, Wei, above n 69, Wei, above n 69.
\end{itemize}
privatisation may not be necessary for successful reforms, measures to diversify ownership and encourage the entry of new private companies are critical. Privatising large public enterprises and opening capital markets require institution building, regulatory reform and the development of human capital; changes that can only be implemented gradually. Hence, it is impractical to expect policy measures to have a quick impact on growth. However, where theory and experience show the benefits, and where the results are uncertain or politically difficult to accept, the decision to reform can be issued quickly but cautiously at the beginning, even if implementation takes years.

1.3.2 Cooperative Public–Private Model

While many economies have looked to private-enterprise regimes as a cure for their economic problems, many privatisation objectives have not been achieved in transitional economies. The impact of privatisation differs across countries depending on the power of the current private sector and factors other than ownership in determining a company’s performance (e.g., the lack of regulatory structure and institutional capacity). In such situations, available results are evidence that, even in a competitive environment, if the government has no agenda other than as a passive investor, factors other than ownership determine a company’s performance. Hence, there may be no significant difference between the performance of public and private

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74 Gelb, Jefferson and Singh, above n 68.
76 Ibid, p 31.
pharmaceutical companies, but rather private companies operating in competitive industries, are forced to run efficiently.\textsuperscript{79}

Underestimating the clear distinction between privatisation (narrowly defined as a class of institutional reform) and liberalisation (as a change in the relative prices operating in the economy) has also caused policy failure in many transitional countries.\textsuperscript{80} The interconnectedness of economic liberalisation and privatisation reveals how, in the absence of other policy reforms that increase competition in the economy, the impact of privatisation on economic efficiency is likely to be modest.\textsuperscript{81}

Moreover, although slow privatisation progress is attributable to economic constraints,\textsuperscript{82} responses to pressure for economic reform will be determined not so much by economic criteria as by the political and bureaucratic resources available to decision-makers.\textsuperscript{83} The substantial role of externalities, the critical role of pharmaceutical quality and the high level of knowledge required to participate in the health care system at all levels have important implications for the design of pharmaceutical policy in general, and for a privatised system of the provision of services and sector management in particular.\textsuperscript{84}

Some studies have investigated how to improve the performance of pharmaceutical public enterprises in developing countries, which often undergo accelerated/unplanned structural adjustment programs and incorporate a host of economic policy reforms over a short time, by improving public enterprises and increasing public–private cooperation.\textsuperscript{85} The evidence shows private sector participation is not a departure from historical patterns of governance, but an

\textsuperscript{79} Ibid.
\textsuperscript{80} Mick Moore, 'Economic Liberalization versus Political Pluralism in Sri Lanka?' (1990) 24(2) Modern Asian Studies 34.
\textsuperscript{81} Van De Walle, above n 56.
\textsuperscript{82} Michael R. Reich, 'The Politics of Health Sector Reform in Developing Countries: Three Cases of Pharmaceutical Policy' (1995) 32(1) Health Policy 47.
\textsuperscript{83} Cook and Minogue, above n 11.
extension of the interdependence of the public and private sectors. The national pharmaceutical policy in many developing countries serves as a framework within which public–private parties cooperate with each other to satisfy the public interest. Thus, authoritative responsibilities can be shared using a complex array of interdependent institutions, rather than a hierarchy in which top-down, state-run mechanisms legitimate the activities of regulatory actors. The cooperation between the government and the private sector can improve competition in the pharmaceutical system and reduce the risk of market failure. In essence, privatisation and public–private partnerships reflect market principles and together constitute a strategy for improving public management.

Nonetheless, privatisation reform may be maintained for the sake of industry by corporate bias within the regulator and the new patient–industry context. Hence, any political, economic or structural changes need to redirect pharmaceutical regulation in the interests of health. A different way to view privatisation is to introduce privatisation as a mechanism for governmentalisation, where private actors progressively commit themselves to commonly public goals as the price of access to opportunities to deliver goods and services that might alternatively be provided directly by the government. Privatisation might extend these rules to private participants through budgeting or regulation.

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87 World Health Organization, Essential Medicines and Health Products http://www.who.int/medicines/services/inn/en (last access: 02/04/2015).
89 The advocates of private systems emphasise the value of competition. They argue that health care 'would appear to have no characteristics that differentiate it, sharply, from other goods in the market' and should be under market mechanisms. Conversely, the advocates of public systems emphasise the 'market failures' and avoiding generalisation from other sectors. Barbara McPake and Anne Mills, 'What Can We Learn From International Comparisons of Health Systems and Health System Reform?' (2000) 78(6) Bulletin of the World Health Organization (WHO) 811, p 815.
90 Emanuel Savas, Privatization and Public-Private Partnerships (Seven Bridges Press, 2 ed, 2000), p 15.
The government, nonetheless, influences economic activity not only indirectly using taxes and transfers, but also directly by owning many companies. This direct business of the government varies over time between countries and often includes waves of nationalising and privatising government companies. One could see waves of nationalisation after World War II, in both Eastern and Western Europe, and waves of privatisation in the same countries in the 1980–90s. Apart from these broadly observed waves, there seem to have been minor ones in some countries (e.g., in France), and more than one wave in some industrialising and developing countries (e.g., Mexico). Building on this anecdotal evidence, some research has dealt with fluctuations over time in the size of the government-owned company sector.

In several transitional economies, governments have conducted a round of privatisation followed by expropriation and nationalisation. According to the available data, this cycle in resource-rich economies is a prime instance of unstable institutional reform, and the primary trade-off is given by equality (public ownership) vs. efficiency (private ownership). As argued in the literature, the nationalisation–privatisation cycle can make privatisation of the pharmaceutical sector a risky reform policy in transitional economies. The connection between resource ownership and the equality-efficiency trade-off depends on external (e.g., the commodity price) and internal conditions (the tax system) that affect the value of social welfare under each regulatory regime. Based on the available findings in this regard, executive power and legal entrenchment are two legal mechanisms that impact the privatisation-nationalisation cycle. Large grants of executive power and a lack of legislative

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94 Mexico pursued a postcolonial free market system without many government companies until 1910. Then in its revolutionary period, from 1910–1940, Mexico nationalised extensively, mainly foreign-owned private companies, only to privatize and let in more private foreign companies again from 1940 to 1958. This was followed by nationalisation, culminating in 1982, when virtually all banks were taken over by the government; finally, Mexico started to privatize again after 1983. Ibid, p 4.

95 Chua, above n 77.


98 Chang, Hevia and Loayza, above n 96.

99 Siegmund, above n 93.
reinforcement allow governments to change private property rights rapidly, through shifting economic regimes from privatisation to nationalisation.\footnote{Enrico C. Perotti, 'Credible Privatization' (1995) \textit{The American Economic Review} 847, Francesca Cornelli and David D. Li, 'Large Shareholders, Private Benefits of Control, and Optimal Schemes of Privatization' (1997) \textit{The RAND Journal of Economics} 585, Maxim Boycko, Andrei Shleifer and Robert W. Vishny, 'A Theory of Privatisation' (1996) \textit{The Economic Journal} 309.} By establishing legal restrictions and safeguards on the executive power and developing legislative power, transitional economies are more likely to promote private property rights and foster economic development in their countries.\footnote{Kapoor, above n 97.}

The reviewed literature provides invaluable insight into the potential benefits and drawbacks of pharmaceutical sector privatisation, the effects of public–private cooperation in the pharmaceutical regulatory system, available methods for implementing privatisation, the role of government in the regulatory reform process, the human rights concerns in regulatory reform, and evaluating pharmaceutical regulatory reforms from various parts of the world. The present thesis contributes to existing knowledge by evaluating privatisation as a pharmaceutical reform strategy in the Iranian regulatory system, as a middle-income country with a transitional economy. It assesses the effects of significant and recent economic changes, for example, the pharmaceutical generic system, the irrational use of medicines and the increased use of product patents, the effects of removing economic sanctions on the national pharmaceutical market, and the upcoming issues related joining the WTO. The fact that there have been no comprehensive studies about the given problem in the current Iranian pharmaceutical regulatory system enhances the novelty of the present research.

1.4 Research Questions

The Iranian Government has been undertaking a range of miscellaneous economic policy reforms to improve its current state-controlled pharmaceutical regulatory regime. Meanwhile, there is a concern that mass and rapid privatisation of the pharmaceutical sector will put the structural system in a dubious position. Since this issue is of growing interest, the present research seeks to determine whether the full and rapid privatisation of Iran’s pharmaceutical system is the optimal choice and meets the government’s reform policy agenda.
Therefore, the main research questions are as follows:

RQ 1: How has pharmaceutical sector privatisation been carried out in Iran towards meeting the stated objectives by the Iranian Government in the Iranian Constitution, the Development Plans and Iran’s 20-year National Vision Plan?

RQ 2: What are the ‘structural rigidities’ and the origins of regulatory reform policy failure in Iran?

a) What are the reform implications for the Iranian pharmaceutical sector in the Post-sanctions Era?102

b) Which challenges should the Iranian pharmaceutical industry overcome in order to join the WTO?

RQ 3: Which model of regulatory reform strategy can enhance the pharmaceutical private sector’s participation in Iran’s pharmaceutical regime?

1.5 Research Objectives

Privatisation is a valid administration tool and one of the most important factors in increasing the use of the market to allocate resources through the interaction of free and self-directed market forces. During the past decade, many developing countries have been undertaking structural adjustment. However, the success of market reforms depends on how quickly countries can develop necessary institutional and market-specific capital. While rapid actions bring efficiency gains more quickly, for socio-political as well as economic reasons evaluating the experience of developing countries leans towards gradualism.103 Where macroeconomic imbalances or the structural problems of public enterprises are severe there is little alternative to adventurous and expeditious actions. Hence, to choose and implement any kind of

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103 Umali and Maguire, above n 75, p 26.
reform one must first consider the timing of the changes (whether to initiate them before, during or after a crisis, for example), and the scope of the policies (whether they should be comprehensive or partial).  

The present research argues that now that the Iranian policy-makers intend to apply privatisation as a reform policy, such a reform should be done well. This research, thus, examines how problems brought about by rapid pharmaceutical sector privatisation come to the fore in Iran’s slumping economy, where the market system and its associated institutions are not entirely developed. It also investigates the impact of the private/public regulatory institutions on the pharmaceutical sector’s performance in Iran and seeks to learn the lessons derived from other developing countries’ privatisation experiences. Therefore, instead of pointing to the expansion of privatisation of the entire pharmaceutical sector as an inevitable change, the main objective of this research is to evaluate which model of regulatory reform could enhance the private sector’s participation in Iran’s pharmaceutical system.

1.6 Research Methodology

The government has ultimate power, because it enjoys a special position with regard to individuals, regulates the lives of people and provides them with many services. Such a position leads to two things: power and opportunity to both violate and promote human rights. However, power alone is not sufficient to violate or promote human rights, there must also be opportunities to do so. Over the years, this position of the government (the principal status as human rights violator and promoter) has decreased as non-governmental actors have acquired a similar position due to the delegation of powers and functions by governments in a globalised and free market economy. In such a scenario, it would mean that governments can bypass their human rights obligations by privatising and outsourcing their activities to private companies. This is an unsound and unsatisfactory premise for any theory that seeks to humanise business.

104 Ibid.

105 This thesis is concerned with the broad meaning of privatisation, where the role of government in the economic sector is limited, while that of the private sector is deliberately expanded. In the strict sense, the term privatisation means a shift of productive activities from the public sector to private sector ownership and control. Paul Starr, 'The Meaning of Privatization' (1988) 6(1) Yale Law and Policy Review 6, p 9.
The business approach perceives pharmaceutical industries primarily as economic entities and logically places profits at the top, as reflected in the financial statements. This approach is grounded in the well-known assertion that the only social responsibility of business is to increase the profits for its shareholders. As stakeholders' profit maximisation guides the business approach, the protection and promotion of stakeholders' human rights are not in themselves considered a profit that can be quantified in dollars. Hence, the business approach does not take a principled stand regarding human rights; it is profit that determines whether human rights are to be respected and, if so, then which standards are to be followed. The business approach introduces 'cost and benefits' analysis to human rights discourse by connecting the pharmaceutical industry's compliance with human rights obligations to financial profits. However, any policy approach that requires assigning human rights and life itself as a measurable value and encourages a trade-off between human rights and other goals is questionable.

Over the years, various regulatory theories, strategies, and models have been raised about how the behaviour of targeted subjects can be regulated, and how optimal results as to the implementation, enforcement and internationalisation of given rules can be achieved. Scholars have canvassed regulatory tools, for example command and control, voluntarism, self-regulation, responsive regulation, reflexive regulation, information-based regulation, economism and market mechanisms. In so doing, several theoretical and empirical studies have attempted to investigate the relationship —positive or negative— between human rights issues and the financial performance of public or private pharmaceutical companies. Although the extant results coming from this research have not been conclusive or one-sided, it is increasingly suggested that there is a positive (co-)relationship between human rights issues and the ensuing economic benefits.

'Policy' for this thesis is defined as the conscious attempt of public officials or executives entrusted with public funds to achieve certain objectives through a set of


Chapter 1 – Introduction

Options for policy reform are presented in a way that matches the typical patterns found in the diagnostic process, emphasising the connections that exist between different policy elements. Because the pharmaceutical sector is not usually a homogeneous block and, therefore, needs a combination of policies to address a given problem, a set of typical synergistic policy packages is presented. These bundles need to be combined and sequenced to match the top-level, longer-term policy objectives. In practice, the challenge is to develop a good representation of reality from data sets that can be sketchy or incoherent, complemented by anecdotal information from the field and a skilled interpretation of the political importance of an issue. Reforms that must reduce entitlements are often considered balanced if the level of protests from two opposing sides is equal. However, commercial interest is usually much better organised and better able to express their interests than are citizens (in this case, patients). 

Since no one-size-fits-all approach applies to pharmaceutical policy, even two countries with similar objectives may need different sets of policies, depending on their starting position, pre-existing laws and regulations, perceptions among providers and patients, and implementation capacity. Choices may be even harder for middle-income countries that need to bridge the divide between a demanding urban population and large numbers of poor people in rural areas. At the same time, the growing private markets in these countries may be flooded with medicines of questionable origin and quality. In each case, policy-makers and the implementing agencies need to select and combine their policy measures in a way that not only addresses the main problems conceptually but is also practically viable and sustainable.

This thesis attempts to demonstrate that the business approach will often fail to protect the human rights of people in developing countries, particularly in Iran. Adopting a case study method, this study examines the consequences, interests and networks involved in the Iranian pharmaceutical regulatory system based on descriptive, explanatory and prescriptive approaches. Employing multiple sources of evidence makes this method useful for descriptive research studies (in which the focus is on a given situation/context and where generalisability is less important) and

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109 Seiter, above n 18, p 1.
for describing the implementation of a program or policy.\textsuperscript{111} While the case study method is used for both theory building and theory testing, in this research, where there are several variables of interest, this method is used for theory testing.\textsuperscript{112}

This research seeks to address two specific issues: identify an appropriate theory for regulating the conduct of Iran's pharmaceutical industry and apply the identified theory to develop a regulatory framework.\textsuperscript{113} This study, therefore, deals with the question of a suitable theory. In the current study, the theory of responsive regulation, which is part of the wider critique that the command and control model has attracted in recent times,\textsuperscript{114} has been proven to be highly influential both generally and in the specific context of corporate regulation. The efficacy of responsive regulation is specifically tested in the context of the problem investigated in this thesis: finding a model of regulatory reform that enhances the pharmaceutical private sector's participation in Iran. The thesis then outlines how a regulatory framework based on such a theory could be developed. The evaluation is, also, supported by the experience of other developing countries to demonstrate how useful the rapid approach to privatisation can be in transitional economies. The privatisation experiences of Hungary (1990–2004) and Indonesia (2001–onwards), spanning the years before and after they implemented mass privatization, in general, and in the pharmaceutical context, are examined to expose the challenges that privatisation may cause to transitional economies, as experienced in the case of Iran.

1.6.1 Case Selection Rationale

Especially since the 1980s and after the beginning of the economic and political transition in many developing countries in East Asia, Eastern Europe, Africa, and Latin and South America, the significant challenge faced by policy-makers has been how to reform their economic and regulatory structures. Among the various aspects


\textsuperscript{112} Susan Rose, Nigel Spinks and Ana Isabel Canhoto, Management Research: Applying the Principles (Routledge, 2014).

\textsuperscript{113} In this thesis, regulation is taken to mean the employment of legal instruments for the implementation of socio-economic policy objectives. Thus, the pharmaceutical regulator is the entity that creates and enforces the pharmaceutical rules/regulations. Johan Den Hertog, 'General Theories of Regulation' (1999) Economic Institute/CLAV 223, p 223.

\textsuperscript{114} Christine Parker, The Open Corporation (Cambridge University Press, 2002), pp 8-12.
that can influence governments to adopt pharmaceutical privatisation the most
significant factors are their particular political/administrative circumstance, their past
and the way they went through a transformational and structural change.\textsuperscript{115}

Privatisation as a reform, which often emerges after a drastic structural or regime
change, makes governments reconsider their regulation and enables (if not mandates)
privatisation (usually the rapid approach to privatisation) consistent with their
respective constitutions. Good examples of this situation are the experience of
Indonesia (an Eastern Asian transitional country) and Hungary (an Eastern European
transitional country), which have undergone several reform strategies during the last
three decades. Unfortunately, their initial attempts were a failure. It is, for example,
the Eastern European experience (including the Hungarian process) that has led
Kornai to argue that ‘in spite of generating a whole series of welcome changes,
reform is doomed to fail. The system is incapable of stepping away from its own
shadow. No partial alteration of the system can produce a lasting breakthrough.’\textsuperscript{116}

In addition to their different political, geographical and population size contexts,
there are also important differences among Hungary’s and Indonesia’s backgrounds
relating to the initiation of the reform process, the paths of transition and their
outcomes\textsuperscript{117} These countries are located in two different continents with different
population sizes (Indonesia has a population of 254,454,778 million compared to
Hungary with a population of 9,861,673 million)\textsuperscript{118} and geographical size (Indonesia
is approximately 1,904,569 square kilometers while Hungary is about 93,028 square
kilometers).\textsuperscript{119} While the former is insulated to some degree from disease
transmission across land borders due to its geological shape and hence may impact
its adoption of certain regulatory measures, the latter does not share a similar
geographical situation.

\textsuperscript{115} Csizmadia and Madsen, above n 1, p 1.
\textsuperscript{116} See: Janos Kornai, \textit{The Socialist System: The Political Economy of Communism} (Oxford University
\textsuperscript{117} Fischer and Gelb, above n 59, p 2.
\textsuperscript{118} The World Bank, \textit{Population, Total} \textit{The World Bank}
http://data.worldbank.org/indicator/SP.POP.TOTL (last access: 11/02/2016).
\textsuperscript{119} Worldometers, \textit{Indonesia Population} http://www.worldometers.info/world-population/indonesia-
population/ (last access: 25/12/2015), Countrymeters, \textit{Hungary Population}
1.6.1.1 Why Hungary?

The transition of post-communist countries from a planned economy to market economy and the relatively sudden change of system was simultaneously a big challenge and a big shock. The first thing to understand relating to the communist economy is the fact that the communist system was not a result of a social-economic development, but came into existence as an artificial construction of an ideological model. The starting point of the communist economic system was a theory that denies the market private economy and production and promises total equality. The transformational recession in Hungary was due to the loss of old markets and to the creative destruction that was needed to lay the foundations of a new, healthy market economy on the ruins of a distorted communist structure after recovering from the 50 years of communism.

However, the market forces all its actors into the competition, which ultimately results in winners and losers. To create and maintain this system, the government had to use all its tools of power. One of the main and distinctive characteristics of the communist economy was the radical liquidation of private property and the collectivisation of factors of production. The economic organisations became part of the bureaucratic control of the government, and by forcing economic growth, concentrating on heavy industry and eliminating market influences a command/planned economy was created.

The Hungarian governmental companies were characterised by low efficiency, a lack of motivation and a waste of resources. The centrally planned economy resulted in a misshapen economic framework, falling behind the world standard and causing scarcity. The economic structure of Hungary was marked by many manufacturing and heavy industries. The organisations directly serving industrial production existed typically in monopolistic situations. All in all, at the beginning of the transition period, Hungary as a post-communist country faced a lack of vital infrastructure and low service standards.

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120 Csizmadia and Madsen, above n 1, p 2.
121 Ibid, p 10.
1.6.1.2 Why Indonesia?

Meanwhile, political dictatorship, centralisation and growing economic prosperity littered with ‘crony capitalism’ that gave way to economic uncertainty are some common strains of transition experienced in the Iranian and Indonesian cases. As for the Indonesian economy, shaken by the Asian collapse of 1998 and the events of 11 September 2001, reform appeared to stall. To understand the economic policy debate and prospects for continuing economic development in Indonesia, one needs to look at the institutional legacy of its political system. Over a long period, institutions required of a modern democracy were systematically suppressed and replaced with a centralised authority susceptible to astounding levels of corruption. The emerging economic institutions led to markets with substantial government intervention and crony capitalism. 123 This ultimately contributed to the collapse of Indonesian New Order, leaving current economic policy-makers without the aid of a strong central authority to deal with the remnants of the economic system at the time.124

The ideological position of the Indonesian Government resulted in the creation of an all-powerful presidency guided by a small inner circle of policy advisors. Economic policy was formulated by this inner circle and reflected swings of influence between the market-oriented technocrats and the government planning-oriented economic nationalists. While there were some successes and some failures, all policies were formed in a vacuum, not subject to scrutiny or comment by the public or political rivals, and immune from legal challenges in the courts.125

1.6.1.3 Summary Section

Overall, from an academic point of view, the effects and traces of the political and economic systems in Hungary and Indonesia are very interesting to investigate. Studying each country’s evolution of policy reform can indicate how structural factors have affected the economic performance of these countries in the examined

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125 Cassing, above n 123, p 97.
time-periods. Meanwhile, despite contextual differences, as civil law countries, each country has some political, economic and structural features common with Iran – that can provide evidence of the role of the given factors in the privatisation process. For example, the most important common aspects between Hungary and Indonesia are their: adoption of a command and control economic system as a result of an ideological system, a lack of competition and increase of corruption caused by a centralised system; a highly bureaucratic mechanism, in addition to their political dictatorships; and growing economic prosperity littered with crony capitalism. In addition, both Hungary and Indonesia are countries that chose a ‘mass and rapid privatisation reform’ approach at a time when they were at a critical juncture regarding their economic policy formation.126 This allows one to track their steps against Iran’s current regulatory reform journey.

1.7 Data Collection

Since the discussion and data collection on this topic have been performed by evaluating primary and secondary sources (e.g., international agencies and non-governmental entities), and scholarly databases (e.g., LawOne, HeinOnline, Google Scholar), a further search of the keywords (e.g., privatisation of pharmaceutical sector, transitional regulatory systems, regulatory reform strategies, human right perspective to health and access to medicines) was conducted on the websites of the WHO library database and the World Bank Documents and Reports repository. The study’s reliance on the WHO health system themes enabled the analysis to address the existing research on public and private sectors.

Quantitative data (background information that provides data on the study’s demographics), which was readily available at the intermediate level, was obtained from the Iran Statistics Centre,127 Iran Central Bank,128 Iran Health Status Report129 and Iran Drug Statistics Annual Report.130

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124 Ibid, p 104.
The information about pharmaceutical pricing policy and economic, health and pharmaceutical contexts in which pharmaceutical policy is being implemented were also collected from Iran’s Ministry of Health and Medical Education data portal, and pharmaceutical regulatory affairs information resources, including the Iran Drug and Poison Information Center and the Rational Drug Use/Prescribing Auditing Committee.

1.8 Thesis Structure

This thesis includes six chapters, as outlined below.

Chapter 1 introduces the research context, research objectives, research methodology and data collection, literature review and research questions.

Chapter 2 contains the theoretical framework of the research. In this chapter, some insights into the regulatory theory of one area of international/national law are outlined, that is, the protection of human rights. As argued in this chapter, improved regulation alone is unlikely to avoid a recurrence of crises within economic markets. It is further postulated that one possible approach is to expand the terms of the regulation debate to take account of broader socio-economic linkages and impacts. Advocates of human rights might then be able to show how such an approach would assist regulators to predict market behaviour accurately and better understand the market’s social impacts, which in turn might shift assumptions about financial costs and risks.

Chapter 3 surveys the explanations of regulatory behaviour to show the role of protecting access to medicines –as a part of the right to health– in the context of the pharmaceutical area, by discussing WHO’s strategies. This chapter first outlines the international human rights system and its challenges. It then provides some explanations for the perceived failures of the current regulatory system to affect international/national behaviour in regards with public interest and then introduces some aspects of regulatory scholarship that can enrich approaches to protecting the

human right to access medicines. It concludes by considering the value of the concept of responsive regulation to the field.

Chapter 4 contributes to an assessment of the current policy reforms in the Iranian pharmaceutical sector, regarding their urgency, context, content and effectiveness. The chapter consists of two parts. The first part examines the exigency of the current reforms and provides an analysis of the relative performance of the economy since 1980. The second part seeks to evaluate if current reforms have improved the performance of the pharmaceutical system and have facilitated access to medicines for Iranian citizens by determining the ‘structural trap’ preventing Iran from approaching its full potential regarding economic efficiency. It highlights the structural rigidities of Iran’s economic and regulatory regime, most notably the political uncertainty, legal gaps, systematic capture and corruption, and dominance of inefficient public enterprises in the pharmaceutical area.

Chapter 5 discusses the relative merits of public and private governance by considering the primary drivers of political decision-making and draws some conclusions on what role private, or public management plays or should play in regulating the pharmaceutical system. It also discusses the lessons learned from the privatisation experiences of two other transitional economies (Hungary and Indonesia) to show the side-effects of implementing rapid and mass privatisation without the necessary structural preparedness. Further, some implications for resolving the current problems in the pharmaceutical area and recommendations to improve capacity building in the Iranian pharmaceutical industry are discussed.

Chapter 6 concludes the thesis by providing a summary, offering policy recommendations and identifying opportunities for future research.
Chapter 2 – Theoretical Framework

2.1 Introduction

The path of international law over the last century has increased both the breadth and the depth of its coverage. Its breadth has grown through the addition of new areas for regulation, whether that be the environment, telecommunications, health or human rights, and its depth has expanded through the area seen as falling exclusively within the domestic jurisdiction of governments. Despite its elaborate system of norms and institutions, human rights law often appears ineffective. This is partly because international human rights scholars have tended to focus on law as the sole form of regulation in the field, paying little attention to other forms of human rights influence. This chapter outlines some of the insights into reform that regulatory theory offers to one area of international/national law: the protection of human rights. As argued in this chapter, improved regulation alone is unlikely to avoid a recurrence of crises within economic markets. One possible approach is to expand the terms of the regulation debate to take into account broader socio-economic linkages and impacts. Advocates of human rights might then be able to show that an initiative would assist regulators to predict market behaviour accurately and better understand the market’s social impacts, which in turn might shift assumptions about financial costs and risks.

2.2 Human Rights and Global Economic Governance

In the last two decades, as the influence of human rights has spread, so have disparities in global and national income and wealth. Over the same period, rapid economic globalisation has increased interdependence, a trend mediated and 

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institutionalised by global regimes that organise and oversee trade, finance and development relations. Contemporary capitalism merits attention in the context of these global interdependencies and imbalances. The recent circumstances have often been characterised as a crisis of 'the global capitalist system'. Given the attention paid to the global movement towards a market economy, especially the privatisation of public enterprises, some might conclude that privatisation has almost ended the engagement of public enterprises in world economic activity. The global financial recession of 2008–09, however, has been overwhelmingly viewed as a national and global failure of economic policy and regulation that undermined a range of fundamental rights for people in many countries. For many millions of people living in poverty, the crisis continues.

The global recession arguably heightened the risk for many people living in poverty and put many others at risk, including those in relatively wealthier countries that had less than robust financial regulations coupled with a high degree of global market integration. It has been suggested that underlying this crisis are three imbalances between the real and the financial economies –different macro-economies, the economy and the environment— which sets a material limit on economic expansion. Consideration of these three constraints cannot be disentangled from, and therefore forms a key part of, discussions of contemporary global economic governance.

In such a context, less powerful governments are unable to determine or pursue all their economic objectives through domestic policy alone. Their policy options and political autonomy are increasingly subject to international norms, both formal and informal, that may restrict their ability to meet certain human rights obligations. In

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139 See for example: Jeffrey A. Frankel and George Saravelos, 'Are Leading Indicators of Financial Crises Useful for Assessing Country Vulnerability? Evidence From the 2008-09 Global Crisis' (National Bureau of Economic Research, 2010).


other words, as Slaughter suggests, the globe is strewn with disaggregated bits of strong countries that might be enrolled by weak ones.\textsuperscript{142} Hence, despite some attempts, international human rights standards and obligations have rarely been considered in the design, implementation and evaluation of policy measures to bring the global economic crisis under control.\textsuperscript{143}

A principle critique of the global economic institutions, such as the International Monetary Fund (IMF), the World Bank and the World Trade Organization (WTO), is that they shape monetary and fiscal policies by imposing policy conditionality and empowering private actors in global markets.\textsuperscript{144} In parallel, human rights advocates call on governments to take account of human rights standards and obligations when they formulate policy. Because equality is the mainstay of human rights, and the achievement of formal and substantive equality demands an active government, the human rights framework endows government with many positive and negative duties. Many human rights advocates argue that a rights-based approach will bring better economic and developmental results —although they also partially instrumentalise human rights values and concepts.\textsuperscript{145}

The human rights approach focuses on constructing the public domain, while current economic thinking —which for decades has been dominated by an emphasis on the market as the most efficient distributive mechanism— has enhanced the private sphere.\textsuperscript{146} Therefore, many experts, including economists, have recommended expanding the ‘policy space’ or autonomy of governments, especially those in developing countries.\textsuperscript{147} This issue lies at the core of a policy gap that preceded the recent recession. At the same time, nothing intrinsic to economic policy or economic ways of thinking rule out human rights. Important questions, therefore, arise


\textsuperscript{146} Ruggie, above n 141, p 2.

concerning both the value of the ‘policy space’ and ethical criteria that should apply when the policy is formed.

2.3 Role of Government in National Economic Regulation

Economic regulation is mainly exercised on market structures with the limited or excessive competition. Even though regulation is often described as a principal-agent problem between the government and the operator, there are principal-agent relationships involved (e.g., customers serving as the principal, and two agents, namely the government and the regulator). Whether the regulator is regulating a public operator rather than a private operator changes the nature of some issues. For instance, government intervention may be greater with a governmental operator. The government pursues control of its regulator-agent via laws, budget control and clarity requirements rather than by motivations. Direct control of a public enterprise may be less costly than direct control of a private operator. Applying financial incentives may be less beneficial for a national provider than for a private provider.

Nonetheless, in the case of public enterprises, the government should identify the aims of managers who may be more influenced by political pressure, governmental budgeting, and bureaucratic management than are their counterparts in the private sector. Moreover, pricing is more productive with private enterprises because the government should allow private operators to cover costs through their

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148 The regulator is an agent for the government, serving as the principal in the government’s principal-agent relationship with the operator. See generally: John A. Kay and John S. Vickers (eds), Regulatory Reform: An Appraisal, Deregulation or Re-regulation, London (Pinter Publishers, 1990). Two basic schools of thought have emerged on regulatory policy, namely positive theories of regulation and normative theories of regulation. Positive theories of regulation examine why regulation occurs and include theories of market power, interest group theories that describe stakeholders’ interests in regulation, and theories of government opportunism that explain why restrictions on government discretion may be necessary for the sector to provide efficient services for customers. In general, the conclusions of these theories are that regulation occurs because the government is interested in aligning the operator’s interest with the government’s interest, customers desire protection from market power when competition is non-existent or ineffective, players want protection from rivals, or from government opportunism. Normative theories of regulation conclude that regulators should encourage competition where feasible, providing operators with incentives to enhance their performance, provide for price structures that improve economic efficiency and establish regulatory processes that provide for regulation under the law and independence, transparency, predictability, legitimacy and credibility for the regulatory system. See generally: Morgan and Yeung, above n 35.

149 McPake and Mills, above n 89, p817.
prices to motivate financial investment. Competition is also more complicated with public enterprises, and the lack of equity markets for public enterprises impedes estimating the cost of capital.\textsuperscript{150} However, many scholars who advocate free market systems, propose that government needs to limit its engagement in economic sectors and focus on protecting negative individual rights (e.g., life and property).\textsuperscript{151}

2.3.1 Neoliberalism as a Dominant Economic System

If in the 20th century a 'top-down' approach to social and economic growth was a dominant attitude, with the dawn of a new century, the world has entered a new era of 'bottom-up' growth and social improvement (through widespread community participation, improving local resource management, increasing communication and localising financial access).\textsuperscript{152} The changes in the core theoretical schemes and policy instructions of public economics have contributed to the advance of neoliberalism by implementing an economisation of the language of institutional governance and reform in a broad range of social areas, such as health care.\textsuperscript{153}

Neoliberal economic theories, which have dominated policy-making in recent decades, affirm that almost all forms of government intervention distort free markets. Neoliberalism adopts the classical liberalism stand of equating free markets with individual freedom and a distrust of government intervention in the economy.\textsuperscript{154} A fundamental basis of neoliberalism is that the government’s intervention with market mechanisms is the cause of poor economic performance and that returning to market


\textsuperscript{152} Christopher R. Larrison, 'A Comparison of Top-down and Bottom-up Community Development Interventions in Rural Mexico: Practical and Theoretical Implications for Community Development Programs' (National Symposium on Doctoral Research in Social Work: 12th, 2000) http://hdl.handle.net/1811/36912 (last access: 23/01/2017), p 68.


fundamentalism will protect the public interest. Therefore, the government's role should be minimal, but coherent.

As a contemporary economic approach adjusted to new global economic conditions, neoliberalism calls for the deregulation of commercial transactions, the privatisation of public enterprises and government-provided services, the use of market mediators in the public sector, and public welfare spending to be considered as a cost of global production rather than as a source of local demand. In the public sector, deregulation involves liberalisation, privatisation and the imposition of economic criteria in the residual governmental sector. In the private sector, deregulation is endorsed by a new juridical–political framework that offers passive support for market solutions. It includes regulatory measures to enhance tax expenditures governed by private actions, based on financial subsidies for selected economic activities, and a more general redirection of economic policy to the private sector's demands.

The neoliberal notion of empowerment led to enhanced government intervention to develop new forms of governance that were supposedly more suited to a market-driven global economy. Under their influence, governments across the world reduced the range of services they provided, privatised public institutions and services, sold public assets and lowered taxes. In a market economy, the government does not control critical resources, valuable goods or other substantial divisions of the economy. In this way, institutions determine how the economy operates, how supply is produced or what demands are necessary. Such a system is very well regulated and relatively safe. A market economy that permits the market to operate freely would be contrasted with the command system, in which the government monitors and owns the most profitable industries. In a market economy system property is mainly owned by private individuals, and the separation of the market

158 Ibid, p 461.
159 Ibid, p 454.
and the government prevents the government from becoming too powerful and controlling.\footnote{See generally: R. I. McKinnon, \textit{The Order of Economic Liberalization: Financial Control in the Transition to a Market Economy} (The Johns Hopkins University Press, 2 ed, 1993).}

However, neoliberal strategies are pursued on many different levels. Although neoliberalism is associated with an anti-oppressive suspicion of all forms of deliberate interventionism, the possible, worldwide success of the advocates of neoliberalism can only be understood through their strategic use of the government as a tool for implementing marketisation policies.\footnote{Madra and Adaman, above n 153, p 9.} Thus, neoliberal strategies typically contain the selective transfer of national assets and authorities upwards, downwards and sideways, as intervention is remeasured to ensure circumstances for operating international markets and developing supply-side competitiveness in different sectors at the national level.\footnote{Jessop, above n 157, p 454.}

2.3.1.1 \textbf{Privatisation: A Response to Government Failure}

The theoretical arguments for the advantages of private ownership of the means of production are based on a fundamental precept of welfare economics in which a competitive balance is optimal. While the arguments for government ownership or control rest on market failure or perceived market failure, and while countries have often responded to market failure with government ownership, privatisation, in turn, is a response to the failing of government ownership.\footnote{Megginson and Netter, above n 138, p 329.}

The earliest theoretical basis guiding privatisation of public enterprises can be traced back to the famous work of Adam Smith, the \textit{‘Wealth of Nations’}.\footnote{See generally: A. Smith, E. Cannan and M. Lerner, \textit{An Inquiry Into the Nature and Causes of the Wealth of Nations} (The Modern Library, 1937).} He argued that managers of other people’s businesses could not be expected to seek to maximise profits with the same concerned caution with which partners in a private company frequently endeavour to do. This is because, without an ownership stake, an employee manager is not entitled to most of the profits generated through efficiency.\footnote{Tbid.} Thus, it seems that privatisation originates from the neo-classical...
economists, who desire less government intervention in the economy and believe in the superior performance of the private sector. According to neo-classical economists, a free-market economy without government intervention will lead to economic welfare that will trickle-down to the poorest citizens.166 Government intervention in the economy is seen as useless and harmful due to its activities as a restraining mechanism on economic progress. Privatisation is perceived within the framework of the neoclassical economic theory that advocates liberalisation of the economy and the restriction of the administrative role in the economy.

Vickers and Yarrow note that there is a prima facie case, supported by available evidence, that private monitoring of managers is more efficient than public control.167 However, they believe that any evaluation of privatisation must take account of both the relevant market structures and the competition and regulatory policies that are simultaneously pursued and that the ineffectiveness of government enterprises does not necessarily mean that privatisation is happening. Proceeding on the assumption that shareholders wish the company to maximise profit, Yarrow argues that managerial incentives will then depend upon the separation of ownership and control, the availability of performance information to shareholders, the effectiveness of the incorporation mechanism and legal constraints, such as limited responsibility.168

Meanwhile, Sheshinski and Lopez–Calva contend that privatisation tends to have the greatest positive impact in those cases where the role of the government in lessening a market failure is the weakest, for example for public enterprises in competitive markets or markets that can become freely competitive; hence, there should be 'important efficiency gains from changes to private ownership in competitive structures.'169 In fact, the effects of competition can be so high that public enterprises, in an increasingly global environment, may be forced to respond to pressures that maximise production efficiency without the ownership change of privatisation.

In contrast, the justification for privatisation is less compelling in markets for public goods and natural monopolies where competitive concerns are not strong. However,

169 Sheshinski and López-Calva, above n 55, p.9.
even in those markets, Shleifer et al. have argued that public enterprises are rarely the appropriate solution.\(^\text{170}\) Specifically, Boycko et al. present a model in which privatisation effectively drives an effective coordination between politicians and managers (e.g., depoliticises companies) and leads to their restructuring, even when politicians and managers can use subsidies to convince privatised companies not to restructure.\(^\text{171}\) In their model, the company chooses only its level of spending on labour, and two players have deviating preferences over it: the politician and the manager. Therefore, privatisation changes the bargaining power –between the government and the manager (or shareholders). First, privatisation transfers many of the control rights over company decisions from the government to the manager. The government must then subsidise the company to produce more than the manager wants, rather than just order the higher output and make the manager incur the cost of smaller profits. Second, privatisation typically raises cash flow rights of the managers and private investors and increases their interests in profits and efficiency. For management ownership, the government stops trying to subsidise companies to maintain high outputs; as a result, the budget constraint increases and restructuring occurs.\(^\text{172}\)

### 2.3.2 Facing Criticisms of Privatisation

Although privatisation may be a quick fix, it cannot be a solution to the problems of public enterprises. Inappropriately designed privatisation raises vulnerability to near-term crises and longer-term risks. Privatisation programs may often be slow, uneven and afflicted by unexpected obstacles, and their implementation may often fail to achieve anticipated purposes. Typical start-up problems include staff opposition; mismatches between financial resources; ambiguity in responsibilities and premature delegation of functions to non-governmental agents, leading to deteriorating service quality, and disruptions in reporting, accountability and quality control.\(^\text{173}\) Medium-term concerns include rising system costs; specifically, downsizing administrative units may yield designs for the primary functions that are neither technically efficient

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\(^\text{170}\) Rafael La Porta, Florencio Lopez-de-Silanes and Andrei Shleifer, 'Government Ownership of Banks' (2002) 57(1) *Journal of Finance* 265.


\(^\text{172}\) Ibid.

\(^\text{173}\) Jesse et al, above n 77.
nor cost–effective because of dis-economies of scale. The critics argue that most types of privatisation represent a zero–sum game between public norms and private power so that the government must sacrifice one set of goals entirely to the other because the two games are fundamentally incompatible. For instance, the government can impact the efficiency of privatised industries and companies, positively or negatively, through the political implications of privatisation.

A positive effect, as Villalonga points out, takes place if the government chooses to privatised a company in an industry that will rapidly grow to make privatisation look good. Conversely, there is the probability of unintended, detrimental effects, such as a government’s miscalculation or failure to select the best privatisation strategy. In fact, the problem of public enterprises is not an ownership issue, but rather arises from a lack of clear objectives, and systems that support and encourage fulfilment of those aims. There is significant agreement on when privatisation makes good sense and when it seems risky. In some circumstances, privatisation may aid in fulfilling a public enterprise’s objectives because of the culture and system it supports; in other cases, it may not. Giving priority to privatisation goals other than efficiency will lead to some adverse effects; a government might hasten to privatis a public enterprise during a period of industry recession only because it wants to increase its revenues in that period for political reasons.

Moreover, one of the most important reasons for government intervention arises not because of market failure, but as a result of distributive concerns. Redistribution has been a central question for several economic schools. It is important to recognise at the outset that redistribution of social goods and opportunities may be necessary. The human rights framework also recognises that for governments to meet their

174 Ibid.
176 Villalonga, above n 41, p 52.
178 Ibid.
human rights commitments they should redistribute available resources to achieve
the universal and progressive fulfilment of economic, social and cultural rights.\textsuperscript{180}

The political shock generated by the recent economic crisis has, however, challenged
the neoliberal thinkers' hypothesis of efficient markets: that markets not only
regulate themselves but over time allocate resources in the most efficient and
equitable manner.\textsuperscript{181} Competitive markets create wealth, but they also create income
inequalities. In addition, fiscal policies (that address public expenditure and
revenues) possibly have the biggest impact on distributive justice and the attainment
of economic and social rights.\textsuperscript{182}

Neoliberal economists traditionally hold that taxation distorts markets and obstructs
their ability to allocate resources efficiently. It has become evident, however, that
markets do not always, or naturally, allocate resources fairly. The persistent rise in
inequality in recent years, both within and between countries, illustrates this and
demonstrates the inadequacy of existing tax systems to correct the bias that market-
led economic policies have created.\textsuperscript{183} Increasing tax competition to attract foreign
direct investment has caused a dramatic change in the structure of tax systems. Many
governments have tended to increase indirect taxes, such as Value Added Tax while
reducing progressive income tax rates.\textsuperscript{184} Yet, while aggregate wealth has increased
under this policy regime, growth in many countries has been associated with sharp
increases in inequality, and large numbers of people living in poverty have been

\textsuperscript{180} See for example: Paul Farmer, \textit{Pathologies of Power: Health, Human Rights, and the New War on
the Poor} (Univ of California Press, 2004).

\textsuperscript{181} The neoliberal perspective does not eradicate the government's interests, but it shapes and
reformulates them in ways that are less independent of the industry. Those who
advocate neoliberalism argue that the government is inherently inefficient when compared
with markets and it should concentrate on making policy decisions rather than on delivering
services. Thus, the value of markets is not just limited to their capacity to efficiently produce and
distribute goods; they have inherent value that provides various benefits for individuals and
society. See: Prechel and Harms, above n155, p 4.

\textsuperscript{182} See generally: M. J. Trebilcock and E. M. Iacobucci, 'Privatization and Accountability' (2003)

\textsuperscript{183} See generally: Alan J. Auerbach, 'Long-term Objectives for Government Debt' (2009)
\textit{FinanzArchiv/Public Finance Analysis} 472, Vito Tanzi and Hamid Reza Davoodi, \textit{Corruption,
Growth, and Public Finances} (International Monetary Fund, 2000).

\textsuperscript{184} See: Christian Aid, 'False Profits: Robbing the Poor to Keep the Rich Tax-free' (2009) \textit{A Christian
Aid Report}. 
excluded from the benefits of growth and often, even middle-class incomes have stagnated or been relatively depressed.185

The neoliberal belief that market mechanisms can guarantee non-government participants will do as the government or citizens wish has also been criticised by social scientists. These critics indicate that the government should still structure and manage the policy process, set targets for other participants and should review and regulate these agents regarding these aims.186 For example, both the neoliberal and the rational choice theories draw on macroeconomic analysis regarding the notion of governance and define profit/utility maximisation by individual actors.187

Nonetheless, neoliberals set up such analysis to enhance marketisation and argue that the government has just changed the way in which it rules the people, while the advocates of rational choice theory criticise the neoliberal approaches to governance through a critique of the concept of public interest.188 The latter also believe that the government has indeed lost power, and such an action leads to the use of bribes and incentives and threats to withdraw benefits and goods in the system. Rational choice theorists provide neoliberals with a critique of bureaucratic government, arguing that bureaucrats act to optimise their power chance.189 Once rational choice theorists rely on such a micro-analysis of government they face the same issue regarding all kinds of institutions, including political parties and the market economy itself. The domination of the micro level raises questions about the roots, perseverance and effects of the social norms, laws and institutions which govern individuals. Hence, the absence of any adequate higher authority means that such institutions should be assumed as self-enforcing.

Moreover, when social scientists assess public sector neoliberal reforms, they often conclude that these changes have rarely rolled back the government at all. Abraham draws attention to the unintended consequences of such reforms, indicating that neoliberal reforms result in fragmented service delivery and weakened central control.

188 Bevir, above n 186, p 138.
189 Ibid, p 175.
without developing suitable markets.\textsuperscript{190} These reforms can lead to a reproduction of policy networks, in both the formation of public policy and the delivery of public services. Thus, it seems logical that, as the role of the private sector in providing public interest increases, governmental control would be reduced.

However, while the old arguments between socialism and capitalism have not been revived, there appears to be no serious interest in reverting to command economies.\textsuperscript{191} Many economic theories have emphasised the government’s responsibility to maintain prices, curb inflation, levy taxes, equalise the balance of payments, and create conditions in which economies can operate efficiently and generate outcomes that are socially as well as economically sustainable.\textsuperscript{192} In such circumstances, advocates of economic and social rights could benefit from the insights that economic researchers have gathered about the generation and management of public revenues and expenditure, policy instruments relating to social security transfers and taxation. For instance, under human rights law, governments are obliged to use the ‘maximum of their available resources’ to progressively achieve economic and social rights.\textsuperscript{193} This suggests that an effective taxation system is indispensable in fulfilling all human rights. When the government’s role in generating and distributing individual and aggregate wealth is considered, the economic and human rights spheres come much closer together.

Therefore, for the first time in a generation, many economists and economic institutions are reviewing certain dominant doctrines and assumptions and the role of government in mediating economic flows and outcomes. In this regard, some neoliberal scholars, such as Harvey, emphasise the role of government in designing and preserving the neoliberal institutional framework, which he defines as secure private property rights, free markets and free trade.\textsuperscript{194} Neoliberalism as a form of governmentality is redefining government interests to be more responsive to and to converge with industrial interests. Accordingly, the primary role of government


\textsuperscript{191} Jessop, above n 157, p 680.


\textsuperscript{193} United Nations, International Covenant on Economic, Social and Cultural Rights (ICESCR), 1966, Art. 2 (1).

\textsuperscript{194} David Harvey, A Brief History of Neoliberalism (Oxford University Press, 2005).
should neither be to merely direct the actions of the public through regulation and acts nor just to establish a set of rules and incentives. Such a trend reflects the neoliberal belief in the possibility of government's failure and the need to involve relevant participants in supply-side policies.195

2.4 Trade-Offs in Economic Policy-Making: The Necessity for Revision

The regulatory reach and powers of the government and the conditions under which they may be exercised have been the subject of much debate among economists. Some approaches still emphasise the function of public agencies by introducing command and control and nationalisation of industries196 as the best tools to guide public goals. However, between the market-based government as facilitator and the command economy, there are many different views about the government's role in governance and its relationship with markets. If there is one issue on which all new governance scholars agree, it is that the old governance model –where hierarchically organised agencies could handle the whole process of public issues through a centralised authority– has limited utility in dealing with many of today's most significant global challenges, and that is because 'those who steer the boat have far more power over its destination than those who row it.'197

Nowadays, most of the traditional approaches have been disqualified due to the growing complexity of diverse societies and the need for multi-level collaboration, as well as the belief that effective policies cannot be developed without significant local involvement.198 Looking forward, certain obstacles to achieving congruence between human rights and economic principles and approaches need to be recognised. Comprehensive binding arrangements may emerge from longer-term

195 Jessop, above n 157, p 454.
196 Nationalisation is the process of converting private assets into public assets by bringing them under the public ownership of a government. It comes about because of certain ideological or political considerations that overwhelm the reasonable goal of economic efficiency. Chua, above n 77, p 260. Government ownership grew in developing countries primarily because it was perceived as necessary to promote growth. Dennis A. Rondinelli and Max Iacono, 'Strategic Management of Privatization: A Framework for Planning and Implementation' (1996) 16(3) Public Administration & Development (1986-1998) 247. Nationalisation, however, is distinguished from property redistribution in that the government retains control of nationalised property.
developments. However, in the near term, new governance theory calls for a building-blocks approach that develops different elements of an overall solution 'and embeds them within an international political framework.'

International human rights standards are comprehensive, deal with all categories of rights, and provide special protection to marginalised groups that too often benefit last and least from economic growth and suffer first and most in economic downturns. The human rights approach requires rights to be recognised and protected by law, anchored in international commitments that can be independently monitored—at least in theory. The point is to understand the value of the human rights framework, not necessarily to substitute it as a new and over-arching paradigm that has all the answers.

Some suggest that human rights principles, like non-discrimination and non-retrogression (and its framework of obligations to respect, protect and fulfil), can provide a normative framework against which economic policy can be evaluated. When rights-based approaches stress participation and empowerment they reflect many elements of human rights. In addition, certain other streams of thought within economic philosophy affirm many of the principles put forward by human rights advocates and offer real possibilities for intellectual and policy congruence. They include, for example, pro-poor approaches to economic growth, advocated by many economists, that place poverty and equity at the centre of economic policy-making. Therefore, although there are disagreements about which policy prescriptions are most effective, many economists are not averse to taking human rights seriously, especially in the context of addressing poverty.

The economic challenges and their aftermath present a clear opportunity to articulate the ways in which human rights principles, as an ethical and legal framework, might shape and improve economic policy, both nationally and globally. This is a major undertaking which could guide human rights advocates, and allies in other fields, as

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202 Marta Foresti, Kate Higgins and Bhavna Sharma, 'Project Briefing' (2010).
they work towards new approaches to economic policy. Human rights advocates and economists repeatedly return to the need for an active government. Both human rights schools and many schools of economic thinking emphasise the central role of the government as a guarantor of rights and as an enabler of economic activity. From a human rights perspective, the issue is not whether the government is strong or weak, but whether it fulfils its responsibility in relation to human rights. On the one hand, human rights advocates are cautious and suspicious of strong governments, often perceiving them as authoritarian. On the other hand, a well-organised and active government is often needed to establish and maintain the rule of law, and support an independent and fully functioning judiciary.

A classic understanding of human rights provides a good point of departure for evaluating such trade-offs; the right of all to participate equally in the governance of a country is particularly relevant. A discussion about trade-offs is, therefore, a discussion about priorities and the processes by which decisions are made. As such, it engages key human rights principles and concepts. However, cooperation can lead to the opposite direction, in which partnerships require effective government regulation. A range of processes, for example, the functional contrast of the government, globalisation and the neoliberal reforms themselves, may leave many governments increasingly dependent on private organisations for the delivery and success of their policies. Based on this view, even when the government preserves its dominance, it and the other players of the economic system are interconnected in that they must exchange resources to achieve their purposes. This implies that governments should not only refrain from interfering unduly in private sector’s activities but also take steps to ensure other actors do not do so, and they should create conditions favourable to citizen participation.

Economists who adopt a more instrumental view would tend to argue that, since human rights impose opportunity costs and trade-offs, they must be optimised, preferably using cost–benefit analysis or a similar calculus. They presume that an aggregate enhancement of wealth justifies the sacrifice of interests (often those of

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204 Ibid.

205 Pongsiri, above n 150, p 489.

people who live in poverty and/or are powerless). Too often, those who have limited resources of power are not able to influence economic policy or ensure that it takes account of their interests. The realities of power, international as well as national, and the fact that privileges are not readily surrendered, severely restrict not only access to decision-making on economic policy but also the autonomy of many governments.\footnote{Slaughter and Rhoades, above n 142.}

The redistribution of wealth also requires the government to coordinate the large social and economic investments that must be deployed to provide universal access to basic rights, including public health. Under international human rights law, governments are not only responsible for respecting, protecting and fulfilling human rights (further discussed in Chapter 3), but also for creating the broader social, political and economic conditions in which citizens can exercise human rights freely.\footnote{Committee on Economic, Social and Cultural Rights, General Comment No.14: The Right to the Highest Attainable Standard of Health (Art. 12), UN doc. E/C.12/2000/4, 2000.} Hence, the role of the government sits at the centre of social and economic policy and human rights objectives. More than any other institution, by implementing effective policies, governments determine whether people prosper, overcome poverty and enjoy consensual governance.

International human rights law further requires governments to be accountable for their actions. Applied skilfully, human rights principles can expose abuses of power, including malpractice by government officials and the improper influence of private interests on official decisions;\footnote{See for example: ICHRP Corruption and Human Rights: Integrating Human Rights in Anti-corruption Agendas, Geneva, 2010, ICHRP Corruption and Human Rights: Making the Connection, Geneva, 2009.} however, there is limited evidence of this in international practice.\footnote{Ruggie, above n 141141, p3.} For business and human rights, there is no shared understanding of the problem, let alone any consensus on solutions.

When considering these issues, it is important to begin by noting that economics and human rights are distinct and largely self-contained fields. Equally important, both are markedly heterogeneous. Several schools of thought in economics, often referred to as progressive, do not share the assumptions, methods, normative foundations or...
policy conclusions of mainstream economic theory. Economic theories, therefore, focus on setting priorities. In contrast, human rights thinking is grounded in universal principles, and all human rights are equal in status and are indivisible. Consequently, prioritising one right over another poses a challenge for human rights advocates.

For example, Briggs argues that the role of government should be to act as a welfare state, using government intervention in the market economy to modify the actions of the market. Governments determine whether or not to regulate/own natural monopolies or other monopolies, interfere in the case of externalities (e.g., regulating the pharmaceutical sector) and help provide public goods (e.g., affording essential medicines). Suspicious about trade-offs, human rights advocates often criticise economic analyses that calculate the benefits of long-term aggregate outcomes and discount violations of individual rights as short-term losses and collateral.

Many economists, on the other hand, criticise advocates of human rights for avoiding tough choices, and regard human rights principles as unspecific and unenforceable policy tools. From their perspective, human rights advocates appear to affirm broad principles over specific policy choices. For many human rights activists, the realisation of human rights is an end goal. Yet, long-term structural interventions of the kind necessary to build effective and inclusive education, health and social protection systems, reduce endemic poverty or sustain modern economies cannot be

211 'Mainstream' or 'Dominant' economics, often referred to as the New-classical economics, is traced back to the work of theorists, for example Friedman and Lucas. Its theorists advance three inter-related hypotheses, concerning rational expectations, the real business cycle, and efficient markets. Petrasek and Nagaraj, above n 143.


214 A public good is 'non-rival,' in that one or more people can use or consume it at the same time without diminishing its availability. They are also non-excludable in that no one can be excluded from using them. A private good is also a product that must be purchased to be consumed, and its consumption by one individual prevents another individual from consuming it. Economists refer to private goods as rivalrous and excludable. Joseph Stiglitz, Making Globalization Work (Penguin, 2007), p 281.


designed solely based on monitoring compliance with individual rights. Some trade-offs are inevitable. Mainstream economics has a largely consequentialist normative framework in which human welfare is generally viewed in terms of utility levels or preference satisfaction.\textsuperscript{217} Therefore, it considers human rights as a means that can be instrumentalised to achieve less distorted or corrupt markets or more equitable development. These are two very different conceptions of human rights. For one group, human rights are a goal representing intrinsic values that should not be compromised; for the other, they are an additional tool or method to be adopted where they have practical value.\textsuperscript{218}

However, it should not be assumed that economists are insensitive to human dignity or that advocates of human rights are uninterested in economic progress. Many economists aim (through taxation and redistribution strategies) to reduce inequities in access to food, education and health care (all basic rights).\textsuperscript{219} Equally, a growing number of experts have developed human rights approaches that address broad questions of development and growth, and more specific issues relating to poverty-reduction programs, budget analysis and corporate accountability.\textsuperscript{220}

2.5 Towards a Polycentric Governance Approach

At the global level, corporate conduct is shaped by three distinct governance systems: the first is the system of public law and governance, domestic and international; the second is a civil governance system involving stakeholders affected by business enterprises and employing various social compliance mechanisms, such as advocacy campaigns and other forms of pressure; and the third is corporate governance, which internalises elements of the other two.\textsuperscript{221} A new regulatory dynamic is required, under which these governance systems: become better aligned in relation to business and human rights, add distinct value, compensate for one another's weaknesses, and

\textsuperscript{217} Consequentialism bases moral evaluation (of policy, for example) primarily on its consequences rather than considering the context or the intrinsic value. See for example: Melis Ceylan, 'Discussion of Ethics in Public Relations and Applicability of Consequentialist Theories' (2007).

\textsuperscript{218} Ruggie, above n 141, p 1.


\textsuperscript{220} See: Seymour and Pincus, above n 200, McKay and Vizard, above n 201.

play mutually reinforcing roles—out of which cumulative change can evolve. New governance theory rests on the premise that the government by itself cannot do all the heavy lifting required to meet the most pressing societal challenges and that it, therefore, needs to engage other actors to leverage its capacities.  

Jessop introduces the neo-corporatist strategy as an approach reconstructed by the public and private participants which intends to harmonise cooperation and competition among them. This approach is based on a commitment to social conciliation, as well as the pursuit of private economic interests in securing a stable and competitive economy, such as that found in a socially-regulated industry. Neo-corporatist networks include policy communities representing functional systems (e.g., education, health and science), and policy implementation become more resilient through the extension of ‘regulated self-regulation’ and public–private partnerships. Compliance with government policies is voluntary or depends on self-regulating corporatist organisations endowed with public status. A fundamental limitation of corporate governance is that regulation of large shareholder intervention may improve protection for small shareholders, but such regulations may expand managerial discretion and scope for abuse. Corporatist arrangements may also become more selective (as they exclude some established industrial interests) and reflect the greater flexibility of decentralisation. The centres of neo-corporatist gravity may also shift to companies and localities and away from a centralised, macroeconomic concentration.

Jessop also argues the second strategy, new statism, which involves a market-conforming, but government-sponsored, approach to economic restructuring, whereby the government seeks to guide market forces in support of a national economic strategy. This guidance depends on how the government’s powers of coordination are arranged and its economic resources. There is a mixture of governmental de-commodification, government-sponsored flexibility and other

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223 Jessop, above n 157, p 460.
224 ibid, p 462.
225 Marco Becht, Patrick Bolton and Ailsa Roell, 'Chapter 1 – Corporate Governance and Control' (2003) 1 Handbook of the Economics of Finance 1, p 1.
226 Jessop, above n 157, p 462.
administrative activities to defend the increasing efficiency and collaborative coherence of a core productive economy. This strategy guides public–private cooperation to serve both the public and private interests.

While the central government preserves base strategic roles, parallel and complementary activities are also encouraged at local levels. However, the central government's desire to protect the core economic competencies is often correlated with neo-mercantilism in the international arena. Neo-communitarianism, as Jessop's third strategy, emphasises the contribution of the 'third sector'—both located between market and government—to economic development, as well as the role of bottom-up economics in developing strategies. It also focuses on empowering localised partnerships that include both the government and business interests and the different local participants. The neo-communitarian strategy aims to redress the imbalance between private prosperity and public poverty, create domestic demand, provide a different kind of fix for small and medium-sized enterprises, and promote empowerment.

The duties resulting when different actors work through the above strategies may satisfy no group fully. However, if prescribed and applied by legitimate and effective institutions, or enforced through corporate self-regulation, these cooperative norms represent the beginning of a more global and coherent response to new challenges to human rights. Hence, recent literature emphasises 'responsive regulation,' informal cooperation, and public–private partnerships.

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227 ibid, p 463.
228 ibid.
2.6 Responsive Human Rights Regulation

Despite the inspirational norms of the international human rights system, its weaknesses and failures to regulate human rights abuses are clear. However, the regulatory theory offers a different and more optimistic perspective. Its focus is not so much on the strength of the treaty texts, their formal methods of implementation, or their impact on governments who are parties to them, but rather on the way that human rights norms as expressed in the treaties can be mobilised by non-governmental actors to regulate the government’s behaviour. It is interested in a much broader range of influences than traditional legal tools and mechanisms. Sell, for example, has chronicled the success of coalitions of activists and developing countries in changing the terms of the WTO’s approaches to intellectual property (IP) in pharmaceuticals, shifting it from an issue of corporate property rights to one of public health.

Regulatory theory suggests the promise of networked governance of human rights, which enables the weak to mobilise human rights principles against oppression, challenging the realist disdain for human rights. This theory also draws attention to the role of networks in designing the architecture of human rights regulation. The second feature of the regulatory theory is its identification of types of behaviour that can undermine the protection of human rights. It suggests the value of self-regulation and peer regulation as effective means of countering ritualism in the human rights field, even in the absence of commitment among participants to the goals of a regulatory regime.

The concept of responsive regulation is valuable in achieving normative goals, such as human rights. The idea of responsive regulation, first developed in the context of business regulation, is to start by identifying the strengths of a system or actor, and then to expand them through building capacity. The basic idea of responsive regulation is that governments should be responsive to the conduct of those they seek

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to regulate in deciding whether an interventionist response is needed. In particular, law enforcers should be responsive to how effectively citizens or corporations are regulating themselves before deciding whether to escalate intervention. As Ayres and Braithwaite discuss, responsive regulation is supposed to ease self-regulation programs and compliance-oriented regulation, which is to be carried out through corporate consent and voluntary organisational processes of reflexive learning.

This shift in economic policy involves a major cultural transformation within the body politic that has improved public–private cooperation. Such assistance can provide settings in which public-sector agencies could engage stakeholders, citizens, voluntary organisations and private companies to take advantage of each sector’s abilities to improve the system. Public–private cooperation can aid the burden of capital investment in the public sector while decreasing development risks for the private sector. Thus, in addition to the unification of various scales of the economic and political organisation, the cooperation between the public–private sectors and between government and society should increase.

What responsive regulation does is to cover the weaknesses of one theory with the strengths of another. When regulation is more legitimate, more procedurally fair, compliance with the law is more likely. This feature of the theory of responsive regulation is attractive for developing countries. Precisely because it deals with the fact that no government has the capacity to enforce all laws, it is useful for thinking about regulation in developing countries with weak enforcement capabilities. It is true that certain minimum capacities must be acquired, but then the theory shows how such limited capacity might be focused and leveraged.

Responsive regulation translates well to the field of human rights, highlighting the value of persuasion, education, and capacity building as the first steps to achieving compliance with human rights norms. The main principles of responsive regulation include flexibility, giving voice to stakeholders, engaging resisters with fairness,

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234 Ian Ayres and John Braithwaite, Responsive Regulation: Transcending the Deregulation Debate (Oxford University Press, 1992).

235 Charlesworth, above n 134, p 886.


nurturing motivation, signalling but not threatening the possibility of escalation and enrolling powerful regulatory partners in networks.\textsuperscript{239} Other lessons from responsive regulation that are applicable to the international human rights system are the value of collaborative regulation, of an assumption that the regulated body has the capacity to change and of eliciting active responsibility for human rights protection.

Perhaps the most important implication of regulatory theory for the international human rights system is the limitation of purely legal approaches to the protection of human rights. The goal of the international human rights system should, rather, be providing forms of access to justice for human rights violations that respond to contexts.\textsuperscript{240} Theories of a responsive regulation point to the weak spots in the international human rights system. Braithwaite, for example, has pointed out that regulation works best when there is a company committed to escalation when dialogic-based sanctions do not work.\textsuperscript{241} He notes the paradox that ‘by having a capability to escalate to tough enforcement, most regulation can be about collaborative capacity building’.\textsuperscript{242} Such a capability is difficult to maintain in the international legal system, which is highly attuned to the distribution of political power and where imposition of formal sanctions is rare.

The responsive regulatory theory has evolved into a deliberative, circular theory of democratic accountability, as opposed to a hierarchical theory where the ultimate guardians of the guardians are part of the government.\textsuperscript{243} This ideal is for guardians of accountability to be organised in a circle, where every guardian is holding everyone else in the circle accountable, where each organisational guardian holds itself accountable in deliberative circles of conversation and where such circles are widened when accountability fails. Developing countries with limited regulatory capacity might benefit from a responsive approach to regulation. These countries mostly have less oversight by non-governmental organisations (NGOs); less governmental regulatory capability; and a less settled, less powerful business custom, at least in the larger business sectors. Responsive regulation, conducted by regulatory

\textsuperscript{239} See generally: Braithwaite, above n 233.
\textsuperscript{240} Christine Parker and John Braithwaite (eds), \textit{Conclusion}, Regulating Law (Oxford University Press, 2004), p 285.
\textsuperscript{241} Braithwaite, above n 233, p 489.
\textsuperscript{242} Ibid, p 475.
\textsuperscript{243} See: John Braithwaite, \textit{Restorative Justice and Responsive Regulation} (Oxford University Press on Demand, 2002).
networks of governmental and non-governmental actors, allows for networking around capacity deficits and helps developing countries to develop a regulatory society model, bypassing the regulatory state.\textsuperscript{244} Thus, for example, business custom shapes the responsive business regulatory law, and governmental regulators check abuse of power in business self-regulatory arrangements - both should have their power checked by the vigilant oversight of NGOs and social movements.\textsuperscript{245} Under responsive regulation, rules remain important under a restorative and responsive model of democratic accountability, but they are just one of the things that emerge from the circles of deliberation.\textsuperscript{246}

### 2.7 Capture and Corruption: The Efficiency of Responsiveness

Although economic regulation is often based on a game between the government and the company, on the former side there are other factors (e.g., committees of legislators) while on the latter side there are participants (e.g., industry associations). Under the economic theories of regulation, all actors are assumed to be maximising their utility, and all of them are expected to be well informed and to learn from past interactions. The two fundamental presumptions are that there is a clear public interest and government is its disinterested servant.\textsuperscript{247} Nevertheless, because of the various roles of actors on both sides, it is insufficient to define individual actors as the faithful guardians of the company’s interests.

The most prominent contributor to economic theory was Stigler, who argued that the greatest beneficiaries of regulation would be large, concentrated, well-organised interests; that is, the industries subject to regulation.\textsuperscript{248} The consequence of this is ‘regulatory capture,’ in which regulation is acquired by the industry and is designed and operated primarily for its benefit. The notion of capture differs based on the general pattern of a system, and its merits or demerits are relative and may vary in different regulatory structures. This concept arose from a binary relationship between industry actors and regulatory agencies, and further consideration of other interest

\textsuperscript{244} P. Selznick, \textit{The Moral Commonwealth} (The University of California Press, 1992), p 64

\textsuperscript{245} Ibid, p 470.

\textsuperscript{246} Charlesworth, above n 134, p 885.

\textsuperscript{247} Ayres and Braithwaite, above n 234.

groups in society led to the term ‘capture’ also being used to describe the self-interested behaviour of legislators and regulatory agencies.\(^{249}\)

Based on capture theory, the primary function of the regulatory system is to protect and promote the public interest.\(^{250}\) Thus, any regulatory plan should be compatible with the public interest, rather than the industry’s/regulator’s interests. This theory focuses on how bureaucratic shifts towards regulation reflect capture by industry interests at the expense of public interest. However, there are some conditions where the regulators are captured by industry’s interests rather than caring about public interest priorities. This occurs when regulators stop to provide some notion of a wider collective public interest and systematically start to favour particular interests. They are often the interests they were supposed to regulate and constrain for the broader public interest and may even lead to regulatory failure.\(^{251}\) Because a politically motivated regulator would maximise its gains from executing industry’s desires, the capture of regulators by industry interests was once viewed as the superior example for regulatory failure.\(^{252}\)

In any business environment, the government, the financial institutions and the enterprise sector form a triangle in which the relationships among these sectors dictate mechanisms of coordination among them. Thus, for example, if both the financial and real sectors are wholly owned and controlled by the government, then coordination would be inherently hierarchical and administrative. Conversely, combinations of two sectors would tend to exercise significant, if not predominant, power over the third sector. Examples of these would include governmental development banks, strategic public enterprises and large financial–industrial groups. The combinations mainly coordinate their behaviour as a matter of policy, and the third sector may have little de facto power to influence these relationships. Alternatively, the third sector may be captured by the sectoral combination, perhaps through social networks, bribery or other forms of impact, hence, it, in fact, has no interest in restraining the more powerful combination. In other words, transition and


\(^{250}\) See: Ayres and Braithwaite, above n 234.


development display a certain path-dependency: ownership networks created early on appear to constrain the effectiveness of even the best-designed legal and regulatory institutions.\(^{253}\) Of course, inherited social norms and relationships can also hinder the influence of formal institutions and, indeed, the rule of law itself.

However, in some circumstances, the capture is not an opportunity to promote the system but is a sign of corruption and the malfunction of the government to regulate the system correctly. The conventional definition of corruption as ‘the abuse of public office for private gain’\(^{254}\) usually evokes little controversy in practice. WHO also defines corruption as ‘act[s] by individuals who unlawfully and wrongly use their official position to benefit themselves or someone related or close to them at the cost of others.’\(^{255}\) Thus, corruption entails an abusive public act, a suborning of government authority, resulting in improper benefits for those involved, including those whose acts are clothed with public authority. Self-dealing or diversion of assets by corporate insiders lies closer to the definition of corruption since it includes the abuse of a position of trust and a fiduciary obligation towards a ‘public’ comprised of actual or potential shareholders.

In particular, in developing and transitional countries, abuses by companies and banks undoubtedly entail corruption when the relationships these institutions have with the government create a channel for private interests to extract benefits through the misuse of public authority. In other words, the public enterprise becomes politicised, and their managers become the tools of individual ministers and legislators.\(^{256}\) Where this involves official decisions allocating improper benefits to private parties, including the decision-makers, one has entered the terrain of corruption. The more the industry influences the regulator’s perspective—to adopt their interests over and above those of patients’, for example, in a health care context—the more the agency could be assumed to be captured.

The capture is likely to increase when informal consultation and meetings between government officials and the industry are permitted and encouraged because the

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\(^{253}\) Meagher, above n 122, p 24.


\(^{256}\) Meagher, above n 122 122, p 13.
opportunities for regulated companies to lobby government officials are expanded. When the interests of industry and, for example, public health diverge or conflict, the role of the government's regulatory agency is crucial. When, for instance, pharmaceutical companies in a market economy are supposed to serve the public by responding to market demand and financial incentives, but, in fact, the financial incentives for pharmaceutical companies are often misaligned with public policy goals so that companies can prosper without advancing the public's health.

Governments are at great risk of capture and corruption by business and even greater risk where regulatory bureaucrats are poor. Abuse of power is best checked by a complex plurality of many separated powers; many semi-autonomous nodes of networked governance. All nodes of separate private, public or hybrid governance need enough autonomy so that they cannot be dominated by other nodes of governance. Equally, each needs enough capacity to check abuse of power by other nodes so that a multiplicity of separated powers can network to stop any node of power from dominating all the others. The required structural coupling among a rich plurality of separated powers is not only about checking abuse, it is also about enhancing the semi-autonomous power of nodes of governance to be responsive to human needs. Nodes of governance must not only check one another's abuses, they must also assist with building one another's capacity to responsively serve human needs and to have integrity.

In this regard, Ayres and Braithwaite argue for the central importance of third parties, particularly NGOs, to be directly involved in regulatory enforcement oversight. Responsive regulation conceives NGOs to be fundamentally important regulators. This is because NGOs do more than just monitor capture of governmental regulators; they also directly regulate business themselves, through naming and shaming.

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257 Watson, above n 249, p 6.
260 Selznick, above n 244.
261 Ayres and Braithwaite, above n 234, Chap. 3.
restorative justice, consumer boycotts, strikes, and litigation that they run themselves.  

2.8 Conclusions

This chapter has argued that, despite some developments, human rights law remains highly imperfect in protecting individual's basic rights. For numerous reasons (e.g., weak legal rules governing cooperation, conflicting objectives, the tendency of national interest to override international interest whenever they collide) governments have rarely succeeded in agreeing on or effectively implementing global public policies (e.g., reform and regulation of financial markets, fulfilment of trade and development objectives, and adoption of equitable global economic policies). To complicate matters further, there is no consensus on the objectives that should drive the reform of global economic institutions. This reminds one also that both the economics and human rights traditions are prone to claim intellectual sovereignty, which does not encourage open-mindedness.

Meanwhile, just as economic thinking can appear disengaged from ethics, rights-based language can be open to manipulation, for instance regarding validating property rights or promoting a narrow understanding of the rule of law. On the other hand, human rights principles are not also necessarily neutral; when applied inappropriately or in ways that do not take account of power dynamics they may do little good. Therefore, developing a dialogue between human rights and economic approaches is the only approach that is possible or that is desired—something that can be undertaken through responsive regulation. In this regard, the core idea of responsive regulation as a strategy has special salience for escalating networks between the economic and the human rights approaches. Mobilising public virtue to regulate private vice is a path around capacity deficits.

Responsiveness is enabled by a society with a strong government, strong markets and strong civil society, where the strength of each institution enables the governance capabilities of the other institutions. Such regulation is, however, a concerted strategy in corrupt regulatory systems, because it puts more discretion in the hands of

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262 See: Parker, above n 114.

regulatory bureaucrats who can use that discretion to increase the returns to corruption. As with responsiveness as a democratic ideal, when considering responsiveness as an effectiveness ideal the theory appears to be one where developing countries are less likely than wealthy countries to enjoy the conditions to make it work. Not only are government regulatory bureaucrats in developing countries more vulnerable to corruption because of their poverty, NGOs have fewer resources to oversee and guard against this than do NGOs in rich countries. More fundamentally, weaker countries lack the organisational capacity to be responsive. Developing countries also have weaker markets that hold back the development of government capacity and a weaker government that holds back the development of all other institutions, including the institutions of civil society that can compensate for the failures of governments.

However, the responsive regulatory theory still offers a more useful theory of ‘what is to be done’ in developing countries than statist theories. Where governmental capacity is weakest, responsive escalation via networking with progressively more private and public enforcers should pay the highest dividends. Moreover, networking regulatory partnerships also structurally reduce the benefits of capture and corruption in those economies that are endemically prone to corruption. The next chapter evaluates to what extent responsive regulation is/should be reflected in the international economic and human rights arenas to protect the human rights of citizens, particularly the right to health and access to medicines, as is the focus of this study.
Chapter 3 – The International Regulatory System and Protecting the Human Right of Access to Medicines

3.1 Introduction

As discussed in the last chapter, human rights law remains highly flawed in protecting individual’s basic rights and is broadly driven by economic agendas. The lack of a consensus on the objectives that should drive the reform of global economic institutions also complicates matters further. Since in such circumstances developing a dialogue between human rights and economic approaches is necessary, Chapter 2 concluded that the core idea of responsive regulation as a strategy has special salience for escalating networks between the economic and the human rights perspectives. The current chapter surveys the international human rights system and its shortcomings. This is followed by explanations for the perceived failures of the current regulatory system to affect international/national regulatory behaviours, and then introduces some aspects of regulatory scholarship that can enrich approaches to protecting the human right of access to medicines. This chapter concludes by considering the value of the concept of responsive regulation to the field.

The declining power and influence of the United Nations (UN), caused by global capitalism and the related shifts in world leadership, has led the new international institutions, for example the World Trade Organization (WTO), World Bank and International Monetary Fund (IMF), to rise to new levels of power and prominence. A core mission of these establishments is to enable free market conditions and

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policies that strengthen trade liberalisation and the private sector globally. Meanwhile, access to medicines is an integral component of the right to health and is the concept that clearly links the pharmaceutical industry to the human rights field. Many international instruments have recognised the right to health and access to medicines and have attempted to make the countries respect, fulfil, provide and protect this right in their constitutions. Therefore, a constitutional guarantee of access to essential medicines has been identified as an important indicator of government commitment to the progressive realisation of the right to the highest attainable standard of health. In this context, confronting public interests (from a human rights perspective) and industry’s interests (from an economic perspective) can put protecting public health at risk. The source of the problems may be the structure of markets, economic incentives for companies, corruption of the legislative process or a variety of other factors. Solving these problems requires systemic reforms.

3.2 Market Economy and Protecting Public Interest of Health

As discussed in the previous chapter, due to the introduction of a free market economy, most countries are engaged in radical changes to their economic function and in the characteristics and role of government and the private sector. The traditional concept of an independent private sector acting in pursuit of its immediate goals, notably profit maximisation, and a public sector with discretionary powers and multiple objectives that relate to achieving long-term goals in the public interest has been challenging. Among the factors that may prompt changes in regulation are new economic changes, shifts in the power of pharmaceutical interest groups and incentives affecting legislators and regulators that cause problems in pharmaceutical policy.

Developing countries often choose privatisation, sometimes as a matter of political and economic ideology, other times only to raise revenue. Efforts to make such a strategy profitable would quite likely mean the reintroduction of government intervention. See for example: S. Berendes et al, ‘Quality of Private and Public Ambulatory Health Care in Low and Middle-Income Countries: Systematic Review of Comparative Studies’ (2011) 8(4) PLoS Med e1000443.
restrictions on government budgets—the major funding source for health care expenditure in most developing countries. The current system of financial regulation produced not just a failure of accountability, it expanded the wealth of a few rather than generating social value by significantly strengthening the economy’s productive capacity. The challenge is to (re)conceive a regulatory framework that will bridge the real and financial economies and encourage financial innovation to catalyse productive investment. Effectively, this amounts to a redistribution of wealth in favour of the rich, achieved firstly by bailing out the highly paid financial sector and secondly by cuts in social spending in response to the threat of a public debt crisis.

The human rights notion of a rights-fulfilling government focuses not so much on the government’s scale (i.e., whether it is minimalist or maximalist) or the question of how much regulation is required, but on the degree to which a given regulatory regime favours certain interests or purposes over others and responds to the needs of the most disadvantaged. The recent financial crisis was arguably caused not so much by the absolute failure of regulation as by a biased regulatory system favouring the interests of major actors in the finance sector. The system does not protect the interests of the less powerful, including the middle classes and those living in poverty.

It might be argued that the government’s obligation to protect human rights was contravened by leaving the financial markets to the care of apparently independent regulators—self-regulating corporations—which led to economic and social distress. It is not clear whether such a conclusion adds much to our knowledge about the regulatory failure that occurred or fully considers the realities of a globalised financial system. Despite some initiatives, there is little evidence that the political leaders in the major economies possess the political will or capacity to reform the regulatory system in a fundamental manner, or in such a way that it achieves more equitable outcomes in the future. A human rights analysis, therefore, should throw


268 Ruggie, above n 141.

light on inequalities in access to power and on failures of accountability that enabled large institutions to unduly influence regulators and legislators in the first place.

Presently, a concept of cooperation between public and private sectors to form an inter-organisational partnership has been widely accepted and will continue to prosper, especially in countries where the privatisation process has been strongly undertaken.270 The IMF, for instance, has recommended that countries increase the scope of private sector provision of health care as part of loan conditions, often to reduce government debt.271 Similarly, the World Bank has indicated that it seeks 'more pragmatic approaches that build on what is available' by engaging with the private sector in countries where public sector services perform weakly.272 In this regard, the role of government in protecting the right to health, as a public interest, and the way that the new global regulatory strategies can affect them, are highlighted in the literature.

3.3 Human Rights Perspective to Health and Access to Medicine

3.3.1 General Obligations of the Human Right to Health

Public health law introduces distinct analytical frameworks through which pharmaceutical legislation can be evaluated. The legal and economic issues that surround pharmaceuticals have also become more complex and politicised because of the increase in global trade. Thus, the role of medicines has become more important to international agendas as health indicators have been increasingly associated with a country's successful development.273 This is because the use of ineffective, poor quality or harmful medicines can result in therapeutic failure, resistance to medicines or death and can even undermine confidence in health systems, pharmaceutical manufacturers and distributors. Governments need to enact comprehensive laws and regulations to ensure that the manufacture, trade and use of medicines are regulated appropriately to protect public health.

270 Pongsiri, above n 150.
The right to the gradual recognition of the right to the highest attainable standard of health first emerged as a social right in World Health Organization (WHO)'s Constitution. It was also included in Article 25(1) of the Universal Declaration of Human Rights (UDHR) and has been confirmed in numerous international and regional treaties since then. The most important convention in this respect, the legally binding International Covenant on Economic, Social and Cultural Rights (ICESCR), details the realisation of the right to health through four concrete and targeted steps, including access to health facilities, goods, and services. The non-binding, but highly respected, General Comment No.14, drafted by the Committee on Economic, Social and Cultural Rights (CESCR), further specifies in Paragraph 43(d) that access to essential medicines is part of the right to health. Paragraphs 34-37 of General Comment No.14 clearly describe governments' legal obligations to respect, protect and fulfil the right to health. The duty to respect is a negative duty to refrain from interfering with the enjoyment of health rights. The duties to protect and fulfil impose affirmative obligations on governments to take measures to safeguard (to protect) health rights and to take action to ensure that health rights can be enjoyed (to fulfil). The right to health framework in General Comment No.14 enumerates the elements of the right to health as accessibility, availability, acceptability and quality of goods and services, including essential medicines 'as defined by WHO Action Program on Essential Drugs.' As the CESCR explains, the right to health is not a right to be healthy, it 'must be understood as a right to the enjoyment of a variety of facilities, goods, services, and conditions necessary for the realisation of the highest attainable standard of health.'

Most countries have ratified at least one of the international or regional treaties that include the right to health. Accordingly, the WHO Member States have substantial

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279 Ibid, para 12.
280 Ibid, para 9.
responsibilities to recognise and support the right to health and guarantee that it will be exercised without discrimination of any kind and to take deliberate, concrete and targeted steps towards the full recognition of the right to health. They are also obliged to develop national regulations to strengthen their health systems.282

3.3.2 Access to Medicines: A Component of the Right to Health

Currently, the notion of access to medicines as a fundamental element of the right to health has become a direct rather than progressive responsibility for governments to respect and fulfil.283 For a derivative right, or a right considered integral to a larger right, there must be a strong logic to that integration. This rationale can be that appropriate medicines are clearly indispensable to the health of people everywhere, and medicines are public goods. A ‘global public good’ addresses an important issue which cannot be addressed adequately by one government acting alone and must, therefore, be addressed multilaterally.284 It is the public health argument that, without access to medicines, it is beyond reason that a functioning health system can be put in place. Accessibility means that medicines can be obtained with reasonable travelling distance from health facilities.285

The rights-based approach to health signals a paradigm shift to using human rights as a pervasive human value enshrined in the global convention, and not merely constitutional declarations on government policy, as a direction for health development. The assumption is that once people are made aware of human rights as a pervasive value of a democratic society, and assume their role as rights holders, they will take actions to hold the government accountable to improve health service delivery.286

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284 Stiglitz, above n 214, p 8.


Moreover, the legal construction of access to medicine is clearly inseparable from other human rights, and such access can be affirmed as a human right by the right to health (Article 12 of ICESCR). It could, therefore, be argued that any regulatory change or structural reform only starts when governments recognise and admit the importance of medicine by considering it as a part of the right to health and include medicine-related rights in national constitutions.

A statement on health or health care in a national constitution is important in and of itself as it represents explicit commitment regarding health and health care for the country’s population. These commitments can be useful as they may be implemented in the future, and their existence is helpful to those advocating for better health and health care as well as for the implementation of the international human right to health.

The operationalisation of health rights is a dynamic and progressive process. The right to health may be incorporated in the constitution as a constitutional right (positive right), which can be enforced in a court of law. In contrast, when it is incorporated as a directive principle of the government, the right cannot generally be enforced by the courts and instead constitutes a socio-economic objective to guide the government’s actions. Constitutional law, being the highest form of domestic law, thus has significant potential to impact individual health circumstances. Constitutional integration of access to medicine, as a derivative right to the right to health, sets priorities for national health policies and programs and also creates the necessary mechanisms to enforce these rights before the domestic courts.

In almost all the constitutions of the world that have a provision addressing health/health care, the relevant provisions are universal, rather than limited to particular groups. Some of the most resounding constitutional commitments to health and

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289 Kinney and Clark, above n 286, p 291. There are however some exceptions. For example, section 28 of the South African Constitution which specifically provides children with certain rights, such as health care, and not just ‘access’ to such rights. Accordingly: (1) Every child has the right: (a) To a name and a nationality from birth; (b) To family care or parental care, or to appropriate alternative care when removed from the family environment; (c) To basic nutrition, shelter, basic healthcare services and social services; (d) To be protected from maltreatment, neglect, abuse or degradation; (e) To be protected from exploitative labour practices; (f) Not to be required or permitted to perform work or provide services that: (i) Are inappropriate for a person of that child’s age; or (ii) Place at risk the child’s wellbeing, education, physical or mental health or spiritual, moral or social development. (1) Every child has the right: (g) Not to be detained except as a measure of last resort, in which case, in addition to the rights a child enjoys under sections 12 and 35, the child may be detained only for the shortest appropriate period of time, and has the right to
health care are in poor countries with tenuous democracies. Provisions on the right to health have currently been included in the constitutions of many developing countries in the East Asian Region (e.g., the Democratic People's Republic of Korea, Indonesia, India and Bangladesh), East and Southern Africa (e.g.,

be: (i) Kept separately from detained persons over the age of 18 years, and (ii) Treated in a manner, and kept in conditions that take account of (h) To have a legal practitioner assigned to the child by the state, and at state expense, in civil proceedings affecting the child, if substantial injustice would otherwise result; and (i) Not to be used directly in armed conflict, and to be protected in times of armed conflict. (2) A child's best interests are of paramount importance in every matter concerning the child. (3) In this section "child" means a person under the age of 18 years.


Ibid, p 298.

Article 56:
The State shall consolidate and develop the system of universal free medical service, and consolidates the section doctor system and the system of preventive medicine to protect people's life and improve working people's health.

Article 72:
Citizens are entitled to free medical care, and all persons who are no longer able to work because of old age, illness or a physical disability, the old and children who have no means of support are all entitled to material assistance. This right is ensured by free medical care, an expanding network of hospitals, sanatoria and other medical institutions, State social insurance and other social security systems.


Article 4 of the Health Law No 36:
Every person shall have the right to health.

Article 28H (1):
Each person has a right to a life of well-being in body and mind, to a place to dwell, to enjoy a good and healthy environment, and to receive medical care. (2): Each person has the right to facilities and special treatment to get the same opportunities and advantages to reach equality and justice.

Article 34 (3):
The state has the responsibility to provide proper medical and public service facilities.


Article 47:
Duty of the State to raise the level of nutrition and the standard of living and to improve public health. The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties and, in particular, the State shall endeavour to bring about prohibition of the consumption except for medicinal purpose of intoxicating drinks and drugs which are injurious to health.


The decisions of the Indian Supreme Court also held that the Directive Principles of State Policy in Part IV of the Indian Constitution were justiciable. See: Suresh & Another v. State of Haryana, 2014 Indlaw SC 815.

Article 18(1):
The State shall regard the raising of the level of nutrition and the improvement of public health as moving its primary duties, and in particular shall adopt effective measures to prevent the consumption, except for medical purposes or for such other purposes as may be prescribed by law, of alcoholic and other intoxicating drinks and drugs which are injurious to health. (2): The State shall adopt effective measures to prevent prostitution and gambling.

Malawi, South Africa and Swaziland) and Central and South America (e.g., Ecuador, Bolivia, El Salvador and Panama) by relatively recent amendments.

Obvious socio-economic disparities between the countries mean that constitutional framers have different understandings of a right to health and health care, as well as the obligations of governments to provide or facilitate the provision of health care services to realise these rights. Moreover, even nations with more resources can have...
significant deficiencies in their health care sectors in terms of access, cost and quality. Nevertheless, the presence of these constitutional provisions exhibits a national commitment to an important human right. They also establish a policy imperative for the legislative and administrative action. A human rights-based approach aims to build the capacity of rights-bearers to claim their rights and of duty-bearers to fulfil their obligations. Taking steps to adopt appropriate legislative measures is an integral part of a government’s obligation to fulfil rights. Furthermore, when the right to health is included as a positive right in a constitution, the (legal) basis for right-holders to claim health-related rights is improved. Thus, any measures taken to include the right to health in the constitutions of the WHO Member States are positive steps towards the realisation of the right to health. With recent advances in techniques for measuring and comparing health system performance, a consensus is emerging as to what services a national health system should assure or provide and what its goals, in terms of health/health care, should be. These developments will assist in bringing meaning and progress to the realisation of the international human right to health across the globe.302

3.3.3 WHO and the Concept of Essential Medicines

In 1975, the World Health Assembly introduced the concept of ‘essential medicines,’ which quickly became a part of the global public health vocabulary.303 Essential medicines were introduced as those that satisfy the priority health care needs of the population and are chosen with due regard to disease prevalence, efficacy, safety and comparative cost-effectiveness.304 They are used for disease prevention, treatment, and control, and apply to most chronic and acute diseases.305 Given that it is a great concern that an estimated one-third of the population in developing countries are unable to access essential medicines on a regular basis,306 WHO’s primary aim was to improve affordable pricing, rational selection, supply and efficient pharmaceutical

302 Kinney and Clark, above n 286, p 302.
303 World Health Organization, above n 285.
305 Ibid.
regulation to reduce the gap between those who benefit from essential medicines and those who do not. Consequently, this concept became a means to encourage governments to recognise access to essential medicines as an integral element of the right to health to improve the health standards of their citizens.

Later, as requested in the Human Rights Council Resolution 12/24, the Office of the United Nations High Commissioner for Human Rights convened an expert consultation on 11 October 2010, in Geneva, Switzerland. The Resolution contained:

[A]n exchange of views on human rights considerations relating to the recognition of access to medicines as one of the fundamental elements in achieving the full exercise of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health progressively.

The expert consultation focused on access to medicines and current obstacles to providing access to them. The WHO Member States were required to have a core obligation to ensure the satisfaction of minimum necessary levels of each of the rights outlined in the ICESCR. Article IV of the 1978 Declaration of Alma-Ata also identified ‘provision of essential medicines’ as one of the elements of primary health care. Therefore, the concept of essential medicines is now widely accepted as a highly pragmatic approach to providing the best of modern, evidence-based and cost-effective health care.

In response to the problems faced by developing countries, WHO also presented the first Model List of Essential Medicines which serves as a guide for the development of national and institutional essential medicine lists is updated and revised every two years.

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309 Ibid.

310 Constitutional recognition of the right to access medicines and technologies has, therefore, become a national progress indicator in WHO’s Medium-term strategic plan for 2008–2013. Department of Essential Drugs and Medicines Policy, above n 307.


312 World Health Organization, Access to Essential Medicines as a Global Necessity https://goo.gl/WeLxY5 (last access: 13/01/2016).
years by the WHO Expert Committee on Selection and Use of Medicines. When it comes to regulation, this program illustrates WHO’s choice of standards rather than rules; hence, beyond having a list, it was necessary to define elements of availability, accessibility, acceptability and quality of care. The rules laid out for compiling the list reflect a cooperative amalgam of public health and human rights concerns, with an emphasis on equal access and therapeutic effectiveness.

Any binding rules controlling the accessibility of medicines are rooted in regulatory system and laws of the market within national jurisdictions. In this regard, although the primary emphasis of the list was on selecting and supplying essential medicines, the concept also provided the basis for pharmaceutical regulation. The element of affordability is an additional consideration regarding the public health relevance of the medicine. Even after registration, accessibility of the medicines for the clear majority of patients in the developing world depends on their affordability in the market. In this regard, at the heart of the operation of the pharmaceutical sector generally, is prioritisation of the public interest not just among different groups but within the government as well.

3.3.4 Coherence and Primacy

Coherence is one of the biggest challenges facing global public policy. The fragmentation of international legal and policy regimes (the separate evolution of rules governing trade, banking and finance, investment, human rights, etc.) means that rather than complement, they often undermine each other. Examples of fragmentation and incoherence abound. Economic institutions, like the WTO, IMF and World Bank (which operate outside the framework of the UN), and

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313 The notion of public/patients’ interest, generally, is included in the interests of public health organisations/patient activist groups, regardless of the absence of reasonable evidence to prove the appropriateness of this coverage. Nonetheless, there may be some cases in which the benefit-to-risk ratio of using a medicine involves both generous benefits and high risks. In other words, patients can sometimes act against their interests or public interest advocates may relinquish the necessary duty of supporting public health and may insist on improving the accessibility of some medicines, regardless of their side effects and in contrast with the public interest. The fact that patient activist groups have campaigned for the increased availability of medicines to treat some types of illnesses does not change this subtle point about the interests of patients. It is, therefore, preferable to distinguish between actions and interests. John Abraham and Tim Reed, 'Progress, Innovation and Regulatory Science in Drug Development: The Politics of International Standard-Setting' (2002) 32(3) Social Studies of Science 337, p 339.

unrepresentative forums of governments that seek to control large parts of the global economic policy agenda contribute to policy incoherence nationally and internationally. A human rights approach would likely support an ex-ante approach: regulation must be designed to approve every financial innovation after a transparent evaluation of risks involved, thus preventing 'toxic' financial products from entering the markets. A human rights approach would likely support an ex-ante approach: regulation must be designed to approve every financial innovation after a transparent evaluation of risks involved, thus preventing 'toxic' financial products from entering the markets.315 Private financial actors, however, have preferred an ex-post approach, largely because an ex-ante approach slows down financial innovation.316

Within the UN, relationships are similarly fragmented. While institutions, such as the WTO, World Bank and IMF, continuously seek to expand their role in the global economic architecture they have historically been, and remain, unwilling to accept that they bear human rights obligations, and have only selectively adopted elements of international human rights law. Therefore, the UN human rights system has only been a marginal player in UN discussions and responses to the recent economic crisis.

It is no doubt beneficial to the interests of some powerful international institutions and actors to have a disjointed global legal, regulatory and policy framework. It is often convenient for governments if dysfunctional international processes prevent them from addressing global issues that are politically or financially costly. Economic and regulatory reforms are made harder because, while governments are discredited by failures of international governance, an improved system of governance would also disadvantage their political interests in other respects. A political consensus on the primacy of human rights is, therefore, still to be achieved—and their relevance to global economic governance is even less accepted. This is essentially a political rather than a legal issue—new norms are not likely to provide the answer. Advocates of human rights need to build new alliances and intensify efforts to mobilise public and political opinion in favour of human rights principles and standards, even while continuing to fight legal battles.319

315 Ruggie, above n 141, p 6.
316 Ibid.
318 Ruggie, above n 141, p 10.
319 Petrasek and Nagaraj, above n 143, p 9.
As noted earlier, apart from being commercial goods, medicines are also regarded as public goods. However, governments do not have sufficient motivations to contribute to global public goods compared to their national public goods. At the same time, there has been a growth of private sector interest in global public goods. There are many goods and services, for example, water, health care, and education, which are best provided on a public and open access basis rather than on a profit basis. Private ownership of certain goods is problematic because private ownership restricts access. WTO strategies, for instance, assume that private sector initiatives are more efficient and preferable, but private markets may not be able to address problems regarding certain public goods (e.g., the need for low-cost medicines for poor people). Moreover, there is no reason why the WTO should disregard the need for assistance with access to public goods when such facilitation represents a new direction, and when it is proving to be very tough to reach agreement on the further liberalisation of private industry.

3.3.4.1 WTO Strategies and Access to Medicines

The most vocalised criticisms of the WTO's TRIPs Agreement, which covers basic principles and standards for the use of patent enforcement and dispute settlement mechanisms, have concerned its impact on the right to health and the impact of patent rights on the price of medicines. While developing countries need access to affordable, life-saving medicines, developing countries' interests are more focused on the profitable proprietary pharmaceutical companies that research, develop and produce patented medicines. Although TRIPs allows flexibility to enable governments to comply with their obligations regarding the right to health, it makes that task more difficult, notably for poorer countries.

TRIPs' proponents justify pharmaceutical patents, indicating that IP protection restricts trade and competition; hence, IP clauses are somewhat divergent in trade

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agreements, which are ordinarily designed to reduce trade barriers. Seiter argues that some sub-segments of the pharmaceutical market are less sensitive to public health outcomes than others, giving additional options to provide room for economic growth in exchange for tougher quality standards and more competitive pressure around essential medicines. In a competitive national market, there is a potential synergy between the more advanced manufacturers and the regulators. Higher regulatory standards create a barrier to entry for low-quality/price competition. Although low prices are important to ensure access to medicines, medicine policy always tends to prioritise quality over price. Otherwise, the risk of negative consequences for health outcomes, declining trust in public health systems or even disaster in the form of mass causalities is too high.

Patents reward people for their inventions, thus encouraging creativity, especially when those attempts are risky as they may result in costly failure. The money raised from patent protection is also said to be essential to fund the considerable costs of research and development; after all, medicines are better to be available to some people rather than non-existent and available to no one. As such, global IP regimes encourage greater technology transfer between countries, more major foreign direct investment, more significant local innovation within compliant governments and accelerate the economic development of developing countries, with benefits for human rights.

However, the development rationale for global IP protection is dubious, particularly given that even developed countries were not required to respect IP rights during their development. Among the numerous factors that impact detrimentally on the accessibility of medicines, high prices generated by patents is a key factor. The exclusion of patented medicines is caused by their high prices rather than any lack of equal effectiveness compared to the cheaper medicines. With the absence of competition, the patentee can set higher prices during the period of protection, which can only be afforded in developed countries. Hence, prices will be artificially inflated.

323 Joseph, above n 320, p 220.
324 Seiter, above n 18, p 115.
326 Ibid.
327 Joseph, above n 320, p 244.
for the prescribed 20-year period, as patent-holders seek to maximise returns on their investment.328

One important criterion for inclusion on the WHO Essential Medicine List is cost-effectiveness. Although only about 5% of medicines on the current list are protected by patent,329 many patented medicines are the only/the most effective treatments available for certain diseases. Given that many governments cannot afford patented medicines, they are not cost-effective; thus, they are excluded from the list. However, governments in developing countries still have progressive obligations to provide all effective medicines, whether they are on the list or not.330 and they should not take retrogressive steps in regard to the availability of such medicines, including precluding the introduction of a patent regime.331

In this regard, in a statement about the relationship between IP and other ICESCR rights in 2001, the CESCR declared that:

[A]ny intellectual property regime that makes it more difficult for a government to comply with its core obligations in relation to health, food, education, especially, or any other right set out in the Covenant, is inconsistent with the legally binding obligations of the State party.332

The CESCR believes that a government’s acceptance of TRIPs or other WTO commitments breaches its ICESCR obligations if fulfilment of the above requirements jeopardises enjoyment of the right to health.

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328 Ibid.
329 World Health Organization Expert Committee, above n 304.
331 The Committee on Economic, Social and Cultural Rights has included the following as examples of Government practices that violate Article 12:
[T]he adoption of laws or policies that interfere with the enjoyment of any of the components of the right to health, and the failure of the State to take into account its legal obligations regarding the right to health when entering into bilateral or multilateral agreements with other States, international organisations and other entities, such as multinational corporations.
As the former UN Special Rapporteur, Paul Hunt indicated in his 2006 report, governments are at the least expected to take advantage of TRIPs flexibilities to make life-saving medicines available to their populations.

State parties should ensure that the right to health is given due attention in international agreements and, to that end, should consider the development of further legal instruments. In relation to the conclusion of other international agreements, States parties should take steps to ensure that these instruments do not adversely impact upon the right to health. Similarly, States parties have an obligation to ensure that their actions as members of international organisations take due account of the right to health.

The recognition of a right of access to medicine was also affirmed by consensus in the UN Human Rights Council in 2009. That said, the Council expressed concerns about its effect on prices and called on all governments to enforce IPRs in a manner which did not restrict the ‘legitimate trade in medicines’ and which provided ‘safeguards against the abuse’ of such rights.

3.3.4.2 TRIPs and Governmental Duties Regarding the Right of Access to Medicines

Considering the adaptabilities allowed under TRIPs, as well as the justification for patents in promoting future research and development, one should examine whether governments can simultaneously combine TRIPs and their human rights duties regarding access to medicines. Article 27(2) of TRIPs allows governments to prohibit the patentability of products, ‘the prevention within their territory of the commercial exploitation of which is necessary to protect...human, animal or plant life or health.’


336 World Trade Organization, Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), Annex 1C of the Marrakech Agreement Establishing the World Trade Organization,
Article 30 contains another exception to TRIPs' obligations regarding patents:

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. The rights of impoverished sick people should be recognised as legitimate third-party interests for the purposes of Article 30.337

Article 31 permits governments to issue compulsory licences in respect of the generic manufacturing of patented medicines for a purpose without the consent of the patent-holder. Such targets might include a government’s need to address an unwillingness by the patent holder to license the sale of the product or to combat anti-competitive practices.338 The patent owner must, however, be notified as soon as possible in such circumstances.

Article 33 of TRIPs requires the WTO Member States to provide protection for patent rights for 20 years. Developing countries were given a period to comply, these timelines have now run out for all Member States, with the expectation of the least developed countries.339 Under Article 6, TRIPs explicitly has no impact on the ‘exhaustion’ of IPRs. However, fatigue rules regulate the control a patent-holder has over patented medicines after their original sale.340 Hence, once IPRs have been exhausted, the patent-holder has no control over subsequent sales. This means that TRIPs has no impact on parallel importation, which involves the importation of

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338 A compulsory licence is a licence granted by the competent national authority to allow a third party to manufacture a patented medicine without the authorisation of the right holder. United Nations General Assembly, above n 333, para 36.


patented goods by one government from another if the product was marketed in the latter government by the patent–holder. 341 Parallel importation can reduce the price of a product if it is sold in another country at a lower price.

TRIPs does not ban governments from adopting laws which allow for the opposing and annulment of patents in appropriate situations. 342 Ellen 't Hoen has concluded that the system is 'highly unlikely [to] provide sufficient economic incentive to keep the generic medicines (means copies of brand-name medicines that have the same dosage, intended use, effects, side-effects, route of administration, risks, safety, and strength as the original medicine and their pharmacological effects are the same as those of their brand-name counterparts) sector in business,' 343 and to fight diseases where the potential paying market is small or uncertain. The battle over TRIPs and pharmaceuticals in the WTO culminated with the adoption of the Declaration on the TRIPs Agreement and Public Health in 2001, in which TRIPs did 'not and should not prevent members from taking measures to protect public health.' 344 Hence, TRIPs 'can and should be interpreted and implemented in a manner supportive of WTO members' right to public health and, in particular, promote access to medicines for all.' 345

However, one general restriction in TRIPs on compulsory licences is that the licence, under Article 31(f), must be issued 'predominantly for the supply of the domestic market.' 346 This provision was perceived as questionable, as many developing countries lack the capacity to manufacture generic pharmaceutical products, and therefore must import generics from countries which have such a capacity. Indeed, governments may export compulsory licensed products so long as such exports are 'less than a predominant part of the production.' 347

341 Abbott and Reichmann, above n 321, p 968.
342 United Nations General Assembly, above n 333, para 50.
344 World Trade Organization, Declaration on the TRIPs Agreement and Public Health, No. WT/MIN(01)/DEC/2, Doha, 2001, p 1, para 3.
345 Ibid.
347 Abbott and Reichmann, above n 321, p 958.
Moreover, the WTO's General Council waived the territorial restriction on compulsory licences for pharmaceutical products in certain circumstances in 2003.\textsuperscript{348} Under the waiver, the regional restrictions on compulsory licences may be lifted to ease the export of generic medicines to governments that inform the TRIPs Council of an aspiration to import due to a lack of manufacturing capacity, to combat public health emergencies as specified in the Declaration. The Doha Declaration and the waiver have prompted some pharmaceutical companies, who feel threatened by compulsory licensing schemes, to make their products available to developing countries on a reasonable/cost-free basis.

### 3.3.4.3 The Doha Declaration, Access to Medicines and Developing Countries

The adoption of the Doha Declaration was the result of a carefully expanded strategy by developing countries and a significant achievement for them. It is a strong political statement that makes it easier for developing countries to adopt unavoidable measures to guarantee access to health care without the fear of facing a legal battle. While acknowledging the role of IP protection ‘for the development of new medicines,’ the Declaration explicitly recognises concerns about its effects on prices.\textsuperscript{349} It is implicit within the Declaration that differentiation in patent rules may be necessary to protect public health. The determination of public health and notably medicines, as an issue needing attention in TRIPs implementation constitutes a recognition that public health-related patents may be treated differently from other patents.\textsuperscript{350} It substantially formulated one aspect of TRIPs to avoid unjustified pressure from pharmaceutical companies and developed countries. Therefore, in cases of ambiguity, panels and the Appellate Body should opt for interpretations that are effectively supportive of WTO Member States’ right to protect public health. The confirmation that the TRIPs Agreement has left room for flexibility at the national level has significant political and legal implications. It indicates that the pressures to impede the use of available flexibilities run counter to the spirit and purpose of the TRIPs Agreement.

\textsuperscript{348} United Nations General Assembly, above n 333, para 27.


In Paragraph 5, the Declaration prescribes the decisive measures and flexibilities within TRIPs. For example, compulsory licences can be used to defeat IP obstacles to access medicines, however, most developing countries have been incapable of using compulsory licences because of the fear that developed countries would impose sanctions on them. Suitable features of any possible solution to the problem of compulsory licensing in countries with little or no manufacturing capacity or insufficient market demand would include: a consistent international legal framework, transparency and uniformity of the applicable rules in the exporting and importing countries, genuine and quick legal procedures in the exporting and importing countries, equality of opportunities for countries in need of medicines, facilitation of a variety of potential suppliers of the required medicines, and broad coverage in terms of health problems and the range of medicines.

The Declaration clarifies that the use of compulsory licensing is not restricted to the cases of emergency; the ‘public health crisis’ can represent ‘a national emergency or other circumstances of extreme urgency’ and an ‘emergency’ may be either a short-term or a long-lasting situation. The Declaration also places the burden on a complaining Member to prove that an emergency or urgency does not exist.

Under the TRIPs Agreement, generic medicines would have to be produced under a compulsory licence with the exception of those from least developed countries that did not have the manufacturing capacity. For many countries the existence of compulsory licensing did not provide any possible relief in providing essential medicines. It caused serious concerns to many developing countries that had neither the manufacturing capabilities nor the infrastructure to take advantage of the compulsory licensing provisions. Consequently, it was agreed under the implementation of Paragraph 6 of the Doha Declaration that the Declaration granted rights to developing countries to waive the provisions of Article 31(f) of the TRIPs Agreement and allowed member countries to export generic pharmaceutical products.

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351 Ministerial Conference of The World Trade Organization, Doha Declaration, 2001, para. 5.
352 World Health Organization, above n 285.
354 Ibid, p 17.
made under compulsory licences to meet the needs of importing countries also subject to certain conditions.355

The fallout of the Doha Declaration brought some positive changes in enabling developing countries to gain access to essential medicines. The pharmaceutical industry, which had always lobbied for high levels of IP protection in developing countries, took the position that the central theme of the declaration was to acknowledge the value of IP protection and to recognise the TRIPs Agreement as part of the solution to better public health and improved access.356 Nonetheless, despite the 2001 Doha Declaration and the 2003 waiver, there has been increasing pressure on the countries wanting to join the WTO to adopt measures that conflict with the spirit of the Doha Declaration. For instance, TRIPs-Plus provisions, which impose even stricter IP obligations than TRIPs on governments, have also been imposed as conditions on governments that have acceded to the WTO. Typical TRIPs-Plus provisions include longer patent terms, a guarantee of patentability for second uses, a security of data exclusivity, further conditions on compulsory licensing, bans on parallel imports, and stronger enforcement mechanisms.357 This conflicts with the widely held view that the Declaration gives broad discretion to governments in deciding how to counter pharmaceutical prices and that the Declaration added up to an explicit statement that public health concerns outweigh full protection of IP. This clarifies a government’s right to adopt an international principle of exhaustion of rights and that the impact of the provisions of the TRIPs Agreement is to leave each Member free to establish its regime for such exhaustion without challenge.358

However, as McBeth claims, the TRIPs Agreement does not directly conflict with the right to health; rather, the greater hindrance to the realisation of the right to health in the context of access to essential medicines is not the framework of international trade law, but the conduct of governments and pharmaceutical corporations under

358 World Trade Organization, Declaration on the TRIPs Agreement and Public Health, No. WT/MIN(01)/DEC/2, Doha, 2001, para 6.
cover of the responsive, or at least ambiguous, IP provisions of the WTO system. For example, technical incapacities impede the ability of some developing countries to utilise TRIPs’ flexibilities. In this respect, they may receive technical assistance under Article 67 of TRIPs. However, such technical assistance had often prompted developing countries to implement TRIPs before they were required to, and indeed to adopt IP laws that extend protection beyond that required under TRIPs.

Although the Member States may issue compulsory licences for importation, they are restricted to importing goods from countries where pharmaceuticals are not patented, or where their term of protection has expired. As the sources for the generic production of newer essential medicines will progressively be exhausted after 2005, settling this problem is of extreme importance to secure access to affordable medicines to address public health needs. In fact, the Doha Declaration was supposed to offer a genuine and efficient solution to the problem posed by Paragraph 6. However, the outcome is far from that and presents a regularly complex solution. It contains increased risks in producing generic medicines coupled with reduced benefits to shrinking markets because of the exclusion of some markets.

Developing countries should, thus, refrain from following the best practice guidelines and pharmaceutical market regulations which attempt to evolve medicines because they consistently make prices more expensive. It is true that providers are more likely to serve the public interest, rather than just their own interests, when the government (in its capacity as an owner, regulator or purchaser) makes determined efforts to shape their incentives to serve the public interest. However, the pharmaceutical markets favour providers in the absence of sufficient oversight and regulation. This challenge is of the utmost importance for international economic and human rights advocates.

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359 McBeth, above n 340, p 150.
3.3.5 Human Rights Ritualism

One can say that, on one level, the human rights system appears to be a success story of international law: the development of human rights norms and institutions at the international level is significant, as is the level of participation in the system. However, the implementation of UN human rights obligations presents a less positive picture: it is partial, inconsistent and based on a haphazard system of shaming. Governments may legally commit themselves to human rights standards, but often this does not translate into human rights protection at the national level. For example, governments often announce human rights initiatives prior to their review, and mission staff in Geneva display a marked willingness to engage with civil society throughout the review process. However, there is a widespread disregard for human rights norms; indeed, treaty participation at the global level does not appear to have a clear effect on the protection of human rights in a country.

Human rights also have a precarious status within international institutions. For example, Darrow and Arbour have examined the way that UN operational activities in development take human rights into account, concluding that human rights have only an uncertain and marginal influence on UN practice. A common complaint is that there are great gaps between human rights standards set out in treaties and human rights protection offered by governments. Scholars have charted the relationship between treaty acceptance and government behaviour, finding little correlation between the two. Some studies show that ratification of human rights treaties is sometimes followed by increased violations of human rights. In other words, governments gain legitimacy from treaty ratification but lose little by failure to

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366 Charlesworth, above n 134, p 359.
367 Darrow and Arbour, above n 317.
implement them. Variations on this conclusion are that treaty participation improves human rights practices in democracies, but not necessarily otherwise.\(^{370}\)

Regulatory theorists have used the term ‘ritualism’ to describe the way of adapting to a normative order, building on sociologist Merton’s typology of five modes of individual adaptation to cultural values: conformity, innovation, ritualism, retreatism and rebellion.\(^{371}\) These modes also appear at the level of organisations and among collectives. All five modes are evident in responses to international human rights regulation, but ritualism is particularly pervasive. It can be defined as ‘acceptance of institutionalized means for securing regulatory goals while losing all focus on achieving the goals or outcomes themselves’.\(^{372}\)

The concept of regulatory ritualism captures an important feature of the international human rights system. The high ratification rates of human rights treaties illustrate the preparedness of UN Member States to accept the institutionalised normative order. This may be a response to pressures from the international community, for example, ratification of human rights treaties may be a conduit for development assistance or newly independent countries may accept human rights treaties to signal their membership of the international community. Ratification is a relatively straightforward step, involving a formal bureaucratic process, but the implementation is much more costly and complex. Rights ritualism is a more common response than an outright rejection of human rights standards and institutions. Ritualism is a technique of embracing the language of human rights precisely to deflect human rights scrutiny and to avoid accountability for human rights abuses, while at the same time gaining the positive reputational benefits or legitimacy associated with human rights commitments.\(^{373}\)

Practices of ritualism can include ratifying human rights treaties without implementing their provisions domestically, perfunctory reporting to international human rights bodies, failing to provide remedies for human rights breaches or to

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\(^{371}\) Robert King Merton, Social Theory and Social Structure (Simon and Schuster, 1968), p 194.


develop a policy to prevent violations. Scrutiny mechanisms can also discourage
governments from undermining the legitimacy gained initially by signing on to
international human rights instruments. It is also possible that involvement over
time in a cooperative regime leads to an internalisation by participants of the regime’s
goals. Along with recognition of the potential offered by self-regulation and peer
review in certain contexts, the regulatory literature also offers the idea of continuous
improvement, including incremental, constantly monitored steps, rather than great
leaps forward.

3.4 Regulatory Theory: Introducing a Progressive Model of Governance

International Relations Realists often dismiss human rights law as idealistic waffle
because the realist theory posits the centrality of one type of actor, governments, and
a single type of motivation, pursuit of interest. Realism is based on assessments of
national interest from the vantage point of those with political and military power; it
discards the more diffuse evidence of what the weak are up to. On this analysis,
human rights law, which gives priority to the interests of individuals and minorities,
is unlikely to play a significant role in international relations. Regulatory theory, in
contrast, draws attention to the multiplicity and complexity of both actors and
motives in the international sphere, deploying the notion of regulatory webs of
influence. It observes that, at the global level, each separate regulatory control
tends to be weak, and strength comes through the weaving together of frail strands to
form the web and its animation by networks.

Regulation holds a variety of functions that play a particular role in a framework in
which the rules and policies are laid. It must be designed and implemented to avoid
policy failure and should be compatible with the existent rules, and with the system’s

374 Charlesworth, above n 134, p 365.
375 Wade M. Cole, ‘Human Rights as Myth and Ceremony? Reevaluating the Effectiveness of Human
376 Ryan Goodman and Derek Jinks, ‘How to Influence States: Socialization and International Human
377 Charlesworth, above n 134, p 367.
379 Braithwaite and Drahos, above n 364, pp 550-563.
380 Ibid.
collective goals. To represent the highest amount of consistency with the whole system, the scope of discretion and preference also alter due to various national priorities.

In this regard, the regulatory theory offers different approaches to the problem of the weak implementation of human rights standards. It draws attention to how international human rights law shapes behaviour both inside and outside international institutions. The concept of regulation has been described as ‘the intentional act of attempting to control, order or influence the behaviour of others’. A more expansive account of regulation includes all forms of pressure to change the course of events, even the unintentional effects of the agency. The regulation thus goes beyond legal rules and mechanisms and comprises political, social and economic pressures. Understood in this way, the notion of regulation is much broader than that used in the international law literature to mean governmental imposition of public obligations on private parties.

The lack of dialogue between the fields of human rights and regulation relates perhaps to their differing traditions. The focus of human rights has been largely on individual claims to universally applicable rights against the government and their capacity to mobilise and promote social change. Regulatory scholarship, on the other hand, is often associated with a quest for efficiency and rational design of institutions. Morgan summarises the popular perception that rights and regulation are antithetical, as ‘rights claims act as constraints on governmental discretion while regulation allows the government to flex its muscles’. However, human rights standards can be invoked by governments in an instrumental way to increase their powers, as well as by individuals and groups to promote governmental reform. Equally, international regulatory institutions can both restrict the governmental power and promote human rights. The main issue here is not so much the relationship

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385 Morgan and Yeung, above n 35.
386 Ibid, p 18.
between the fields of human rights and regulation, but how regulatory theory can inform the field of human rights.

3.4.1 Non-government Participants: New Patrons of Public Interest

The pharmaceutical sector’s regulatory structure and economic governance provide the link between the public interest and the financial outcome. This link can be analysed using a classification of regulatory regimes that examine the relationship between political interests and institutions, especially governments and industries. WHO explains such a notion through the term of ‘stewardship.’ Stewardship – sometimes more narrowly defined as governance – refers to the broad range of functions carried out by governments as they seek to achieve national health policy objectives. In addition to improving overall levels of population health, targets are likely to be framed in terms of equity, coverage, access, quality and patients’ rights. National policy may also define the relative roles and responsibilities of the public, private and voluntary sectors in the provision and financing of health care.

Stewardship includes: maintaining the strategic direction of policy development and implementation; detecting and correcting undesirable trends and distortions; articulating the case for health in national development; regulating the behaviour of a wide range of actors, for instance from pharmaceutical financiers to pharmaceutical providers, and establishing effective accountability mechanisms. Beyond the formal health system, stewardship represents assuring that other areas of government policy and legislation promote peoples’ health. While the scope for exercising stewardship functions is greatest at the national level, the concept can also cover the steering role of regional and local authorities. Thus, a fundamental concern in many countries is to develop the capacity needed to implement stewardship functions. This, in turn, requires a better understanding of what constitutes best

390 Ibid.
391 Ibid.
392 Ibid.
practice when it comes to stewardship and how the national administration can be
developed.

Nonetheless, as Abraham argues, any reform is a selection of values that show the
beliefs of a society which lead to a reallocation of power, benefits and harms to
promote the competition among interest groups in society.\textsuperscript{393} Political will and
qualified managers and regulators are indispensable to achieving effective and
efficient policy reforms, particularly in developing countries. The debate related to
this issue has been divided between those supporting universal governmental
pharmaceutical care availability and those advocating for the private sector to provide
care in areas where the public sector has usually failed. Private sector advocates have
pointed to evidence that the private sector is the primary health provider, as many
poor patients prefer to seek care at private clinics.\textsuperscript{394} Public sector advocates,
however, view government as a crucial player in a system in which efficiency can be
only one of many goals. They also suggest that the private pharmaceutical sector may
be more efficient and responsive to patient needs because of market competition,
which they indicate should overcome government inefficiency and corruption.\textsuperscript{395} In
this regard, in 2016, researchers at IMF stated:

There is much to cheer in the neoliberal agenda. The expansion of global
trade has rescued millions from abject poverty. Foreign direct investment
has often been a way to transfer technology and know-how to developing
economies. Privatisation of public enterprises has in many instances led to
the most efficient provision of services and lowered the fiscal burden on
governments.\textsuperscript{396}

However, some neoliberal policies, such as freedom of capital and financial
consolidation are criticised for increasing inequality, in turn endangering enduring
expansion. Public sector proponents have emphasised inequities in access to
medicine because of the inability of poor citizens to pay for private services. They

\textsuperscript{393} See generally: John Abraham, 'The Science and Politics of Medicines Regulation' (1997) 19(19B)
Sociology of Health & Illness 153.

\textsuperscript{394} Berendes et al, above n 265, p 2.

\textsuperscript{395} See for example: G. Rosenthal and W. Newbrander, 'Public Policy and Private Sector Provision of
Health Services' (1996) 11 International Journal of Health Planning and Management 203.

\textsuperscript{396} Jonathan D. Ostry, Prakash Loungani and David Furceri, 'Neoliberalism: Oversold? ' (2016) 53(2)
IMF Finance and Development, p 54.
note that private markets often fail to deliver public health goods, including safeguarding services (a market failure) and lack of coordinated planning with public health systems, required to curb epidemics.397

Several studies also observed higher prescription pharmaceutical costs in the private sector for similar clinical diagnoses.398 Both generic and brand-name medicines have been found to be higher in price in the private sector.399 For instance, as indicated in a study in Tanzania, Tanzanian private facilities typically used more brand-name medicines, but even generic medicines were five times greater in price.400 Similar findings were reported in India and Bangladesh.401 A study of the Malaysian health system found that an increase in privatisation of pharmaceutical services was associated with an increase in medicine prices and a decrease in the stability of prices.402 Pharmaceutical costs in Colombia and some parts of South Africa have had the same impact.403 Moreover, several World Bank studies found significant fragmentation in purchasing and distribution across and within the public and private sectors, resulting in higher pharmaceutical prices.404

397 See for example: Basu et al, above n 86.


399 Patel et al, above n 398, p 10.

400 Justin-Temu et al, above n 398, p 113.

401 Patel et al, above n 398, p 11.

402 Babar and Izham, above n 398.


As the critics argue, economic liberalisation also increases the possibility of corruption and regulatory capture in the pharmaceutical regulatory system. Much of the corruption found in this system is caused by the large amounts of money involved in it, making it an attractive target for abuse, corruption and unethical practices. Poorly defined and documented processes, a lack of checks and balances, unclear roles and responsibilities, as well as the lack of transparency and accountability in any part of the pharmaceutical chain can also increase vulnerability to corruption. Therefore, the steadiness of non-government participants in protecting public health in the absence of a central monitoring system/the government can be controversial. Even in the absence of corruption, privatisation should not be implemented to improve economic efficiency alone. Less governmental power is not inevitably better; hence, just because privatisation may reduce the role of government in the economy, it is not necessarily beneficial. The consumers, Starr argues, are also interested in access, community participation and distributive justice: ‘Democratic politics, unlike the market, is an arena for explicitly articulating, criticizing, and adapting preferences; it pushes participants to make a case for interests larger than their own. Privatisation diminishes the public sphere of public information, deliberation, and accountability.’ Accordingly, neoliberalism is criticised for being not so much a repudiation of planning than an endeavour to meet the public interest.

The 2016 IMF report leads to three conclusions:

a) The benefits regarding increased growth seem rather difficult to establish when looking at a broad group of countries.

b) The costs regarding increased inequality are significant. Such costs exemplify the trade-off between the growth and equity effects of some aspects of the neoliberal plan.

c) Increased inequality, in turn, damages the level and sustainability of growth. Even if growth is the sole or primary purpose of the neoliberal agenda, advocates of that plan still need to pay attention to the distributional effects.


406 Starr, above n 105, p 23.

407 Ostry, Loungani and Furceri, above n 396, p 54.
However, significant conflicts of interest may apply to both private and public sectors, as large private international contractors, insurance companies and non-governmental organisations (NGOs) may benefit from expanding the role of the private sector. There is also a third perspective indicating that the issue is not merely whether ownership is private or public. As Hanson et al. note, ‘a strengthened evidence base on the performance of the public and private pharmaceutical sectors is essential to guide decision-makers towards policy choices that are appropriate for their contexts.’

Nevertheless, studies comparing the performance of private and public sectors are difficult to implement for various reasons. First, pharmaceutical services are not paired between public and private providers, as some practitioners participate in both systems, and many systems are dually funded or informal (e.g., the role of informal payments in public facilities). Second, public pharmaceutical services and private services have coexisted in many developing countries for decades; most countries have a significant portion of health care expenditures paid for by the government, with most of the remainder paid for by households. In this context, merely identifying what is private or public is not simple.

Therefore, a prime objective of the institutions of economic governance is to ensure a sound investment atmosphere for international corporations. It is necessary to minimise government regulation of the private sector to promote private capital investments and develop international market relations. In fact, privatising the notion of public interest correlates with the privatisation of public industries that is currently in force in most countries around the world. This new policy consensus of the dominant economic institutions has profound implications for advocacy NGOs. Non-government participation, as a phenomenon, may involve an overall restructuring of public and private interests—at stake is not the struggle between government and society, but a re-evaluation of private interest and the public good. Market imperatives of privatisation and deregulation are assumed to be more or less non-


\[411\] Kamat, above n 388, p 156.
negotiable, and corporations, advocacy NGOs and governments are expected to negotiate the interests of their particular constituency to the extent possible. In most developing countries this policy change involves a massive shift from a government-managed and government-protected economy to a 'free enterprise' economy with minimal government subsidies.

The current debates on the role of public and private sectors, nonetheless, point to the dangers of NGOs 'replacing' the government in market economies. Given expanding market economies, NGOs are stepping in to respond to the needs and demands of the poor and marginalised sections of society. By pointing to this trend, development analysts caution that there are no mechanisms by which NGOs can be made responsible to the people they serve. Thus, the work of the government still needs to be done, particularly in sectors that are not profitable for private investors. In this regard, a balanced relationship or partnership between governments and NGOs can best serve the public interest.

Ayers and Braithwaite introduce the notion of 'tripartism' as a regulatory policy that advances NGO participation in the regulatory process by granting NGOs access to all the information that is available to the regulator, a seat at the negotiating table with the company and the agency when deals are done, and the same standing to sue or prosecute under the regulatory statute as the regulator. Accordingly, tripartism reduces the temptation pay-off the company can achieve through corruption. Tripartism engenders incentives for regulatory players to develop trust and to derive rewards by learning to be concerned about the interests of others. Also, under tripartism, NGOs can add substantially to the capacity of agencies to monitor outcomes. The attraction of cooperative strategies to NGOs is also enhanced by their direct involvement in the game and by the new information they gain. When tripartism succeeds in building trust and honest communication, all players will be better able to recognise when the others are cooperating.

However, the leading question is under what circumstances will private managers be more likely to act in the public’s interest. The debate over privatisation needs to be

412 Ibid, p 159.
413 Ibid, p 164.
414 Ayres and Braithwaite, above n 234, p 440.
415 Ibid, p 441.
viewed in a larger context and recast in the light of the recent argument that has raged in the private sector over mergers and acquisitions. Refocusing the debate to assess the influence of privatisation on managerial control moves the discussion away from the ideological ground of private vs. public to the more pragmatic field of managerial behaviour and responsibility. Based on this approach, the advantages and disadvantages of pharmaceutical sector privatisation can be measured against the standards of proper administration — regardless of ownership. What emerges are three conclusions:

a) Neither public nor private managers will always act in the best interests of their shareholders.

b) Profits and the public interest overlap best when the privatised service or asset is in a competitive market. It takes competition from other companies to discipline managerial behaviour.

c) When these conditions are not met, continued governmental involvement will be required. The simple transfer of ownership from public to private hands will not necessarily reduce the cost or enhance the quality of services.

Freeman introduces a new approach in which, instead of considering privatisation as a means of shrinking government, it is a mechanism for expanding government's reach into realms traditionally thought private. In other words, she considers privatisation as a tool of 'publicisation,' through which private actors increasingly commit themselves to public goals as the price of access to lucrative opportunities to deliver goods and services that might otherwise be provided directly by the government. Therefore, instead of compromising norms of responsibility, due process, equality, and rationality, privatisation might extend these standards to private participants through regulatory means (e.g., budgeting strategies or legal contracts).

The publicisation effect would, of course, be highly dependent on the political will of the Parliament and the executive branch, as well as the judiciary system. However, the question remains whether this effect can be predictably built into a privatisation


417 Ibid, p 27.

418 See generally: Freeman, above n 92.
scheme and, if so, how can this be best done. Specifically, justification of publicisation and evaluation of its success must overcome three main objections. The first one is that publicisation will not occur because there is no incentive for the government to demand it. The second is that it will not address the most serious risks associated with privatisation. The third one is that if publicisation occurs, it will effectively turn private actors into public ones, undermining the benefits of privatisation.

Therefore, the potential for extending public norms to private participants presumes that the features of any privatisation scheme are thoroughly extrinsic and there is nothing inevitable about the shape it may take.419 One, then, can conclude that the primary criterion is that privatisation works best when private managers find it in their interests to serve the public interest. For this to occur, the government must define the public interest in such a way that private providers can understand it and contract for it. The best way to motivate this alignment between the private sector and the public interest is through competition among potential providers, which may include governmental entities, making them respond to the expressed wishes of the citizens.420 A foundation of the new economic thought, concerning the overlapping disciplines of public and private sectors, is mainly oriented towards the concept of a mixed economy that comprises a vast variety of economic patterns, which are neither entirely dominated by government enterprises, nor operating under an entirely unregulated system of competitive private companies.421 Such a regulatory environment creates greater interdependencies, requiring more coordination across public and private organisational boundaries.

3.5 Conclusions

Examples of laws and rules intended to prevent undesirable market results include rules enhancing the accessibility of health care, or provisions ensuring an income in the event of sickness. The political decision-making process consists of various participants who will aim for their targets under different constraints. Several regulatory theories have sought to evaluate the relationships between public and

419 Ibid.
420 Goodman and Loveman, above n 416.
421 Pongsiri, above n 150.
private participants in the regulatory system to understand their behaviour and prioritise their objectives from different perspectives. In contrast to the market economy, it is unclear in the political decision-making process how participant interaction will lead to maximum economic welfare.

Increasingly, there is a consensus that human rights should incorporate the ability of individuals to maintain and restore good health through access to at least a basic level of primary care, including essential medicines. WHO, the World Bank and major international development NGOs all promote rights-based approaches to poverty reduction and health development. However, the right to health is not reflected in the current global situation, in which entire populations—particularly the poor and underprivileged—commonly have little or no access to essential medicines or other basic health services. However, access to medicines cannot be addressed in isolation either from the rest of the health system or from the overall health situation in each country. Access to medicines is an integral part of healthcare, the various components of which are mutually supportive. Measures in all these areas will need to be backed by the systematic and ongoing assessment of the needs of a country. On all levels, there will be a need for institutional development.

Since governments are expected to adopt and implement the best regulatory strategy, there are many tools to localise pharmaceutical strategies to make them adaptable to national regulatory systems. Based on the discussion in this chapter, developing economies are more lacking in all the capacities necessary to make responsive regulation work well than are developed countries. Whatever the level of these deficits, in an era of networked governance, weaker actors can enrol stronger ones to their projects if they are adept.

As discussed in this chapter, the health sector is characterised by complexity, a plurality of players (national and state governments, public and private providers, professions, and consumer groups), rapid change in its environment, and a recent proliferation of regulatory agencies and regulatory strategies. This chapter argues that responsive regulation—the use by regulators of mechanisms that are responsive to the context, conduct and culture of those being regulated—is a promising strategy for improving the quality and safety of patient care. The governance of health safety and quality, which presents contemporary research on regulatory thinking. While definitions of regulation abound, this thesis uses the term to mean governance in the
broad sense of steering the flow of events, rather than the narrow sense of enforced compliance with rules. In the new regulatory state, with its increasing privatisation, regulation by government and its agents has become more rather than less common, but the crucial difference from the old command and control view is that governments increasingly ‘steer not row’ and are seeking flexible, participatory and devolved forms of regulation. These changes are possible given the changed nature of organisations in the information age, where power flows through networks that are more fluid and complex than older structures of governance. This perspective is particularly appropriate in the health sector with its multiple players and where the governments generally have left the regulation of health care performance to the medical profession. Responsive regulatory escalation can, hence, be accomplished both by escalating governmental intervention and networking of new players of domestic and transnational governance.

Based on the theoretical contexts discussed in this chapter and the previous one, the following chapter evaluates how the Iranian regulator is facing the current global economic and political shifts towards regulatory governance and how it is dealing with the necessity of national regulatory reform in the pharmaceutical area. Thus, the next chapter seeks to assess how the Iranian economic system is structured, how privatisation of the economy has gone so far, and how it has influenced the national pharmaceutical industry and the rights of Iranian citizens to health and access to medicines.
Chapter 4 – The Pharmaceutical System in Iran: Realities and Rigidities

4.1 Introduction

As discussed in the foregoing chapter, the pharmaceutical system, in contrast with most other business sectors, has always been exposed to more governmental interferences, often justified by the economic theories of market failure in health care and the critical role of medicines in public health. As a general principle, the aim of all pharmaceutical laws should be to protect patients, and the government should pay attention to regular assessment of different parts of the system to ensure that medicines to be used by the public meet the established standards of quality, safety, and efficacy. The argument advanced in the preceding chapter, then, followed some explanations for the perceived failures of the current regulatory system affecting international/national behaviours and introduced some aspects of regulatory scholarship that may enhance approaches to protecting the human right of health and access to medicines. Such a multidimensional structure of the pharmaceutical system and the need for a common framework for dealing with existing problems have led to the development of national pharmaceutical policies.

The aim of this chapter is to provide an overview of Iran’s pharmaceutical regulatory framework and its major topics regarding the National Development Plan goals and provide a broad picture of the legal infrastructure in the Iranian pharmaceutical market as a case study. In so doing, this chapter presents a chronological history of the Iranian pharmaceutical market since the Revolution and the major events that have occurred. This chapter contributes to the assessment of the current policy reforms in the Iranian pharmaceutical sector in regard to their urgency, context, content and effectiveness. The chapter consists of two stages. The first examines the exigency of the current reforms and provides an analysis of the relative performance of the economy since 1980. The second seeks to determine whether current reforms have improved the performance of the pharmaceutical system and have facilitated access to medicines for Iranian citizens, determining the ‘structural trap’ preventing
Iran from approaching its full potential regarding economic efficiency. It highlights the structural rigidities of Iran’s economic and regulatory regime, most notably the political uncertainty, legal gaps, systematic capture and corruption, and dominance of inefficient public enterprises in the pharmaceutical area, that highlight the importance of adopting a responsive regulatory approach.

4.2 Country Profile: Demographic, Economic, Health and Pharmaceutical Information

Iran is the second-largest economy in the Middle East and North African region after Saudi Arabia. It also has the second-largest population of the region after Egypt, with an estimated 78.8 million people in 2015. Iran’s economy is characterised by the hydrocarbon, agriculture and services sectors, and a noticeable state presence in manufacturing and financial services. Related to demographic, economic, health and pharmaceutical contexts, Iran is currently a developing country. Yet, Iran is an upper-middle-income country ($4,036 US to $12,475 US) according to the World Bank’s classification. The gross domestic product (GDP) per capita in Iran was last recorded at $393.7 billion US in 2014. Iran’s inflation remains significantly above the world average and, at the microeconomic level, there is little indication that Iran has increased competitiveness in non-traditional exports. Iran’s economy has continued to be remarkably dependent on oil, and fluctuations in oil prices exert influence on the economy’s structure.

The current pharmaceutical policies focus on imports. The national production sales value has grown, but not in accordance with that of the imported medicine sales.

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423 Statistical Center of Iran, https://www.amar.org.ir/english/ (last access: 24/12/2016).


426 GDP is a monetary measure of the market value of all final goods and services produced in a period (quarterly or yearly). The GDP per capita in Iran is equivalent to 47% of the world’s average. It averaged $4868.07 US from 1960 until 2014, reaching an all-time high of $8372.61 US in 1976 and a record low of $2511.00 US in 1960. Iran’s currency is Rial. Ibid.

427 International Monetary Fund, ‘The Islamic Republic of Iran Staff Report, Article IV Consultation’ (2002).
value. About 96.1% of medicines in use are produced in local pharmaceutical factories, and pharmaceutical production consisted mainly of 89 companies in 2010. Domestic production of medicines decreases the final price of pharmaceutical services. It thus makes medicines more affordable and presents more feasible and reliable procurement opportunities. Pharmaceutical supply management, including pharmaceutical selection, registration, procurement, distribution, pricing and subsidisation, good management production and rational use of medicine is undertaken centrally by the Ministry of Health’s Food and Drug Organisation. The pharmaceutical market concentration ratio is low. Raw and packaged materials are provided by domestic suppliers and importers. Tamin Pharmaceutical Investment Company, Sobhan Pharma Group and Shafadarou Corporation are the largest public owners of the pharmaceutical industry. Data reveal an increasing rate of privatisation in the pharmaceutical sector; there are 93 private companies engaged in importing medicine, in addition to national pharmaceutical and medical equipment corporations. Iran’s pharmaceutical market has experienced an almost six times increase in market value between 2008 to 2015. However, most of this increase is due to national currency (Rial) devaluation, having experienced several drastic devaluations in the past three decades. This obviously influenced the pharmaceutical market, which depends heavily on international currencies.

The pharmaceutical legal framework in Iran can be categorised into five discrete types:

- The first type expresses the major goals and insights. At this level, there is the Constitution that is the basis for all other legal decisions in different parts of the legislative system.
- The second type is the long- and middle-term plans and laws which are approved and declared by the Parliament or Iran’s Supreme Leader to be presumed as a base for shorter plans.
- The third type is the pharmaceutical laws approved by the Parliament.
- The fourth type is the regulations (acts and by-laws) approved by the cabinet (government).
- The fifth type is the international regulations and agreements.

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429 Kebriaeezadeh et al, above n 26, p 2.
4.3 Historical Overview of Iran’s Economic Policies after the Islamic Revolution

Under a nationalistic view, industrial history and culture refer to both the potential problems and the viable solutions perceived by national regulators. When regulators are confronted with new decisions, they inevitably make use of policy paradigms that have accumulated national authorisation over time. By emphasising the importance of unusual national patterns in regulators’ approaches to problems, their relations with industry and their understanding of acceptable solutions, the nation-centred view challenges the notion that universal laws of utility maximisation, efficiency and the relative power of interest groups entirely constitute policy outcomes. The filter of culture and the availability of current resources are distinct national policy styles that govern the interaction between the government’s problem-solving approach and the relationship between the government and other participants in the policy process.

The reforms in various parts of the infrastructure and investments that were started in Iran by Pahlavi’s monarchy in the 1960s resulted in huge economic growth. They helped the country to become one of the strongest economies in the region and the world. Before the Revolution, Iran was one of the fastest-growing developing countries, and between 1960 and 1975 it experienced an average growth rate of 28.38% GDP per capita, which was significantly higher than that of developing countries, for example, China and India had only around 11% to 15% growth. A new trend started in 1976 and continued until 1979, resulting in privatisation of 99% of Iran’s national companies, including the pharmaceutical companies. However, this growth did not last long; rather, it was the start of increasing social dissatisfaction and the poverty of the common population. These factors inevitably led to a Revolution in 1979.

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434 Shekoufeh Nikfar et al, ‘Monitoring of National Drug Policy (NDP) and Its Standardized Indicators; Conformity to Decisions of the National Drug Selecting Committee in Iran’ (2005) 5(1) BMC International Health and Human Rights 1, p 5.

After the Revolution, macroeconomics in Iran was influenced by two important factors: negative GDP per capita growth and high and volatile inflation rates during the 1980s. By 1990, Iran’s GDP per capita declined to about 60% of its level in 1975, and the country was classified as a lower-middle-income country. The Revolution announced an expanded role for the government to safeguard the redistributive nature of the Revolution, to control the economy and decrease the critical situation caused by reducing the oil price in the global market.

The prevalent role of government in the economy was aggravated by the eight-year war with Iraq and the continuing economic embargo by the US (freezing Iranian assets). Since the early 1980s, Iran has been under various US economic sanctions as a punishment for alleged international transgressions. During this period, the theocratic regime of Iran has moved forward on many economic fronts but has been effectively held back in its efforts to reach the pre-Revolution level of national prosperity. After the Revolution in 1979, the US exports to Iran remained negligible due to Iran’s own import embargo of American products, which was finally lifted in 1991. During this period some American goods were imported to Iran through intermediaries from other countries in multiples of their original prices. In 1993, US exports started to decline and the comprehensive sanctions were imposed in 1994. The major category of US exported goods to Iran was machinery and electronics. Therefore, the sanctions forced Iran to import equivalent products of lower quality and possibly at higher prices from other countries. Because most of the US exported goods to Iran were highly essential goods with little or no substitutes, this made Iran’s demand for such products relatively inelastic in the short run.

US sanctions also included some financial measures that deprived Iran of financing by the Export-Import Bank, export credits, loan guarantee and export insurance. Moreover, the US instructed its representatives in international financial institutions to vote against the extension of credit or other financial assistance to Iran. These institutions included the World Bank, the International Development Association, the Asian Development Bank and the International Monetary Fund (IMF). The financial

439 Ibid, p 415.
obstacles were originally initiated in 1984 and were supplemented with the comprehensive sanctions in 1995, which prohibited all financial transactions with Iran. The financial measures weakened Iran's financial ability and forced it to find alternative financing at substantially higher cost from commercial banks in other countries.440

The inability of the economy to adjust to external shocks points to the rigidity of pre-existing economic structures inherited from the Pahlavi era, and the institutional setup and policy response by the government in the post-revolution period. In such circumstances, the risks of failing to implement new structural plans strengthened the opposition to economic liberalisation. Nationalisation was implemented to increase the government's access to revenue and generate substantial profit with which they would be able to finance investments in preferred economic sectors. Nationalisation manifested itself in large-scale confiscation and reallocation of property, massive nationalisation of major industries (including the pharmaceutical industry) and the establishment of revolutionary foundations (see: Section 4.8.4) to ensure and advance the growth of living standards of the low-income and rural populations.

Since 1980, the Iranian economy has been highly subsidised, with massive public enterprises that hold a significant share of the economic productivity. Most of the public enterprises, particularly in the manufacturing sector, used to be privately owned and were profit-making companies before the Revolution; their owners were either dependent on the former regime or foreigners who left Iran after the Revolution. The extension of public enterprises became possible with the absence of hard budget restraints, the lack of competition and the government's monitoring and performance standards. Public enterprises prevented the growth of the private sector with their access to subsidies. These enterprises operated in a highly protected domestic market and the government actively supported public enterprises for socio-political aims by allocating various subsidies, tariffs and taxes.441 Thus, there was little incentive for public enterprises to restructure and reduce their costs.

440 Ibid, p 418.
However, the most important damage to the Iranian economy from the financial sanctions is due to the poor investment environment that has resulted. It is difficult to calculate the number of damages to Iran’s economy that has been specifically caused by the financial sanctions as various factors are involved and their costs are unknown. No doubt, the financial obstacles caused Iran to sign unfavourable oil contracts and forced it to borrow money at a high cost.442

The trade sanctions' effects on Iran's non-oil exports and capital goods imports have been significant as compared to their effect on Iran's oil exports. Iran could find other buyers for its oil in a rather short time because oil is a fungible commodity and the world market for oil is to a certain extent competitive. The financial sanctions' impact on Iran has curtailed Iran's ability to borrow funds and to finance its oil development projects. Because of the sanctions, Iran has paid higher rates of interest on its loans and has guaranteed excessively high rates of return on investment on its oil buyback projects.443

4.4 Principle 44 of the Iranian Constitution

After the Revolution, the new Constitution determined the rules of the Islamic economy and introduced growth and development in various aspects of the social, economic and political sectors as the main goals of the new regime.444 The general policies of the administration followed Principle 44, which specifies that:

The economy of the Islamic Republic of Iran is to consist of three sectors: Governmental, cooperative and private and is to be based on systematic and sound planning. The governmental sector is to include all large-scale and leading industries, foreign trade, major minerals, banking, insurance, power generation, dams and large-scale irrigation networks, radio, and television, post, telegraph and telephone services, aviation, shipping, roads, and railroads. All these will be owned and administered by the government. The cooperative sector is to include participating companies and enterprises concerned with production and distribution, in urban and rural areas, by Islamic criteria. The private sector consists of those activities

442 Ibid, p. 421.
443 Ibid, p. 431.
concerned with agriculture, industry, trade and services that supplement the commercial operations of the government and cooperative sector [...].

According to the last part of the Principle, the expansion of private ownership is not problematic, as far as it enhances the national economy and is not against Islamic rules. However, a closer analysis of Principle 44 reveals that, at the time of drafting, the regulator adopted a restricted approach towards delegating primary economic activities and authorities to the private sector, which led to a total centralisation of the system.

After the cease-fire with Iraq (1988), new economic reforms were started, named the first generation of the ‘Structural Adjustment Reforms’. Implementation of these reforms was an inevitable response to structural rigidities and imbalances that had paralysed the economy. The government based its policies on an economically liberal, politically authoritarian and philosophically traditional approach, which led to the Cabinet being confronted by more radical deputies.

This set of reforms was designed to provide a market-friendly environment conducive to developing the private sector, developing non-oil exports, gradually decreasing subsidies and sharply reducing the government’s role in allocating and distributing resources and an overall shift towards the use of market mechanisms. Privatisation of major industries was one of the main actions taken by the government from the middle of the 1st Five-year Economic, Social and Cultural Development Plan (1989–1994). Accordingly, some public enterprises had to be sold to the

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445 Ibid.
446 Ibid.
447 The first generation of ‘Structural Adjustment Reforms’ had been implemented in nearly all developing countries by the mid-1980s with varying degrees of success. In fact, countries in South East Asia, Latin America, and several countries in North Africa and the Middle-East have either completed or are during their second generation of Structural Adjustment Reforms (including institutional reforms designed to improve the quality and effectiveness of the government and public institutions). World Bank, ‘Annual Development Report’ (2000).
450 Since 1989, Iran has produced and pursued five Economic, Social and Cultural Development Plans in a bid to help reconstruct the country after the eight-year war with Iraq and achieve sustainable development. These efforts have been in line with the six development plans implemented prior to the 1979 Islamic Revolution. However, the fact is that neither the pre- nor post-revolution development plans have fully achieved the goals they have laid out. As such,
private sector, and the government was urged to transfer some of its monitoring roles in the manufacturing area to semi-governmental or private entities.

Such a policy was also continued in the 2nd Development Plan (1995–2000), and the policy-makers emphasised the necessity of accelerating and completing the government’s investment in infrastructure. It was expected that by reforming the regulatory environment the government could persuade private financiers to invest more in public enterprises and facilitate the process of privatisation. However, either due to a drastic shift from nationalisation to privatisation within a short period, or the unexpected economic crises (e.g., the reduction in oil prices and a weak administrative structure) the 2nd Development Plan’s achievement record turned out to be discouraging. It made some policy-makers admit that ‘Iran’s economy was, chronically ill and it would continue to be so unless there is fundamental restructuring.’

There was also a new political controversy between those who considered economic liberalisation to be a significant deviation from the anti-imperialist approach of the regime, and those who believed that adopting a restricted approach towards the role of the private sector was a refusal to recognise the private sector as a leading sector of the national economy, addressed in Principle 44.

To resolve this controversy and to decrease the risk of policy failure, in 2006 the Iranian Parliament decided to reinterpret the primary purposes of Principle 44 while preserving its original format. The Parliament distinguished and ratified ‘The Interpretation of the Supreme Leader [Ayatollah Ali Khamenei] Regarding Principle 44’, which precisely defines the scope of the Principle’s purposes as:

- sustainable growth of the national economy;
- promotion of broad-based public ownership to achieve greater social justice;

Many Iranian economists now believe that the era for such plans has ended and that governments instead need long-term strategic approaches toward growth and development. See for example: Jahangir Amuzegar, ‘Iran’s 20-year Economic Perspective: Promises and Pitfalls’ (2009) 16(3) Middle East Policy 41.


452 The ideology of the Iranian Leftists was an eclectic combination of Third-Worldism, nationalism and Islamic culture.
Chapter 4 – The Pharmaceutical System in Iran: Realities and Rigidities

- intensifying the efficiency of economic enterprises and productivity of human and material resources and technology;
- enhancing the competitive capability of the national economy;
- reducing the financial and administrative burden on the government encumbered as a result of its predominant role in economic activities.\(^{453}\)

4.5 An overview of Iran’s Pharmaceutical Industry: Strategies and Structure

4.5.1 Public Health Care and Access to Medicine in the New Constitution

Before the Revolution, the pharmaceutical industry was dominated by multinational companies, with a few national companies producing generic medicines in the form of branded generic products or under the licence of multinational corporations. Importation was the primary source of providing medicine, and only a few types of medicines were produced by local businesses.\(^{454}\) However, just after the Revolution (1979), two major motions caused fundamental changes in the health sector: nationalisation of the pharmaceutical industry, and the (pharmaceutical) generic system (denoting the non-proprietary name of medicines).

The most prominent goals of the Revolution were self-sufficiency, policies that are not reliant on other countries in the pharmaceutical industry, and producing essential medicines.\(^{455}\) Therefore, all pharmaceutical companies dominated by multinational corporations were driven out of the country. Even though there is no principle in the new Constitution to ensure equitable access to medicines, according to WHO’s reports, Iran is one of the countries that has indicated a commitment to affordable health facilities, goods and services in their Constitution, within Principles 3(12), 29, and 43(1).\(^{456}\) Principle 3(12) declares the government’s duty to make health care and

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social insurance affordable to all citizens without using mandatory language to target the issue. Principle 29 articulates the importance of the government's accountability to consider the right to health and medical issues—although without specific mandatory language. Principle 43(1) also places the need for medical treatment alongside other necessities, for example, education and food supply, as bases for government policies.\textsuperscript{457} In so doing, the government was meant to act as the public health guardian by controlling private powers for public purposes.

Iranian legislators also incorporated the contents of the relevant international conventions, including the Universal Declaration of Human Rights (UDHR) (1948) and the International Covenant on Economic, Social and Cultural Rights (ICESCR) (1968), into Iranian law through legislation. The contents of these treaties are recognised as binding in the same way as the National Acts and domestic obligations (Principles 3, 29, and 43). Any further laws also need to fully comply with the Constitutional requirements, such as 'The Law of Enhancing the Administrative System and Eliminating the Corruption' (2011), which is based on Principle 123 of the Constitution, 'The Law of National Public Insurance (1994), 'The Law Establishing the Medical Organisation System' (2004), and 'The Comprehensive Law of Social Welfare' (2004) that are in accordance with Principles 21 and 29 of the Constitution. However, the government still needs to mandate the given enactments in some areas that are not obligatory enough and develop a systematic monitoring mechanism to guarantee the proper implementation of the rules.\textsuperscript{458}

\textsuperscript{457} Principle 3(12):
[T]he government of the Islamic Republic of Iran has the duty of directing all its resources to the following goals:

[T]he planning of a correct and just economic system, by Islamic criteria to create welfare, eliminate poverty, and abolish all forms of deprivation of food, housing, work, health care, and the provision of social insurance for all […].

Principle 29:
Every person has the right to the enjoyment of Social Security. It covers […] unexpected misfortune, accidents, and occurrences giving rise to the need for health services and medical care and treatment, through insurance.

Principle 43(1):
The economy of the Islamic Republic of Iran […] is based on the following criteria: The provision of necessities for all citizens: housing, food, clothing, hygiene, medical treatment, education, and the necessary facilities for the establishment of a family […].


Moreover, passed in 1955, the *Medicine, Drug, Food, and Drink Affairs Law Act* is the cornerstone for the current pharmaceutical procedures in Iran. Most of the by-laws and ordinances are designed and approved by the Pharmaceutical Affairs Department. Along with the Constitution, which determines the general goals of the health system, National Pharmaceutical Policy also contains pharmaceutical policies.

### 4.5.2 Iranian National Pharmaceutical Policy

It is crucial for policy-makers to ensure equity in access to medicines, pharmaceutical efficacy, quality and safety, and rational use of medicines, which are indicators of the National Pharmaceutical Policy in the evaluation of pharmaceutical system performance. The Iranian National Pharmaceutical Policy process brings together interested parties (including pharmaceutical prescribers and dispensers), legislation/regulation, quality control, local production, pharmaceutical evaluation, selection and registration, and rational use.459 The Iranian pharmaceutical regulations are based on the National Pharmaceutical List, a comprehensive medical list, selected by the Iran Drug Selecting Committee, which includes the necessary medicines for citizens. All pharmaceutical supply management, including registration, procurement, inspection, quality control and post-marketing control is carried out for a medicine that it is accepted to be on the National Pharmaceutical List and only medicines that exist on the list should be prescribed. Adding/deleting medicines from the National Pharmaceutical List, registering health facilities and goods, financial interventions, pricing and reimbursement, monitoring the supply chain, and promoting rational use of medicine are some of the responsibilities of national pharmaceutical authorities.

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4.5.2.1 General Pharmaceutical Policy Schemes

Because the generic system has dominated Iran's pharmaceutical industry, it inevitably influences internal elements. Evidence shows that pharmaceutical companies established and developed to produce raw materials and generics accounted for approximately 70% of Iran's pharmaceutical companies after the Revolution. WHO's support for conducting generic replacement and a severe shortage of medicine during the war (1980–1988) were the factors driving the government towards the generic system. The generic market expanded because the generic medicines were more attractive compared to branded ones. The rapid growth of emerging markets that spend a lot on generic medicines increased the generic market's portion.

Directing a whole generic-based system had some benefits for Iran's pharmaceutical sector and assisted the country to deal with the constraints of the 1980s. Local production of generic medicines gave rise to improved equity of access by using an essential medicine list, fixed prices and manufacturing and prescribing medicines using the international non-proprietary name. Generics were cheaper for two reasons. The first reason was the different pricing structures of generic pharmaceutical manufacturers; more than 16% of brand pharmaceutical prices are included for research and development costs. Since generic medicines do not have research and development expenditures compared to new medicines, manufacturers can retain quality and provide medicines that are more affordable for patients. The second reason also was that legal limitations for generics were far less than for

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460 Food and Drug Organization, 'Descriptive Progress Report' (Iranian Ministry of Health and Medical Education, 2005).

461 L. Garattini and F. Tediosi, 'A Comparative Analysis of Generics Markets in Five European Countries' (2000) 51(3) Health Policy 149, p 156. Iraq invaded Iran on 22 September 1980, triggering a bitter eight-year war which destabilised the region and devastated both countries. The then Iraqi leader, Saddam Hussein, claimed as a reason for the invasion a territorial dispute over the Shatt al-Arab, the waterway which forms the boundary between the two countries.


innovated medicines. The value of the generic market becomes more worthwhile with the patent expiry of innovative medicines.

However, the generic system affected Iran’s pharmaceutical industry’s development negatively as a result of decisive internal factors. Government policies had significant effects on pharmaceutical development through pharmaceutical tariffs, the absence of incentives for pharmaceutical exports and a lack of marketing standards. Emphasis on policies regarding essential medicine availability with affordable price reduced market competitiveness. Effects of the generic system on the quality of medicines were also controversial. The generic system had a remarkably unfavourable impact on technological infrastructure in the pharmaceutical industry while exerting strict price control policies.

To support domestic production, the technical capability of the pharmaceutical industry improved, but this improvement stopped at the pharmaceutical formulation level, and there were no efficient ways to enhance pharmaceutical exports. Research and development costs, which are spent in leading pharmaceutical industries, are about 16% of a company’s sales whereas pharmaceutical research and development investment in Iran were—and continues to be—minuscule. Evidence shows that research and development projects have not been based on market needs. Subsidies that the government allocated to pharmaceutical manufacturers to buy raw materials also caused a reduction in innovation.

4.5.2.2 Removal of Subsidies and Unification of the Exchange Rate

To increase the availability and affordability of pharmaceuticals the Iranian Government subsidies the local manufacturing of medicines. As a result, strict price

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465 Foroughi, above n 463.
466 Cheraghali, above n 455, p 5.
468 Cheraghali, above n 455, p 2.
controls and unrealistic low prices for local pharmaceuticals gave them a relative economic advantage over imported medicines.469 Because of the economic sanctions, access to new technology and raw materials became challenging, and due to lack of substantial investment in the research and development area, the national industry remained as a formulation based industry. The decrease of investments by multinational companies in Iran’s pharmaceutical manufacturing and technology sector also hindered the Government to upgrade its technology capabilities and manufacture high tech medicines.470 The government itself imported pharmaceuticals as finished products as well as raw materials, and the introduction of new pharmaceuticals into the Iranian market made the market more dependant to foreign markets and created significant obstacles for the Iranian Government later in the 1980s. Local production was supported by the government via the provision of hard currency at a subsidised rate and a high tariff on imported medicines from 1980–1993. As a highly centralised system, the government also directly intervened in the production, supply, dissemination and consumption of medicines by supporting local pharmaceutical companies with hard currency at the subsidised rate from 1980–1993.471 The multiple exchange rate system prevailed from the start of the war in 1980 until 2002, except for a short period of unification in 1993.472 Also, there was an active informal market that was reflected in a parallel exchange rate with a significant markup above the Tehran Stock Exchange rate. Local production of medicines was stimulated by the government to enhance domestic manufacturing, reducing dependence on imports and providing universal access followed by strict price monitoring.

The centralised policy of allocating medicines and the fact that the pharmaceutical producers had to use the currency at the official rate restricted the access of pharmaceutical suppliers to foreign exchange. Therefore, every decrease in government financial sources caused disturbances in pharmaceutical supplies.

469 F. Siamak Nejad, 'Subsidizing the Pharmaceuticals in Iran' (1998) 9 Razi Magazine 3, p 5. Moreover, the market is still characterized by low pricing levels, and generic medicines have dominated the market.

470 Mehralian et al, above n 454, p 198.


472 For instance, the official floating rate of 1750 Rials per USD applied to the import of essential goods, a fixed or “export” rate of 3000 Rials per USD applied to capital goods imports of public enterprises and a variable Tehran stock exchange rate of 8180 Rials per USD applied to other imports. See for example: Y. H. Farzin (ed), The Political Economy of Foreign Exchange Reform, Iran After the Revolution: Crisis of an Islamic State (I. B. Tauris, 1996).
Subsequently, the 3rd Development Plan (2001–2005) was designed to develop a stronger private sector and reform the health network. The overall objectives of the Plan were to decrease the system of subsidies and protection, to increase the role of the private sector and to abandon the redistribution policies of the earlier period. It started with the unification of the exchange rate, which is the central point of the reform program, formulated in consultation with the IMF.

By March 2000, three officially recognised exchange rates were applied to different categories of transactions. However, the government also adopted a market-based inflated exchange rate and ended the multiple exchange rate system. Exchange rate unification was an important step towards amending the system of subsidies. However, for unification to succeed the government assumed the entire cost of the exchange rate difference arising from the standardisation of imports of essential goods and capital imports. Meanwhile, the 3rd Development Plan legalised the importation of non-essential medicines by the private sector using the stock market rates.

By 2002, apart from a few imported medicines, subsidies were entirely withdrawn from the local industry. Non-tariff barriers were replaced with tariffs, which were a less distorted form of protection. Furthermore, import-licensing requirements were modernised and bureaucratic procedures were reduced. Recent reforms also included simplifying corporate and income taxes and providing incentives for foreign investors. By encouraging competition, the government allowed companies to use their capacity to produce brand medicines under the provision of still being committed to providing generic medicines.

Further economic liberalisation and the lack of subsidised currency caused an increase in prices and improved imports. Throughout this period, domestic production constituted a significant share of the market. However, it did not lead to the establishment of independent private companies with market-oriented, sustainable growth and development strategies, due to the fact that the strict

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473 On the downside, exchange rate unification imposed substantial fiscal costs, around 3% to 6% of GDP. International Monetary Fund, (2002).

centralised system had clogged any chance of improving non-government actors and market competition.

4.5.3 Coordination among Various Levels of the Ministry of Health

Most analysts support the WHO's recommendation indicating that countries should phase in devolution under local guidance, subject to stringent criteria, with the Ministry of Health continuing to take responsibility for specialised services, medical supplies, and other essential functions. This advice illustrates a persistent theme that: the major rationale for pharmaceutical privatisation is improved effectiveness.

Iran's health care system has an uncommonly complex structure that is at once centralised and fragmented. The Iranian Ministry of Health operates an integrated system of health care, providing primary, secondary and tertiary care across the country. At the general directorate level within the Ministry, the division of health service responsibility into defined areas of activity is, in principle, good management practice. However, lines of accountability are not defined well enough to monitor the performance of individual directorates; hence, there is considerable overlap of responsibility among the general branches which is a significant management weakness. Pharmaceutical services are provided by the public, quasi-public and small private entities, but relations between them are not well structured or regulated.

Also, decision-making and implementation agencies vary in form, structure, objectives and achievements, while the Ministry of Health is strongly centralised. Even though each province has its local health administration, structured to solve a broad range of health problems, local decision-making is not encouraged. Dealing with local health concerns that require local solutions is, therefore, difficult and becomes a bureaucratic process since the central organisation must be informed of or

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consulted in every decision. The current system is the result of historical developments, rather than a rational planning process.477

4.5.3.1 Establishment of the Food and Drug Organisation

Until 2011 the Food and Drug Branch of the Ministry of Health was the leading agency in the Drug Regulatory Authority’s structure. Therefore, the government was both in charge of protecting domestic industry and responsible for monitoring the functions of producers, along with playing the role of public agent to defend consumers’ rights. This indirect intervention of government in controlling the system affected policy-making by politicising the priorities and goals of the pharmaceutical sector. The subsequent defects and disadvantages of such intervention highlighted the necessity of taking the policy-making process out of the government’s direct control to reduce further political side-effects and enhance the technical aspects of decision-making.478

In 2011, the Food and Drug Branch developed into the Food and Drug Organisation, as a semi-autonomous authority, following the general purposes of Iran’s 20-year National Vision Plan479 and Articles 84, 87, 94, 95 and 137 of the 4th Development Plan (2006–2011), to ease access to low-cost medicines. Since then, the Food and Drug Organisation has continued to work as a division of the executive department that is headed by a director, who is appointed by the Minister of Health, to have a greater influence over decision-making and administrative activities. Thus, the production, importation and distribution of medicinal products are performed under strict control by the authorities and involve registration and licensing by the Food and Drug Organisation.

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4.5.3.2 Pharmaceutical Registration

The Food and Drug Organisation is responsible for selecting medicines for registration, evaluating their side-effects and rational usage; and, with governmental subsidies, providing essential medicinal products for specific diseases. These activities are never contracted out to the private sector. However, the Iranian pharmaceutical registration scheme has a unique structure in which many medicines illegally come into the market before registration and only then will they be evaluated by the Food and Drug Organisation as to whether they should be added to the National Pharmaceutical List. Under Article 93 of the 4th Development Plan, physicians are urged not to prescribe items that are not on the National Pharmaceutical List.\(^{480}\)

However, the legislator has allowed some products that are not on the National Pharmaceutical List to be made available in limited supply for some patients in critical situations. According to the Act of Emergency Pharmaceutical Centers (2008), pharmaceutical products that are not registered on the National Pharmaceutical List can be imported by institutions called Emergency Pharmaceutical Centers, whenever a shortage or crisis occurs or available alternatives are not deemed by a physician to be sufficient for a specific patient. Moreover, according to this Act, marketing, advertising and/or promoting these products are prohibited. New and infrequently-prescribed medicines can also be separately imported or manufactured and offered through individual stores affiliated with the Red Crescent Society, the private sector and voluntary associations formed to support people suffering from specific disorders.

According to the Iranian E-commerce Act (2004),\(^{481}\) in the sale of pharmaceuticals and medical products to end customers, any type of pharmaceutical sale to patients and customers over the internet, including via online pharmacies, is prohibited. While medicinal supplements have been regulated by the Executive Instructions for Online Purchasing of ‘Non-medicinal’ Products in National Pharmacies, as the only pharmaceutical products that are allowed to be traded on the online market, there are


no rules regarding online purchasing of 'medicines'. According to the Medical, Pharmaceutical, Edibles and Potables Act (1995) and subsequent amendments, it is a crime to import, export, sell and purchase medicines without acquiring a licence from the Ministry of Health. Counterfeit medicine is defined as any pharmaceutical product that has not passed the Food and Drug Organisation's regulatory process, due to their common problems associated with their active ingredients or impurities. Article 18 of the Act refers to the punishments for importing, producing and dispensing counterfeit medicines.

4.5.3.3 Pharmaceutical Accessibility, Affordability, and Pricing

Since the general direction of policies focuses on pharmaceutical availability and affordability, the generic system has resulted in improving accessibility in the domestic market. The existence of an international non-proprietary name system for listing medicines, and their procurement, distribution and sale in private pharmacies are also the strengths of Iran's National Pharmaceutical Policy. Private pharmacies are responsible for providing medicines on the National Pharmaceutical List at a fixed price for all patients as announced by the Ministry of Health. They should acquire their medicines from distribution centres which work under the control of the government. It should be noted that the international non-proprietary name system listing that exists in Iran does not preclude the availability of patent medicines. If the patent medicine is approved and on the National Pharmaceutical List it would also be subsidised. A specific guideline has also been established in Iran for the availability of medicines that are not included on the National Pharmaceutical List.

482 'Executive Instructions for Online Purchasing of Non-medicinal Products in National Pharmacies' (Food and Drug Organization (FDO), 2014) http://www.fda.gov.ir/item/1391 (last access: 06/06/2016).

483 Food and Drug Organization, Executive Instructions for Operations of Single-Prescription Emergency Centers Iranian Ministry of Health and Medical Education http://www.fda.gov.ir/item/209 (last access: 06/06/2016).

484 Private pharmacies belong to pharmacists who can establish their pharmacies under district regulation and legislation of the Ministry of Health.
According to this guideline, doctors who prescribe a non-National Pharmaceutical List medicine should sign an agreement and accept responsibility for any possible unwanted side-effects a patient might experience because of using that medicine.\textsuperscript{485} The physician should also convince the pharmaceutical regulatory office of the ineffectiveness of existing similar medicines on the List. The medicine will be imported for that patient without any subsidy or insurance coverage only if it prescribed by the doctor\textsuperscript{486}

The affordability of medicine for all people has been considered by both health insurance mechanisms and pharmaceutical pricing regulations. In June 2011, the new \textit{Pharmaceutical Pricing Act (2011)} was introduced by the Food and Drug Organisation, which addresses some general goals, including quality assurance, safety, efficiency improvement, and assured accessibility.\textsuperscript{487} According to the new regulation, the price of original medicines in their patent-protection period is calculated by considering their prices in either exporter or reference countries; moreover, the price of a particular medicine in Iran’s market must be lower than its price in all those countries. The price-setting for a patent-expired original medicine is calculated based on either the reference countries’ prices or by calculating a 20\% reduction of the under-patent prices, whichever is lower. The price of domestic or imported generic medicines is calculated either as being at least 60\% lower than the lowest price of the original product in reference countries or by considering the lowest price of that generic medicine in reference countries, whichever is lower.\textsuperscript{488}

Governmental budgets, additional funds, social security funds and out-of-pocket payments constitute the financial resources of the Iranian pharmaceutical system. In Iran, the pharmaceutical pricing mechanism is based on total price and, compared to the standard inflation rate, usually has little benefit margin.\textsuperscript{489} Although Iran is

\textsuperscript{485} Nikfar et al, above n 434, p 8.
\textsuperscript{486} Food and Drug Organization, \textit{Guideline for Accessibility to Drugs Out of Iran Drug List} Iranian Ministry of Health and Medical Education http://www.fda.gov.ir/list/content?catId=52 (last access: 23/01/2017).
\textsuperscript{488} The reference countries in Pharmaceutical Pricing Act are Greece, Turkey, Spain, Saudi Arabia, and Aljazeera.
\textsuperscript{489} Sauwakon Ratanawijiratisin and Eshetu Wondemagegnehu, \textit{Effective Drug Regulation; A Multicountry Study} World Health Organization https://goo.gl/nP5KeK (last access: 23/04/2017).
moving away from price regulation by adopting new reform policies, pharmaceutical price controls may remain in effect.

As evidence shows, during the recent decade, accessibility to insurance coverage has grown remarkably, possibly because of GDP growth. Nonetheless, the health insurance system in Iran has a very fragmented structure. There are dozens of public health insurance organisations as well as many private ones covering small portions of the population. After enacting the Law of Welfare and Social Security (2004), the main policies of these organisations and funds were transferred to the Ministry of Welfare and Social Security. The reform in health insurance structure has also been mentioned in mid-term plan laws. Article 38 of the law of the 5th Development Plan (2010) discusses the integration of different health insurance organisations and the requirement that government must establish the obligatory and general health insurance mechanisms. According to this law, the current fragmented structure of health insurance will be integrated into a new organisation called the ‘Iranian Health Insurance Organisation’.

There are four main insurers in Iran, each with different benefits package co-payments and referral systems. These organisations benefit from government subsidy support at various levels. Once the Food and Drug Organisation allows a medicine to enter the market it also decides whether it should be included in the public health care insurance package. The list of medicines covered by insurance organisations is almost the same as and is based on, the National Pharmaceutical List. However, insurance coverage has not expanded concurrently, and pharmaceutical service delivery is still not equitable.

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491 The Social Security Organisation provides insurance for formal sector employees and self-employed labourers and their dependents, through mandatory insurance schemes, and provides pensions for pensioners. The Armed Forces Medical Services Organisation provides coverage for almost 2.5 million members of the military and their dependents. The Medical Service Insurance Organisation provides insurance for government employees, rural households, self-employed persons and others, e.g., students. Also, the Imam Khomeini Relief Foundation covers the poor and destitute. In 1994, 40% of the population was benefiting from medical insurance coverage. The figure increased to 95% in 2011. However, due to the lack of an integrated insurance database and geographical coverage, it is estimated that 8%-12% of people are covered by more than one insurance scheme. If covered by health insurance, patients pay 25% of the fee for outpatient and 10% of the tax for inpatient treatment. Effat Mohammadi and Mojtaba Nuhì, 'Analysing the Relevance of Health Insurance Organizations and National Medical System' (2011).

do not make a contract with an insurance company, but instead prescribe very expensive medicines for their patients and increase the amount of out-of-pocket payments in the system. The second reason is that the substantially low price of locally-produced generic medicines has encouraged irrational use and the smuggling of pharmaceutical products into neighbouring countries, causing further government intervention to improve the control of both official and non-official (black) markets.

Moreover, pharmaceutical consumers and providers in Iran have some discretion to freely interpret the content of insurance packages within certain limits. It becomes more important in the case of schemes which are profit-oriented, where investor-type private owners have been given a public financing role. It also may be expected that the government, as the owner of and the biggest participant in the industry, will behave in a way very much like a private owner. When programs are targeted at cutting back budget expenditure the government is interested in eliminating the health budget’s deficit. As such, in the Iranian system, government representatives would vote for all measures that result in a reduction in expenditure. The government would, in any case, not be the holder of the position of general director, which is essential for exercising management authority. Thus, the possibility for government representatives to oversee everyday matters is restricted.

The other main consequence of low medical fees is a severe reduction in medical care providers’ income. According to the ‘target income’ hypothesis, doctors have a target income in mind that they seek to achieve. Thus, while the decision-makers try to maintain a low level of pharmaceutical expenditure, by strictly controlling medical fees, doctors try to find additional methods to increase their income. Medical service profits provide a method of revenue generation to recompense for the below-market value levels of medical fees. In addition to the problem of supplier-induced

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demand, private pharmaceutical providers may face financial difficulties in covering the costs of their services. This has led them to compensate their financial shortage through unofficial or under-the-table fees.\(^{497}\) Therefore, informal fees/payments, which are paid to the doctors, increase the share of an individual’s payment for their expenses and reduce the use of services by patients who find it difficult to afford such extra charges.

This situation occurs despite a reduction in out-of-pocket spending on medical care services is one of the main targets of the 4th Development Plan. According to the Plan, Iranians’ out-of-pocket health care expenses should have been reduced from 60% to 30% by the end of the project (March 2009).\(^{498}\) Failure to achieve this objective led to the same target being repeated in the 5th Development Plan (2011–2016).

4.5.4 Health Sector Evolution Plan

In May 2014, a series of reforms, called the Health Sector Evolution Plans, was launched in the health system, in a stepwise process and mainly based on the 5th Development Plan.\(^{499}\)

Some of the pharmaceutical-related provisions of the Evolution Plan are:

- providing free basic health insurance to all Iranian uninsured individuals through the Health Insurance Organisation;
- reducing out-of-pocket payments for inpatient services at hospitals affiliated with the Ministry of Health;
- increasing access to medicines by making use of private facilities where necessary;
- improving the referral system and giving institutions more administrative and financial autonomy;
- supporting the more rational use of medicines;
- restructuring the Ministry of Health to enhance its core functions of setting priorities;


\(^{498}\) Davari, Haycox and Walley, above n 492, p 18.

\(^{499}\) Mohammadi and Nuhi, above n 491.
The plan is supported by the following financial sources: an increased public annual budget for the health sector (around a 59% increase in 2015 compared to 2014), resources of the Targeted Subsidies’ Law (2004) (10% of total grants) and an exact 1% value-added tax on health. Additionally, the financial sources were estimated to be 70% higher in 2015 (March 21, 2015–March 20, 2016) compared to 2014 (March 21, 2014–March 20, 2015). However, it is still difficult to make reliable estimates regarding the extent of out-of-pocket payments, and it seems that these payments are much higher than the Ministry of Health figures suggest, accounting for almost half of the total expenditure on health care. Analysing pharmaceutical financial sources is difficult because the Iranian sources of health care financing mechanisms have never been clearly defined. At present, Iran has three primary sources of pharmaceutical care funding: the general government budget, funded by tax revenue and allocated, mainly, to the Ministry of Health, the Ministry of Welfare and public agencies; insurance companies; and out-of-pocket payments, in the form of direct aid to private doctors and institutions, premiums paid for voluntary health insurance and co-payments.

Despite the high rate of tax avoidance and the size of the underground economy in Iran, policy-makers and managers should define specific objectives to gradually replace current financial sources of the Health Sector Evolution Plans with other sources that are progressive. To secure financial sources and increase fairness, a special progressive tax would be the best source and the contribution of people should be based on their income and wealth.

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500 Ibid.
503 As Ali Rabiei, the Minister of Social Welfare stated the out-of-pocket payment had increased almost 41% since 2005. While during 2005–2012 this increase was less than 34%. This payment may be in the form of: direct aid to private doctors and institutions; premiums paid for voluntary health insurance and co-payments for medicines and services. Ali Rabiei, The Increase of Healthcare Expenditure in Iran Persian Deutsche Welle http://bit.ly/2bAW4Vt (last access: 03/04/2016).
504 Mohammadi and Nahi, above n 491.
The present combination of rules and regulations for direct and indirect taxation provides essential infrastructure for this transition. Technical concerns of pharmaceutical providers (e.g., non-efficient insurance provider processes) should be addressed through proper statutory amendments. Strict monitoring of the reform processes and assessing the results are crucial. An accurate policy analysis for the continuation of the program components and new revisions/interventions can facilitate the process in the 6th Development Plan (2016–2021), in line with the general health policies.\textsuperscript{506} In general, based on the monitoring reports of the National Institute for Health Research, the general population is satisfied with most of the Health Sector Evolution Plan’s components and that satisfaction increased slightly during the first year of the program.\textsuperscript{507}

4.6 Future Implications of the Iranian Pharmaceutical Industry

4.6.1 Reforming in the Post-sanctions Era

On 2 April 2015, the United Nations (UN)’s Security Council’s five permanent members plus Germany (P5+1) and Iran reached a provisional agreement in Switzerland on a framework that, once finalised and implemented, would lift most of the economic sanctions in exchange for restrictions on Iran’s nuclear program, expanding for at least ten years. As a result, the UN sanctions were lifted on 16 January 2016.\textsuperscript{508}

‘No, our sanctions do not include medicines’\textsuperscript{509} was the only response to any objections in regard to the critical consequences that the sanctions had on Iranian citizens’ health made by the Iranian Government to the relevant international organisations that imposed economic sanctions. Although at first sight, this response might seem correct, the primary reason for the medicine shortage in the country, during the 12 years of sanctions, originated from banning all foreign banking systems

\textsuperscript{504} See for example: David de Ferranti, ‘Out-of-Pocket Expenses, and Insurance Must be Addressed for China to Achieve Its Health Goals’ (2008) \url{https://goo.gl/AgjUYU} (last access: 15/12/2015).

\textsuperscript{505} Moradi-Lakeh and Vosoogh-Moghadam, above n 501, p 639.

\textsuperscript{506} Geoff Dyer and Najmeh Bozorgmehr, \textit{Iran Sanctions Lifted Financial Times} \url{https://www.ft.com/content/7ca5b856-bc62-11e5-9f0b-87b8d13baec2} (last access: 29/03/2016).

\textsuperscript{507} Abolghasem Bayyenat, ‘U.S. Sanctions and Iran’s Economic Realities’ (2011) \url{http://www.irandiplomacywatch.com} (last access: 02/11/2016).
from trading with the Iranian Government or Iran's private banks.\textsuperscript{510} This condition would, of course, hamper any opportunity to import necessary medicines into the country. While during these years the government tried to find alternative options to purchase essential medicines and other medicinal products from abroad, the US Government threatened its allies by placing significant fines on those banks and organisations that had cooperated with the Iranian Government in this regard and banned them from continuing any mutual dealings.\textsuperscript{511}

However, the critical situation facing the pharmaceutical sector during the sanctions period did not just occur due to the sanctions. The situation worsened when a combination of internal administrative, economic malfunction and international economic and political pressures revealed the shortages and inappropriateness of Iran's rigid, State-centred regulatory model. The irrational dependence on the importation of medicines, particularly during 2005–2013, and the lack of support for domestic pharmaceutical companies to produce most of the medicines at a lower price led to serious problems for the government in providing essential medicines.\textsuperscript{512}

During 2005–2013, the government exacerbated Iran's economic centralisation, almost eliminating any genuine attempts to privatise the major industries in the national economy, and completely misinterpreted the primary purposes of Principle 44 of the Iranian Constitution.\textsuperscript{513} As a consequence, up to 95% of public enterprises and entities that were transferred during this period were, in fact, transferred to semi-government organisations or public institutions and have since been returned to the government sector, either directly or indirectly.\textsuperscript{514}

The artificial privatisation, in addition to the increase of pharmaceutical importation during this time, weakened the national pharmaceutical producers and caused an extreme decrease in domestic production from 97% to 92%.\textsuperscript{515} Despite the

\textsuperscript{510} See: Varun Vira et al, 'Sanctions on Iran: Reactions and Impact' (2011) AIE Iran Tracker.
\textsuperscript{511} Siamak Namazi, 'Sanctions and Medical Supply Shortages in Iran' (2013), p 3.
\textsuperscript{512} Tudi Boycott, Iran's Economy After Sanctions http://boycott.tudi.ir/ (last access: 25/01/2016).
\textsuperscript{514} Radio Farda, 'Emphasize of the Minister of Road on Minor Privatization During Ahmadinejad's Administration' (2015) http://www.radiofarda.com/content/f2-iran-ahmadinejad-unable-to-do-proper-privatization-roads-minister/27304196.html (last access: 06/06/2016).
government's attempts to rigidly control the black market, this phenomenon was also exacerbated during the Sanctions Era (2011–2016). Hence, many types of essential medicines were not found in the market, which presented an opportunity for smugglers to import some essential medicines into the country illegally and sell them at whatever price they wanted to.\footnote{Mohammad Reza Saberi, *Pharmaceutical Online Purchasing Is Prohibited* Asre Iran News Agency http://bit.ly/2bOdoU9 (last access: 09/02/2016), and also: Jaame-Jam News, *The Risk of Online Pharmacies* http://press.jamejamonline.ir/Newspreview/154746648783869338 (last access: 09/02/2016).}

Nonetheless, the current nuclear deal between the P5+1 and Iran has put an end to the comprehensive economic sanctions, so that the Iranian Government can now embrace new opportunities to reconsider its general policies, including those in the health sector. Enabling the banking system to communicate with foreign banks and organisations, initiating trade cooperation with multi-national companies and revitalising the local private sector, besides the significant reduction of the expense of international business projects, are just some of the future objectives. For the recovery to be sustained, long-standing structural reforms are needed. Due to the lifting of sanctions and a more business-oriented environment, real GDP growth is projected to reach 4.8\% in 2017.\footnote{World Bank, *Iran’s Economic Outlook* (2016) http://www.worldbank.org/en/country/iran/publication/economic-outlook-spring-2016 (last access: 27/04/2017).} On the production side, growth will be mainly driven by higher hydrocarbon production and, on the expenditure side, consumption, investment, and exports are expected to be the primary drivers of the GDP.\footnote{Ibid.}

Notwithstanding the narrowing of the output gap over the coming years, inflation is forecast to remain moderate by Iran's standard. The lifting of sanctions and the positive impact this will have on the banking system will significantly reduce international transaction costs. Strong capital inflows, including foreign direct investment and the repatriation of part of the frozen assets, could put upward pressure on the Iranian Rial which will help contain imported inflation. Fiscal policy is projected to be slightly contractionary, with the deficit expected to narrow to 1\% in 2017, mostly because of improved oil revenues.\footnote{Ibid.} In general, during the Post-sanctions Era the government will acquire diverse economic opportunities to develop
the country’s economic growth; however, it should be conservative and realistic about the plan and take all the possible risks into account.

With the complete elimination of sanctions in due course, the Iranian pharmaceutical market is predicted to maintain its growth for years to come, similar to what occurred during the Iran–Iraq War about three decades ago. Although the same experience may occur even without government intervention, any economic growth soon will not necessarily indicate real growth, but may just cause a return to the Pre-sanctions Era level. The current situation can, in fact, be considered as a catalyst for the authorities to use lessons learned during the sanctions period to modify and lead various policy reforms, including pharmaceutical reform.

By resuming the transfer of money between Iranian and Western banks, it is also anticipated that the price of imported medicines will decrease 7% in the Post-sanctions Era, while the situation for internally-produced medicines will not change. This reduction stems from the elimination of unnecessary expenses that the government had to incur to import medicines during the sanctions period. Additionally, to control any possible increase in price in the pharmaceutical industry, the government’s plan is to enhance foreign investment in the public sector and encourage them to participate in the pharmaceutical sector by providing a secure economic atmosphere to increase the supply and decrease the price.

Nonetheless, foreign investment should be an option alongside domestic investment—not an alternative—in the absence of domestic investment. The government should use foreign investment only when it would be more cost-effective compared with national investment plans. Some of the most active areas where foreign investment can play a very positive and advantageous role are to improve pharmaceutical technology and optimise the pharmaceutical manufacturing sector—areas in which the industry is currently suffering. Meanwhile, the top priority of the Ministry of

520 After the ceasefire, the country reached its highest economic growth, sometimes even more that 10%. However, after three years, in 1991, it decreased drastically to less than 5%. Vaez Mahdavi, above n 515.


Health must be to support domestic private investors in the industry and strengthen them for competition with future foreign investors.\(^{523}\)

Pharmaceutical experts foresee in the Post-sanctions Era an increase in the percentage of pharmaceutical exports and financial challenges regarding the transfer of money to the country by national/private pharmaceutical companies.\(^{524}\) Reforming the tax system is another necessity that the government seriously needs to consider to reduce the financial pressure on manufacturing units and employees.\(^{525}\) On top of these reforms, however, the government needs to implement some reforms in the national banking system. Currently, the banking system is not working as a facilitator; instead, it has become an independent, new agent in Iran’s economy which hinders economic growth. Preparation for banking system reforms can begin immediately with the establishment of proper accounting and asset valuation standards, reform of banking, contract, enterprise and bankruptcy laws, and the drafting of prudent regulations. Only after this process is complete can a market-based banking system emerge and interest rates be liberalised.\(^{526}\)

By taking all these into account, the national authorities have adopted a comprehensive strategy encompassing market-based reforms, as reflected in the government’s 20-year National Vision Document and the recently issued 6th Development Plan, for the 2016–2021 period. On the economic front, during the five years, the plan envisages an annual economic growth rate of 8% and considers reforms in the government and financial and banking sector, and allocation/management of oil revenues among the government’s top priorities.\(^{527}\) The vision, mission, goals, principles and values of the reform strategy are based on an opportunity-based orientation, to achieve the objectives of Iran’s 2025 Development Vision.


\(^{524}\) Zarif, above n 102.

\(^{525}\) Renani, above n 522.

\(^{526}\) Fischer and Gelb, above n 59, p 103.

\(^{527}\) World Bank, above n 425.
The current centralised pharmaceutical system in Iran will not be responsive to the future economic requirements or the government. Not only should the system protect the private sector, but it should consider it as a cooperator, not a competitor. The pharmaceutical industry needs ‘real privatisation’ in which, instead of merely changing the name of the current authorities, some powers of government are substantially delegated to the private sector. However, Iran is still in the first phase of economic development, reducing the public budget and encouraging the private sector. In this regard, the recent survey conducted by the Iranian Chamber of Commerce shows that the majority of participants in the private pharmaceutical industry believe that WTO accession is a necessity.

Proponents of pharmaceutical privatisation use the regulatory requirements of joining the WTO and the Trade-related Aspects of Intellectual Property Rights (TRIPs) Agreement as strong reasons to justify the necessity for privatisation to increase economic growth and foreign investments to increase the market share for both local and international industries, and to promote transparency and predictability of end markets in and outside of Iran. They consider full WTO membership as a win-win for all and a significant step towards creating a global organisation.

Iran intends to become a full member of the WTO and this will obviously have a drastic impact on both the national pharmaceutical industry and the pharmaceutical market in Iran. When Iran becomes a full member, due to restrictions on the presence of copied patent medicines on the market, Iran’s Government must allocate substantially more resources to provide high-tech medicines to the national health care system.

Iran contains nearly 1% of the world’s population, but only about 0.3% of the global market and, to survive in the manufacturing area, Iran should increase its


529 Iran first applied for WTO membership in July 1996, but the progress was frozen. The WTO only started to consider Iran’s membership in 2005 and, four years later, Iran presented a file detailing its relevant laws and regulations. Financial Tribune, Challenges Ahead For Iran’s WTO Accession http://financialtribune.com/articles/economy-business-and-markets/23362/challenges-ahead-iran%E2%80%99s-wto-accession (last access 06/06/2016).

530 Tom Miles, Iran, Biggest Economy Outside WTO, Says it’s Ready to Join REUTERS http://www.reuters.com/article/us-iran-wto-idUSKBNOU2NZ20151217 (last access: 06/06/2016).
pharmaceutical investment up to $10–12 billion US by 2020. Concerns mostly revolve around the domestic industry, with low competitive capabilities due to weak manufacturing infrastructure. Hence, the lack of proper infrastructure and definite plans, trade deregulation, tariff cuts and general lack of compliance with global free-trade rules can significantly harm national pharmaceutical manufacturing.

Moreover, joining the WTO negotiations and membership itself will be much costlier now than in the past. From a legal perspective, delayed membership means more expensive membership if negotiations do not follow the right level of technical and regulatory preparation. It appears that the ‘developing country’ status no longer guarantees a smooth adjustment to membership requirements. As an acceding country, Iran can no longer expect that its integration into the multilateral trading system will be without difficulty. Also, WTO-plus commitments/WTO-minus rights are currently the dominant discourse in accession negotiations. There is no predefined set of duties and obligations for newcomers, and WTO built-in rights and obligations are not guaranteed for new members. As such, the newcomers are usually less privileged and more committed than their peers who are General Agreement on Tariffs and Trade (GATT) founders or who, for one reason or another and under different circumstances, have joined the WTO. Given the lack of a regulatory framework for membership negotiations, there are also ample opportunities for incumbent members to hinder the process during every stage of the multilateral and bilateral access negotiations. Taking this for granted, Iran’s policy-makers and negotiators should also bear in mind that different approaches to negotiations can result in various terms of membership.

Another issue that will possibly endanger domestic producers is the conduct of multinational pharmaceutical companies. Research and development started to be outsourced and located overseas with the cost-minimising trends of global competition. The core competence of the leading companies remains their capacity

534 Alavi, above n 532.
to absorb the knowledge created by their business partners, their global network, etc.\textsuperscript{536} To build these competencies, companies must maintain significant research and development potential. Global competition makes companies outsource and integrate research and development on an international level.\textsuperscript{537} Research and development functions are mostly uncoupled from local production systems. The global research and development networks strongly influence national innovation policies.\textsuperscript{538} The financial strength, the investments in research and development, the scale and variety of production, the experience in using economic opportunities, marketing and promotion have even made these entities powerful enough to control the pharmaceutical markets in foreign countries.

All of these can lead to making medicine a political or even military tool that can be used to place pressure on governments.\textsuperscript{539} A good example of this is what happened in Iraq through the Oil-for-Food program, established by the UN in 1995 (under the Security Council Resolution 986).\textsuperscript{540} The program was initially introduced in 1995 as a response to arguments that Iraqi citizens were inordinately affected by the international economic sanctions aimed at the demilitarisation of Saddam Hussein’s Iraq, imposed in the wake of the first Gulf War. The international community responded with an Oil-for-Food program administered by UN, which intended to provide essential food and medicine for the Iraqi people.\textsuperscript{541} From 1997 through early 2003, the UN ‘Oil for Food’ program allowed Iraq to export oil in exchange for humanitarian supplies. The program sold Iraqi oil at below-market

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\textsuperscript{537} Balázs Lengyel and Vladislav Cadil, 'Innovation Policy Challenges in Transition Countries: Foreign Business R&D in the Czech Republic and Hungary' (2009) 16(1) \textit{Transition Studies Review} 174, p 177.


\end{footnotesize}
prices, which benefited the recipients of oil contracts, and overpaid for Iraqi imports, which helped Iraqi suppliers.542

Accordingly, Iran’s pharmaceutical sector is likely to face huge technical changes, both before and after its WTO membership is accepted – particularly in the pharmaceutical patents and Intellectual Property Rights (IPRs) area, which is a huge gap in Iran’s current regulatory system.543

4.6.2.1 TRIPs Obligations: Intellectual Property Rules

The enforcement of intellectual property rights (patent law) in the pharmaceutical market has been a controversial issue because it threatens the access of poor populations to essential medicines. Nevertheless, it is considered as one of the innovation-driven factors that help innovative companies to compensate for their research and development investment via a 20-year monopoly for a product.

The TRIPs Agreement has probably given rise to the most insistent human rights criticisms of the WTO—its impact on the right to health. The development rationale for global IP protection is highly suspect, given that developed countries did not respect such rights during their paths to development.544 Specific concerns beyond high prices arise regarding the pharmaceutical industry, such as an innovation loss and questions about the real cost to the private sector of pharmaceutical research and development. The Doha Declaration, however, was a step in the right direction. Although patents are immensely valuable and they spur innovation and promote industry, where there is an apparent public health crisis it would be criminal to stand by and prioritise the benefits of pharmaceutical companies over the right to health of the whole society.


543 Mohsen Sadeghi, Protection of Pharmaceutical Innovations and WTO’s Accession (Mizan Legal Foundation, 2008), p 234.

544 See generally: Joseph, above n 320.
Moving towards recognising IPRs, Iran needs to improve public health and increase the supply, availability and affordability of medicines after membership of the WTO. There is also a need to adopt national patent legislation to take advantage of the flexibilities in TRIPs and the Doha Declaration. The main challenges still comprise an array of excessive regulations in Iran that should be drastically reduced so that the country can speak the same language as the world international trade system. The government has to reduce its 25,000–30,000 regulations regarding foreign trade down to 2,000 to prepare the economy for global interactions that, along with other preparations for WTO membership, would take the government years to implement. Implementing appropriate amendments to national laws is a necessity and should not be regarded as inconsequential or a political choice.

Lack of IPR protection law in Iran is also a concern for international pharmaceutical companies. Despite the presence of laws protecting patents and IPRs in Iran since 1925, there is still no comprehensive IPR law to provide full protection for innovations, especially in the pharmaceutical sector. So far, international pharmaceutical companies mostly operate in Iran through providing dealerships to Iranian companies to sell their products. Interestingly some Iranian companies represent more than one foreign company and sometimes even rival companies.

Meanwhile, the pharmaceutical industry should meet its corporate responsibility and respond to the growing public concern about the accountability and the social and economic impact of its comparatively high-priced medicines and corporate policies. The pharmaceutical industry should play a greater role in addressing the unequal

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545 Article 65(2):
A developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5.


546 Hariri, above n 531.


549 Recently, Food and Drug Organisation encourages the international companies to establish their direct operating office in Iran and manage all aspects of their medicines in Iran market through their office. A. M. Cheraghali, ‘Trends in Iran Pharmaceutical Market’ (2017) 6(1) Iranian Journal of Pharmaceutical Research 1.
access to essential medicines between the rich and the poor. Iran should also consider legally challenging pharmaceutical companies that are reluctant to grant TRIPs flexibilities in the interests of public health under the Doha Declaration.

4.7 How Significant Has the Impact of Pharmaceutical Sector Privatisation Been So Far

According to available evidence, the Iranian pharmaceutical private sector has not yet developed as much as required, and more than 70% of the domestic industries are owned by the government and its related bodies or public organisations. The lack of competition delivers fewer motives for improving the quality of pharmaceuticals, and the generic system has weakened the private pharmaceutical sector. The government has not considered that, by enhancing the role of the private sector without addressing possible drawbacks, potential consequences may lead to further deterioration of the pharmaceutical regulatory system, particularly regarding equity of access. The term ‘structural trap’ reflects the actual reason that has prevented efficiency improvements in Iran’s pharmaceutical system. It refers to a situation in which political and economic obstacles divert the reallocation of capital from low productivity companies to higher productivity ones. There is evidence that a structural trap has been a fundamental impediment to the structural conversion and growth of the Iranian pharmaceutical sector since 1980.

Evaluating the case of Iran’s pharmaceutical sector reform reveals that privatisation has followed a reverse path in Iran. The government should have started the economic reform process by privatising the non-exclusive markets, and then gradually extended it to the exclusive markets that are under the monopoly of the government. Such private markets would include insurance, banking or heavy industries, followed by, in the final step, the natural monopoly markets, for example, the pharmaceutical industry. If the current uncertainties about privatisation continue, the productive participation of the private sector could be risky. This is because,

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550 See for example: Cheraghali, above n 430.
without a monitoring mechanism to examine the function of the private sector, privatisation can lead to a private monopoly in the market. This situation will put public health at risk because the private monopoly might not be as concerned about public health as the government is, and the probability of capture or economic lobbying might increase drastically, threatening both the government’s and the public’s benefits.

Current pharmaceutical reforms have had a limited impact on private sector investment in production activities. Informal evidence indicates such investment is small-scale and primarily in assembly operations, satisfying the growing domestic demand for consumer non-durables, and is not sufficient to enhance large-scale private investment.\textsuperscript{553} Significant private investment in production activities, like that of the pre-Revolution period, is rare.

Iran’s local pharmaceutical sector suffers mainly from poor gross manufacturing practice in some parts of the local industry. The average age of pharmaceutical companies in Iran is over a half a century and they desperately need to renovate their facilities and equipment. The lack of new investments in large-scale companies is an important hurdle for upgrading these facilities. The investments needed are substantial and their major shareholders, which are mostly semi-governmental organisations, are not interested in making such investments.

A lack of effective research and development activities and marketing strategies are also the main weakness of Iran’s pharmaceutical market. Local pharmaceutical companies’ marketing strategies are poorly developed and mostly focus on price wars by providing discount offers to pharmacy outlets. Due to a lack of efficient research and development projects in local pharmaceutical companies, it is unlikely that they will produce new breakthrough products for years to come. Therefore, the overall technological capacity of the national pharmaceutical industry is still limited to manufacturing and formulation of generic medicines. To overcome these problems, a clear definition of roles and responsibilities across tiers of government, good tax legislation providing incentives to improve services, and incentive

structures that enhance accountability and intergovernmental cooperation and de-concentrate local service delivery are of the utmost importance.554

4.8 Structural Rigidity: Origins of Policy Failure in Iran

Trying to understand agency behaviour cannot reflect reality. Recognising this, Noll and Bruce created the term ‘external signals’ to illustrate organisational behaviour as the result of various external forces, for example, the marketplace or political controversies.555 Allowing a government agency to maintain its autonomy involves creating a base of support among multiple external groups. As Noll and Bruce argue, agencies try to serve the public interest, but because the public interest is such an elusive concept, agencies have difficulty identifying it. They judge the extent to which their decisions satisfy the public interest by observing the responses of other institutions to their policies and rules. Among these sources of performance indicators are the congressional committees that decide upon the agency’s budget and legislative program, the relevant budget examiners in the corresponding government or local government agencies, and the elemental interest groups engaging in company procedures, who can take their case to the politicians.556

Evaluation of Iranian policy reform during the past four decades confirms that policymakers will need to mobilise political will and draw on a range of legal, political, technical and managerial strategies to steer reform implementation in the pharmaceutical sector. The Iranian authorities must acknowledge that the bureaucratic institutional culture and economic and political rigidities have prevented the national pharmaceutical industry from positively responding to necessary changes. The World Bank’s Governance Indicator provides a measurement of the performance of the political stability, government effectiveness and accountability, regulatory quality, the rule of law and control of corruption.557 Failing to resolve

554 Dethier, above n 475.
556 Ibid.
557 Perdana and Friawan, above n 124, p 3.
problems in any one of these areas would break the link between the reform policy and the desired outcome.

4.8.1 The Government’s Socialist Approach and Crony Islamic Capitalism

The main point that should not be neglected is the actual role of the political situation, which guides the Iranian economic reforms on a broader scale, directly or indirectly. The first problematic factor of the pharmaceutical privatisation process has been the socialist approach of the national authorities towards the economy. The anti-imperialist approach of the current regime still deprives the country of many opportunities for economic development, and the government has not been able to attract foreign investment and international aid to improve the economic situation since 1979. The financial effects of sanctions have had a more powerful impact than the political effects. Nonetheless, apart from the sanctions’ economic damages, the ruling clergy’s ideological economic policies are much to be blamed for Iran’s economic ills. The Islamic government policy of economic independence detached Iran from the globalisation process and has been an obstacle to the transfer of capital, technology and knowhow to the Iranian economy. Because the economy is mainly empowered by oil exports, it is the lower oil prices or the volume of exported oil that cause an economic downturn in Iran, rather than the limited economic hardship that the US sanctions have caused. As it seems, while the regime may survive the enhanced sanctions, the economy is not likely to prosper without the American and Western support and that is of the main reasons of tension between the ‘Islamists’ and the ‘modernists’ within the regime.

The growing power struggle within the regime has disabled the government, impacting on its ability to create an institutional framework useful to large-scale private investment in productive activities. The purpose of privatisation has not been explicitly declared by the government and it reflects an Islamic crony capitalism, in which success in business depends on close relationships between businesspeople and government officials. Nevertheless, crony capitalism is not particular to Iran, the

558 Hassan Ghazizadeh Hashemi, Socialist Privatization with Governmental Tariffs Hamshahi News http://hamshahionline.ir/details/320513/Lifeskills/heathsubpage (last access: 06/07/2016).
559 Dethier, above n 475.
560 Moret, above n 437, Torbat, above n 438.
561 Torbat, above n 438, p 429.
experience of privatisation in some other developing countries (e.g., Indonesia) indicates that capitalist development in developing countries is not the product of market mechanisms. Instead, the governments in these countries proceed economic changes by picking and implementing some random reform strategies, regardless of the effectiveness of those strategies in their countries.562

In such circumstances, the ideological appearance of the Islamic Republic of Iran, with the denial of corruption and ever-expanding consumption of goods, disguise the significance of an efficient private sector. The dominance of public enterprises has affected the performance of the economic system by having an inflationary impact on the economy. The financial cost of governmental pharmaceutical enterprises shows that many of them are loss-making and highly dependent on substantial government subsidies. The leading cause of excessive monetary expansion and inflation can be found in the government’s unwillingness to oppose the credit demands of politically powerful groups (both inside and outside the government).564

Public enterprises have gradually become the most dangerous rivals for Iran’s small private sector due to their increasing rent-seeking in the system.565 Accordingly, the current policy reform is likely to miss, or severely underestimate, the potential to harness private actors in servicing public goals or recognise the extent of private involvement in evidently public affairs. Despite being an influential interest group, the industry’s private sector is not able to impact on the regulatory policy-making process.

Private or non-governmental participants in the pharmaceutical sector could, potentially, have many opportunities to engage with the system, defend their interests or discuss issues with the executive body and legislature as independent or less dependent participants with some advantages. Nonetheless, peculiar legal restrictions (e.g., Principle 44 of the Constitution) preclude them from communicating with authorities unless capture occurs. This infinite legal loop provides the best

562 Overall, the weakness of such an attitude has been proven in the experiences of many countries in Eastern Europe or those which gained independence after the collapse of the Soviet Union. Ibid.

563 International Monetary Fund, above n 473.


opportunity for different interest groups and also government institutions to apply their will and define their benefits as public interest while there is no similarity between them.

4.8.2 Re-interpretation of Principle 44

There are some implications for regulatory agency behaviour based on observed and perceived increases in the strength and frequency of judicial review. The fact that regulators may invalidate the rules on an ever-expanding and ill-defined set of grounds creates uncertainty and excessive deliberation about the way the rules must be constructed.566 Rules can take much longer to develop and, in some cases, the combination of rigid rulemaking processes and extensive reconsideration of rules that have been sent back to the agency can often be incapacitating. Generally, agencies become unwilling to experiment with radical or innovative ideas in promoting new rules, preferring to rely on the safer ground that has already been tested under judicial review.567 As Baldwin et al. also argue, increased judicial supervision may cause agencies to seek alternative procedures that are not legally subject to appeal, including informal rulemaking, guidance, policy statements and the like.568

In this regard, eliminating the ambiguities and generalisation of Principle 44 through introducing a new interpretation was expected to be an affirmative action, filling the existing legal gap and assisting the government to facilitate the implementation of the privatisation policy. Accordingly, the government was obliged to allocate 80% of government shares to the private sector.569 However, while the new interpretation targeted structural reform, it reduced the process of privatisation to a delegation of

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568 Baldwin, Cave and Lodge, above n 108, p 32.

569 'The Law of Amending Some Parts of the 4th Development Plan and Implementing the General Policies of the Principle 44' (2006), 'The Executive Statute of Delegating Certain Entities and Plans' (2009), 'The Act of Attraction and Protection of Foreign Investment' (2002) and 'The Law for Establishment of the Privatisation Organisation, and The Law of the National Service Management' (2008) are just some examples of many regulations, bills and guidelines that were codified in this area. The Privatisation Organisation, a subsection of the Ministry of Economy, was established per Article 15 of the 3rd Development Plan (2000) and started working in 2001 as a national joint stock company. It is a legal entity and has independent financial resources, and the Minister of Economy is also the Head of the enterprise.
some authorities and assets—mostly to semi-governmental bodies and to a few private entities—and still refers to improving public ownership.570

In any case, the current ambiguity cannot be resolved by interpretation, and the policy-makers should have solved the problem fundamentally by amending the Principle’s original text. This is because the original wording emphasises the necessity of centralisation and the government’s ownership of the major industries. Accordingly, the drastic shift towards privatisation by the transfer of large government industries and their accountability to the private sector is a grave breach of Principle 44. The latest opinion survey by the research centre of the Iranian Chamber of Commerce, conducted in 2010, also admits that, contrary to expectations, privatisation has neither reduced the size of the government, nor the role of national companies in the national economy.571 In general, it cannot be disputed that introducing a new interpretation of Principle 44 has led to the daring undertaking of the comprehensive economic reforms over the past decades that have the potential to provide an enormous boost to Iran’s economy in the long-term.

4.8.3 Critics of the Function of the Food and Drug Organisation

Despite the Minister of Health’s and the Head of the Food and Drug Organisation’s pro-privatisation approach, evidence shows that the government and the Food and Drug Organisation have stopped supporting private sector engagement in the areas of pharmaceutical production and distribution over the past two years.572 However,
by allocating one-fourth of the general government budget to the health sector, the
government’s socialist approach to health is once again confirmed.\footnote{573}{Ghazizadeh Hashemi, above n 558.}

While it was expected that the pharmaceutical regulatory authority would direct the
whole system, the complexity of the industry has increased the possibility of errors.
For instance, the Food and Drug Organisation is directly accountable to the Ministry
of Health and, indirectly, to the Parliament, and its policies must be compatible with
the general health plans ratified by the Parliament. However, the current structure of
the system does not recognise the separation of the legislature, the executive’s
interests and the pharmaceutical industry’s interests. Such centralised governance
and direct government intervention in the pharmaceutical sector needs to be
reconsidered by the Ministry of Health in response to the implications of Principle
44 and the general health policies of the Constitution.

The current system also precludes non-government participants from undertaking a
role in the pharmaceutical market. Placing pharmaceutical regulatory, manufacturing
and supply responsibilities under the management of one organisation has
contributed to an organisational intricacy in the pharmaceutical structure that causes
capture. Unofficial decision-making based on personal relationships with the
regulatory or industry authority is an absolute form of regulatory capture in the
system. As an example, the licensing process is still opinion-based, and this situation
has also distracted the Food and Drug Organisation from focusing on regulation. It
creates a conflict of interest between interest groups (including the Ministry of
Health, the Ministry of Welfare, insurance organisations, pharmacists, distributor
companies, domestic producer businesses and doctors) in respect of mandates and
resource allocation. Conflict of interests, in this regard, can be a motivating force
generating unethical behaviour in many other parts of the Iranian pharmaceutical
chain. Under the current regime, the pharmaceutical producer can be the buyer of
services. Also, the pharmaceutical importers and distributors are either directly
responsible for monitoring or have a significant influence on the control system.

Another aspect of the malfunction of the Food and Drug Organisation’s structure
refers to the gaps in the distribution chain which leads to irrational prescribing and
increased costs with little or no additional health benefits.\footnote{574}{World Health Organization, above n 285.} However, no budget has
been allocated to educate people and improve public awareness about the rational use of medicines. Overuse of pharmaceuticals is very common in Iran: 40% of Iranians use medicines without a prescription, and 10% to 15% of pharmaceutical usage occurs without any medical consultation. This phenomenon is partly because of the increased expectations of patients. The constant reference to pharmaceutical growth has affected the definition of patients and consumers. Their role tends to be simply classified under an ideology of consumerism defined by a craving for pharmaceuticals, whether created by advertising or an amalgam of industry marketing activities and cultural expectations. While demands for new and innovative medicines have significantly increased in recent years, these expectations have far exceeded the ability of the health insurance organisations to meet them. The implementation of real health insurance systems, which has been central to financing reform in Iran, has proved problematic. General government revenues often continue to play a significant funding role, despite the switch to social health insurance contributions. Where social insurance has been weak, this functional failure can be attributed to the weak macroeconomic context, the reliance on out-of-pocket payments, poor compliance and informal payments. These elements are the responsibility of the pharmaceutical system, particularly providers.

The other cause of irrational use of medicines also originates from the nature and structure of the pharmaceutical delivery and monitoring system. The patient's freedom to select a clinician makes it impractical to develop any systematic referral system, which makes patients' use of the various levels of pharmaceutical services haphazard. Although doctors are strongly advised by the authorities to be committed to the ethical standards, in some cases over-prescribing occurs because doctors do not balance the costs of additional prescriptions against their therapeutic benefits. In addition, in terms of information about the side-effects of some medicines, it is

575 Rational use of medicine means the promotion of therapeutically sound and cost-effective use of medicines by health professionals and consumers. Ibid.
576 Salamat News, above n 494.
578 Davari, Haycox and Walley, above n 492.
579 Akhavan Beihabani, Tanghaz and Rezaie, above n 27.
580 Mohammad Hossein Mir Dehghan, Prescribing Medicines out of the INF Is Against the Medical Ethics Gotegu Radio http://www.radiogoftogoo.ir/rss,-/asset_publisher/dNXeBaq?cP oy/content/id/2525073 (last access: 04/12/2016).
not always in a physician’s and their organisation’s best interest to disclose negative information about medicines. In some cases, realising that publishing negative information would hurt the demand for their services, physicians, and other medical institutions may decide to conceal such information.  

This is a severe management problem because pharmaceutical monitoring and regulations are measures of a government’s capacity to implement beneficial practices in pharmaceutical management. If a government does not enforce legislation and regulation, it means that programs for pharmaceutical enhancement exist only on paper and not in reality. The Iranian authorities, thus, should seek out appropriate ways to put ethical principles into practice, and the ultimate goals should be accomplished through changing doctors’ attitudes and improving patient–physician relationships.

To solve these problems, first, public hospitals and other universal medical service providers should be provided with full financing to remove the incentives to overprescribe medicines. If not, providers will charge fees that cover the gap between the costs and government subsidies. Second, government departments, such as the Ministry of Health, the Food and Drug Organisation and the Ministry of Welfare, should play an active role and work together to establish efficient and adequate mechanisms or guidelines used for pharmaceutical pricing, distribution, purchasing and utilisation. A health governance perspective on reforms includes equal attention to different leading participants in the sector, as well as multiple sets of relationships among policy-makers, users, providers and insurers.

4.8.4 Institutional Capture and Pharmaceutical Corruption

Policy reform in Iran must be applied in such a way that calibrates local needs, reduces the financial burden of the government, strengthens the industry and pursues

581 Alireza Zali, Any Type of Relationship Between the Doctors and the Pharmaceutical Companies Are Against the Medical Ethics Nasim News Agency http://www.nasimonline.ir/Content/Detail/950728/ (last access: 04/13/2016).
reformist policies that help the industry to get more engaged in the regional and international markets. The kinds of institutional choices that define agency structures and processes include the scope of the agency’s authority, its independence from other bureaus of government, its governance structure and procedural rules concerning transparency and public participation in regulatory processes. These preferences are remarkably interrelated. Internal factors relating to agencies and the staff they employ, the extent to which regulatory agencies are controlled by politicians, and the way their power is exerted, may be important to understanding organisational behaviour. Scholars have suggested that formal independence from government is derived from employment conditions of key decision-makers, agency jurisdiction, a location outside the administrative branch structure, freedom from monitoring within the organisational order, and the clarity of the division of powers between the regulator and the rest of government. More independent agencies are assumed to have greater autonomy in setting their agendas and making their decisions.

The literature on bureaucracy and public administration reveals a tension between agency officials as purely self-interested utility maximisers and those who suggest motivations based on a combination of self-interest and concern for other values. Some argue that politicians delegate authority to agencies to allow regulatory decisions to remain above the political battle, or because the technical complexity of regulatory issues are better dealt with by a genuinely expert body. Others conclude that agencies can maintain their discretion for a variety of reasons and regulators may be capable of cultivating their political legitimacy directly with interested parties,

585 See generally: Horn, above n 567.

Accordingly, the governance structure can also have a profound impact on agency decision-making and is closely related to the question of independence. For instance, the heads of executive agencies may be more politically vulnerable since they can be dismissed based on the policy preferences of the officials in charge.\footnote{See for example: Giandomenico Majone, 'The Rise of the Regulatory State in Europe' (1994) 17(3) West European Politics 77.} Decisions about policies to allow transparency and public participation in agency processes can also have a profound impact on regulatory outcomes. As Stewart argues, in general, public participation is said to force regulators to take social interests into account and to protect them from political pressures.\footnote{See generally: Richard B. Stewart, 'The Reformation of American Administrative Law' (1975) 88(8) Harvard Law Review 1667.}

The question is, do officials concern themselves with the agency, its mission and what it intends to accomplish on behalf of the public? Sometimes the desire to stay in office drives officials to make decisions that please the regulated industry officials, and the legislators and executive branch officials who control their budgets and authority. Agency leaders who favour negotiation and compromise will make different decisions than those who see themselves as advocates for an executive branch agenda or those who value their personal autonomy in making choices and acting decisively.\footnote{Wilson, above n 590, p 219.}

In this regard, a problematic factor in the Iranian pharmaceutical system has been the politicisation of a regulatory regime which is the result of the strong influence of Iran’s public enterprises. Like many developing countries, the regulatory system is often insufficiently robust in its political relations with industry. This prevents proper public accountability, makes the industry highly vulnerable to industrial capture and permits the industry’s experts to have a significant conflict of interest while providing their expert advice. Currently, there are thousands of government and semi-government companies in the country where their boards are directly elected by
government authorities.\textsuperscript{594} Appointing staff members has not been based on qualifications and meritocracy, and instead is mostly carried out based on political considerations. Such a high degree of politicisation is an obstacle to any structural reform and pharmaceutical policy-makers face the difficult task of formulating, agreeing on and finalising new, appropriate and politically feasible regulatory practices quickly enough to make the most of a limited public attention span.\textsuperscript{595}

The direct government intervention in the pharmaceutical sector has increased the possibility of regulatory capture and rent-seeking in the system.\textsuperscript{596} Thus, certain groups and semi-governmental rent-seekers (e.g., Shasta Insurance Company or Astan Ghods Razavi Organisation), are implicitly granted economic power as long as they do not compete for political power, which has resulted in them basing their activities on a non-market mechanism.\textsuperscript{597} The available evidence shows that, about two decades ago, the most significant administrative problem in Iran was policy malfunction, and corruption was a secondary concern (meaning that at least some parts of the system were not corrupted).\textsuperscript{598} However, during the last decade, almost all parts of the pharmaceutical administrative system have been affected by ‘black corruption’, which means that even when the corrupt person is fired, corruption remains.\textsuperscript{599} In essence, the nature of corruption has changed, and all relationships have been damaged.

Bribery, for instance, is becoming a very regular phenomenon in the administrative system and those who bribe do not attempt to deny or hide their illegal, unethical

\begin{itemize}
\item \textsuperscript{594} Ahmad Mir Motahhari, \textit{Reasons for Development of Semi-Governmental Entities in National Economy} Khabar News Agency \texttt{http://www.khabaronline.ir/detail/234373/Economy/macroeconomics} (last access: 22/01/2017).
\item \textsuperscript{595} A. Zomorrodian, ‘Bottlenecks of the Production of Pharmaceutical Ingredients in Iran’ (1989) 8 \textit{Razi Magazine} 33, p 36.
\item \textsuperscript{596} In their arguments, Tullock et al. define rent-seeking as the political activity of individuals and groups to devote scarce resources to the pursuit of monopoly rights granted by governments. Gordon Tullock, \textit{Rent Seeking} (Edward Elgar, 1993), James M. Buchanan, Robert D. Tollison and Gordon Tullock, \textit{Toward a Theory of the Rent-Seeking Society} (University Press, 1980). See also: Charles K. Rowley, Robert D. Tollison and Gordon Tullock, \textit{The Political Economy of Rent-Seeking} (Kluwer Academic Publishers, 1988).
\item \textsuperscript{597} Saber Feyzi, \textit{The Biggest Case of Privatization in Iran’s History} \textit{Eghtesad News} \texttt{http://bit.ly/3bUtVbu} (last access: 25/02/2016), Mir Motahhari, above n 594.
\item \textsuperscript{598} Renani, above n 522.
\item \textsuperscript{599} Ibid.
\end{itemize}

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This has led to a situation in which even uncorrupt officials will be persuaded to accept bribery as a conventional administrative process. Officials or experts serving on government committees may place undue pressure or influence on the final decision to favour a company, instead of basing the decision on scientific evidence. Alternatively, suppliers can offer officials a bribe to register a medicine without the required information or to leave out findings on a medicine's quality in inspection reports, thus falsifying evidence. One of the most troubling consequences of this situation is the importation of medicines (usually 'me-too' medicines, as minor alternatives of existing medicines) which are not approved to go to the market in developed countries, through illegal ports, facilitating pharmaceutical smuggling, in addition to creating instability in the currency market.

Because the Iranian Government acts both as the purchaser and regulator of the pharmaceutical sector it may be tempted to use regulation as an instrument to control pharmaceutical expenditure. The interests of bureaucrats and politicians can be served through giving certain groups of consumers the privilege of cross-subsidies in a disguised form which makes more room for politicians and bureaucrats to put their objectives into effect. Notably, the Iranian multiple exchange rate system has provided implicit foreign exchange subsidies to those groups with privileged access to official exchange rates. This is one of the main avenues for rent-seeking, by redirecting the resources into non-productive areas. Such a system also generates

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603 World Health Organization, above n 22.


605 Something that strengthened the possibility of corruption is the timing of the handover of some government authorities' assets to the private sector. For example, if one considers the 20 years (1991–2011) up to 90% of such delegations were done during the 2000s. More importantly, 95% of delegations in the 2000s were in the second half of the decade, when the country was in a serious imbalanced and unstable situation, both politically and economically. Akhundi, above n 570.

massive subsidies for public enterprises and big importers of basic commodities, and revolutionary foundations (e.g., Boniads and the Islamic Revolutionary Guard Corps), which are also importers of essential and capital goods for their production activities.

Boniads are parastatal institutions, which were created after the Revolution, to safeguard the ideological orientation of Iran’s Islamic Government. They are the beneficiaries of assets confiscated from the former royal family and other deported elites or assets nationalised after the Revolution. These organisations, which operate in the name of the deprived masses, have developed into chains and control a very substantial section of productive activities and employment in agriculture, industry and services. Boniads that are largely unaccountable to the government have been favoured to receive implicit and explicit subsidies from the government, though this is changing with the current reforms.607

The Islamic Revolutionary Guard Corps is also a quasi-governmental institution that, apart from being a military force with naval, air and ground components is organized alongside the regular Iranian military and is the backbone of the current political structure and a major player in Iran’s economy. As Khalaji indicates:

> Once a theocratic regime, the Islamic Republic has evolved into a garrison system, in which the military dominates political, economic, and cultural life and preserves the regime from domestic rather than external opponents. They operate legal businesses, register themselves as foreign companies, and engage in illegal smuggling [... of goods, industrial equipment, medicines]. Some reports suggest that the Revolutionary Guards have used force to assume control of large economic projects. The Islamic Revolutionary Guard Corps is a major obstacle to democratization and economic privatisation and choking off its financial resources will not be easy; it is quite adept at diversifying its complicated economic activities. In fact, what was once a revolutionary guard is now a Mafia.608

There is informal evidence that these revolutionary foundations sell foreign exchange in the informal markets. However, official reactions to corruption and financial

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608 Khalaji, above n 565, para 13.
4.9 Conclusions

There are many concerns surrounding the current Iranian political, structural and regulatory regime that has hindered an effective implementation of pharmaceutical reforms after the Islamic Revolution (1979) and which have flagged a need for significant changes in the system’s structure. The Iranian pharmaceutical sector has become a highly regulated and State-centred industry with the nationalisation of all primary industries just after the Revolution. Although the fundamental purpose of nationalising the pharmaceutical industry was to guarantee public interest and facilitate pharmaceutical service delivery, during the four past decades the pharmaceutical sector has continued to face serious challenges.

Currently, Iran’s pharmaceutical system is dysfunctional in several respects, including insufficient industry development; the unaffordability of medicines; controversies around the quality of domestically produced generic medicines; regular shortages of some medicines in the market; irrational prescribing by physicians; self-medication by patients; pharmacies selling medicines without a prescription; counterfeit medicines; proliferation of unethical competition between distribution companies; and the inefficient structure of the current supply chain. Despite limited liberalisation in government regulations in recent years, the sector is still substantially influenced by government decisions.

Meanwhile, in relation to its nuclear activities, in the past decade, Iran has faced diverse regional and international sanctions and restrictions in different fields, including the gas and oil, and banking and insurance sectors. Because of these sanctions and restrictions Iran’s industrial sector, including the national pharmaceutical industry, has faced profound difficulties in procuring machinery, technology and even finished products and active pharmaceutical ingredients. This

609 Seif, above n 513.
is largely the result of difficulties in accessing lines of international credit for Iranian pharmaceutical companies. On the other hand, and due to the reduction of the country’s international income, Iran’s national currency lost its value against international currencies. These factors have caused both substantial price increases and a shortage of medicines in the Iranian pharmaceutical market.

Assessing the experiences of pharmaceutical sector privatisation in Iran reveals that none of the necessary considerations, including the possibility of a new monopoly by the private sector, the risk of a natural monopoly; the need to prepare a suitable regulatory mechanism, the need to protect the public interest and improve the capability of new providers to serve the public needs, were considered or measured in the process of privatisation. Pharmaceutical legislation in Iran encompasses many aspects. However, other legislative aspects of the pharmaceutical system have not received enough attention, including the balance between industrial and health objectives; sub-standard and low-quality medicines; IPRs rules; electronic health around cybermedicine and online pharmacies; and public education about pharmaceuticals.

In addition to the economic factors, privatisation of the pharmaceutical industry is part of an ongoing, highly politicised process. Some of the factors that influence privatisation of the pharmaceutical sector include: the history of the asset’s ownership; the financial and competitive position of the public enterprise; the government’s ideological view of markets and regulation; the need to pay off influential interest groups in the privatisation process; the government’s ability to commit itself to comply with investors’ property rights after divestment; the capital market situations; and the current institutional framework for corporate governance in the country. It is also necessary to acknowledge the decrease in the investment rate for capital equipment replacement which it is associated with the market shift towards imported medicines, and the lack of well-designed, long-term policies to support the domestic pharmaceutical industry that would enhance domestic production. Low rates of investment, scarce attention to modern technologies and a branded medicine market are possible reasons for the domestic medicine market shrinkage.

Iran, nonetheless, has now reached the point where a clear choice must be made between a strategy that continues to rely primarily on subsidies and government
intervention, with long-term adverse effects on macroeconomic stability and growth and one aimed at sustaining long-term growth through greater efficiency and private sector-led economic development. At this stage, the Iranian economy needs to start the second wave of privatisation. What is necessary is recognition of the perception that existing conceptual categories and understandings of the current economic governance need realignment. To reform the structural system Iranian policy-makers must introduce a localised pattern of privatisation that suits the overall economic, political and structural framework. Since neither the rigid State-centred nor a fully privatised system can develop a sustainable and functional pharmaceutical system for Iran, the new reforms require the government to emphasise its role in steering the pharmaceutical system by regulation. Finding legitimate pharmaceutical strategies would assist regulators to extend public values to private participants to assure the public law scholars that there are some tools available to advance the structure of the pharmaceutical industry. Considering this fact, the next chapter argues that, now that the Iranian Government has started to implement pharmaceutical policy reforms, it is time to determine when and how to effectively implement them to defeat policy failure.
Chapter 5 – Iran’s Pharmaceutical Industry: Reform Implications

5.1 Introduction

As discussed in the last chapter, Iran stands at a historical junction in reforming its economic structure and, more prominently, its pharmaceutical regulatory system through privatisation. Since protecting the public interest and human rights of Iranian citizens is the Iranian Government’s primary objective, this goal works as a double-edged sword in the sense that it is persuasive enough to be prioritised above any other issue, while the Iranian Constitution’s narrow definition of privatisation restricts the government in meeting such a purpose. Pharmaceutical reform progress in Iran has been slow, though privatisation policy has been underway since mid-1990. The main contextual obstacle to reforming the Iranian pharmaceutical regulatory regime is unrealistic expectations about the likely benefits of change, both by decision-makers and the population as a whole. The demands made concerning the improvements have been unsustainable, which in turn has hampered further implementation. The slow advancement of privatisation, nonetheless, is not restricted to Iran and has been one of the impediments to eliminating the structural trap in several developing and transitional countries. This chapter discusses the relative merits of public and private governance by considering the primary drivers of political decision-making and drawing some conclusions as to what role private or public management does or should play in regulating the pharmaceutical system. It also discusses the lessons learned from privatisation experiences in two other transitional economies (Hungary and Indonesia) to show the side-effects of implementing a rapid and mass privatisation program while lacking the necessary structural preparedness. Further, some recommendations to resolve the current problems in the pharmaceutical area and recommendations to improve capacity building in the Iranian pharmaceutical industry are discussed.
5.2 Government Ownership or Private Ownership? The Pros and Cons

The relative success of many developing countries highlights the active role of public enterprises and government intervention in promoting capitalist development. Public enterprises are one of the primary sources of government deficit because of their growing claims on government budgets. Yet, the developmental function of the government cannot be generalised and there is growing concern about the performance of public enterprises in developing countries. Enterprise reform, which requires the imposition of bottom-up discipline, definition and transfer of the property, and management reform are at the heart of the transformation process.

Successful State-centred development occurs, generally, in sharp contrast to government failure, and the regulation of public enterprises by politicians suffers serious drawbacks. Firstly, it is widely known that any public institution enabled to exercise control for a temporary purpose tends to make it a permanent task. It may thus, as Shleifer argues, be challenging for dispossessed citizens to intervene to reverse governmental control once it has ceased to exist. Secondly, it is difficult to motivate politicians in office to represent voters' interests over their individual interests and to prevent conflicts of interests. If politicians are inclined to participate in patronage and corruption, then public enterprise inefficiency is not just because of weak inducements but the result of an intentional process. Government' purposes can also change from one administration to the next.

One argument to justify the substantial cost of public ownership in the presence of market failure (e.g., monopoly power or external factors), concerns the inability of a ruling government to commit to market-friendly tax and regulatory policies, which discourages private investment and may result in direct government involvement in production, as an alternative. Similarly, governmental control of infrastructure

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613 Fischer and Gelb, above n 59, p 98.

614 See: Shleifer, above n 38.


616 Hadi Salehi Esfahani and Ali Toossi Ardakani, 'What Determines the Extent of Public Ownership?' (The University of Illinois at Urbana-Champaign, 2002).
may be the result of the reluctance of private investors to provide a financial resource for considerable investments which may be subject to political decisions.\textsuperscript{617}

Some, like Martinelli, argue that public enterprises may build plants in economically unfavourable, but politically attractive, regions.\textsuperscript{618} Politicians may even distort the regulatory framework ahead of a public enterprise's sale, by decreasing competition, therefore, maximising revenues (or bribes). Even if one takes away the clearest cases of political abuses, the empirical evidence of public enterprises solving market failures is quite inadequate. Public monopolies often exploit their market power not through high prices, but by sheer inefficiency and granting preferred treatment to political constituencies.\textsuperscript{619}

The main argument against governmental control comes from the combination of broader unlimited powers as the government can write rules, enforce them and modify legislation to its advantage. Given that there may be countries with weak institutions to constrain public abuse, the case for governmental control is difficult, particularly in those contexts where its need may be, in principle, the greatest. The public commitment view is also supported by considerable evidence showing that the size of the public sector is smaller in countries equipped with better institutions, especially those restricting the risk of arbitrary changes in policies.\textsuperscript{620}

Evidence of the actual role of public enterprises must conflict with the view that social goals, for example promoting health and access to medicines, may be best realised via public enterprises. While the shareholder-wealth-maximising model of corporate organisations is beginning to dominate, in part because of the advantages of having a clear corporate goal, governments have many objectives other than profit or shareholder-wealth maximisation.\textsuperscript{621} However, public ownership of companies may result in problems in defining the goals for them. The inability of the government to commit to a policy can considerably reduce the efficiency of a company's


\textsuperscript{620}Knack and Keefer, above n 617, p 7.

operations and governance. There is an argument that there will be differences in the performance of government and private enterprises because there is a more comprehensive range of supervising tools under private ownership. Governments can intervene in the operations of any business, either public or private. Nevertheless, the transaction costs of intervening in production arrangements and other company decisions are greater when companies are private. 622 In general, public enterprises display significantly lower production efficiencies in comparison with private counterparts. 623 The primary causes are due to a general lack of accountability, leading to a lack of managerial motivation to adapt, problems of, or official ability to, perform; and the use of public enterprises for political purposes.

On the other hand, redefining the government's previously encompassing role is one of the greatest challenges for reform. Institutions and professions taken for granted in market economies have to be re-created and improved to support markets. 624 Theoretical work that examines privatisation offers many reasons why, even in the case of market failure, government ownership has important weaknesses. 625 Arguably, privatisation can lead to increased efficiency and improved welfare only in settings with enough capacity to ensure appropriate protection of property rights, contract enforcement, control of market abuse, reasonable regulation, and commercial dispute settlement based on law, not payments. 626 As a reform policy, privatisation can help the government to increase the profitability of those government areas that are not advantageous enough to strengthen the function of the economic sector. Also, administrative inability is less detectable when hidden inside a public institution than when it is subject to public monitoring as public regulation of private activity. Thus, many of the theoretical arguments for privatisation are based on the premise that the harmful effects of government intervention have a


624 Fischer and Gelb, above n 59, p 100.

625 Shleifer, above n 38.

greater impact on public ownership than under governmental regulation, not that the adverse consequences can be eradicated by privatisation.

Privatisation outcomes are entirely influenced by the institutional setting in which delegations take place. By default, continuing rights to regulate belong to the government. Nonetheless, the power to adjust enforcement under unspecified probabilities could be granted to the semi-autonomous judiciary or regulatory authorities. If these institutions operate under a framework in which they can avoid being captured, allowing them to improve enduring enforcement rights has several advantages over the affirmation of direct governmental control. Evidence suggests that the most important institutions are those that restrain the executive and reinforce its accountability, for example, those that limit abuse of power over those that regulate relationships among individuals. The reason may be that those power-restraining institutions also have the right political incentives to favour substantial private interests, to control market power, and thus undermine a level playing field and the process of entry by new producers.

Nonetheless, regulation fails just as privatisation does, namely when it leads to regulatory or to governmental capture. There is a broad consensus that privatisation usually loses much of its potential in poor institutional contexts when poor regulation leads either to public or private abuse. Private ownership is also supposed to increase public expenditure, first because tax revenue is managed by smaller entities and, second, because of reproduction of management frameworks. Varied international experiences, mainly in developing countries, show that although privatisation is a means to shift a centralised and governmental economy to a market economy it is not a panacea and, if not applied correctly, can lead to an increased financial burden on central government. Hence, when the government cannot precisely determine its objectives due to a lack of experience, it may retain direct control to avoid costly contract renegotiation procedures with private parties. To

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628 J. Hellmann, G. Jones and D. Kaufmann, 'Seize the State, Seize the Day' (World Bank 2000).

629 Perotti and Bortolotti, above n 150, p 8.

630 Ibid.

631 See for example: Gaal et al., above n 77.

the extent that intervention has substantial costs, governmental ownership/control is preferred to private ownership.

Private ownership or governance by the private sector increases transparency and efficiency\(^{633}\) and can eliminate the causes of corruption (e.g., weak control, lack of public interest in honest administration and little likelihood of being penalised, and thus have an impact on the level of corruption).\(^{634}\) Nevertheless, one would not expect privatisation by itself to reduce these causes, unless it changes behaviour through accountability and transparency. In other words, administrative arrangements may not often work as hoped and privatisation can merely change the location of corruption, the amounts involved and the identity of the perpetrators and beneficiaries. While corruption may accompany transition in all countries, where corrupt agents hold more power than the corrupt officials this leads to regulatory capture. Consequently, the private capture of the privatisation process reduces the government’s ability to control the behaviour of the most powerful private owners.\(^{635}\)

Some of the literature on regulatory capture has also highlighted how regulators are encouraged to become compliant with industry wishes through implicit promises of productive future careers in the regulated industry.\(^{636}\) The primary argument advanced by Stigler was that strong industry lobbies had incentives, information and organisational cost advantages that allowed them to overcome collective action problems and engage in lobbying for regulation designed for the industry’s benefit.\(^{637}\) In this respect, multilevel regulatory capture is an essential political and institutional constellation that facilitates growing political and economic power. Jorgensen probes the links between pharmaceutical policy and the private pharmaceutical industry’s political action through financing political campaigns and lobbying.\(^{638}\) Jorgensen’s


\(^{634}\) Dethier, above n 475.


\(^{637}\) Stigler, above n 248.

thesis is that the industry can convince legislators to define policy problems in ways that advance its interests. The industry reinforces this policy framework by selectively providing information to legislators, subsidising their work and targeting campaign contributions to influential legislators and allies. In this way, the industry displaces the public interest in developing pharmaceutical policy. Gagnon also argues that the current architecture of pharmaceutical markets has created a misalignment of financial incentives and public health that is a central cause of harmful practices. As an example, he explains that companies have strong financial motivations to develop so-called ‘me-too medicines’ (as minor alternatives to existing medicines) and to market them by exaggerating their benefits and failing to reveal their full risks; this is much safer than developing new pharmaceuticals but is still cost-effective.

To make regulation politically feasible, regulators seek compromises that require the regulated industry to share the benefits of regulation with other politically pertinent interest groups, including competing companies and potential consumers. Wilson emphasises the need to understand regulators as operators within the wider political system. He identified particular relationships between the diffusion of a regulatory policy’s costs and benefits and the character and strength of interest group influence over regulatory outcomes. Policy issues yield benefits only to a strong interest group.

The claim that the opportunistic manner of public officials, when faced with the demands of competing interest groups, will nonetheless reflect the efficient arbitration of these interests is also challengeable. Buchanan, for example, suggested the concept of ‘government failure’ to represent conditions where government intervention leads to a more chaotic and unskilled allocation of resources and goods than would occur without it. The same may happen in relation to any

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641 Wilson, above n 590.


patient advocacy organisations that accept funding from pharmaceutical companies to finance their activities. Dependency on such funds creates conflicts of interest which can make patient advocacy groups biased towards the interests of pharmaceutical donors. Rose postulates that organisations are often interested in ensuring that they are trusted, but instead they need to focus on developing actions and policies to ensure that they remain trustworthy. Patient advocacy organisations could accomplish this issue by admitting conflicts of interest, using oversight committees, restricting the amount of funding they accept from pharmaceutical companies, and not letting industry donors specify how organisations will use the contributions they take.

Light et al. argue that the pharmaceutical industry has corrupted the practice of medicine through its influence over what pharmaceuticals are developed, how they are tested, and how medical knowledge is created. They indicate that the pharmaceutical industry has a business model that relies on developing and aggressively marketing accumulative modifications of existing medicines that are not only more expensive without providing much more benefit, but in some cases are even harmful. They believe the current market incentives do not, overall, advance public health goals. A paramount characteristic of countries with successful privatisation has been their ability to monitor economic performance by imposing discipline on companies, which are the recipients of subsidies and other government assistance. This principle called a ‘reciprocal control mechanism’ by Amsden, allows the government to influence the behaviour of target industries by subjecting them to national policy goals based on their local content, export targets, technical capacity and prices in domestic and international markets. Thus, developing policies and

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446 Ibid, p 686.
regulatory responsibility within institutions are preliminary steps to ensuring the appropriate relationships among participants.

In essence, privatisation can be a useful strategy only when it is part of a larger economic policy reform, and it is used to develop the private sector. It is beneficial if the government guarantees: market competition; a decrease in expenses; an increase in quality; a restructuring of the minor governmental entities, which are supposed to be delegated to the private sector; and the codification of effective regulations to reduce inequality and eliminate corruption in the system. Otherwise, not only does privatisation not improve the economic system, but it will result in a flawed policy that will not be coherent with other parts of the structural system.

5.3 Policy Reform Illustrated in Country Examples

Economists contend that free trade rules are preferable to restrictive trade rules because free trade maximises the global output of goods and services, while restrictive measures reduce the production of goods and services. As the effects of free trade include lower prices and increased consumer choices, the consequences of protectionism carry with its quotas and tariffs that increase prices of both domestic and imported products. If handled well, privatisation may lead to systematic citizen involvement in setting the goals, design and financing of economic policy, and in monitoring service provision and other functions. Privatisation spurs providers to obtain the skills, material support and authority they need to offer high-quality services. Privatisation can further enable clients to secure information, financing and bargaining power, and offer the authorities a chance to discard impractical obligations and carve out a new role and image.

However, moving from a command economy to a market economy requires an entirely new set of institutions to be established in a short period. There must be a

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goal to achieve complete intellectual and moral reconstruction for complete economic restructuring to occur and a new institutional system to be established. Usually, the reformatory macro-strategy approach and gradual reformation are the two methods that are adopted by governments at the very early stage of implementing regulatory reform. In the macro-strategic reformation approach, vast interventions are required compared to gradual reforms, which include several reformation plans. Along with macro-strategic reformation, the pharmaceutical sector, for example, faces three stages. The first stage emphasises a reduction in the public budget and encourages the private sector, while the second stage focuses on the efficiency of health system management of human resources and privatisation. In the third stage, having a multi-sectoral view, the outputs of the pharmaceutical system along with pharmaceutical services are of more concern. These stages can be applied to any type of policy reform to different systems, including privatisation policy, as in Hungary and Indonesia. The gradual or more modest reform, however, includes the introduction of user charges in public clinics or granting autonomy to the national teaching hospital. This reformation is defined as those attempts to target only one part of the pharmaceutical system or one type of service delivery. Privatisation of the pharmaceutical system that has involved only shifting a few functions to the district or regional Ministry of Health offices is another example of the more modest type of reforms.

Nevertheless, the transition from a command to the market system in many developing countries has been based on a rapid approach – the mass privatisation of public enterprises as quickly as possible. The rationale for this experiment is articulated, for example, by Shleifer and Vishny, who believe that privatisation then offers a huge political benefit for the creation of institutions supporting private property, because it creates the very private owners who then begin lobbying the...
government to create market-supporting institutions. Institutions would follow private property rather than the other way around. 656

Because of the complexity of pharmaceutical system issues, sharing the experiences between countries could help to overcome potential weaknesses. Considering such experiences can help to illustrate that, even in different contexts, implementing a rapid and mass privatisation strategy in transitional economies that lack the necessary infrastructure does not work—at least in the long-term. As such, this chapter analyses the experience of Hungary and Indonesia, as two civil law, 657 industrialising countries with transitional economies, which have experienced policy failure as a result of implementing rapid and unsuccessful privatisation reforms to serve as useful examples for Iran.

The effects and traces of political and economic systems in Hungary and Indonesia indicate how structural factors affected the economic performance of these transitional countries in the examined time-periods. Although such a case selection is based on the different political systems, geographical situation, size and population of these two countries (and their differences with Iran), it highlights similar challenges that caused policy failure in these countries (common mistakes/challenges that the Iranian Government is either facing or can possibly face in the near future).

The most important common aspects between Hungary and Indonesia, besides political dictatorship and growing economic prosperity, are: that they adopted a command and control economic system as a result of an ideological system, their lack of competition, the increase in corruption caused by a centralised system, their highly bureaucratic mechanisms, their concentration on heavy industry; and that they eliminated market influences. 658 The Hungarian and Indonesian governmental companies were also characterised by low efficiency, a lack of motivation and a waste of resources, while quality, research and development, and efficiency were totally ignored. 659 In other words, the centrally planned economy resulted in a misshapen economic framework, falling behind the world standard and causing

656 Shleifer and Vishny, above n 615, pp 10-11.
657 Indonesia's legal system (like the Iranian legal system) includes Sharia law, as well.
659 Ibid.
scarce. The organisations directly serving industrial production typically existed in monopolistic contexts, not only because of their large size but also due to the administrative restrictions under which these organisations were assigned the responsibility of bureaucratic coordination and control. Both Hungary and Indonesia are cases which chose ‘mass and rapid privatisation reform,’ at a time when they were at a critical juncture regarding their economic policy formation. Based on the finding of the present research, in both countries, the transition to privatisation was, hence, based on a more ‘trial and error’ method, which made it a long process.

As a consequence, despite implementing various reform policies, to date, Hungary and Indonesia are likely to still deal with many challenges resulting from economic liberalisation. These challenges include increasing inequalities of income and access to economic opportunities between different groups and regions, and between large, medium and small enterprises. Although these gaps are caused by many factors, privatisation of industries may augment and aggravate them. Such characteristics which are, by and large, common with the Iranian transition journey, allow one to track their progress against that of the current Iranian regulatory system.

5.3.1 The Case of Hungary

Hungary's experience is typical of the post-socialist transition countries in Eastern Europe. Among the transitional countries, Hungary has a long history of economic reform and it has continued to experience financial difficulty in the period following the collapse of communism. The transformational recession in Hungary was due to the loss of old markets and to the creative destruction that was needed to lay the foundations of a new, healthy market economy on the ruins of a distorted communist structure after recovering from communism. However, the movement towards integration into the world trading system was not exploited. Based on the available evidence about economic transformation in Hungary, the consensus has been that privatisation in the post-communist period has taken place in an environment

\[\text{See for example: Meagher, above n 122.}\]

\[\text{An economic organisation under the leadership of the Soviet Union that comprised the countries of the Eastern Bloc along with many socialist states elsewhere in the world. Brown, above n 653, p 285.}\]
characterised by weak ownership rights on the part of political actors and secure ownership rights on the part of enterprise insiders.662

In 1989, Central and Eastern European countries were confronted with the responsibility of managing a drastic transformation of societal and economic conditions in a manner that resulted in radical reforms to their constitutions regarding their economic structure. Over the past decades, privatisation has been high, as these countries have moved to dismantle their previous, dominantly governmental, economies. The massive redistribution of property that occurred reshaped not only their economic systems but their political and social systems as well. However, in the absence of significant restructuring, privatisation alone could not solve the underlying problems facing the previously public enterprises.663 Thus, the rapid strategy of privatisation was not successful in most of these countries. A central reason for that is the weakness of the political demand for the rule of law.664

Throughout the communist years, Hungary was under a form of government that did not promote free trade. The international trade that took place was the result of the socialist division of labour imposed by the former Soviet Union. Protectionism was a policy that was adhered to in the Eastern European countries, and if there was any form of trade, it took place within the Eastern bloc and other nations in the communist world.665 The objective behind this was to create regional integration based on specialisation that led to economies of scale but removed incentives to upgrade products. With the advent of free trade in the former Eastern bloc countries, significant changes occurred, for example, the removal of government business monopolies, the implementation of a unified exchange rate, the increased access to foreign currencies and the replacement of quotas for average tariff protection.666


663 Brown, above n 653, p 289.


665 The term Eastern Bloc referred to the former communist states of Eastern and Central Europe, including the countries of the Warsaw Pact, along with Yugoslavia and Albania, which were not aligned with the Soviet Union after 1948 and 1960 respectively.

666 Brown, above n 653, p 280.
Hungary decided to move rapidly towards a market economy and to create a policy framework, change the fundamental character of its relations with other countries, and join the global economy.\(^{667}\) The latest transitional period involved unprecedented changes to both the size and type of industrial organisations. First, the regulatory system shifted from a state-controlled system to a public, but not state-controlled, system. Then, it turned to privatisation and, finally moved towards public–private cooperation.\(^ {668}\) Under these circumstances, the transformation of legal status and organisational forms of business, supported by political changes, became a preparatory phase of privatisation and influenced the reorganisation of public enterprises.\(^ {669}\)

In 1988–1989, the government opened the country up to foreign direct investment by passing legislation on joint ventures, foreign investment and corporatisation of public enterprises. By this time, rapid and mass privatisation had begun and such an early transition bred speculation, fraud, theft and corruption. The Hungarian government also created pressures for companies, banks and officials (e.g., regulators and tax collectors) to accommodate economic distress by colluding to avoid application of the laws. The government also encouraged officials to supplement declining real public-sector wages through bribery, misappropriation, self-dealing, and other forms of corruption. The absence of competition, disciplining mechanisms and transparency meant that this situation could continue unchallenged. Among the varieties of corruption practiced in Hungary, certain methods depended on the use of official authority to direct resources and advantages to individuals. These practices usually impacted the financial system, as they involved banks, other credit sources, purchases of assets or shares, or the use of government funds.\(^ {670}\) Corrupt financial practices thus affected the financial sector and extended beyond it. The economic crisis pushed individuals and companies into participating in the informal economy, with the various forms of asset-diversion and extortion that this entails. These strategies became more likely to foster corruption because of the political and social

\(^{667}\) Ibid, p 288.

\(^{668}\) Tamás Kovács et al, 'Pharmaceutical Pricing and Reimbursement Project' (National Health Insurance Fund Administration (OEP), 2007).


\(^{670}\) See: Gaál et al, above n 77.
repression imposed by communism, which left few real restraints on corruption in the initial period of transition.\textsuperscript{171}

The first transition crisis in Hungary drove most companies and banks to the brink of insolvency, and frequently beyond. From 1987 to 1990, approximately 8% of all public enterprises were rapidly privatised; that is, had their assets shifted to other entities without notice or compensation to the government.\textsuperscript{672} Indeed, some of the larger foreign investment deals involved informal, or at best legally opaque, privatisations. During the transition crisis of 1989–1993, gross domestic product (GDP) and industrial output contracted by 18% and 25% respectively.\textsuperscript{673} Unemployment rose to about 10%, inflation climbed beyond 33% and bankruptcies soared to over 10,000.\textsuperscript{674}

At the same time, restructuring and privatisation were moving control of public means of production into private hands at an uneven, yet unprecedented, rate. These dislocations presented opportunities to those able to gain access to productive assets and to exploit insider knowledge and connections. The government, via the public commercial banks, directed credit to selected companies, but virtually ignored the credit needs of small, medium-sized and start-up companies. Thus, no one was held responsible when loans were extended or rolled over to non-paying companies. Though they were insolvent, banks were considered ‘profitable’ since they counted unpaid interest as income and were not required to provision against non-performing loans.\textsuperscript{675} Loan officers were necessarily expected to give loans as required by client enterprises, and their bureaucratic and political masters. In short, credit allocation became, to a significant extent, personalised, politicised and corrupt.\textsuperscript{176}

Hungary's productive sectors were still dominated by public enterprises as the 1990s began. At the end of the 1980s, Hungary had one of the largest public sectors in the world, as well as a mostly stagnant economy, depending on Soviet Union trade for

\textsuperscript{171} See generally: Dethier, above n 475.
\textsuperscript{172} Meagher, above n 122, p 4.
\textsuperscript{173} Ibid.
\textsuperscript{174} Ibid.
\textsuperscript{176} See: Csizmadia and Madsen, above n 1.
40% of its earnings. Thus, the most severe economic downturn occurred after the dissolution of the Soviet Union in 1991. The early 1990s in Hungary saw rapid institutional change and a severe economic downturn. The government, favouring privatisation and not willing to interrupt these changes, adopted a policy of non-interference, thus enabling enterprise managers to privatise their companies in a legal and policy vacuum. However, episodes of insecure and corrupt banking led to failures and scandals.

Problems arose because mostly no one was monitoring the managers. In some cases, it appears that bank regulators, who should have been monitoring the situation or acting, were pressured to look the other way. The lack of clear priorities has been a recurring problem since 1990. In a rapidly changing economic and legal environment, it is almost impossible to separate short-term losses and long-term gains, and generosity from corruption. It is reasonable that top public enterprise managers try to avoid harsh measures; they tend to guarantee their interests through wage rises, toleration of weak performance, theft, and corruption.

In 1996–1997, when commercial banks were privatised, some managers obtained much larger discounts and much more significant number of shares than the law permits. Since managers often controlled a ring of companies, they had complete freedom to shift assets without obtaining the permission of other parties. Banks were implicated in a few ways: some were members of corporate groups, some probably facilitated asset-stripping and fraudulent debt washing, and some were established in part with misappropriated capital. Banks also were known to have supported various forms of self-dealing by managers and major owners. Related-party loans (loans to owners, board members, employees or their relations) were not regulated at the beginning of Hungary’s transition. Those cases involved political influence exerted on government banking supervisors by officials or politicians close to the banks.

Managers in many cases took advantage of privatisation delays to wash the debt from their companies and to speed up the acquisition process (e.g., by filing for bankruptcy

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677 Meagher, above n 122, p 25.
679 Voszka, above n 662, p 297.
Scores of big businesses were rapidly privatised with constellations of companies in hundreds of new interconnected entities with both private ownership and some participation by the government—frequently a controlling block of shares owned by a public enterprise. Where the transactions were indeed designed to create an ongoing, at least partially private, concern, cross-shareholdings and interlocks were expected to provide a means to coordinate behaviour among the associated companies. Since many such transactions were undertaken to forestall bankruptcy or takeover, the corporate groups and the networks that came into being frequently combined distressed enterprises with banks, with the latter providing loans in return for shares of equity.

Thus, Hungary’s early efforts did not yield the kind of private ownership structure that could support, or operate in, a competitive and transparent marketplace. One might summarise this situation by saying that early transition ownership structures in Hungary combined all the private enrichment opportunities, and all the public governance nightmares, of both conglomerate and public ownership. In a sense, networks of ownership and control were sufficiently opaque that the actual role of public and private actors was unknown to anyone, but insiders. While mass privatisation is not always corrupt or illegal, these transactions were at best problematic. It was usually not clear that the public enterprise’s management had any authority to sell government assets, and it was often unclear to whom the assets were being sold. Hence, such transactions, at a minimum, presented a conflict of interest if they were not outright theft. Indeed, the proceeds of these sales usually did not go to the national budget, but to the enterprise or a subsidiary and the relevant managers. The initial Hungarian privatisation programs, therefore, were considered failures.

A subsequent program in 1991 took as its objective sorting out some of the improprieties and fallout from the early privatisation attempts. Contrary to expectations, this also brought no improvement in the productivity indices, but it

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680 Meagher, above n 122, p 8.
681 Ibid, p 11.
682 Hanley, King and János, above n 675, p 142.
683 Ibid.
significantly altered the pattern of decision-making powers. Public companies did not have a single master. Between 1990–1998, there were several rounds of the reorganisation of government asset management agencies. These changes in the government asset management agencies meant new desk officers, lost papers and confused new ideas. Therefore, because of the mass and rapid changes, public enterprises managers viewed themselves as the bastions of stability and professional competence. Also, the most important public enterprises remained under the control of politics and they have always been subjecting to political influences among partners in the coalition, which makes the outcome even more unpredictable.

Since 1990, policy-makers have permitted different government asset management agencies to sell 5–15% of the equity in a divested company to employees of the company with a 50% discount. Obviously, the idea was to increase staff interest in privatisation. This was only a possibility, and privatisation of major utilities was delayed until 1995 due to confusion over who owned what. Gradually, however, the possibility has become an informal acquired right of staff. Since about 1995, it has also been acceptable for managers of the public enterprises to be entitled to a larger number of shares than regular employees.

Delegating huge responsibility to the relatively small and fragmented local governments came at great cost to the economy. While the counties were supposed to act on behalf of local authorities they turned to units that were not only unrelated to the localities but even worked as parallel regulatory bodies. The central government had no direct control over the local governments; thus, the enforcement of the laws given to the local governments was critical. The lack of coordination among the Hungarian Ministries also led to the sectoral law transfer of tasks and

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685 Ownership control over a typical public enterprise was initially exercised by the Branch Ministry (1990-1992), then by the State Property Agency (1992-1993) or the Hungarian State Holding Company (1994-1995) and finally, by the State Privatisation and Holding Company (1995 onwards).

686 Mihályi, above n 678, p 13.


688 See generally: Dethier, above n 475.
responsibilities to the local administration without financial support. Hence, local
governments were not able to provide services as prescribed by law.\textsuperscript{689}

In terms of research and development, Hungary entered its transition period in the
era of globalisation. The country faced the challenges of global competition and the
fall of the centrally planned economy. Foreign-owned companies became decisive in
the innovation system.\textsuperscript{690} At the beginning of Hungary’s transition period, the
research and development expenditures of national companies decreased
considerably.\textsuperscript{691} The fall of the planned economy and the quick reintegration into the
world’s market economy caused structural changes in research and development
financing.\textsuperscript{692}

Once privatisation started, it became apparent that public enterprise managers had
pursued fundamentally different strategies:

- For very large companies, where the internal structure was diversified both
  in a technological and in a geographic sense, people expected splits and other
  rearrangements. It was evident that privatisation would lead to the emergence
  of some new companies on the ruins of the old public enterprises, and creation
  of new managerial positions. Thus, even the middle level of public enterprise
  management became committed to privatisation.

- Privatisation appeared as a panacea for many troubled companies for
  financial reasons. Many large companies drifted toward the verge of
  economic collapse, despite a relatively good overall market situation.

- There were at least two groups of companies, however, where management
  was against privatisation.\textsuperscript{693}

In big companies, where management had been accustomed to privileges,
privatisation was expected to sweep all this away. Arguably, even the vast Hungarian
companies were small by international standards so, once privatised, they would
develop enough to prevent the price of their companies falling. In small and medium-

\textsuperscript{689} Balás and Hegedüs, above n 654.

\textsuperscript{690} Balázs Lengyel and Loet Leydesdorff, ‘Measuring the Knowledge Base in Hungary: Triple Helix

\textsuperscript{691} Andras Varga, ‘An Overview of Recent Developments in Computational Methods for Periodic

\textsuperscript{692} Lengyel and Cadil, above n 538, p 178.

\textsuperscript{693} Mihályi, above n 678.
sized companies, those managers who were against a public sell-off aspired to become owners themselves. In most cases, the management had no resources at the beginning of the privatisation process, but they hoped that within some years they would enhance themselves enough or the price of their companies to drop.\textsuperscript{694} One widely used method to achieve these two goals was the reorganisation of the public enterprise into a holding company with many subsidiaries. This had two interrelated consequences. First, the holding company itself became financially opaque to outside inspectors. Second, the creation of subsidiaries and different joint ventures with private partners opened the way for various forms of self-dealing, whereby management could bleed out its own company and redirect the profits into their private ventures.\textsuperscript{695}

The combination of government ownership with extensive corporate networks and a relatively chaotic environment caused lobbying and misappropriation in financial transactions. Rapid and mass privatisation in Hungary (in the absence of functioning safeguards and market institutions) opened the door to massive self-enrichment by enterprise insiders, and a loosely supervised banking system facilitated the rise of the oligarchs. Hungary’s experiments with market socialism had ushered in a complex and opaque business environment. Hybrid (public–private) corporate groups—in many cases run by former governmental managers—linked enterprises, banks and the government in a collusive mutual embrace.\textsuperscript{696} When these factors gained dominance in Hungary, the country faced painful choices about its path ahead, with its future hanging in the balance.

After all, the agreements into which Hungary has entered with international agencies, for example, the International Monetary Fund (IMF) and European Union (EU), rule out recourse for a broad range of policy options on which governments have historically relied on to influence economic activities.\textsuperscript{697} In March 1992, Hungary signed ‘Europe agreements’ with the European Community that committed it to creating industrial free markets within 10 years. However, in comparison to trade

\textsuperscript{694} Meagher, above n 122, p 35.
\textsuperscript{695} Mihályi, above n 678, p 12.
\textsuperscript{696} Meagher, above n 122122, p 1.
\textsuperscript{697} Hanley, King and János, above n 675, p 161.
barriers that were in effect in the last ‘pre-transition’ year (1989), the Hungarian tariffs were 58% higher.

The reasons given for these high tariffs were that 40% to 50% of the exports from Central and Eastern Europe were on goods that fell into the ‘sensitive’ category. Some scholars have called for a slower pace of liberalisation for these ‘sensitive’ sectors. The requirements of EU accession probably played an even more important role in encouraging effective reform of Hungary’s financial sector, given the EU’s detailed monitoring and the prize of EU membership at the end of the process. The EU’s Commission Opinion stressed that, for Hungary to join, it must tackle corruption, limit the growth of the budget deficit and foreign debt, increase the development of health care, and improve customs control and consumer and environmental protection. In addition to the tariff quotas, import ceilings, voluntary restraints, anti-dumping procedures and other acts were also implemented. Thus, international standards and regimes directly affected internal governance, serving as a disciplining force, providing political cover and thus enabling policymakers to hold the line on tough decisions.

The Eastern European region furnishes several examples of alternative approaches Hungary might have chosen, with a far greater set of consequences. It might have taken the path of putting off reform as long as possible, then making gradual changes. The opposite strategy, of focusing efforts on mass privatisation while institutional reform moved at a slower pace, has provided what appear to be some quick benefits amid the pain of restructuring but has more recently shown itself to be deeply flawed. The case of Hungary suggests that privatisation can carry a transitional economy across a verge where the extent of public ownership is simply too insignificant to enable the government to exercise control. This threshold varies from place to place. The effect of passing below such a threshold can be cumulative since public entities have usually owned many cross-shareholdings in networks of companies and banks. The impact of divestment depends, of course, on the existence of

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698 See generally: Csizmadia and Madsen, above n 1.
699 Brown, above n 653, p 281.
701 Meagher, above n 122, p 73.
of several other checks and balances. For instance, in the Hungarian transition, the best policy was not necessarily to attack corruption but to treat the disease itself. Another essential factor is the role of effective corporate governance, in which: real protection exists for minority shareholders; self-dealing and connected transactions are policed, and decisions duly taken are enforceable by law. In this sense, the environment of transition can bring corporate and public-sector governance into close mutual dependency.703

5.3.1.1 Pharmaceutical Regulation in Hungary: Main Design Features and Implementations

In Hungary, Act CLIV of 1997 on Health assigns responsibility for health services to the National Assembly, the national government, the Ministry of Health, the National Public Health and Medical Officer Service, and the owners of health facilities.704 The Hungarian Ministry of Health is the central authority for implementation, control and enforcement of regulations, including the registration and licensing of pharmaceutical providers. The National Public Health and Medical Officer Service, as one of the most relevant agencies of the Ministry of Health, has national institutes and is responsible for monitoring the quality of pharmaceutical services. Therefore, the current structure of the Hungarian health-care system represents a considerable departure from the former, highly-centralised, state-socialist model. The previous hierarchical relationships have also, partly, been replaced by contractual relationships and quasi-public arrangements.705

The Hungarian intergovernmental finance system has also played a significant role in the transition but, because of continued reforms, it has been over-regulated with partial and uncoordinated modifications.706 In 2002, the Hungarian Government suspended some of the restrictions on the privatisation of delivery organisations.

704 Ibid.
705 See: Hungarian Spectrum, Political Action and the Critical Mass Hungarian Spectrum <http://hungarianspectrum.org/tag/parliamentary-democracy/> (last access: 07/12/2015).
706 The establishment of the independent the National Health Insurance Fund Administration did not secure funding for pharmaceutical services, as was expected. Instead, it became a very effective tool in the hands of the central government to contain expenditures and even to withdraw funds from the health sector. The current state of regulation also leaves little scope for the National Health Insurance Fund Administration to develop its function as a purchaser of health care. Gaál, above n 703.
Nevertheless, the impact of the new privatisation of the delivery system could not be realised because of a strong reliance on the central government’s financial support.\textsuperscript{707} This sterile kind of privatisation put an enormous financial burden on the Hungarian government. Years of strong spending increases were followed by periods of negative growth, due either to organisational reforms of the health sector or cost-containment measures introduced following the economic crisis.\textsuperscript{708} In 2010 the Hungarian Government initiated a new reorganisation process to revise pharmaceutical sector strategies in view of privatisation, making task assignments transparent and estimating the actual investment and financial sources needed. The plan focused on the reform, including changes in the ownership and operation of pharmacies and, finally, after years of substantial growth, pharmaceutical spending reduced sharply in 2012.\textsuperscript{709} This was, partly, due to the impact of new mandatory tendering processes for publicly-financed medications, which resulted in price reductions.\textsuperscript{710}

In general, the Hungarian government seems to be returning to the pharmaceutical policy pattern of the previous government by focusing on ensuring strong public influence in the governance and organization of the pharmaceutical sector.\textsuperscript{711} For example, pharmaceutical services are primarily funded by social health insurance from the National Health Insurance Fund Administration for recurrent costs. Despite having several branches at county levels, to administer contracting and payments to local providers, budgets are tightly controlled by the central government and pharmaceutical services are predominantly delivered by local, state-owned public providers.\textsuperscript{712}

\textsuperscript{707} Ibid.
\textsuperscript{711} See: Gaál, above n 703.
\textsuperscript{712} Gaál et al., above n 77.
The supply of medicinal products in Hungary is generally adequate and reliable and medicines of acceptable quality are available at affordable prices. The Hungarian pharmaceutical marketing rules are also compatible with the EU regulations. According to the guidelines of the EU (measures introduced in Directive 2010/84/EU of 2012), a pharmacovigilance system has been established in Hungary and the National Institute of Pharmacy is responsible for collecting, registering and assessing the side-effects of pharmaceuticals. Each local government manages its system of medicine procurement, inventory, dispensing and financing. However, there are still some problems with the affordability of essential medicines due to the limitation of social security funding, which partly flows from Hungary’s low GDP. The government, as the financing entity, applies various methods to keep the prices of medicines down to provide a broad range of medicines and improve access to them. Therefore, the procurement and financing of products by hospitals is not a realistic alternative to patients buying the medicines themselves. Consequently, in the case of certain subsidised medicines, the competition is not limited to the pharmaceutical market but also exists in the market of the affected active substance.

Although the National Health Insurance Fund Administration in Hungary endeavors to increase the use of generic medicines, there is no accurate information as to whether this has occurred due to the introduction of various incentives. The simplified procedure may be used to establish that a generic medicine is equivalent to a branded medicine. Pharmacies are obliged to stock the cheaper preferred medicines of the National Health Insurance Fund Administration and to inform consumers about the cheapest available medicine if the active substance is the same for several medicines. The Hungarian pharmaceutical system is of a mixed nature; the biggest wholesalers are obliged to distribute the full line of pharmaceutical products. Certain wholesalers owned by manufacturers are permitted only to trade in their branded medicines. Although the wholesale market is highly concentrated, due to the size of the country, in the case of certain medicines, there may be no multilevel wholesale supply chains or independent local wholesalers. In the market for non-

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714 Borbás et al, above n. 658.
716 Gaál et al, above n. 77.
subsidised medicines, no effective price regulation is present for the price and the markup, and both inter-brand and intra-brand competition takes place. Nonetheless, the intensity of such competition is considered to be low, and this can be traced back to the fact that consumers are not provided with easy access to either medicines or information on prices.

The Hungarian pharmaceutical sector reform was characterised by privatisation, with the aim of moving away from a failed and distrusted state-centered model of integrated health services and, by the end, the new contract model of service delivery was established and operated. In the early period of the economic transition the market was liberalised, and all pharmaceutical companies except for one were privatised. The majority of the wholesale and retail industries and all of the state-owned pharmacies were also privatised by the end of 1997. The emphasis was on incentives to produce the necessary structural changes without direct government intervention. Hence, privatisation was the dominant tendency throughout the restructuring process, and the pharmaceutical sector became more pluralistic, with responsibilities divided among several organisations. The pharmaceutical industry also became comprehensively regulated, from production to marketing and distribution. Nevertheless, currently, the Hungarian politicians always intervene in domestic issues and the centralist tendencies exist in government. Practically, the Hungarian privatisation has developed pharmaceutical services which are still publicly financed. While the role of the national government as the direct funder and provider of services has decreased since the mid-1990s, it implies more extensive regulation and its role as a funder purchaser and regulator has grown. The main functions of pharmaceutical policy formulation, coordination, regulation, financing high cost, public health, covering the co-payment for certain medicines and prostheses for citizens with low incomes are carried out by some institutions under the direct control of the Ministry of Health. However, some functions have been

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718 See: Dethier, above n 475.
719 Gaál, above n 703.
720 Balás and Hegedus, above n 654.
721 Gaál, above n 703.
delegated to quasi-public organizations, and others have been deconcentrated. In better words, significant privatisation has taken place in primary care only.

Although the purchase-provider contract model in Hungary has been supported by all the main political parties, there is no consensus on the future direction of privatisation, either regarding financing or delivery of services. Active contracting does not take place in Hungary, but is often a formality for establishing the basis for provider reimbursement. The lack of consensus about privatisation in recent Hungarian pharmaceutical policy is reflected by the pilot status and repeated redrafting of regionalisation programs.

On the other side of the coin, however, it has been an efficient method to facilitate the public-private partnership that describes a variety of relationships between the private and public bodies. The aim of this partnership is to enhance efficiency and reduce expenditure in the public sector and create opportunities for the private sector. Such a method may range from unofficial and strategic alliances to programs that entail sketching, structuring, financing and operating assets (with or without transfer) that used to be in the public domain. In effect, the private sector develops assets and provides services which are financed or coordinated by the public sector. In line with the policy of the present government, the Hungarian Parliament debated and accepted a less restrictive policy to create a greater chance for private investment in the pharmaceutical sector, and removed most of the restrictions concerning the entity of private investors. Currently, the pharmaceutical sector may not be as regulated as it used to be and it has turned out to be less dependent on the government, especially in pharmaceutical financing. The private sector’s participation has also increased due to the general health care reforms.

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722 Ibid.
723 Gaál et al, above n 77.
724 Ibid.
725 See: Boncz et al, above n 715; ibid; Gulácsi, David and Dozsa, above n 717.
726 Saltman, Bankauskaite and Vrangbeak, above n 475.
727 Mel Caplis and Lloyd Orcales, above n 654.
729 Gaál, above n 703.
730 Lieberman, Capuno and Van Minh, above n 84.
5.3.2 The Case of Indonesia

In order to understand the economic policy debate and prospects for a continuation of economic development in Indonesia, one needs to look at the institutional legacy of its political system. Changes in the political landscape affected the speed and quality of economic recovery and privatisation in Indonesia. Over a long period, Indonesian institutions required of a modern democracy were systematically suppressed and replaced with a centralised authority susceptible to astounding levels of corruption. Hence, political dictatorship, centralisation and growing economic prosperity littered with ‘crony capitalism’ that gave way to economic uncertainty are some strains of the transition common to the Iranian and Indonesian cases. Economic policy in Indonesia was formulated by an all-powerful presidency guided by a small inner circle of policy advisors. This reflected swing of influence between the market-oriented technocrats and the government planning-oriented economic nationalists. While there were some successes and some failures, all policies in Indonesia were formed in a vacuum, and not subject to scrutiny or comment by the public or political rivals.

There is a strong element of competition among the countries in the East Asian region to liberalise their markets to make their economies more attractive to global investments. In this regard, economic globalisation has given the Indonesian Government a substantial justification for undertaking market-oriented reforms that can help maintain high and sustainable rates of exports necessary for healthy economic growth. Indonesia’s participation and efforts to promote several regional cooperation schemes are an essential element of its liberalisation policy. Regional cooperation helps its participants to take part in global economic integration more effectively as a group of local economies. The system of globalisation has necessitated the introduction of a series of structural adjustments in Indonesia’s

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731 Cassing, above n 123, p 95.
732 Ibid, p 97.
economy through liberalisation, marketisation and deregulation, as well as privatisation. The objective of these modifications is to improve the economy’s international competitiveness. Accordingly, the Indonesian industries and companies will become internationally competitive only if the economy continues to open. Such a goal has led the government to give a greater role to the business sector in the development process.

However, developing countries, such as Indonesia, must be given a longer period to adjust than the industrialised nations, according to the World Trade Organization (WTO) principles, to be able to fully participate. It is because economic liberalisation is being used as a justification for economic reform that the sustainability of the reform program itself will depend on the ability of the government and society-at-large to redress the negative public perception of the impact of liberalisation.

Economic transition and implementing privatisation have weakened the capacity of the central government in Indonesia to deal with and resolve the complicated financial and legal issues. The policies prior to privatisation influenced the final design of the fundamental laws of privatisation in Indonesia. The fact that the government is still facing budget constraints has complicated the situation more. Dealing with a series of conflicts has also shifted some of the economic and political resources away from productive activities and has caused the business climate to deteriorate, discouraging international investors from investing their funds in the country.

Indonesia’s rapid and mass privatisation reform (which started in 2001) was not its first attempt to reform its economic and regulatory system. Substantial reforms were undertaken in Indonesia from 1986 to about 1990. During this entire period, no less than 20 policy packages to deregulate and liberalise the economy were issued, but none were successful. The process of economic liberalisation, deregulation and privatisation since the early 1980s in Indonesia provided greater space for the business sector. Such universal trends in the 1980s provided an additional source of inspiration for the Indonesian Government. Since the mid-1980s, Indonesia’s trade and investment regimes have been substantially liberalised. These policies were

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735 Ibid, p 54.
736 Perdana and Friawan, above n 124, p 2.
introduced in response to what the government perceived to be a trend toward economic liberalisation and the international integration of markets. Furthermore, it was expected that the country would gain significant net benefits from its participation in this process. Market liberalisation served the government and regime well as did the more active involvement of the business sector which helped sustain economic growth and, in turn, strengthened the legitimacy of the governing system. At the same time, however, there was always a strong tendency on the part of the government to maintain control over the business community. A kind of collusion evolved in which the current regime or political leadership provided privileges to groups of companies that in turn were expected to help support the government. During this development, independent business entities were being squeezed out.

Until the beginning of the East Asian financial crisis (1997), the Indonesian economy grew by an average of 7% per annum. The economy experienced a slowdown in the mid-1970s and again in the mid-1980s when the world economy was experiencing inflation. Each time, however, the Indonesian economy came out stronger, as the financial crises forced the government to undertake the necessary reforms to sustain the country’s economic growth. The sudden drop in oil prices in 1986 and the currency transition following an agreement that increased Indonesia’s external debt payments caused an economic crisis that resulted in more drastic measures.

In the early 1990s, Indonesia experienced a reform weariness or a policy passivity. Further efforts to liberalise trade policy were unsuccessful. In the East Asian region, Indonesia is the only country that began with the liberalisation of its capital account. However, like many other countries in the region, it began export policy reforms

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737 See generally: Ahmad et al, above n 654.
739 Ibid.
740 Soesastro, above n 734, p 54, The Asian financial crisis was a period of financial crisis that gripped much of East Asia beginning in July 1997 and raised fears of a worldwide economic meltdown due to financial contagion. Indonesia, South Korea, and Thailand were the countries most affected by the crisis. For more see: Raghuram G. Rajan and Luigi Zingales, 'Which Capitalism? Lessons from the East Asian Crisis' (1998) 11(3) Journal of Applied Corporate Finance 40.
741 Mel Caplis and Lloyd Orcales, above n 654.
742 See generally: Halydier, above n 738.
before undertaking import liberalisation, which resulted in a double falsification policy. Thus, Indonesia’s earlier deregulation measures were not considered substantial because they failed to address the issue of nontariff barriers that affected a large proportion of imports. Close to 1,500 essential items — which represented about 35% of the value of Indonesia’s total imports — were subject to some form of nontariff barriers, usually a licensing restriction.

In the middle of 1994, the issuance of liberalisation measures in the investment field followed a poor non-oil export performance and a marked decline in approvals of foreign direct investment. These events strengthened the necessity to compete with other countries in the region, such as China, Vietnam and India, which also undertook liberalisation policies. Indonesia also began to experience declining export competitiveness that caused the slowing down of foreign investments. These liberalisation measures were to be understood as the government’s determination to implement its commitments under the WTO. However, while overall progress was achieved in reducing tariffs, a few sectors remained highly protected.

The failure of earlier privatisation attempts, combined with the extraordinary political circumstances in 1998, helped to establish fertile ground for a rapid approach to privatisation that led to new financial problems. The international community considered that Indonesia could manage this unprecedented economic transition and minimise its adverse effects.

However, the arrangements of economic and structural reform were not effective and drafting of the new reforming law resulted in confusion and debate about the law and its interpretation. The 1998 crisis, although it started as a financial crisis, turned into a more complicated, multi-dimensional crisis. In addition to economic problems, the country also had to deal with the socio-political changes. For example, an economic collapse brought an end to the highly centralised, autocratic government, which paved the way for a democratic transition and the liberalisation movement. However,

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743 Ibid.
744 Soesastro, above n 734, p 54.
745 Ibid.
746 Ibid.
changes in the political landscape also affected the speed and quality of economic recovery and privatisation.\textsuperscript{747}

There were some arguments against privatisation in the Indonesian transition process. The first group argued that it was not privatisation per se that was problematic, but what motivated it.\textsuperscript{748} In an ideal situation, the primary objective of privatisation is to increase the value of the enterprise. However, during the crisis, the primary purpose was to help finance the government’s budget deficit. Consequently, the government tended to sell government enterprises at a lower price than their potential value. The second group opposed the sale of many governmental enterprises, not because they opposed privatisation, but rather because they did not gain from the sales.\textsuperscript{749} These groups were legislative politicians from which the government had to get permission before any deals with potential investors were made. Although these groups did not cause the whole privatisation process to collapse, they were quite influential in delaying the sale of some companies, which led to lower international market confidence in the country’s economy.\textsuperscript{750}

The fall of the new order regime in 1999 and the subsequent mass and rapid privatisation in 2001 promised to fundamentally change the locus, both of responsibility and of accountability, for public service delivery in Indonesia. Nevertheless, the drafting of the law on Regional Administration No.22/1999 remained largely bureaucratic, with little feedback from the politicians and even fewer consultations with the regions.\textsuperscript{751} By the time the first drafts emerged at the end of 1999, the core structure for a radical and rapid privatisation approach was set.\textsuperscript{752} Tight deadlines and revenue assignment made Indonesia’s structural reform even more radical. By law, within a year of approval, all implementing regulations were to be prepared and by a year and a half after parliamentary approval (January 2001)

\textsuperscript{747} Perdana and Friawan, above n 124, p 1.

\textsuperscript{748} See: James Alm, Jorge Martinez-Vazquez and Sri Mulyani Indrawati, Reforming Intergovernmental Fiscal Relations and the Rebuilding of Indonesia: The Big Bang Program and Its Economic Consequences (Edward Elgar Publishing, 2005).

\textsuperscript{749} Ibid.

\textsuperscript{750} Perdana and Friawan, above n 124, p 23.

\textsuperscript{751} Indonesian Parliament Law on Regional Administration No. 22/1999.

\textsuperscript{752} Alm, Martinez-Vazquez and Indrawati, above n 748, p 18.
the law had to be implemented. The dynamic assignment of revenues to the regions added to the pressure on the government.

_Law on Regional Administration No. 22/1999_ was assumed to be a permit for the formation and amalgamation of new local governments without any obligatory consequences. The numbers of new districts and municipalities increased more than 10% every year. In this law, the local legislative body had, to some extent, immense authority, ranging from hiring, evaluating and firing the head of the local executive to influencing the local budget. Therefore, the local Parliament became the most powerful local body. A strong legislature was needed to execute check and balance activities, but its excessive authority could become a barrier to creating good governance and efficient local administration. The high increase in the number of new, fragmented authorities later generated concerns about economic efficiency and problems regarding optimal size and capacity. Along with the possible extension of corruption, the relatively high cost of developing the new governance system and the firm reliance of local government on fiscal transfers from central government are examples of the economic inefficiency resulting from the formation of the new administrations.

_Law on Regional Administration No. 22/1999_ did not define local government functions directly, rather it delivered them indirectly by specifying what the centre (Art. 7) and the province (Art. 9) did. Article 11 specified local government’s essential functions, but not to a level of operational detail. The utilisation of a residual approach that listed only the specific functions of central and provincial government and left the rest to the local administration has been unclear about the division of power and authority between central and local government. The omission of a general clause in the law that the local administration was bound by national legislation (omitted because the drafting team felt it was self-evident) further obscured the exact extent and nature of reform. Moreover, some central agencies managed to get a presidential decree issued that exempted their authorities from

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753 Perdana and Friawan, above n 124, p 15.
754 Ibid, p 15.
755 See for example: Kuncoro, above n 633.
756 Law on Regional Administration No. 22/1999, Art. 7 and 9.
757 Ibid, Art. 11.
758 Alm, Martinez-Vazquez and Indrawati, above n 748, p 22.
This situation created a gap between the central government's fundamental duties and the local government's duties and the discrepancy between services for the central government's duties and sectors for local governments. In this case, the local administration could freely determine their own role, the function could either be very extensive or very narrow. This condition created a dispute between the central and local governments.

By bringing government closer to the people, privatisation served as a driving force towards generating improvements in Indonesia's notably weak governance environment. Therefore, Indonesia continued to be recognised as suffering from one of the internationally highest levels of corruption; this has proven corrosive to both the public service and the private sector environment. Before the crisis, corruption was moderate-to high but more concentrated, and predictable and, hence, it did not create too great a problem for the business climate. The negative impact of corruption was less in a centralised political system than in a fragmented system. The important feature of corruption in Indonesia was that the whole power structure, including government employees, was based on the patron-client relationship. Here, government employees' allowances and their performance appraisals were mainly determined by their superiors, and thus emerged a network of patronage and personal loyalty. After the crisis, corruption was more fragmented, less particular and involved more players.

Structural and economic reform granted more authority and opportunity to local governments to create many new regulations which stimulated bribes by companies in Indonesia. Therefore, business uncertainty increased after the implementation of the reform and business players could not calculate the costs since the new regulations were numerous, and involved not only central government bureaucrats

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759 Ibid.
760 Perdana and Friawan, above n 124, p 14
761 Taufik Rinaldi, Marini Purnomo and Dewi Damayanti, 'Fighting Corruption in Decentralized Indonesia: Case Studies on Handling Local Government Corruption' (World Bank, 2007).
762 Ibid.
764 Lieberman, Capuno and Van Minh, above n 84.
765 Perdana and Friawan, above n 124, p 24.
but local government officials, politicians and political parties.\textsuperscript{766} Although this structure perpetuated corruption, the economic growth during the new order period was high.\textsuperscript{767} This might have occurred because the political stability at that time created an environment of certainty for business activities. Most costs related to corruption and the bureaucratic process could be foreseen and measured as part of the transaction cost.

The Asian region’s economic crisis, in general, shows that maintaining macroeconomic stability has become much more challenging in the globalised world.\textsuperscript{768} The potential benefits of economic reform depend crucially on the governance system. The issue is not whether to open markets it involves much more than the proper sequencing of the liberalisation process—but rather it is how to maintain a workable and credible commitment to open economic policies.

In the economic realm alone, the Indonesian Government’s agenda is already overloaded. What happened in Indonesia immediately after recognising the reform policy in 2001 reveals that the nature of corruption has changed. Currently, the nature of centralised corruption in Indonesia is gone, replaced by a more fragmented bribe collection system where the central government, the Ministries, local governments and legislative members are demanding bribes.\textsuperscript{769} At the local level, new regulations concerning taxes, levies and various types of permits are created to be artificially complementary as a way to extract indirect revenue in the form of bribes and direct funds.\textsuperscript{770}

If privatisation and economic liberalisation in Indonesia had been carried out correctly, they would have enhanced public participation and the nation’s political unity and economic efficiency.\textsuperscript{771} Two trends can be identified in this regard. One is

\textsuperscript{766} Ibid, p 26.
\textsuperscript{768} Soesastro, above n 734, p 53.
\textsuperscript{769} See: Rinaldi, Purnomo and Damayanti, above n 761.
\textsuperscript{770} Ibid.
\textsuperscript{771} There are two competing arguments on the relation between corruption and economic efficiency. The first argues that to avoid bureaucratic process, corruption is needed to enhance economic efficiency because it operates as lubricate money. The second argues that because of the bureaucrats’ unrestricted power on the regulation, the deadweight of regulatory burden may endogenously, instead of exogenous, set by corrupt bureaucrats so that they can arrange the
to limit and replace the role of government by improving competition that may create a big challenge for the government to develop sophisticated new skills in public administration to deal with the new issues. The other trend is a longing for the old-style industrial policy of selective targeting, for example a move to a new rationale for import substitution. The good industrial policy is still an open trade regime that fosters a competitive environment and ensures an efficient allocation of resources.\textsuperscript{772}

Nonetheless, to date and as previously noted, Indonesia is likely to still deal with many challenges resulting from economic liberalisation. These include increasing inequalities of income and access to economic opportunities between different groups and regions, and between large, medium and small enterprises.\textsuperscript{773} Although this situation is caused by many factors, privatisation of industries may augment and aggravate them. The government, seemingly, assumes that its success in undertaking first-order adjustments allows it to take these ‘second-order’ challenges lightly.\textsuperscript{774} However, these problems are likely to become more severe and complicated as the process of international integration expands.

The emergence of crony capitalism in Indonesia has its origin in the interest of the government to maintain political control over the private sector and to manage its financial resources. The business community in Indonesia feels that, in pursuing its policy of privatisation via several deregulation and liberalisation policy packages, the government must do a great deal more to make Indonesian industries internationally competitive. While some have called for a more proactive policy, for example some form of industrial targeting, the policy packages have been inclined to be reactive, incoherent, and discriminatory, because they often exclude certain groups or sectors from the deregulation, thus creating an environment of unfair competition.\textsuperscript{775}

The call for some form of competition legislation is not a new development in Indonesia, but the need for more transparent rules of the game is felt more urgently. However, the burden will not rest with government alone. In fact, this problem can


\textsuperscript{773} Ibid.

\textsuperscript{774} Soesastro, above n 734, p 54.

\textsuperscript{775} See for example: Robison and Hadiz, above n 763.
be solved by developing a new pattern of corporate governance. The vision for a new governance model must assure the full involvement of non-governmental organisations (NGOs) and a dynamic and balanced partnership between the three sectors: government, market and NGOs. These areas should not be separated and hierarchical. However, in the case of Indonesia, NGOs have been feeble due to political concerns.776

5.3.2.1 Pharmaceutical Regulation in Indonesia: Main Design Features and Implementations

Pharmaceutical sector reform in Indonesia was initiated by decentralising of most public health services to local governments, establishing the health insurance scheme for the poor, establishing the National Agency for Drug and Food Control as an independent agency, and introducing competitive tendering for public procurement of medicines. The key legislation related to devolution—the law on Regional Administrations No. 22/1999 and its guidelines—have affected the Indonesian pharmaceutical service provision by replacing the relevant responsibility that previously had largely been in the hands of regional governments. The rapid approach in reform has its merits, but the regulatory framework in Indonesia shows that the experience of such an approach in this country did not provide enough detail on functional and operational responsibilities, resulting in confusion and divergence between provinces.

A closer look at public sector outlays in Indonesia reveals a shift in the financing burden from the central to local governments. The pharmaceutical system of Indonesia is characterised by a public-private partnership, where the private sector dominates in providing services. According to the report of Chee et al. for US Aid, Indonesia’s public sector accounted for roughly a fourth of total health expenditure, and 40% of the poor in Indonesia seek medical care from private providers.777 However, little is known about these providers. Privately-provided services are largely paid out by out-of-pocket payments and only a minority of formal sector

776 Soesastro, above n 734.
777 Mel Caplis and Lloyd Orcales, above n 654.
employees benefit from insurance or employer-financed health programs in Indonesia.\textsuperscript{778}

In Indonesia, compliance with quality assurance procedures has been poor, partly because responsibilities have not been clear and districts do not have the technical capacity to handle the task. Moreover, hospitals buy medicines and unbranded products outside the Essential Medicine List. Although there were attempts to relax some restrictions on foreign pharmaceutical companies, encourage generic medicine prescriptions in public health centers and enforce good manufacturing practice, inconsistencies and missteps weakened or negated these pre-2001 reforms, and the outcomes were unsatisfactory.\textsuperscript{779} This is partly because the governmental enterprises impose their inefficiencies on the market. These units are protected by tariffs and limits on final product imports, constraints on foreign investment and restrictions on registering new medicines, opening new pharmacies and the non-pharmaceutical activities of retailers.

There have been changes to the regulations, covering unbranded generic medicine prices and the participation of foreign manufacturers in the national pharmaceutical market, while state-owned pharmaceutical manufacturers have been corporatised and partially privatised. Although there is both public- and private-owned pharmaceutical manufacturers in Indonesia, national production and distribution of unbranded generics were the main means by which the Ministry of Health supplied the public sector until the late 1990s. Since then, government production has been converted to state-owned enterprises which are expected to operate on commercial lines.\textsuperscript{780}

The public sector in Indonesia has managed to maintain adequate supplies of essential medicines in primary care clinics.\textsuperscript{781} Despite this, it seems that even privatisation has not improved medicine accessibility, and most Indonesians still pay more than they need to for their medicines when they buy from the private sector or public hospitals.\textsuperscript{782} The largest share of medicines sold in Indonesia is branded

\textsuperscript{778} See: Halydier, above n 738.
\textsuperscript{779} Ibid.
\textsuperscript{780} World Bank, above n 772
\textsuperscript{781} See: Lieberman, Capuno and Van Minh, above n 84.
\textsuperscript{782} The World Bank, above n 772.
generics. The prices paid for most branded generic medicines are often over six times greater than international reference prices or four to five times higher than the lowest-price generic substitute available in Indonesia.\textsuperscript{783} For many of these medicines an alternative inexpensive, unbranded generic is available in high quality. However, enforcement by local authorities is weak and illegal activity is blatant and widespread.\textsuperscript{784}

Since the 1990s Indonesia has gradually opened up its pharmaceutical market to international trade. But, recent changes mean that foreign manufacturers that have no manufacturing operation face uncertainty which may influence the availability of some more particular patented medicines.\textsuperscript{785} Regulations also impede importation of generics, even for some essential products. The Indonesian Government involvement appears to be limited and provinces reveal no common pattern of procurement. Some are not supplying any medicines and plan to reduce future medicine supply, while some still buy medicines to cover emergencies and temporary district shortfalls.\textsuperscript{786}

The slow emergence of a consensus among the Indonesian pharmaceutical sector players and policymakers on privatisation partly reflects a government-wide determination to avoid service interruptions. However, this focus has also allowed the government to postpone difficult decisions over the role and scale of the main central ministries. The Indonesian Ministry of Health also tends to view the public as passive service recipients rather than discerning customers, owners and potential allies and presents itself as a policing and standards-upholding authority, rather than a technical agency.\textsuperscript{787}

Generally speaking, two strands of thinking on privatisation are evident within the Indonesian Ministry of Health. The first is distilled in the 2003 Order that lists 29 strategic issues related to core public health functions and adds key steps to address them, such as minimum service standards, partnerships with NGOs and facilities for the poor.\textsuperscript{788} The decree points to accountability mechanisms and traditional

\textsuperscript{783} Ibid.
\textsuperscript{785} The World Bank, above n 772.
\textsuperscript{786} Lieberman, Capuno and Van Minh, above n 84.
\textsuperscript{787} Ibid.
\textsuperscript{788} Ibid.
command and control instruments to limit the risks of service disruption. The Ministry of Health depends on central and donor funding to achieve this end. Nevertheless, each form of funding is unreliable and, as such, the Ministry has looked for district support. This approach is risky. Detailed, extensive minimum service standards undermine privatisation, and poorer districts reject them because of limited fiscal capacity. The second approach within the Indonesian Ministry of Health takes a more benign and constructive view of privatisation. The Ministry’s officials, who support this approach, are attempting to apply the strength of privatisation as an accelerator for sector reform, with provinces playing a remarkable mid-level role. However, the given rule limits provinces to backstopping central- and district-level initiatives.

5.4 Reform Policy: Issues of Timing and Sequencing

5.4.1 Impact of Reform and Policy Failure

Privatisation of the pharmaceutical sector may have sustained momentum in improving health status in Hungary and Indonesia and may even have reversed worsening trends. However, many expenditure management problems require not only a good capacity, but also appropriate organisational models and incentive structures in both countries. In fact, the example of pharmaceutical care in Indonesia and Hungary indicates the complexity of the coordination problems involved. Pharmaceutical systems, in both countries, suffer from high out-of-pocket payments. However, both cases promote their respective social health insurance systems and desire to achieve universal health coverage. With the adoption of pharmaceutical devolution policy, and based on the trend of cost sharing, it is observed that the respective governments are shifting from being direct providers of pharmaceutical services to insurers, as evidenced by the increasing share of the social health insurance benefit in the government expenditure on health.

In both Hungary and Indonesia, integration between programs within and across provinces and counties remains poor due to the wrong structure. Evidently, administrative preparation for privatisation had been inadequate and many officials

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789 Ibid.
790 Ibid.
791 Mel Caplis and Lloyd Orcales, above n 654.
in both countries were unaware of the precise nature and extent of their new expenditure responsibilities and powers. Although local governments in both countries have been able to meet fiscal targets in recent years, there is still a systemic imbalance in the intergovernmental finance structure and expenditure and revenue assignments are not well matched in both cases.

The supply and quality of medicines at the local level have become a concern owing to limited funds, deficient pharmaceutical management systems, and loopholes in procurement rules in both countries. To ensure pharmaceutical quality in all public health facilities the central Ministry of Health, in Hungary and Indonesia, has adopted national formularies and drawn up an Essential Medicine List and advocated generic medicines. However, these regulatory measures have not ensured the overall quality of medicines in Indonesia or Hungary owing to lack of enforcement mechanisms.

The pharmaceutical policy change may increase medicine prices because of lower procurement volumes. It would, likely, extend variations in pharmaceutical prices, reducing equity and lowering the availability of orphan medicines rather than acting as a tool to decrease the price. Hence, in regards to essential medicines, it may be timely to review the options for price regulation. Many upper-income countries, including Canada, the US and Switzerland, regulate prescription medicine prices. The focus of price regulation in these countries is on patented medicines where there is little or no competition. They also, increasingly, use competitive methods to determine the prices of off-patent, multi-source medicines. However, this approach is not widely accepted in many developing countries due to the structure of the regulatory system and legal loops.

792 Lieberman, Capuno and Van Minh, above n 84.
793 See also: Section 2.3.1 in Chapter 2 about WHO’s strategies for good governance in the pharmaceutical area.
794 Lieberman, Capuno and Van Minh, above n 84.
795 'Pharmaceutical Price Controls in OECD Countries Implications for U.S. Consumers, Pricing, Research and Development, and Innovation' (U.S. Department of Commerce International Trade Administration, December 2004).
Hungary and Indonesia have high distribution costs that explain to a significant degree why even the cheapest generics cost more than the international reference price.\textsuperscript{797} In this condition, patients who can afford to are willing to pay extra for branded or originator products. Therefore, the responsibility of providing pharmaceuticals in a devolved setting seems to be biased to the private sector, with the government acting as a regulator and financier. When the governments are inclining towards the private sector to provide pharmaceuticals, the governments should ensure that the greatest possible number of citizens are covered by social health insurance to provide their health care needs.\textsuperscript{798}

Considering the findings of the current study, in both countries, private providers dominate the pharmaceutical systems. With the adoption of pharmaceutical devolution, it is observed that the respective governments are shifting from being direct providers of pharmaceutical services to insurers. Analysing the experiences of both countries illustrates the contributions needed from the government during the privatisation of pharmaceutical services. The Ministry of Health, in both countries, has taken steps to fulfill this new role, but no real transformation into stewardship has yet occurred. Nor have the governments moved to emphasise core public health functions, or seen marked improvements in specific areas, such as pharmaceuticals.

In a general sense, pharmaceutical sector reform in Indonesia and Hungary may help to sustain overall improvements in health that have occurred during the last two decades. However, experiences in these countries reveal that privatisation dividends have been modest for many reasons. These include ambiguities in goals, lack of detailed design, inconsistency with other policies and poorly thought-out implementation strategies. The participation of quasi-public institutions has helped both governments to restructure the centralised/state-centered pharmaceutical sector to enhance its functionality. This delegation, however, occurred mainly from the national to the local governments, not the private sector. Inequitable economic growth, population pressures that brought epidemiological changes and political uncertainties have limited the potential gains from privatization and weakness in privatisation also contributed to lower-than-expected health payoffs.\textsuperscript{799}

\textsuperscript{797} The World Bank, above n 772.
\textsuperscript{798} Mel Caplis and Lloyd Orcales, above n 654.
\textsuperscript{799} Ibid.
Rapid, pharmaceutical sector reform in Indonesia and Hungary has also fragmented the pharmaceutical information system and undermined coordination among various sectors. Thus, the limited data that flow through the system are not reliable enough to use in policy analysis and it is a serious challenge for the ongoing privatisation efforts. According to the privatisation experience in both countries, there was a lack of coordination and unified approach to privatisation, and insignificant monitoring resulted in insufficient learning from the experiment. Policy weaknesses also stem from regulations, introduced in the rapid fashion, that lacked details on functional and operational responsibilities and brought confusion and divergence for the pharmaceutical system.\textsuperscript{800}

Despite different political, economic and structural contexts in Hungary and Indonesia, the nature of implementing a rapid reform strategy made both governments adopt a mass and rapid approach to reform. Assessment of these countries' experiences reveals that adopting such a strategy led to many political and economic challenges caused by a lack of suitable infrastructure. As the findings indicate, the model of development in both countries emphasised heavy industry and large monopolistic companies which facilitated central control, most of their international trade was shaped by government agreements, rather than market considerations (as in the case of Iran). In both countries, decentralisation and economic liberalisation were followed by privatisation. Despite adopting a rapid and mass privatisation policy, privatisation dividends appears so far as to be modest in both countries.

The policy failures experienced by the given countries illustrate that, when chosen as a policy reform, privatisation must be aligned with other changes, for example, the political, structural and economic spheres. Otherwise, not only will the outcomes not improve but rather they will lead to a dysfunctional economic system and may cause a crisis. They also demonstrate that, in the absence of proper regulatory, economic and legal infrastructure, the consequences of the mass and rapid privatisation of an economic and regulatory system can be very similar across regulatory systems in different contexts.

\textsuperscript{800} Ahmad et al, above n 654.
However, the fact that some transitional countries, including Hungary and Indonesia, have experienced only small gains from privatisation reflects circumstances outside the control of policy-makers. Both countries introduced privatisation in less than favourable economic and political environments. For example, before 1998 the impact of the East Asian financial crisis in Indonesia was grave, and uneven regional growth aggravated the situation. 801 The overthrow of the Soeharto regime in 1998, and then de facto secession of the erstwhile province of East Timor in 2000, contributed to the movement for economic reform. 802 Similarly, the organisational base of the current Hungarian economic system was created because of the political and economic changes brought about by the collapse of the communist regime, through producing policy proposals using international models and experiences. 803 Another set of reasons for the modest gains from economic reform in these countries relates to the weaknesses in the policies themselves. While external factors limited the potential benefits, better management by the governments would have helped. 804 In both cases, weak governance, including corruption in the main branches of government, led to the loss of revenue and a waste of limited resources.

According to the available evidence, therefore, uneven and rapid privatisation reform arrangements have not worked as was hoped in Hungary and Indonesia and have caused a major crisis in both systems. It supports the hypothesis that in transitional countries with unstable and evolving economic, political and regulatory systems, rapid and mass privatisation as a policy reform will not be effective. The economic reform trend in Hungary and Indonesia also demonstrates that both heavily concentrated and heavily fragmented types of government are likely to be severely problematic. 805

Overall, no matter how much a country is developed or what its population or location is, privatisation should occur with consideration of the required political, structural and economic requirements. Without this, it will become a flawed policy.

802 Lieberman, Capuno and Van Minh, above n 84.
803 Ibid.
804 Lieberman, Capuno and Van Minh, above n 84.
that cannot improve the economic system or align with other parts of the regulatory structure because the substantial reform strategy concerns capacity-building through restructuring the old institutions.\textsuperscript{806}

As Zinnes et al. show, change in ownership is not enough to improve macroeconomic performance; however, the gains from privatisation come from a change in ownership combined with other reforms, for example, institutions to address incentives and issues related to contracts, hardened budget constraints, removal of barriers to entry, as well as an effective regulatory framework.\textsuperscript{807} The evidence from the two transitional economies discussed in this chapter is very similar. Privatisation improves performance and helps develop capital markets, but various factors, including the level of development, impact the success of the privatisation policy.\textsuperscript{808} In this regard, testing for the effects of privatisation on company performance is even more challenging in transitional economies, where capital markets are weak and prudential regulation poor, than in non-transitional economies.\textsuperscript{809} This is because in developing countries economic privatisation often occurs at the same time as other main changes in the political and economic environment.\textsuperscript{810}

Two methodological difficulties are especially noticeable in attempts to measure the impact of ownership on performance in developing countries. First, in comparing public to private enterprises, it is hard to identify the appropriate set of comparison companies or criteria, especially when the private sector is weak or limited. Second, there are common fundamental reasons why some individual companies are public and others are private, including the degree of anticipated market failure within a single industry. These elements also have compelling effects on the performance issue. It is crucial to evaluate the effects of government ownership in cases where the ownership structure is itself endogenous to the system, including both political and performance goals. Thus, the privatisation experience of industrialised countries,

\textsuperscript{806} William Hsiao, 'Inside the Black Box of Health Systems' (World Health Organization, 2000).
\textsuperscript{807} Clifford Zinnes, Yair Eilat and Jeffrey Sachs, 'Benchmarking Competitiveness in Transition Economies' (2001) 9(2) Economics of Transition 315.
\textsuperscript{809} Kikeri, Nellis and Shirley, above n 619.
\textsuperscript{810} Djankov and Murrell, above n 51, p 1.
which does not address the problems of immature or underdeveloped capital markets, cannot be generalised to developing countries.

In addition, unlike privatisation in industrialised countries, privatisation in developing countries is usually guided by the international contributor agencies (e.g., the World Bank or IMF) as a prerequisite for development and structural adjustment loans. While privatisation refers to the transfer of ownership from the government to the private sector, restructuring programs involve different forms of liberalisation measures, such as reduced controls and the removal of all anti-competitive impediments, which change the market dynamics. 811

Research by La Porta et al. refers to another aspect of the difference between privatisation in developed and developing countries, showing how corporate governance generally, and corporate legal systems specifically, influence capital market size, ownership structure and efficiency. 812 There are differences between countries in the degree to which the legal system protects investors, which in turn affects the development and operation of external capital markets. La Porta et al. examined the determinants of government performance in many countries. To measure government interventionism they considered proxies for the amount and quality of regulation, the prevalence of corruption, red tape and bureaucratic delays. As a rule, they found that civil law countries, particularly French civil law countries, are more interventionist than common law countries. 813

In any event, the framework and operation of a country’s legal system impact on the functioning of financial markets, the corporate governance in that country and the process of privatisation. Since privatisation is a significant change in the management structure of a company, how well the legal system protects investors is supposedly an origin of the success of privatisation in improving business performance. Further, privatisation ordinarily follows changes to a country’s legal system. For example, industrialised countries that implement large-scale privatisation programs often need to significantly change their corporate governance systems, while governments from transitional economies, such as Iran, for example, must create such a system almost

811 See: Starr, above n 105.
812 La Porta, Lopez-de-Silanes and Shleifer, above n 170.
813 Both the Hungarian and the Indonesian legal systems are civil law system, as is the Iranian legal system. See: Rafael La Porta et al, 'The Quality of Government' (1999) 15(1) Journal of Law, Economics, and organization 222.
from scratch. Because privatisation occurs at the same time as other main changes in the country, including the legal system, it is impossible to completely isolate the impact of privatisation on company operations from the other changes affecting the business.814

A related factor in determining reform success is the extent to which there is the institutional capacity to steer the reform process and avoid policy risk-taking to achieve the goals. Given the specific goals pursued by the government, the privatisation process takes different forms, varying from one country to another. Still, one of the more complex issues in this field is when to privatise, whether to privatise rapidly or gradually and what order to follow when privatising enterprises (sequencing).

5.4.2 Developing Regulatory Networks

Contrary to Montesquieu’s clear conception of a separation of public powers between the executive, judiciary and legislature,815 separations of public and private powers may be unclear in many cases: ‘The more richly plural the separations into semi-autonomous powers, the more the dependence of each power on many other guardians of power will secure their independence from domination by one power’.816 This virtue is especially present where each separated power can enrol others through networks of governance. The power of regulators is divided between the public and the private sectors, where separations are many and transcend private-public divides.817 Nodes of governance need to be sufficiently networked to be able to stop the power of one node from dominating other nodes of governance.818

The question of interest at this stage is how a developing country’s regulators with the interests of the poor at heart, might act in such a world of networked governance where extant networking favours the rich and the abusers of human rights. At the level of national companies in developing economies national NGOs can sometimes

814 See: Starr, above n 105.
817 Ibid.
818 Charlesworth, above n 134, p 895.
network with government regulators to improve the responsiveness of regulation. Professionals and other non-government authorities did more of the regulating of business in what are today developed economies as one goes back through their histories to when they were developing economies.\textsuperscript{819} For many decades after the Western industrial revolution began, one sees very different ways in different metropoles that regulation is networked by a plurality of private, professional, and governmental actors.\textsuperscript{820} Only in recent decades has the transformation of regulatory thinking to the idea of a government regulator being ultimately in charge of a regulatory domain been apparent. No sooner had this transformation been consolidated when, what some like to refer to as, a post-regulatory government began to develop.\textsuperscript{821}

NGOs have already demonstrated their interest in monitoring corporate activity and recognised it as a priority for future work.\textsuperscript{822} They should consider the adoption of more detailed norms for business enterprises that have been developed to date, and seek to ground their scrutiny of corporate behaviour in those principles. Corporate governance reform means applying ideas from private-sector management to the public sector. It is the process of transforming government assets, government agencies, or local organisations into corporations.\textsuperscript{823} Corporatisation leads to the creation of public corporations where the government preserves a majority ownership of the company’s share. However, corporatisation can be a forerunner to partial or full privatisation. In fact, although corporatisation, which involves publicly owned corporations, is to be distinguished from privatisation, once a service has been corporatized it is often relatively easy to privatise or partially privatise it. The term may also refer to the development of governmental corporatism, similar to corporate

\textsuperscript{819} Ibid, p 890.

\textsuperscript{820} The industrial revolution started in the period from about 1760 to sometime between 1820 and 1840. Sasha Couville, ‘Social Accountability Audits: Challenging or Defending Democratic Governance?’ (2003) 25(3) Law & Policy 269.

\textsuperscript{821} John Braithwaite, Markets in Vice, Markets in Virtue (Oxford University Press on Demand, 2005).


nationalism, which gives responsibility for public social tasks as an alternative to privatisation.\footnote{824}{See generally: Scott Lash, 'The End of Neo-Corporatism? The Breakdown of Centralised Bargaining in Sweden' (1985) 23(2) British Journal of Industrial Relations 215.}

In addition, to the extent that other institutions develop laws regarding corporate duties, NGOs can help with the monitoring process—just as they do regarding government obligations around human rights. They remain central actors in mobilising shame upon violators, leading to the termination of offensive conduct.\footnote{825}{See: Peter J. Spiro, 'New Players on the International Stage' (Paper presented at the Hofstra L. & Pol'y Symp., 1997).}

Existing networks of governance in many developing countries are more oriented towards violating human rights than towards enhancing them.\footnote{826}{Charlesworth, above n 134, p 891.} Developing country corporations and securities regulators mostly have very limited standard-setting capabilities, let alone enforcement capabilities. However, even within developed economies, networked NGO power or the networked governance capabilities of government regulators are often limited compared to networked corporate power. Braithwaite and Drahos show that the interests of the strong are not monolithic, and that the weak can often enrol the power of one strong actor against another.\footnote{827}{Braithwaite and Drahos, above n 364, pp 264-267.} In a world of networked power, the role is to actively network with those with power that you do not yourself control. Responsively escalating networked regulation is something governments can do by enrolling NGOs, and NGOs can do by enrolling governmental agencies of different kinds. Some even go further, arguing that NGOs have come to replace other well-established political organisations, such as trade unions, welfare associations and trade associations, that traditionally represent the interests of various constituencies of society.\footnote{828}{Kamat, above n 388, p 159.} Business actors can also responsively escalate networked regulation by enrolling government agencies and NGOs.\footnote{829}{Charlesworth, above n 134, p 893.}

In this sense, the concept of meta-regulation can be situated in the broader literature in which governance is seen as 'collaborations', 'partnerships' or 'networks' in which the government, public law and also hierarchical command-and-control regulation is not necessarily the dominant, and the only imperative, method of
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The term ‘meta-regulation’ itself has been used as a descriptive term within the literature on ‘new governance’ to consider the ways in which the government’s role in governance and regulation is evolving and dividing. The government sets the regulation because of policies to apply transparency, efficiency and market competition principles to itself (e.g., regulating or auditing the quality assurance mechanisms of semi-independent government agencies, newly privatised entities and public departments). Meta-regulation refers to ways that external regulators deliberately seek to encourage targets to develop their own internal, self-regulatory responses to public problems. As Coglianese and Mendelson discuss, external regulators can direct or shape targets to regulate themselves in any number of ways, from explicitly threatening future discretion-eliminating forms of regulation and sanctions, to providing rewards or recognition for companies that choose self-control.

Such networked governance monitors the actors interacting in networks and enrolling one another, sometimes in conflicting projects, sometimes in synergy. The other actors in the network do not have enough links to enrol the network development required for responsive regulation. In a meta-regulating model of governance, national and international NGOs are the dominant actors rather than experts from large bureaucratic institutions (including the government). Thus, they have been identified as the dominant organisational form that can implement the commitment to bottom-up development and assist national governments in protecting the public interest. NGOs are, thus, established within the policy processes and plans of all official development agencies that accord a significant and often directive role in development programs.

The meta-regulatory law might also recognise, incorporate or empower initiatives developed by non-governmental actors or partnerships of actors that can regulate corporate governance processes. This law includes international networks of governance, more traditional governmental regulatory enforcement activity, and

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831 Coglianese and Mendelson, above n 175, p.6.

832 Ayres and Braithwaite, above n 234, p 441.
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traditional law that authorises empowers co-opts or recognises the regulatory influence of industry, professional or civil society bodies to set and enforce standards. Relevant policy goals might also come from other sources, such as human rights instruments at a global level. The meta-regulation law must be aimed at making sure these goals are built into the practice and structure of the enterprise. These, as Parker notes, include high-level statements and demonstrations of commitment to compliance, with legal and ethical obligations, institutionalised in management and performance measurement systems and standard operating procedures, internal reporting and monitoring systems for collecting information about compliance with those procedures, and comprehensive reviews of the performance of the whole system, including its design and operation.

The meta-regulatory law is also a response to the recognition that law itself is governed by non-legal regulation and should, therefore, seek to adapt itself to plural forms of regulation. It connects with communities, networks and organisations that are rich with the possibility of regulating themselves and one another responsibly, and work with that chance to stimulate their fundamental commitment to responsibility.

5.5 Enhancing the Pharmaceutical Structure: Some Viable Recommendations for Iran

Those who advocate developing large private sectors as quickly as possible in Iran offer both political and economic arguments to support their view. Accordingly, if democracy is to become a viable political system in transitional countries, the

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835 See generally: Parker, above n 114.


837 See for example: Brada, above n 2.
government's monopoly over the bases of political power must be broken so that countervailing sources of political influence may emerge.\textsuperscript{838} Otherwise, the managers of public companies may hinder economic reforms and dissolve or transfer to their possession the assets of the enterprises they manage. Privatisation can lead to a growing middle class that cooperates in the creation and preservation of an efficient system of property rights and the following of economic policies that would enable the private sector to grow.

However, a linear sequence of individual policy changes is not the right concept to follow when considering comprehensive system reform. The problem is better resolved by sequentially introducing groups of complementary policy changes. What is needed is not merely the introduction of a broad range of policies, but the matching of policies with the necessities of the pharmaceutical issue being addressed, the availability of various regulatory participants and the original characteristics of them.

Policy-makers have several options to improve a regulatory design. They can, for example, prefer complementary policy mixes over single policy approaches to avoid the dangers of various options or optimise opportunities for win-win results, for citizens, government and the pharmaceutical industry and motivating business to go beyond conformity with existing legal requirements.

The details of the reform path to be followed by a country depend on the state of the economy, on the population's tolerance for the disruptions that are sure to accompany the reform process, and on the political situation in each country.\textsuperscript{839} It will take more time to learn how to gain a deeper understanding of the reform's effects. One should also keep in mind the 'compared-to-what' question and whether it is possible to choose not to engage in reform. Pharmaceutical sector reform cannot be developed from a single global or regional policy formula. Since there is no consensus on what effective pharmaceutical reform should be, one should consider national history, values and culture to help each government adopt the appropriate approach to reform. It is also important to have sufficient information and reliable analytical tools to recognise the main problems and to develop solutions that are relevant to the given conditions. Thus, exceptional attention must be given to the rational basis for the


\textsuperscript{839} Fischer and Gelb, above n 59, p 101.
design of pharmaceutical sector reform, as well as to investment in the essential underpinnings of the reform strategies.

In general, Iranian authorities could follow three broad strategies in the current circumstances: they can maintain the current situation, they can put into action extensive and coordinated reforms, or they can implement temperate politically-neutral reforms. The first option would facilitate some limitations on private sector investment and financial strengthening in response to lower oil earnings. However, it leaves the economic and political structure widely unchanged. The changed domestic political power balance would allocate resources to favor regional strategic objectives at the expense of internal financial purposes, and this will have adverse effects on growth. The third option will also transfer into a form of the first choice. Steps to address politically favorable matters may temporarily conceal domestic economic dissatisfaction.

Although improving the reform process is necessary to achieve the national pharmaceutical policy's targets, practical reform of public enterprises will take time to materialise. Under the second option of widespread change, liberalisation of the economy and an early correction of structural deformities would authorise a sustained increase in growth, picking up sharply over the medium to long-term. This study suggests that Iranian policy-makers must adopt the second option to enhance pharmaceutical infrastructure and gradually develop a competitive pharmaceutical market in the country to strengthen the small, national private sector. Rapid economic and regulatory reform could be riskier for the public interest when a nation lacks a coherent structural and financial mechanism to control pharmaceutical prices and guarantee the protection of the right to health and access to medicines for citizens. Adopting a large-scale privatisation is often a significant catalyst to modernising a country's corporate governance system, and transitional economies, like Iran, that initiate privatisation programs must create such systems mainly from scratch. The success of the second strategy would fundamentally rely upon a shift in the domestic political power balance away from the advocates of the state-oriented command economy to the market-based associates. By considering the present economic and political capacities, the most realistic method of reform would be for the Iranian government to acknowledge the necessity to maintain its central authority over the industry and guide any further structural reform as a possible peripheral option. Whatever the solution is, it is not a drastic change from nationalisation to
privatisation, but in the modest improvement from a centralised to a semi-centralised and public-private cooperative pharmaceutical industry. Such a partial privatisation approach is not about the immediate privatisation of the government sector, but instead of applying a hybrid system—a combination of the old government-planned system and the modern market-oriented forces. As an institutional tool for handling sources of market failure, public-private cooperation can develop equity, mutual benefit, and accountability in transactions between public and private organisations. Since the government is accountable both for providing services and surveying the marketplace, in public-private cooperation, a bright and organised regulatory framework can expand government interests by ensuring that significant cooperative relationships are conducted efficiently and that the resources available to them are adequate in line with broader policy purposes. The Iranian Government can assure its presence as the primary authority while still applying reform policy by separating the notions of the comprehensive structural reforms from the progressive policy reforms.

5.5.1 Reaching a Political Consensus

Currently, the administrative autonomy in Iran is politically controlled. Besley and Coate argue along similar lines that politically appointed regulators tend to pursue unrelated political goals. Assessing the reasons for the failure of privatisation, particularly in developing countries, shows that reforms are usually not valid since the motivation for privatisation is political. In contrast, reforms backed by a strong political will within a politically-stable setting have sometimes achieved success in otherwise unfavourable circumstances. As discussed in Chapter 4, the lack of political will has posed a major obstacle to reform in Iran and explains some of the slowness in introducing change. Inconsistent policies in Iran indicate that official responses to economic transition problems are based on expediency rather than strategy. Frequent political changes of both

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841 See for example: Mel Caplis and Lloyd Orcales, above n 654, Lieberman, Capuno and Van Minh, above n 84.

842 See for example: Dethier, above n 475, Lieberman, Capuno and Van Minh, above n 84.

843 Vaez Mahdavi, above n 515.
governments and high-level officials within the relevant Ministries have often led to multiple authorities competing for reform proposals and overall stagnation. While there is an understanding of the importance of this issue in Iran, it is less clear how best to steer diverse interests into policy coalitions to support reform.844 The mandate of policy-makers to amend the regulatory institutions should be subject to public review. Their management should include consumer and NGO representatives. More importantly, the regulators should be subject to meeting different targets. A task of the external representatives would be then to publicly report their views on the regulatory effort, and to contribute to enhancing public monitoring.

5.5.2 Strengthening Domestic Pharmaceutical Manufacturing: A National Protection Fund

Statistical research by the Iranian Mission Group in the WTO anticipates that, after accession, the percentage of local producers in the domestic market will decrease in the short term, but this situation will be temporary and will increase over an extended period.845 The same is expected to happen in regard to foreign markets. This could be due to the renovation of the industry updating the production and technological methods to allow them to operate in a competitive market with higher quality. At this point, it is likely that the domestic pharmaceutical market will be temporarily monopolised by multi-national and international companies. The primary concern in this regard would be the government’s policies to protect domestic industries, along with developing international technical relations.

Establishing a ‘Protection Fund’ for the national pharmaceutical industry to improve its strength and increase competition could be a useful tool during the transition period (after joining the WTO). The primary function of this Fund could be to facilitate comprehensive reform in the national pharmaceutical system, both in quality and quantity aspects. Issues of investment and financial structure, technological equipment, extending human resources, and increasing manufacturing outcomes all come under this reform. Such a reform can be a step forward to prepare

844 Perotti and Bortolotti, above n 150, p 14.
845 Harini, above n 531.
the pharmaceutical industry to gain the necessary abilities to compete with foreign pharmaceutical companies after joining the WTO, by strengthening a more competitive environment. Following is a suggestion for the government to design a balanced economic and sustainable plan to move forward.

The first move should be to cover the costs of the Fund by accessing government revenues and tariffs related to imported medicines that are not produced in the country, in addition to motivating and strengthening national producers by allocating facilities and grants. To protect the domestic pharmaceutical industry, importing pharmaceutical products that can be produced by local manufacturers should be strongly prohibited by setting 100% tariffs for imported medicines. Furthermore, the Fund must be jointly established, managed and monitored by a government and pharmaceutical industry syndicate, adopting a cooperative approach, which makes relevant policies for a 2–3-year period.

As next step, any pharmaceutical company that has the financial ability and inclination to participate in the Fund should regulate its plans and submit them to the Fund for approval. The Fund must also support the manufacturing units based on their level of success. Hence, those companies that are not successful in improving their manufacturing quality and cannot participate in a competitive atmosphere must be banned from receiving any further support from the Fund and continue their activities in areas other than the pharmaceutical sector.

5.5.3 Implementing Responsive Regulation at National Pharmaceutical Level

Expanding access to essential medicines for Iranian citizens requires attention to a diverse set of policy challenges. Although there are two sets of national and international recommendations to address this issue, national health policies and systems are not always fully attuned to ensuring that medicines are available, affordable, or appropriate. Solutions must begin with an understanding of local health conditions in their broadest epidemiological, economic, regulatory, and even cultural

context. Increasing access must be a process requiring ongoing support from a range of stakeholders. Reforms are most effective when they focus on the most critical access problems, rather than attempting to address all barriers simultaneously. In this regard, the Iranian regulators need adequate data collection and analysis to assess and set priorities in problem areas. This division into national and international levels, however, should be viewed with caution, since increasing access will ultimately involve a complex interplay of many actors operating at many levels concurrently and dynamically.847

The challenge for pharmaceutical safety and quality is to design safer systems and inculcate a culture of safety, while the challenge for governance is to ensure that these systems and practices are applied. The argument of responsive regulation is that pharmaceutical regulators are more likely to succeed if they use strategies that are responsive to the culture of those being regulated. Similarly, designing safer systems must consider human factors. Responsive regulation is an approach that values trust, transparency and professionalism.848 In meta-regulation, an external regulator checks that a self-regulator is regulating internally to standards that are externally acceptable. It is publicly regulated self-regulation: private rule enforcement, publicly monitored. External regulation may act through a governance network, as it is important that health providers manage not only their own risks, but also the way their network partners manage their risks. Everyone learns how to continuously improve by monitoring everyone else, and thus governance is not top-down but collaborative. A meta-regulator needs power to enforce self-regulation when an issue requires both the problem-solving creativity of self-regulation, and the assurance that minimum standards are met.849

Dynamism can be built into enforced self-regulation to prod reluctant managers by requiring continuous improvement. The difficult part about enforced self-regulation is that, unlike voluntary self-regulation, it is enforceable. Hence, if a responsible body fails to meet one of the privately written but publicly ratified rules, the organisation and its managers can be sanctioned for that failure. This enforced self-regulation

849 Ibid, p 57.
strategy attempts to secure the creativity, flexibility, and cost-effectiveness of moving away from command and control, while simultaneously retaining public enforcement capability. The more complex and dynamic the care process, the more relevant a policy of devolution of management decisions closer to the complexities of managing staff and patients. In addition, a regulatory strategy that harnesses management creativity to deliver continuous improvement in quality allows leaders to raise the standards of the whole sector. Doctors are no longer expected to rely solely on their own clinical judgement or to apply received wisdom from their teachers, but instead to practise evidence-based medicine, or at least to consult guidelines and clinical protocols as to contemporary best practice. Triple-loop learning takes voluntary regulation some steps further. The first loop occurs when self-regulatory innovators monitor their effectiveness at improving an outcome. The second loop occurs when policy learning is monitored by clinicians and senior managers who, in response, change their management systems, culture and practices. The third loop occurs when a regulator (such as the Ministry of Health) learns from monitoring the organisation's double-loop learning and revises its regulatory goals for the whole field.\textsuperscript{850}

5.5.4 Improving the Framework for Pharmaceutical Technological Capacity Building

Innovation and research and development play a crucial role in contemporary economic policies and strategies.\textsuperscript{851} Industrial sectors differ in how national innovation policies affect global research and development networks, and how they can help local suppliers of multinational companies, university–industry cooperation, etc. For example, the pharmaceutical industry is a technology-intensive and science-based industry. Pharmaceutical companies have very specific research and development activities; they focus on a narrow research field defined by global industry leaders. Pharmaceutical research and development is mostly led by intra-

\textsuperscript{850} Ibid, p 58.

\textsuperscript{851} Lengyel and Cadil, above n 538, p 175.
organisational coordination; most of the university research and development contracts consist of clinical trials.852

The technological gap between developed and most developing countries is vast because the existing market and non-market mechanisms have often failed to promote the efficient transfer of technology.853 Technological advances, the transformation of production processes and the attendant shift towards global markets necessitate a constant search for alternative strategies by companies and for improved policy tools by governments that will empower them to respond more efficiently to the new global competition. These developments have given rise to conceptual and policy shifts.854

As an important source of pharmaceutical innovation, technology transfer remains a critical component of the capacity building. The technological sophistication of the information transferred to such pharmaceutical companies often depends on the local structure of the intellectual property (IP) protection regime. Companies in developing countries appear to be shifting their objectives in technology transfer transactions from merely obtaining technical knowledge to receiving technical capability.855

Cooperation among pharmaceutical companies becomes an increasingly important strategic feature for acquiring technological capacity. Intellectual property rights

852 Ibid, p 177.
853 For instance, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization (2010) is an international instrument; that its objective is the fair and equitable sharing of benefits arising from utilising genetic resources, thereby contributing to the conservation and sustainable use of biodiversity. To advance fair and equitable benefit sharing, the Nagoya Protocol addresses appropriate access to genetic resources and transfer of relevant technologies and awareness raising, capacity building and transfer of technology activities on access and benefit sharing. The Protocol reinforces access and benefit sharing linked to traditional knowledge by requiring countries to develop mechanisms to support the development of community protocols and other community-based procedures and tools. It requires all countries to establish “appropriate, efficient and proportionate” measures to ensure that genetic resources and traditional knowledge utilised within their jurisdiction have been accessed with prior informed consent and mutually agreed on terms, as required by the country of origin. Applications for intellectual property protection or government funding for biodiversity-based research and development could be used as opportunities to examine compliance with access and benefit-sharing requirements. United Nations, Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization to the Convention on Biological Diversity, Secretariat of the Convention on Biological Diversity, United Nations Environmental Programme, Montreal, Canada, 2010.
(IPRs) are considered an essential element in the framework of the transfer of technology and foreign direct investment by many governments and as an important means used by companies to preserve their technological assets. Patents and other methods of IP protection have thus become important strategic and marketing assets; this is particularly the case in the pharmaceutical industry. What seems to be important for companies are not IPRs in isolation, but the whole package of technological assets. Technology suppliers' concerns about keeping control of their technology have also had a marked impact on their transfer strategies, which have become more selective and cautious; this is more noticeable in the field of pharmaceuticals where knowledge advances ease the application of technology and duplication.856

Given these developments, governments have given considerable attention in recent years to the creation of an environment conducive to technology transfer and development. Many of the control and screening mechanisms have been abolished. However, it is not clear to what extent other objectives are achieved, especially when transactions, such as contracts for obtaining and installing machinery and equipment, or public procurement including pharmaceutical products, are usually outside the qualification of technology transfer agencies. Better data and advisory services are being provided to local companies concerning the selection of technologies and foreign suppliers and the negotiation of contracts.857

These requirements have brought about a new policy approach, which focuses more on effective collaboration between partners to attain real technology transfer rather than on the control of legal aspects of transactions. Many countries have further liberalised, in varying degrees, the provisions of their technology transfer legislation or have relaxed its implementation. They have modified their IP laws to enhance protection, introduce new enforcement measures, provide more legal certainty and security for investment, with a view to facilitating the transfer of technology and promote research and development; and improve the attractiveness of their industry’s technology transfer. This has been due to: concerns about the possibility of deterrent effects on foreign investment, technology transfer and incorporation of pharmaceuticals technology, the belief that the increased negotiating capabilities of

856 ibid.
public enterprises may have lessened the need for government intervention; the experience gained by skilled authorities, leading to greater selectivity and flexibility in the application of controls; and foreign companies' concerns about the restrictive nature of the legislation.858

5.5.5 Dealing with Pharmaceutical Corruption via Good Governance

Privatisation can be one of the main incentives for governments to increase transparency and efficiency and reduce corruption.859 It also affects the causes of corruption, for example, weak controls, lack of transparency, incentives to dishonesty in administration and the low likelihood of being penalized for corruption, impacting the level of corruption. However, a pattern of privatisation that is premature can put the economy on a path of theft and self-deal rather than value-creation. Even though privatisation can eliminate or decrease administrative corruption – one should not expect privatisation, by itself, to reduce the causes of corruption unless it changes behaviour through accountability and various democratic practices.860

Privatisation can be self-perpetuating when opportunistic individuals find it easy to use their leverage against policy-makers, bureaucrats and competitors. Poorly designed privatisation can foster such undesirable patterns by fragmenting ownership, thereby putting effective control into the hands of incumbent management.861 This means that attention must urgently be paid to shoring up law and order and building an institutional framework to buttresses transparency, competition, and financial discipline.862

The pharmaceutical system consists of decision-making places along the pharmaceutical supply chain, defined as manufacture, registration, selection, procurement, distribution, prescribing and dispensing. Each one of these decision points demands uniform and transparent procedures or corruption can take place: the

858 ibid.
859 Kuncoro, above n 633.
860 See generally: Gagnon, above n 639.
861 Black, Kraakman and Tarassova, above n 635.
862 Meagher, above n 122, p 71.
legal basis for pharmaceutical registration may be weak, vulnerable or deficient; suppliers may pay government officials to register their medicines without the requisite information; government officials may deliberately delay the registration of a pharmaceutical product to favour market conditions for another supplier; or officials may deliberately slow down registration procedures to require payment from a provider.863

Policy-makers in Iran need to know the sources of vulnerability to corruption and fraud, and practices for tackling corruption at each of the decision points along the pharmaceutical value chain. In this way, authorities will be able to identify where and how corruption can or does occur, prioritise areas for intervention, and implement effective anti-corruption strategies to improve transparency and accountability and protect access to good-quality medicines. There are demonstrative tools now available that can help policy-makers to assess the vulnerabilities of a pharmaceutical system to corruption at these points and to prioritise interventions before investments are made to strengthen the system.864

Iranian policy-makers also need to determine whether areas, where anti-corruption strategies can be easily implemented, should be prioritised or whether priority should be given to tackling sensitive areas with higher returns, even though these may involve serious political negotiations or significant investment costs (e.g., strengthening pharmaceutical quality control capacity). Nonetheless, there is no single prescription, government preferences will vary depending on resources and commitment, and a choice can only be made after undertaking a diagnostic of the vulnerability of the pharmaceutical system to corruption.865

Larger measures of anti-corruption strategies include international best practices (e.g., investing more resources in a national pharmaceutical regulatory agency or enforcement capacity) and following international guidelines in areas like pharmaceutical procurement. For example, the WHO’s Good Governance for Medicines Program is implemented through a three-step process, including a national


865 Ibid.
assessment of transparency and vulnerability to corruption of domestic public pharmaceutical systems development via a consultative process of a national ‘Good Governance for Medicines’ framework, introducing the essential components that need to be in place; and implementing the national program by training the public pharmaceutical sector in good governance principles.866

Good governance is a somewhat abstract term that incorporates the rules under which a defined entity or function operates, as well as the mechanisms to enforce these rules, for the benefit of the ‘common good’.867 In the health sector, the multilateral relationship among clients, regulators and providers adds to the complexity of governance arrangements. Governance arrangements in the pharmaceutical industry focus on fair access to markets, quality assurance along the entire supply chain, transparency in the use of public funds to buy medicines, effectiveness and patient safety in the use of medicines, and cost-effective use.868 The Good Governance program includes two basic approaches: a disciplined approach and a values approach.869 The first approach, based on legislative reforms, establishes the laws against corruption with adequate penal consequences for violating these laws. It also defines the administrative structures and processes needed to create transparent public pharmaceutical systems, as well as defines the legal sanctions to be applied for non-compliance with the law.870 It is, therefore, by nature top-down. If there are

866 Eloy Anello, ‘Ethical Infrastructure for Good Governance in the Public Pharmaceutical Sector ’ (Department of Medicines Policy and Standards (PSM), WHO, 2006).

867 Although there is no clear consensus on a single definition of ‘governance,’ there is broad agreement on the general principles that characterise ‘good governance’. The United Nations Development Program defines governance as the exercise of political, economic and administrative authority in the management of a country’s affairs at all levels. It also recognises nine good governance principles: participation, consensus orientation, strategic vision, responsiveness, effectiveness and efficiency, accountability, transparency, equity and the rule of law. See: United Nations Development Program, Why Good Governance Makes for Better Development https://goo.gl/9M9nxZ (last access: 19/06/2016). For the Organization for Economic Co-operation and Development (OECD), governance denotes the use of political authority and the exercise of control in a society regards the management of its resources for social and economic development. This broad definition encompasses the role of public authorities in establishing the environment in which economic operators function and in determining the distribution of benefits as well as the relationship between the ruler and the ruled. See also: Organization for Economic Cooperation and Development, G20/OECD Principles of Corporate Governance, 2015. For the World Bank, good governance is epitomised by predictable, open and enlightened policy-making (that is, a transparent processes), a bureaucracy imbued with a professional ethos, an executive arm of government accountable for its actions, and a strong civil society participating in public affairs, and all behaving under the rule of law. See generally: World Bank, What Is Governance? http://go.worldbank.org/G2CHLXXQ00 (last access: 19/06/2016).

868 Seiter, above n 18, p 118.

869 United Nations Development Program, above n 867.

870 Ibid.
only structures and procedures, corruption is still possible. However, to achieve a significant impact, the disciplined approach needs to be coordinated with the values approach. The second approach promotes institutional integrity by encouraging moral values and ethical principles. It attempts to motivate ethical conduct by instilling in public servants and high-level officials a sense of belonging to, and personal identification with, a joint project. The values approach tends to be bottom-up.

In essence, the Good Governance program seeks to raise awareness of the potential for corruption and its impact on pharmaceutical system functioning and to minimise such corruption by promoting and implementing good governance within the public pharmaceutical sector. The program addresses the side-effects of corruption and unethical conduct in the pharmaceutical industry as outlined below:

a) Health: the waste of public resources reduces the government’s capacity to provide quality-assured essential medicines, and unsafe medical products proliferate the market. It also leads to an increase in the irrational use of medicines.

b) Economy: it is estimated that pharmaceutical expenditure in low-income countries amounts to 25%-65% of total health care spending. These important sums of money provide potential room for major financial loss; lower the quality, equity and effectiveness of health care services, and decrease the volume and increase the cost of provided services.

c) Image and Trust: incompetence and lack of transparency reduce public institutions’ credibility, deteriorate public and donor trust, and lower investments in these countries.

However, implementing good governance in the pharmaceutical sector is difficult to achieve in a generally lawless environment or in the absence of regulatory

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871 Ibid.
873 Ibid.
874 Ibid.
enforcement capacity.\textsuperscript{875} Success depends on engaging the public and, where possible the pharmaceutical industry, as participants to ensure the effective implementation of anti-corruption strategies. Iran should also adopt relevant and efficient policies to deter any conflict of interest. This measure aims to ensure that all activities related to the pharmaceutical sector are carried out with complete neutrality and transparency. The policy should contain a standardised conflict of interest form and express clear and comprehensive sanctions and penalties in case a conflict of interest is not declared. However, having any interest in the sector would not, necessarily, preclude individuals from providing their services to the Ministry of Health, but they should not be authorised to participate in its work when this risk undermines the Ministry of Health’s professional neutrality.\textsuperscript{876}

5.6 Conclusions

The issue of public versus private governance in circumstances of market failure depends on the relative ability to commit to an efficient allocation of power. The government’s role in making markets work, dealing with externalities and facilitating public investments is crucial. Reforms fail not because market liberalisation proceeds rapidly but because supportive, institutional reforms move too slowly. Rapid market reform depends on having market-oriented institutions in place. The inadequacy of such institutions in Hungary, as well as Indonesia, has hindered the effectiveness of economic liberalisation and privatisation of industries in these countries despite a short-term positive outcome.\textsuperscript{877}

The role of the government in facilitating this transformation is to step out of the production and distribution of common goods and services and to help create an alternative market structure before the old structures are eliminated.\textsuperscript{878} The structural adjustment also requires an efficient and responsive government to guide the reform

\textsuperscript{875} Seiter, above n 18, p 119.

\textsuperscript{874} Improving ‘Core Capacities’ can help countries to gain them. The Core Capacities refer to a country’s capabilities in the expected normal defined in the regulation. World Health Organization, above n 12.

\textsuperscript{877} Lieberman, Capuno and Van Minh, above n 84, Kuncoro, above n 633.

\textsuperscript{878} Umali and Maguire, above n 75, p 26.
process—to make quick decisions, to give clear signals and to implement the changes. Both the goals and the process require government attention.879

In countries where individual commitment is hindered by weak legal enforcement, a case can be made for some form of government control. In such situations, there is too little institutional capacity for proper government regulation, and the balance lean towards more direct regulatory scrutiny. This strategy can be applied by reducing the number of government authorities and their responsibilities, and delegating certain qualifications to the private sector, without dismantling the state's governance. Nonetheless, the government must have a well-organised plan to reform the national pharmaceutical structure. In particular, the following are needed: more investment in pharmaceutical infrastructures, reinvestment in the private sector, revising pharmaceutical regulations in order to enhance the opportunities for the domestic industry to enter the international market, and promoting national and international investment in the pharmaceutical industry.

Having such a resilient regulatory structure helps agencies to balance different influences and deter the possibility of one interest being promoted over another. The separation of enterprises from the Ministry of Health and their corporatisation, the creation of independent regulators, and the shift to temporary mixed ownership are all policies required for the move from government ownership to regulatory governance.

For-profit companies and the owners of mediator institutions, including public-interest organisations, can contribute ability, cost-savings, quality and diversity in the performance of public functions and assist the regulator to decrease the possibility of capture. Hence, creating an institutional design in which public interest groups have the right to access necessary information, to negotiate with companies and to prosecute, maintains the regulatory balance in the system. Furthermore, because government officials are likely to remain in business for years to come it is important to intensify their effectiveness in the roles they are unlikely to discard in the future. In fact, a market-friendly approach to public enterprise reform need not be government-unfriendly. By applying this model, the public interest is guaranteed in

879 Ibid, p 42.
a better way by reducing the government’s financial concerns, while still maintaining its monitoring and regulating position.

As discussed in this chapter, Iran’s pharmaceutical industry has significant potential capabilities for future growth and development. Although a more competitive environment is required to improve the pharmaceutical industry, neither a rigid State-centred nor a fully-privatised system can develop a sustainable, desirable and functional pharmaceutical system for Iran at this stage. While eliminating regulatory discrimination against the private sector and privatisation of small companies can start immediately, the privatisation of large enterprises raises a more difficult problem. Preparation for the restructuring and privatisation of most larger companies is likely to take several years and the execution to take much longer. Furthermore, to improve the pharmaceutical industry, enhancement of technological capabilities and investment in research and development should be considered. Thus, preliminary steps, such as clarifying ownership rights and corporatisation, and moving responsibility to boards of directors, should be taken as rapidly as possible.

Because such situations are usually associated with corrupt politicians and unconstrained abuse of power, the state’s governance should remain a final solution, not recommended except in situations where privatisation leads to uncertainty. In sum, a continuing degree of government control, rather than absolute ownership, may have a role when proper institutional mechanisms are not (yet) in place. However, this role must be continually reduced in Iran’s pharmaceutical regulatory system by developing transitional, focused regulatory institutions that may help to weaken the political constraint on decision-making. Besides the responsibility of protecting the domestic industry, the Iranian regulator should play the role of public agent to defend consumers’ rights.

In a sound organisational structure, the power to acquire and use resources and freedom from the influence of politics is essential for ensuring independent and unbiased decision-making. The Iranian Government must change its attitude toward mass privatisation and consider it simply as a possible reform strategy to improve the national economy, rather than a goal per se. The gradual establishment of institutions partially autonomous from political power must be a central element

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in developing an optimal form of regulatory governance. Countries in crisis may reform public enterprises quickly despite these concerns, but others may prefer to undertake progressive change, which need not be altogether wrong.

The available evidence demonstrates that the mass and rapid privatisation of Iran's pharmaceutical system is not politically, economically or structurally feasible in the short-term and may lead to failure. In addition, it will not make Iran's economy more efficient if inevitable ineffectiveness endures elsewhere in the economy. Therefore, the partial and gradual privatisation method would be the soundest policy to meet the overall development goals indicated in Iran's 20-year National Vision Plan—particularly when the new economic reforms require that the government place greater emphasis on its role in steering the pharmaceutical system by regulating a mixed public and private market.
Chapter 6 – Conclusions

6.1 The Pharmaceutical Sector in Iran: The Necessity for Reform

Based on the reasons argued in Chapter 2 of this research, ‘pharmaceuticals’ have become an integral part of the wider discourse on human rights, and a major concern for many health-related international organisations/conventions. In particular, World Health Organization (WHO) Member States are required to be responsible for protecting their citizens’ health by providing safe and adequate medicines and public interests before those of pharmaceutical providers. However, access to medicines has frequently been disrupted by war and insurrection, and in some instances obstacles to progress have been raised by those intolerant of change. This issue focused public and professional concerns on how the commercial interests of pharmaceutical companies may diverge from, or conflict with, the interests of patients and public health. The reasoning behind the creation of new government regulatory authorities is, therefore, that they should be entirely independent of the commercial interests of the pharmaceutical industry and should act on behalf of the public interest by checking the adequacy of the test data produced by the industry. In such situations, emergency aid in the form of donated or heavily subsidised medicinal supplies may, for a considerable time, be the only means of maintaining even a modicum of access. Throughout the world, millions of people have been displaced due to conflicts and natural disasters. These populations are especially vulnerable to disease. Often

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caught between warring factions, they remain in a state of the legal gap without recourse to human rights.\footnote{Leach, Paluzzi and Munderi, above n 847, p 104.}

During the last five decades, it has become an international norm that any health care policy must take into account patient access to medications and the systems that are needed to provide them.\footnote{United Nations General Assembly, above n 333.} As a public policy response, pharmaceutical laws and regulations need to be updated to keep pace with new challenges in the environment, as discussed in Chapter 3. Nonetheless, structural reforms have not normally been an easy task for many regulatory regimes, and there are many challenging dilemmas to face and prerequisites to choose from when implementing a proper pharmaceutical reform policy without experiencing policy failure. As seen in Chapters 4 and 5 of this thesis, ineffective policies may be caused by reasons other than regulatory functions. Even when regulation works, it may be difficult to determine the desired outcomes and to measure their impact. It may be that one regulatory mechanism on its own is unable to produce the expected results. The challenge is, then, to recognise factors that will assist the regulatory mechanism to achieve the desired targets. In a regulatory transition stage, what can effectively make a policy successful is its ability to match theoretical and practical considerations that guarantee the practicability of a policy reform.

Many economic theories offer relatively little guidance on some important considerations, such as the distribution of wealth across the population, the role of foreign ownership and control, and the extent to which the government should play an active role. Difficult choices are also faced with the number of alternative national models in areas, for example, banking and taxation regulation. The most important strategic decision arises, however, out of the interplay between economics and politics. System-wide reform is an intensely political process. Indeed, the main differences among reform strategies primarily reflect differing views of what will be politically sustainable. However, a slower pace has costs, including continued uncertainty and a longer period of poor economic performance, during which the political opposition can consolidate to hinder the reform process. On the other hand, while a rapid approach to economic reform, in which markets are liberalised even
before adequate preparatory steps are taken, avoids the dangers of delay it raises the potential for chaos.885

Therefore, understanding the regulatory reform context is fundamental and many strategic considerations need to be contemplated by policy-makers while negotiating and implementing regulatory reforms. The historical experience of countries, their culture and popular customs all help to shape expectations of the pharmaceutical system and responses to the proposed changes. Seemingly, significant political and economic transformations create the possibility of introducing changes and may give new governments the legitimacy to implement reform policies. The ideological dimensions of national politics and government policies also explicitly shape the reform content and have an impact on approaches to its implementation. Similarly, extended periods of political change and instability inevitably affect the structural context and tend to undermine the sustainability of reform efforts, although they may represent windows of opportunity 886

Bearing these facts in mind, this thesis aimed to evaluate the Iranian pharmaceutical system in its journey towards privatisation reform as a case study. The biggest challenge in this regard was that, while the current Iranian pharmaceutical industry is working adequately to serve local needs, it is still not clear whether the government plans to form a competitive/privatised pharmaceutical industry. In fact, most of the pharmaceutical sector reform policies implemented during the last four decades have been temporary, to directly aid policy-makers to cover up critical situations in different eras. Over time, the Iranian pharmaceutical industry has experienced repeated fluctuations between more and less extensive governmental regulation. This pattern reflects in part the continuing cycle of economic growth and hardship. A good deal of the time, competition advances innovation and growth; however, developing an artificial privatisation context has been destructive and has been linked to predatory pricing, in the pharmaceutical industry.887

After the Islamic Revolution in 1979, self-sufficiency and non-reliance became main goals of the government and the Iranian pharmaceutical sector became regulated and

885 Fischer and Gelb, above n 59, p 104.
State-centred. This policy caused the departure of multinational pharmaceutical companies and the new Islamic Government nationalised almost all Iran’s pharmaceutical companies. Before the Revolution, the government’s approach towards privatisation was developing, and the privatisation strategy was following a rapid process. After the regime change, a radical political change shifted general policies to complete nationalisation, and the owners of major industries (most of whom were related to the previous monarchy) left the country, and their properties were seized by the government during the nationalisation process. Consequently, all industries, including the pharmaceutical industry, were nationalised and came under the direct control of the government.

As seen in Chapter 4, adopting a nationalisation approach was brought about by the need to preserve the country from economic collapse during the Iran–Iraq War that began in 1980, just one year after the Revolution. Such radical changes caused the government to maintain the centralisation and nationalisation policies, as the only option available to preserve the economic sector from collapse, for at least the decade following the Revolution. During that time, the government’s primary goal was to stabilise the country’s financial situation and reconstruct its economic foundation. Therefore, shifting towards privatisation through increasing private sector cooperation and decreasing governmental stewardship was risky.

In this regard, the Iranian Ministry of Health was given the responsibility for all health care services, including the pharmaceutical sector. The aim of policies in this period was to provide integrated health care services through a horizontal structure, and it was acknowledged by the government that medical assistance services should be delivered equitably, continuously and according to the population’s priorities. More specifically, nationalisation of the pharmaceutical system aimed to provide therapeutic and pharmaceutical care to citizens free of charge, subsidised by contributions from citizens and allocations from the government budget. However, the extent to which these objectives have been met through nationalisation is debatable. Due to Iran’s stable, state-oriented political and administrative structure, nationalisation of the leading industries led to a completely centralised system. This meant that not only was the government’s authority stabilised, but nationalisation eliminated the minor cooperation of the private sector and non-governmental participants in the national economy.
As a consequence, although the core purpose of nationalisation of the pharmaceutical system was to guarantee the public interest and facilitate pharmaceutical service delivery, increased financial and regulatory burdens of the government have hindered its ability to achieve its primary purpose of protecting public health interests. These concerns compelled Iranian policy-makers, officials and pharmaceutical experts to contemplate implementing policy reform in the pharmaceutical system to override these problems and to help adapt to the current international and national political, economic and structural conditions. Nonetheless, repeatedly revising the general health care strategies has caused much confusion and uncertainty within the national pharmaceutical sector.

The economy-first policy reform that started after the ceasefire with Iraq (1989) desired a modern, industrial-based economy that is integrated into the global economy. The Iranian Government decided to relinquish some of its responsibilities by completely shedding some of its national enterprises and agencies and encouraging their independence. It transferred ownership of many pharmaceutical companies to private, semi-private or public entities, and also authorised some private insurance companies to facilitate privatisation. However, such a strategic move seemed to be sensitive and challenging, and it was the start of creating a malformed model of privatisation in a highly-regulated system. The necessity of having a free market as a prerequisite to privatisation and market liberalisation was underestimated by the government. Thus, the economic reforms were not applied effectively to minimise the role of the government and did not improve competition in the market.

However, from 2013 to the present, elimination of international sanctions and the necessity for Iran’s stronger engagement in the global economic market, as well as joining the World Trade Organization (WTO), has made the government take privatisation strategy more seriously. Since early May 2014, there has been a new wave of shifting from nationalisation to privatisation through the implementation of Iran’s National Health Sector Evolution Plan, with the objective of promoting health in society. After several years, the government’s substantial commitment to improving public health has been demonstrated through their approval and funding.
of pharmaceutical sector reform programs. Following the announcement of Iran’s 5th Development Plan, the reform plans were prepared and announced to all health centres by the Ministry of Health. The central issue in the new program relates to the method of dividing responsibility between government and non-governmental actors in the pharmaceutical sector. Accordingly, the government has focused on privatisation of the pharmaceutical industry, and the emphasis is on the notion that pharmaceutical regulation needs to take into consideration, both private and social objectives. Therefore, public intervention in health care pursues multiple goals, which relate to both health and pharmaceutical industry policies. Nonetheless, assessing Iran’s pharmaceutical sector reform is a challenging task because the new health care reform has just begun and there is limited empirical evidence to draw upon when making conclusions about its efficacy. Moreover, because the details of the plan are yet to be revealed to the public, any assessment now is, necessarily, tentative and preliminary.

6.2 Privatisation of the Pharmaceutical Sector: Proponents vs. Opponents

In theory, as some scholars argue, under certain circumstances, the allocation of resources using the market mechanism is optimal. Therefore, advocates of pharmaceutical sector privatisation believe that in the Post-sanctions Era, Iran needs to decrease its central authorities and strengthen the private sector to actively participate in international economic relations. The implications of joining the WTO and encouraging the private sector to take part in the market to reduce the government’s financial burden are factors of utmost importance. Accordingly, the government must stop a socialistic privatisation process and try to make the pharmaceutical market beneficial and competitive by allocating certain government tariffs and purchasing pharmaceutical services from the private sector.

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892 Ghazizadeh Hashemi, above n 558.
893 Ibid.
The lack of a free market, an independent and vigorous private sector to compete with its international peers, a stable economic and political situation, and a guarantee to protect public interest via the private sector are some of the main factors that restrict the Iranian Government from considering privatisation as a legitimate reformatory option. Not only have most of the reform plans not downsized the government sector but they have also resulted in considerable reluctance among officials to cooperate with the private sector. The increase of public debt to the banks indicates that this trend has not resulted in any improvement in government finance.894

Critics of privatisation in Iran refer to the malfunction of the pharmaceutical sector privatisation in the current economic and regulatory structure, arguing that privatisation requires coordinated infrastructure and real economic liberalisation – something that is missing in Iran's ideological (anti-capitalist) policies.895 Because the pharmaceutical sector has always been administered via a State-centred mechanism, despite some unfinished efforts to convert it to a private industry before the Revolution, privatisation has never been considered the best model for this sector. Severe bureaucracy in the system is another major obstacle. Implementation of the government's financial policies has been based on mistrust, and any administrative activities can be very time-consuming and frustrating. However, such a bureaucratic process does not necessarily have anything to do with decreasing corruption in the system.

The static, complex and administrative method of pricing in Iran's pharmaceutical market has also led to bargaining is an essential element that has heightened the malfunction of the market and hindered the reform process. The artificial suppression of prices leaves little room for any incentives towards improving the quality of and developing the industry. Hence, because the necessary conditions are not adhered to in Iran's economy, the allocation of resources is not optimal, leading to a demand for methods to improve the distribution. This mechanism has, in practice, paralysed the

894 Safarzadeh Parizi, above n 497, p 48.
price function, and the price factor cannot play a leading role in the demand and supply market. Simultaneously, it has caused pharmaceutical trafficking from Iran to other neighbouring countries.

Critics argue against privatisation of the pharmaceutical industry by stating that the anticipated benefits of privatisation depend on the Iranian pharmaceutical market conditions that frequently fail to materialise. There is a growing consensus that private entities are able to deny access to socio-economic rights. The transfer of governmental authority to the private sector through privatisation can intensify this phenomenon, not only by increasing the social significance of corporate action but also by moving welfare-related functions (once associated exclusively with the government) to the private sector. In essence, there will always be a risk that pharmaceutical privatisation just replaces the public monopoly with a private one, because of political obstacles that impede efforts from the start. The opponents conclude that the Iranian Government must not take the risk of privatisation and get rid of a socialist approach without evaluating the peripheral requirements and prerequisites.

The opponents of pharmaceutical sector privatisation consider government regulation as a tool to achieve efficiency in the allocation of resources—notably when the absence of a competitive market has led to unexpected expenses and significant burdens for the government. According to them, government regulation is necessary for establishing the maximum quantity of medicines, as public goods, and for enforcing the payment of these goods. Hence, regulation can be explained not only by imperfect competition, unbalanced market operation and missing markets but also by the need to prevent or correct undesirable market results. Furthermore, it can be necessary to correct adverse market results for reasons other than economics, for example, considerations of justice and ethical principles. In general, the opponents assume that government regulation is efficient and can be implemented without

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894 See for example: Cheraghali, above n 430.
895 Cooperation of The Ministry of Health and Medical Education (MOHME) and the Iranian Police Force Against Pharmaceutical Trafficking, above n 494.
significant cost. Thus, transaction costs and information costs, which underlie market failure, are assumed to be absent in the case of government regulation.

However, such assumptions have been criticised in both empirical and theoretical research. Academic research indicates that the partial aim for efficient allocation does not make the economy more efficient if certain inefficiencies persist elsewhere in the economy. These inefficiencies are a consequence of such things as external effects, taxation, imperfect competition and flawed information. The opponents also do not explain how a given view on the public interest translates into legislative actions that maximise economic welfare. The political decision-making process consists of various participants and in contrast to the market economy, it is unclear in the political decision-making process how participant interaction will lead to maximum economic welfare.

6.3 **Full Privatisation of the Pharmaceutical Regulatory System: Panacea or Placebo?**

In general, privatisation programs lead to significant improvements in market regulation, transparency rules and other required factors of modern financial systems. Privatisation works in the sense that divested companies often become more efficient, more profitable, increase their capital investment spending and become financially healthier. These outcomes hold for both transitional and non-transitional economies, though the results vary more in transitional countries. There is also limited empirical evidence as to whether non-privatising reform measures, such as price deregulation, market liberalisation and increased use of incentives, can enhance the performance of public enterprises; however, it also seems likely that these reforms would be even more productive if coupled with privatisation. Privatisation of the pharmaceutical sector stands to yield expected results where the market system and its institutions are well developed and are functioning properly.

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901 Posner, above n 192.


904 Megginson and Netter, above n 138138, p 338.
Overall, results of the available evidence show that in Iran, like most developing
countries, the pharmaceutical regulatory system, structure and mechanisms are in
place, but they often do not function properly and need some revisions.905 This factor
impedes the implementation of reform strategies and the achievement of
pharmaceutical objectives. Although the legislative and regulatory environment
governing privatisation has been established, the progress of privatisation has been
very limited. While the direction of current reforms is clear, the pace and sequence
of reforms are far from satisfactory. Privatisation in the pharmaceutical system has
been limited to sales of government equity shares to private investors and
revolutionary foundations, without transferring the majority control of the private
sector. This has not yet been resolved by the national authorities, and the objectives
of national pharmaceutical policies have not been met— the problem still exists.
Although improving the reform process is necessary to achieve the National
Pharmaceutical Policy’s targets, practical reform of public enterprises will take time
to materialise. Adopting a large-scale privatisation program is often a major catalyst
to modernising a country’s corporate governance system, and transitional economies
that initiate privatisation programs must create such systems largely from scratch.
The scope for successful pharmaceutical reforms depends on complementary
reforms, not only in financial markets but also in the political atmosphere and
regulatory institutions.

The difference between free markets and command and control systems fails to
capture the full range of options that lie between the polar extremes of absolute
discretion and total control. Privatisation usually leads managers to place greater
emphasis on the pursuit of profits. However, whether this is advantageous to society
depends on the trade-off between possible market failures due to a lack of
competition and deficiencies in government control of public companies. The
competitive and regulatory environment is more important than the question of
ownership per se.906

Accordingly, it is necessary to distinguish planned pharmaceutical reform from
variations/changes in the pharmaceutical sector that are imposed as a result of
pressures from outside the industry (e.g., political or economic pressures).

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905 Nikfar et al, above n 434, p 9.
906 See generally: Yarrow, above n 168.
Nevertheless, changes imposed by broad governmental initiatives, often with international support, usually do not have the legitimate goal of advancing the pharmaceutical system. Rather, they seek to achieve different goals, such as macroeconomic stability.\textsuperscript{907} Other reforms also result from national plans to resolve, for example, a severe financial crisis, usually in the form of structural adjustment. The modifications enforced from outside may also come from a variety of sources, such as deep political (e.g., revolutions or regime changes), social or economic reforms (e.g., moving from a communist rule or socialist economics).

The impact of institutional issues in the context of privatisation should not be underestimated because they require more coordination, compared with a national context. Many problems related to the management of expenditure need appropriate organisational models and appropriate incentive structures. The evidence from Iran’s pharmaceutical sector indicates the complexity of the coordination problems involved, which have been entirely different from what occurs in free market economies. The expansion of the private sector may contribute to the development of pharmaceutical infrastructure by increasing the number of medical facilities and satisfying patients who can pay for private health care. However, it also exacerbates the existing inequalities regarding access to medicines among those with different levels of income. Furthermore, developing an unregulated private pharmaceutical sector raises strong concerns about quality and service outcomes.

In practice, regulatory governance includes much broader pressures and policies set up by a variety of both government and non-government participants to shape the behaviour of companies and address market failures. Also, the expectations for the future development of regulation and deregulation are mixed. On the one hand, some researchers are convinced of the relative efficiency of the market mechanism and of regulatory mechanisms that support and sustain the market.\textsuperscript{908} They see a greater role for government in competition politics and in setting constraints in regard to the functioning of contracts, such as in the field of safety. On the other hand, there is an assumption that the process of deregulation will be followed in the downward phase

\textsuperscript{907} Berman and Bossert, above n 475, p 4.

of the business cycle by a period of renewed regulation.\textsuperscript{909} The available evidence indicates that self-regulation and meta-regulation can sometimes achieve regulatory goals, but that their effectiveness can depend upon other, non-regulatory inducements and external pressures that bear down upon businesses.\textsuperscript{910}

Meta-regulation and self-regulation may be most appropriate when the government lacks ready access to data about regulatory problems and their possible solutions—precisely the kinds of complicated circumstances where more conventional forms of regulation face their greatest challenges. Hence, in the first place, it is possible that the cause of market failure can be removed by technological or demand factors. Through a strongly increasing demand for pharmaceutical facilities, a natural monopoly can change into a competitive market. A second explanation is that there are more efficient alternatives to regulation for solving the problem of market failure.\textsuperscript{911} It is also possible that better insight exists into the predicted and non-predicted effects of regulations, and theoretical developments stimulate more trust in the operation of the market mechanism.

In this regard, the government should clarify the responsibility, role, and functions of the private sector. It also must set out a level playing field for the public and private participants and put in place appropriate information systems that allow reform results to be monitored and which support the introduction of quality assurance mechanisms. These demands highlight the importance of programs that strengthen institutional governance aimed at public bodies charged with steering the system and eliminate or decrease the systemic corruption in the pharmaceutical regulatory regime. This is because as much as successful privatisation can deter corrupt practices and improve profits in the economic system, if a policy failure occurs it can put the national economy in a precarious situation and lead to insolvency or inflation in the system.

The first step towards stopping corruption in the Iranian pharmaceutical sector is to understand the structure of corruption, the relevant actors and their motivations, and

\textsuperscript{909} Den Hertog, above n 113, p 246.


the critical points where corruption can occur. Priority measures to countervail corruption at these points should be identified for the short, medium and long-term. Priorities should be based on the extent to which the identified corruption is a threat to safety and health in the first instance. The second step is to enhance transparency and accountability mechanisms which are critical at every point in the pharmaceutical system to encourage movement towards stopping corruption sooner rather than later.912

However, at this stage, the government is still evaluating the pros and cons of implementing such policy reform on a large scale, and there are still opportunities for scholars to assist Iranian policy-makers to develop the best reform plan. Analysing the pharmaceutical regulatory reforms in other transitional countries that have experienced comprehensive pharmaceutical sector reforms can be a practical and informative means to assess the processes when countries choose to adopt rapid structural changes regardless of the preparedness of their economic, market or political structures.913 The findings of this research reveal that rapid economic and regulatory reform could be riskier for the public interest when a country lacks a coherent structural and financial mechanism to control pharmaceutical prices and guarantee the protection of the right to health and access to medicines for citizens. In this regard, and considering the current pharmaceutical regulatory system in Iran, joining the WTO could also be very hazardous for Iran’s economy in general, and its pharmaceutical sector in particular.

This study suggests that Iranian policy-makers must adopt a long-term plan to enhance pharmaceutical infrastructure and gradually develop a competitive pharmaceutical market in the country to strengthen the small, national private sector. The point is that privatisation can only become a practical means to improve the economic and regulatory structure of countries if it can work cooperatively with other parts of the economic structure. Otherwise, its presence can be much more destructive than its absence. In short, responsible policy-makers should not vote for

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912 World Health Organization, *Good Governance in the Pharmaceutical Sector* [https://goo.gl/XPCWu0](https://goo.gl/XPCWu0) (last access: 23/01/2017).
913 See: Berman and Bossert, above n 475.
a rapid, and virtually irrevocable, privatisation program without some assurance that all prerequisite policies have been put in place.914

Considering the present economic and political capacities, the most realistic method of reform would be for the Iranian Government to acknowledge the necessity to maintain its central authority over the industry and guide any further structural reform as a possible peripheral option. Whatever the solution is, it is not a drastic change from nationalisation to privatisation, but in the modest improvement from a centralised to a semi-centralised and public–private cooperative pharmaceutical industry. Such a partial privatisation approach is not about the immediate privatisation of the government sector, but rather about applying a hybrid system—a combination of the old government-planned system and the modern market-oriented forces. Public-private cooperation, as an institutional tool for handling sources of market failure, can develop equity, mutual benefit, and accountability in transactions between public and private organisations.

Since the government is accountable both for providing services and surveying the marketplace in public-private partnering, a clear and organised regulatory framework can expand government interests by ensuring that significant cooperative relationships are conducted efficiently and that the resources available to them are adequate in line with broader policy purposes. Such a transparent mechanism also protects the regulatory system from arbitrary commercial disputes and makes the costs and profits equivalent to the risks undertaken. It does not mean simply introducing market mechanisms or privatising public services, but rather that the public and private sectors have common goals and that partnerships can take advantage of each other's strengths to achieve their mutual objectives.915 The Iranian Government can assure its presence as the primary authority while still applying reform policy by separating the notions of the broad structural reforms from the progressive policy reforms.

As Bruno indicates:

[A] hands-off policy during the transition from a centrally planned to a market economy would be most inappropriate. If the necessity for intervention is not acknowledged and guidelines regulating its application

914 Megginson and Netter, above n 138, p 383.
915 See for example: Pongsiri, above n 150.
and defining its purpose are not established, there will be intervention in practice anyway, but without an overall view of its scope, direction, and implications, the intervention will be haphazard and could involve costs that would breach budget constraints and threaten macroeconomic stability.\footnote{Michael Bruno, 'Stabilization and Reform in Eastern Europe: A Preliminary Evaluation' (1992) 39(4) \textit{Staff Papers} 741, p 775.}

### 6.4 Avenues for Further Research

The current state of knowledge in the field of pharmaceutical sector reform in transitional countries seems yet to be inefficient. Since many developing countries are about to face new challenges to restructure their regulatory system, their concerns and obstacles have been very different from those of developed countries. Hence, each transitional country’s experience of change has been a unique story which must be scrutinised and evaluated, independently. The aim of this thesis has been to contribute to knowledge and understanding in the field as there has been little critical analysis of Iran’s approach to its pharmaceutical sector and this is important both for Iran and for international scholars’ knowledge of how developing small or middle-income nations manage their pharmaceutical sector reform. By doing so, this thesis has made a new conclusion concerning the applicability and effectiveness of pharmaceutical privatisation and policy reform in Iran from data analysis. Moreover, most of the available studies, in this regard, advocate applying privatisation in Iran’s pharmaceutical sector while this thesis draws attention to consider a cautious and gradual policy reform in current Iranian regulatory system and be aware of the possible risks that may be caused by the rapid privatisation of the pharmaceutical industry. In sum, the thesis aims at researching the implications of the gaps in the Iranian legal, regulatory and financial systems which need to be amended before taking any further reformist action. While other limited literature regarding privatisation reform in Iran attempts to emphasise the necessity of privatising its pharmaceutical sector and considers the negative points of the centralised system, the objective of the current research was to depict a realistic scheme of the advantages and disadvantages of privatisation reform for the Iranian pharmaceutical regulatory regime.
Nonetheless, there are still some areas that need to be given more thought. Threads for future research include how many current control mechanisms and how much accountability, as defined in the existing regulation, are intrinsically related to the performance of privatisation, and which parts of the regulations need to be revised or amended. Also, further study of the Iranian Government's policies at the local and national levels can reveal much about how these relations, and the very meaning of private and public, are being re-articulated at the level of localised political practice, as well as at the level of national institutional practice. Another research area is to identify the extent of the regulation regarding distinct governance mechanisms that can lessen the problem of transaction costs associated with public–private partnership activities.

More empirical studies are also needed on how regulation will relate to the level of accountability inherent in partnering to fulfil policy functions, and how much responsibility will vary under privatised institutional environments in the new form of the regulatory regime. Focusing on these variables may spur development of a more complicated framework of regulations. One such avenue also includes further study of what role privatisation of Iran's pharmaceutical sector can play in preparing domestic companies to meet the challenges posed by major economic forces, such as globalisation and the rapid growth of the information-based business. These questions should be answered using the mechanisms of economic analysis, and it is hard to imagine a scope of research more inherently interesting to the Iranian economists than analysing the optimum role of government in Iran's economy.
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