The Political Economy of Pharmaceutical Prices: The Case of Turkey, 2002-2012

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THE POLITICAL ECONOMY OF PHARMACEUTICAL PRICES: THE CASE OF TURKEY, 2002-2012

by

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Title: The Political Economy of Pharmaceutical Prices: The Case of Turkey, 2002-2012

This thesis offers an explanation of a particular empirical puzzle, namely why Turkey under the rule of the Justice and Development Party (AKP) has recently shifted to strict pharmaceutical price controls. It adopts a political economy perspective and draws on original, mostly qualitative research. It is argued that the Turkish government pursued a policy of strict drug price controls, because it had to balance two political objectives, namely reducing public pharmaceutical expenditure during an economic crisis, and maintaining public satisfaction with health policy, in particular of its own, relatively poor electorate. The government was able to act upon this political will because the policy goal of low drug prices was not substantially countervailed. There was little political concern about drug shortage or unavailability, nor any about domestic production or the interests of businesspeople close to the government that could have diluted the goal of low prices. The implementation of price cuts was further aided by an effective regulatory framework and a powerful political executive. By analysis of this specific historical case, this thesis seeks to contribute to the theoretical exploration of the political economy of pharmaceutical prices, a currently underresearched field.

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Başlık: İlaç Fiyatlarının Politik Ekonomisi: Türkiye Örneği, 2002-2012

Bu tez muayyen bir ampirik sorunsala açıklama getirmeyi önermektedir: Adalet ve Kalkınma Partisi (AKP) yönetimindeki Türkiye, son dönemde ilaç sektöründe uygulanan sıkı fiyat denetimi politikasına neden geçti. Çalışma, politik ekonomi bakış açısını benimseyerek, özgün ve ağırlıklı olarak nitel bir araştırmaya dayanmaktadır. Türkiye hükümetinin ilaç fiyatlarında sıkı denetim politikası uygulamasının arkasında, iki siyasi amaç olduğu savunulmaktadır: ekonomik kriz sürecinde kamusal ilaç harcamalarını düşürmek ve kamuoyunun, özellikle de ekonomik gelir seviyesi kısmen düşük olan kendi seçmeninin, memnuniyetini kazanmak. Hükümet bu siyasi irade doğrultusunda hareket edebilmiştir çünkü hedeflenen düşük fiyat politikasına karşı ciddi bir muhalefet ortaya çıkmamıştır. Bu hedefi engelleyebilecek ilaç kıtlığı ve bulunamamazlığı gibi konular ancak kısmi bir siyasi kaygı olarak kalmış. Yerel üreticiler ve hükümete yakın işadamları ise ilaç fiyatlarını düşürme iradesine engel olmamışlardır. Fiyat indirimlerinin uygulanması, etkili bir düzenleyici sistem ve güçlü bir siyasi yönetim ile yürütülmüştür. Bu özgün tarihsel örneği inceleyerek, bu tez, bakir bir bir alana, ilaç sektörü fiyatlarının ekonomi-politiğinin teorik araştırmasına katkıda bulunmayı hedeflemektedir.

CONTENTS

ABBREVIATIONS

AİFD	Association of Research Based Pharmaceutical Companies (*Araştırmacı İlaç Firmaları Derneği*)
AKP	Justice and Development Party (*Adalet ve Kalkınma Partisi*)
ANAP	Motherland Party (*Anavatan Partisi*)
Bağ-Kur	Social Insurance Institution for Tradesmen and Craftsmen and Other Self-employed (*Esnaf ve Sanatkârlar ve Diğer Bağımsız Çalışanlar Sosyal Sigortalar Kurumu*)
BCG	Boston Consulting Group
BUMKO	General Directorate of Budget and Fiscal Control (*Bütçe ve Mali Kontrol Genel Müdürlüğü*)
CHP	Republican People's Party (*Cumhuriyet Halk Partisi*)
DPT	State Planning Organization (*Devlet Planlama Teşkilatı*)
DSP	Democratic Left Party (*Demokratik Sol Parti*)
EphMRA	European Pharmaceutical Market Research Association
EKK	Economic Coordination Committee (*Ekonomi Koordinasyon Kurulu*)
HTP	Health Transformation Program (*Sağlıkta Dönüşüm Programı*)
İEGM	General Directorate of Pharmaceuticals and Pharmacy (*İlac ve Eczacilik Genel Müdürlügü*)
İEİS	Pharmaceutical Manufacturers Association (*İlaç Endüstrisi İşverenler Sendikası*)
IMS	Intercontinental Medical Statistics
MHP	National Movement Party (*Milliyetçi Hareket Partisi*)
MoD	Ministry of Development
MoF	Ministry of Finance
MoH	Ministry of Health
MoLSS	Ministry of Labor and Social Security

MÜSİAD	Independent Industrialists and Businessmen Association (*Müstakil Sanayici ve İşadamları Derneği*)
OECD	Organisation of Economic Co-operation and Development
OTC	over-the-counter
PhRMA	Pharmaceutical Research and Manufacturers of America
PPRI	Pharmaceutical Pricing and Reimbursement Information
R&D	Research & Development
SGK	Social Security Institution (*Sosyal Güvenlik Kurumu*)
SSK	Social Insurance Institution (*Sosyal Sigortalar Kurumu*)
SUT	Health Implementation Communiqué (*Sağlık Uygulama Tebliği*)
TEB	Turkish Pharmacists Association
TİTCK	Pharmaceutical and Medical Device Agency of Turkey (*Türkiye İlac ve Tibbi Cihaz Kurumu*)
TİSD	Pharmaceutical Industry Association of Turkey (*Türkiye İlaç Sanayi Derneği*)
TL	Turkish Lira
TÜSİAD	Turkish Industrialists and Businessmen Association (*Türk Sanayicileri ve İşadamları Derneği*)

CHAPTER 1

INTRODUCTION

Medicine prices matter. If too high, they curtail the ability of public health care systems and individual patients to afford medicines. And they matter even more in developmental contexts, as pharmaceutical expenditures in developing and emerging political economies constitute a much larger share of total health expenditures than they do in more advanced political economies. Most social and political research that deals with reasons for high pharmaceutical prices in developmental contexts has focused on the impact of intellectual property rights, especially patents. Indeed, the WTO's 1994 Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) may well be the single most consequential piece of regulation for pharmaceutical prices. Today, one can witness the attempts of Indian policy-makers to relax intellectual property rights in order to reduce pharmaceutical prices, through granting compulsory licenses for cancer drugs to local generic manufacturers (*New York Times*, 01.04.2013).

The academic and public attention to the link between intellectual property rights and pharmaceutical prices is well-deserved and important. However, intellectual property rights are not the only source of high prices, and changing these rights is not the only policy instrument to reduce them. Beyond the structural constraints imposed by the global regime of intellectual property rights implemented by TRIPS, national political economies continue to have significant policy space for pharmaceutical price regulation, primarily by means of statutory maximum prices and by using the market power that comes with comprehensive public reimbursement

of pharmaceutical expenditure. It is this national policy space for reducing drug prices given the current global regime of intellectual property rights that is the topic of this thesis. I propose to study the social and political sources of one particular national policy regime of pharmaceutical price regulation, namely that of Turkey in the 2002-2012 period. The case is interesting, because in late 2009 Turkey shifted from a relatively loose to a very strict regime of drug price controls. This thesis seeks to provide a historically grounded explanation of this particular outcome. The remainder of this chapter introduces the topic in more detail, sketches my arguments regarding the Turkish case, and clarifies the research design of the study.

The Political Economy of Pharmaceutical Prices

The pharmaceutical industry hardly has a profit problem. Without doubt, R&D is necessary for innovating new medicines, so one should not be misguided by the low cost of pill manufacturing.[1] But even when taking R&D expenditure into account, the pharmaceutical sector is still significantly more profitable than most other manufacturing or service sectors. The net profit rate of pharmaceutical companies operating in the United States was at an (unweighted mean) average of 14.0% in the 2004-2009 period, compared with 6.0% in the non-pharmaceutical industry. When considering only R&D-intensive companies, pharmaceutical net profits were 14.5% on average, and non-pharmaceutical net profits were 8.7%. The profit of the ten largest producers, the core of what is usually referred to as multinational pharmaceutical companies that capture a large share of total sales, was even higher

[1] See Light and Warburton (2011) for an attempt to "demythologize" the "high costs" of R&D in the pharmaceutical industry. They specifically question the estimate that the average cost per new approved drug is 802 million USD.

(Spitz & Wickham, 2012, p. 18). One key reason for the pharmaceutical industry's ability to over-price so persistently is that its market has a monopolistic structure. But pharmaceutical monopolies are not natural; they are created by strict state regulation of market entry, most famously, but not only through patents.

Public health and public finance have literally been paying a high price for the high profit margins of the pharmaceutical industry. Considering that in OECD countries an average of 61% of pharmaceutical expenditure is reimbursed by public institutions, high prices directly burden public health care systems. In countries where public reimbursement is relatively low, such as Brazil, India or the United States, high pharmaceutical prices reduce access to medicines, especially for the poor. Both of these problems, the financial burden on public health care systems and reduced access to medicines, appear to be more serious in developing and emerging political economies. In those countries a much larger share of health expenditure is captured by pharmaceutical expenditure. So while it is true in general that the over-pricing of medicines may crowd out both public and private non-pharmaceutical health expenditure, this problem is of particular relevance in less wealthy countries.

The problems that high pharmaceutical prices create for public health and public finance have provided the rationale for public regulation. Government attempts to control the cost and prices of drugs go back at least to the 1950s, with the establishment of formal profit regulations in the United Kingdom in 1958, and with the 1959 Kefauver committee in the United States Senate (Comanor, 1986; Sargent, 1985). Today, the United States is one of the few countries where price-setting is almost entirely free. This distorts the global picture of the profits at which the pharmaceutical industry operates, because the United States is both the largest and one of the most profitable pharmaceutical markets. As long as price regulation

remains lenient in the United States, the multinational pharmaceutical industry will continue to make high profits and is likely to keep its global reputation for it, even if profit margins are considerable lower in some national markets. The picture becomes more nuanced when considering other, especially European and emerging markets. Among them there appears to be significant variation in the stringency with which pharmaceutical prices are regulated. This implies that some states have managed to reduce the adverse effects of pharmaceutical over-pricing on public health and public finance.

Despite the issue's social relevance, there has been relatively little research asking why some states have stricter national regimes of pharmaceutical price regulation than others. In contrast, there exists a large literature on the economic and health outcomes of price controls (Danzon, 1997), and a more descriptive literature on the various public policy instruments available for price and cost control (Mossialos & Oliver, 2005). There is also a substantial grey literature on pharmaceutical pricing and reimbursement, usually sponsored by states or international organizations, which appears motivated primarily by the need to contain pharmaceutical spending (Carone, Schwierz & Xavier, 2012; OECD, 2008; PPRI, 2008). What is commonly considered as "the pharmaceutical regulation literature" does not specifically deal with national regimes of drug price control and reimbursement, but focuses instead on issues such as drug testing and drug approval (Carpenter, 2010; Daemmrich, 2004).[2] Lastly, there is the large literature on intellectual property rights alluded to above, which also does not specifically address

[2] One reason for the relative neglect of pharmaceutical price regulation may be that students of regulation tend to be primarily interested in bureaucracies and regulatory agencies (Levi-Faur, 2010, p. 9). Large-scale cost containment and price regulation is often the domain of political executives and primary law, which would place the issue in the more traditional field of explaining the policy choices of democratic governments.

issues like statutory maximum pricing and public reimbursement (Sell, 2010; Shadlen, 2009; Zeller, 2007). To conclude, we know much about the effects of drug price controls and about the various policies employed, but we know considerably less about the social and political sources of the varying stringency of public pharmaceutical price regulations.

The existing literature that does examine these sources suggests that there are two major factors that influence the stringency of drug price controls in a given country. First, policy proposals to introduce stricter price controls are predominantly motivated by requirements to contain public health care cost; by implication, less so by a political commitment to low prices for patients' non-reimbursed drug consumption. Second, the primary reason why such policies may be diluted, discarded or never proposed in the first place is a political interest in domestic industrial activity in the pharmaceutical sector. In advanced political economies, where domestic pharmaceutical manufacturers tend to be originating multinationals, this political concern for higher prices may be voiced both in terms of medical innovation policy and more traditional industrial policy goals, such as the protection of domestic high-value added production and employment.

The fact that there is no generally dominant policy goal in the regulation of pharmaceutical prices (as opposed to, for instance, the regulation of pharmaceutical safety) is emphasized in an OECD paper on the issue, entitled "Reconciling Social and Industrial Goals" (Jacobzone, 2000). However, there may be dominant policy goals in specific countries. The paper argues that in reality the endowment with domestic pharmaceutical manufacturing (or the hope to attract it) is what essentially defines the policy goal of a given national regime of drug price controls. Jacobzone writes that,

> Two rather different groups of OECD countries with different interests can be identified. The first group of countries has strong RD based national pharmaceutical manufacturing sector, and has implicitly an interest in high prices, although it may be costly for some of its own consumers. Until recently, this first group of countries included some countries with free prices, some which regulate profits, and some with a looser form of price regulation. All these allowed important returns for manufacturers. The second group of countries includes all the countries without an important national drug industry. All these countries have a general interest in having lower-priced drugs, although some may wish to attract or to retain some pharmaceutical RD at the national level. (Jacobzone, 2000, p. 49)

This conflicting political concern for both low and high drug prices can be illustrated by means of three cases that have received more specific analysis in the literature, namely the United Kingdom, Ireland and Taiwan.[3]

At least until the 1990s, the United Kingdom was characterized by both a large domestic pharmaceutical industry with a high rate of exports, and a very comprehensive public health care system, the National Health Service (NHS), which reimburses the majority of pharmaceutical expenditure (63% in 1996). Since 1958, the NHS has regulated prices indirectly through controlling the profits that producers are permitted to make on sales to the NHS (Sargent, 1985, p. 106). Formally, the Pharmaceutical Price Regulation Scheme (PPRS) was a voluntary agreement between the government and pharmaceutical producers. It is interesting, that while the regulations were introduced to increase government control over prices, the official policy goal was emphatically not to minimize public expenditure. According to its 1978 preamble, the objectives of the PPRS are:

[3] Additional literature deals with the role of private interest government in the regulation of pharmaceutical pricing in Denmark and the United Kingdom (Greenwood & Ronit, 1991), drug price controls in Spain (Nonell & Borrell, 2001), the diffusion of pharmaceutical cost containment policies in the European Union (Guillén & Cabiedes, 2003), and the voluntary reduction of prices by producers in order to forestall public regulation in the United States (Ellison & Wolfram, 2006).

> not only that safe and effective medicines are available on reasonable terms to the National Health Service, but also that a strong, efficient and profitable pharmaceutical industry in the United Kingdom is capable of such sustained research and development expenditure as should lead to the future availability of new and improved medicines, both for the National Health Service and for export. (Sargent, 1985, p. 105)

Hence, in the United Kingdom controls on pharmaceutical profits made from government reimbursement were introduced to contain public spending and private profits, but the policy goal was diluted into "fair and reasonable" prices, because of the concomitant, very explicit industrial policy goal to support local production. John Abraham writes that the "government's approach to this policy challenge has been to strike a 'balance' between these conflicting objectives and interests" (Abraham, 2009, p. 947).

The case of Ireland provides an illustration of the possible micro-politics of government-industry relations when the introduction of stricter drug price controls comes onto the political agenda. To provide some background, Ireland's pharmaceutical industrial development constitutes a "success story". Since the 1970s multinational pharmaceutical companies from the United Kingdom and the United States have invested heavily and made the pharmaceutical industry one of Ireland's largest manufacturing sectors. In 2006, pharmaceuticals represented 16% of Irish industrial exports. These investments have also created new employment. In 2005, 5.2% of Irish manufacturing jobs were in the pharmaceutical industry, more than in any other OECD country, and up from only 1.3% in 1985. On the downside for Ireland, many of the pharmaceutical profits are expatriated (van Egeraat & Barry, 2009).

Recent evidence suggests that this industrial boom may literally have come at a high price, because the industry's importance for the Irish economy may be used as a

political lever to prevent stricter regulations. Drug prices in Ireland are relatively high and have, in conjunction with rising standards of health care, strained public health expenditure. As a result, in 2006 Ireland began to introduce stricter controls on pharmaceutical prices and public reimbursement (Barry, Tilson, & Ryan, 2008). Following the global financial crisis, the Irish government introduced austerity measures and in particular attempted to contain public health care costs. However, when the government pushed for even stricter drug price controls, the pharmaceutical industry used its leverage to try to prevent this cut to its profits. In February 2012, the global CEO of the multinational pharmaceutical company Abbott Laboratories wrote a letter to the Irish Prime Minister Enda Kenny, and warned him of the unintended consequences that stricter drug price controls could have.

> In common with other pharmaceutical multinational organisations, we find it difficult to reconcile a policy of pursuing inward manufacturing investment with an attempt to drive medicine prices to among the lowest in the European Union. (*Irish Times*, 15.12.2012)

The Irish case illustrates how the size and mobility of the local pharmaceutical industry may generate enough political concern over domestic economic development to dilute or prevent stricter price controls.

The above consideration of the British and Irish experiences illustrates the fundamental conflict of policy goals that seems likely to arise whenever a state is simultaneously the monopsonistic buyer of medicines on behalf of the public, and concerned about creating investment incentives for a globally mobile industry. This specific conflict of pharmaceutical policy may be interpreted as an instance of a more fundamental conflict inherent in democratic capitalism, as it was recently put by Wolfgang Streeck, between

> two conflicting principles, or regimes, of resource allocation: one operating according to marginal productivity, or what is revealed as merit by a 'free play of market forces', and the other based on social need or entitlement, as certified by the collective choices of democratic politics. (Streeck, 2011, p. 7)

In principle, the same conflict between social policy and industrial policy goals should be expected to arise in developmental contexts, such as Turkey. However, there are important differences between developmental and advanced industrial contexts that need to be considered here. First, the welfare state in emerging political economies tends to be considerably less mature, that is less comprehensive and less institutionalized, because more novel. This is likely to be reflected in a different politics of the welfare state. Second, the pharmaceutical sector in emerging economies has a distinct structure. With partial exception of India and China, most developing and emerging political economies have some degree of domestic generic companies that produce for the local market (some of them owned by foreign multinationals), host manufacturing sites of foreign multinationals, and import those on-patent drugs that multinationals cannot or do not want to manufacture locally. This difference in industrial structure is likely to produce different political concerns regarding the development of domestic production, and may hence affect the policy goals behind pharmaceutical price regulation. These general ideas regarding social policy and industrial policy dimensions of pharmaceuticals in developmental contexts are meant to draw attention to the kind of circumstances one may expect to see in Turkey.

The case of Taiwan provides an example of pharmaceutical price regulation in such a developmental context that is worth to be considered in some detail. For one, because the seminal work of Joseph Wong (2004; 2005; 2006; 2010; 2011; Wong &

Quach, 2009) provides detailed analysis of the Taiwanese health policy trajectory since the 1990s, with specific reference to the development of the pharmaceutical industry and government regulation of pharmaceutical prices. Moreover, because the case appears sufficiently similar to the Turkish case in order to allow for some fruitful comparisons later in the thesis. Taiwan, which had stunned the world with its rapid industrialization during the 1970s and 1980s, underwent an equally important process of social development since the 1990s. In a global atmosphere of welfare state retrenchment, Taiwan introduced a universal and redistributive system of National Health Insurance (NHI) in 1995, financed primarily through payroll premiums, some government subsidies, and only a relatively low rate of out-of-pocket payments (about 30%); all resembling the SGK system in Turkey.

One result of this extension of coverage was rising public health expenditure. In fact, the NHI was running deficits between 1998 and 2003 (Wong, 2010, pp. 169-171, 174-175). The instability of health care financing was fueled in part by rising pharmaceutical expenditure, itself a result of lenient price regulations and excessive prescribing practices. As drug and non-drug spending of the NHI have increased at largely equal rates, pharmaceutical expenditure continued to account for around 25% of the NHI's total health expenditure (Wang, 2012). The need for reform became obvious by the late 1990s, just a few years after the introduction of universal coverage. Wong (2010, p. 177) argues that the Taiwanese government was then faced with three solutions, namely the reduction of the public share in health care financing, stricter cost containment, or increasing the NHI's revenues, that is premiums. While the details of the policy process must be omitted here, Wong argues that popular, democratic pressures prevented privatization of cost and largely restricted the ability to raise premiums. Cost containment therefore became the

politically most feasible solution to the policy problem of financial instability of health care expenditure.

One of the instruments that Taiwan's government used to implement cost containment was global budgeting, where the NHI and health care providers (e.g. hospitals) "would negotiate on an annual basis the total budget allocation for services rendered in each category of care" (Wong, 2010, p. 178), and one of the categories were pharmaceuticals. While the reform measures have been less successful at reducing public pharmaceutical expenditure, they have pushed down producer prices and profits, apparently to the benefit of health service providers such as large hospital, which are allowed to keep the difference if they purchase medicines for less than their allotted global budget (Wang, 2012; Wong, 2010, p. 178). With this in mind, pharmaceutical manufacturer prices and hence producer profits appear to have been relatively low in Taiwan, especially when compared with those in OECD countries (Wang, 2012).

While being cautious not to oversimplify the historical reasons for low drug prices and profits in Taiwan, and hence for the NHI's specific rules of reimbursement (which merits a more detailed study), the relatively small domestic pharmaceutical industry is likely to played a role. In 2009, only 43% of Taiwan's pharmaceutical market value was produced domestically, and the pharmaceutical trade deficit was near to 2 billion USD (Chen, 2010). Most local industry is generic manufacturing, while most patented drugs are imported (Wang, 2012). While the Taiwanese government is concerned with developing domestic production of high value-added biotechnology and medical technology (Wong, 2011), the investment incentives that were introduced did not include "price subsidies" by the public health system, as was the case in the United Kingdom. Instead it employs instruments like

tax benefits or government grants that are linked more directly to private investments. In contrast to Ireland, low prices may also be less harmful to Taiwan as its strategy is more explicitly aimed at developing a – less mobile – genuinely domestic industry, rather than focusing on foreign direct investments (FDIs).

The case of Taiwan suggests that, in developmental contexts, the impact of industrial policy goals on pharmaceutical price regulation may not have to be negative, as proposed by Jacobzone (2000). A government may attempt to develop pharmaceutical industry and still maintain relatively low manufacturer prices, especially when its strategy is not based on attracting FDI from multinational pharmaceutical companies. On the other hand, the social policy goal to contain cost in order to maintain public health care does seem to be a driving force behind stricter pharmaceutical price regulations, especially in a system with a large single-payer public health care system.

The above review of three country cases of pharmaceutical price regulation, and especially that of Taiwan, provides us with some useful insights into the social and economic structures and the related political logics that may produce either strict or lenient drug price controls. At the very least, social policy goals and industrial policy goals appear to be useful rubrics under which the political sources of pharmaceutical price regulation can be examined. However, with partial exception of the work of Joseph Wong, the literature does not consider the causes of these regimes of price and profit regulation with sufficient historical detail in order to really understand the mechanisms that may lead to low-profit or high-profit regimes. The correlation of high public pharmaceutical expenditure with low prices, and of large domestic pharmaceutical production with high prices, does not produce sufficient

explanations of concrete outcomes. For this purpose, historically more specific studies are required.

I began this section by outlining the problems that high drug prices create for public health and public finance. Political concern for these problems has historically motivated the regulation of pharmaceutical prices and, in turn, of pharmaceutical profits. While states are essentially facing the same problems, policy responses have varied greatly. A review of the literature suggested a comparative framework to study the social and political sources of this variation. More specifically, new empirical studies that seek to understand the sources of national regimes of pharmaceutical price regulation may benefit from considering them simultaneously in the historical contexts and political incentive structures of social policy and industrial policy. This thesis presents such a case study, namely of Turkey's policy regime of pharmaceutical price regulation that has been transforming significantly over the last decade.

The Case of Turkey's Shift to Strict Drug Price Controls

This section sketches the substantial arguments that will be put forth in this thesis. Underpinning the entire study are the observations that drug prices, producer revenues, and public spending fell suddenly beginning in 2009, and that government regulations played an active and significant part in this development. For purposes of chronology and readability, I will wait until the beginning of Chapter 3 to present comprehensive data that supports these observations. However, Table 1 gives the reader a first impression of how Turkey, which was chosen as one of seven "pharmerging" markets by the global drug industry in 2009, has since then

experienced stagnating producer revenues and decreasing average prices. It should be noted that around 85% of the Turkish pharmaceutical market is financed by the state through reimbursement by the public social security system.

Table 1. Drug Expenditure, Producer Revenues and Average Prices, 2002-2012

	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Public Drug Expenditure (bn TL)	5.23	6.80	7.90	8.69	10.10	11.14	12.96	16.07	15.35	15.87	14.77
Producer Revenues (bn TL)	4.76	6.24	7.71	8.34	9.28	10.84	11.87	13.85	13.61	13.73	12.93
Average Price (TL/box)	6.04	7.26	8.08	7.80	8.08	8.35	8.75	9.94	9.54	8.82	8.28

Note: Revenue and average price figures are for the prescription drug market; at nominal ex-manufacturer sales prices, including producer discounts.
Source: İEİS (2013)

In order to understand how and why this shift occurred, one needs to consider the longer-term historical and institutional legacies of pharmaceutical expenditure and prices, as well as the immediate social and political forces that led the Turkish government to eventually adopt such a new policy approach. Regarding the former, I argue that the 2002-2008 period produced four important legacies in the form of policies and politics. First, Turkish politics was altered by the surprising electoral success of the AKP, which brought to power a relatively stable and assertive single-party government with its unique constituencies among the lower classes, and among "Anatolian" business people.[4] Second, a comprehensive health policy reform largely extended the coverage of public health care insurance. The bottom half (some 43%) of the Turkish population for the first time became eligible for public reimbursement of medicines, which also increased the state's overall spending on pharmaceuticals. Third, as part of the health care reform, a new and potentially effective regulatory framework for pharmaceutical pricing and reimbursement was implemented. Fourth,

[4] It has been pointed out in the literature that this particular group of business people, who primarily are represented by the volunatary business associations MÜSIAD, ASKON, and TUSKON, cannot be conceptualized easily as "Anatolian", as its geographical distribution is more complex (Buğra & Savaşkan, 2012, p. 46). Accordingly, I use the terms "Anatolian business people" and "Anatolian bourgeosie" in quotation marks throughout the thesis.

a large lawsuit and a "scandal" developed when it became known that pharmaceutical producers had been selling to the state at "excessive" prices, which weakened the position of the pharmaceutical industry vis-à-vis society and the state.

After these changes had occurred and their legacies had been established, pharmaceutical policy became driven by the domestic consequences of the global financial crisis. I argue that the AKP government in 2009 adopted a policy of strict drug price controls for fairly contingent reasons. AKP regulators decided to achieve massive pharmaceutical cost containment by reducing producer prices, because they needed to reconcile their commitment to a prudent budget that would help the AKP steer Turkey through the aftermath of the global financial crisis, with their commitment to maintaining the high satisfaction of their electorate with the AKP's populist health policy.

While this policy proposal was not exceptional to Turkey, the AKP government turned out to be able to effectively implement its political will to reduce drug prices. The existence of an effective regulatory framework, a more compliant private sector after the shock of the Roche case, and a powerful political executive certainly contributed to this. Equally important was the fact that the AKP's political commitment to low drug prices was not diluted by competing policy goals in policy areas other than public expenditure management. Specifically, strict pharmaceutical price regulation was not countervailed by commitments to support future medical innovation, to maximize the availability of medicines, to increase local production, or to favor businesspeople close to the government. However, I will also argue that it was the political need to contain drug shortage that eventually halted the government's commitment to decrease prices even further and hence created the pricing and reimbursement regulations that are still in place today.

Research Design

In the following I attempt to make explicit some of the central theoretical assumptions and methodological considerations that informed the research process. Moreover, I present my major data sources. Theoretically, this thesis employs a political economy perspective on pharmaceutical prices.[5] At the most basic level, this implies the assumption that the economy is not an autonomous system, but instead interrelated with politics and society (Gourevitch, 1993). That this assumption is true may be least contested for the pharmaceutical market, where an economic model of supply and demand has little explanatory power. Such a broad definition of political economy appears to do justice to the actual diversity of the academic field, and to the ontology of the economy, but as such it provides little guidance to research that seeks to answer specific empirical questions. If almost everything potentially matters, where should one look more carefully?

On a practical level, the task was made easier by the fact that the tightening of the Turkish drug price control regime coincided with a single policy, namely the global budget that was passed in 2009. Accordingly, I operationalized my research question, "Why did Turkey shift to a strict regime of drug price controls?" by asking more specifically "Why did the AKP government propose, pass and effectively implement the global pharma budget policy in 2009?" As regards data collection, this allowed me to trace the policy-making process and to evaluate the positions of the actors involved. This policy-specific operationalization of the research question also

[5] Beckert (2011) recently surveyed sociological explanations of price formation in market economies, which challenge the assumption of economics that prices under normal conditions are determined by supply and demand. Unfortunately for the purpose of this thesis, he excludes "the direct setting of prices by the state" (Beckert, 2011, p. 768) from his survey, as it does not constitute a market-economy mechanism of price formation.

opened up the comparative public policy strand of the political economy literature as a source of inspiration for theorizing the sources of the regulatory regime change.

Comparative political economy has developed a tradition to theorize causal factors in terms of three larger groups, namely interests, institutions, and ideas. Each of these three factors entails an important question that can be asked in order to identify sources of a political-economic outcome (Blyth, 2009, pp. 196-197). The interest-based approach suggests to ask "who benefits," as a crucial component to understand why a policy was chosen and implemented successfully. Institutionalists, whose work is often more explicitly comparative, often find that the structure of interests does not account for across-case variation, and therefore ask "who varies and why" in order to reveal the political and economic institutions that shape actions beyond the underlying objective interests. Lastly, constructionists think that agents do not evaluate the expected outcomes of a policy according to their objective interests, but that both of these are ideas that are constructed; by implication they ask "who constructs." There is no reason to assume a priori which of these factors is most important in the evolution of an actual policy. Instead, I used all three of the questions to guide the collection and interpretation of data.

Despite the relative open-endedness of my research question, the analysis of interests remained at the center, as only a clear picture of the involved actors' interests in drug price controls provides a standard of comparison against which the actual realization of interests can be evaluated. Hence, the task was to identify the interests and concerns vested in strict drug price controls and to then examine which of them were realized and why. My answer to this question draws on a non-parsimonious array of factors, especially the changing representation of interests and the power this wields, economic and political institutions, the ideational construction

of political concerns, but also the importance of key events as well as political leadership and political entrepreneurship.

Methodologically, this thesis can be considered as a single-outcome study; that is, as a study of one case with no inferential claim about outcomes in other, apparently similar cases (Gerring, 2006). The aim is to offer a relatively complete explanation of Turkey's policy regime change in pharmaceutical price regulation, that is, to account for a very large share of the observed variation (on the scale of "regulatory stringency," or "pharmaceutical profit permitting"). In light of this goal, my explanation considers a multiplicity of factors, without the constraint that these need to be systematic, that is valid in other cases of strict price controls. The reason for this modesty regarding the broader validity of the causal factors identified in this study is not a belief that the Turkish case is inherently unique and thus incomparable, but that it is beyond the scope of this thesis to carry out a systematic cross-case analysis that could position my case in a population of comparable cases.

In order to identify the set of causal factors with which I propose to explain Turkey's shift to strict drug price controls, I employ a method that resembles what is described as process-tracing in the literature. The basic logic of this method is "to work backwards from a known outcome by tracing the *empirical* process that led to it" (Beach & Pedersen, 2011, p. 23). One methodological disadvantage of tracing a positive process is that such factors whose absence contributes to the outcome are easily overlooked, especially if no or few comparative cases are examined. To counter this problem, following the tracing of the positive historical process, I consider the potential impact of the absence of some factors on the outcome, namely the absence of "countervailing policy goals" such as political concern for domestic production or for medicine availability.

It is characteristic for process-tracing that the decision of how far one should "work backwards" is somewhat arbitrary. For instance, I argue in this thesis that the AKP government's populist use of health policy is one of the two immediate political reasons why strict drug price controls were proposed in September 2009. This factor was generated by the AKP's rise to power, its specific social base, and its comprehensive health care reform. At this point, my backward-tracing stops, but one could of course go back further and identify the historical causes of the health care reform (which was not just a policy proposal of the AKP). Putting an end, or rather a beginning, to this historical process-tracing somewhere is a practical necessity for the researcher and how this judgment call is made eventually also reflects the researcher's understanding of what the "proximate" and what the "deeper" causes of an outcome are.

The empirical research for this thesis was almost exclusively limited to events that occurred in 2002-2012. This necessarily over-emphasizes the "politics of the AKP era" and may identify factors as distinct features of AKP rule that may also be attributed to Turkish democracy in general. Because of these blinkers, my research has problems seeing factors that lie before 2002 or beyond the characteristics of the AKP government in the general structures of Turkish democracy. For instance, economic policy-making by executive decree (which is how the drug price controls were implemented) is an institutional legacy of the 1980s, and political clientelism (which may be considered as the origin of the AKP's health populism) is entrenched in Turkish democracy in general. These factors may have contributed to the outcome I am explaining, but my research did not examine them explicitly. While a restricted vision is a necessary element of any historical research, my objective here was to make explicit where I did not look. Let the reader beware.

The research for this thesis focused on pharmaceutical producers and how the prices they can charge have changed due to stricter government control. This choice does not imply underestimation of other sources of high pharmaceutical prices. It is an interesting fact that the distribution of pharmaceutical retail prices, and thus revenues, between producers, wholesalers, pharmacists and the state (through value-added taxation) varies significantly across national political economies. In Sweden, for instance, 80% of the final retail price goes to the producer, while a combined 20% go to pharmacists and wholesalers. In Germany, on the other hand, only 58% goes to the producer, 28% to the distributors, and 14% to the treasury (OECD, 2008, p. 33). While there are no official figures for Turkey, 8% of the retail price goes to the state as value-added tax, and most probably no less than 20% goes to pharmacists and wholesalers. In short, public finance and public health may also be harmed by high retail profit margins.

Pharmacists and wholesalers should have an interest in higher producer prices, as their revenues are generated by mark-up pricing. Therefore, the distributors of pharmaceuticals are both part of the problem (high prices and profits) and the solution, as their influence in a national political economy is an important source whether or not a government develops the political will and ability to regulate pharmaceutical prices and public expenditure more strictly. Nevertheless, the role of pharmacists and warehouses is only of peripheral concern for this thesis. I chose not to explicitly examine the role of distributors in Turkey's shift to strict drug price controls, because of obvious space constraints and (justifying the first reason) because Turkey's reduction in pharmaceutical expenditure was primarily a result of decreasing producer prices.

Let me now consider the empirical data that were used to develop the arguments of this thesis. The fact that the object of study is a very recent policy change predefines the kind of empirical material that is available for analysis. To my best knowledge, there is no secondary literature that deals with the 2009 shift to strict drug price controls.[6] Thus, readers should be cautious as the empirical material of this thesis has not been dealt with before in any published work. However, there is secondary literature that deals with the same conjuncture at which the shift occurred, namely Turkey in the aftermath of the financial crisis in 2009. In particular, Öniş and Güven's (2011) study of the response of the AKP government to the global financial crisis, and Öniş's (2012) analysis of the AKP era have generated important knowledge on which my arguments built.

The three main primary sources I used are descriptive statistics, news reports, and interviews. Descriptive statistics of pharmaceutical prices, expenditure and market size were employed to establish that and how the shift to strict drug price controls occurred. Crucially, I needed to show that most of the price reductions in the 2009-2012 period were the result of the 2009 policy change (and not, say, of discretionary bureaucratic decisions), in order to justify my focus on the 2009 policy change. Data on market prices and public discounts were obtained from the pharmaceutical industry and the drug regulatory agency. Most, if not all, of the market price data are collected by the global healthcare consultancy IMS Health. Their data are not known to be unreliable.

The primary data used in support of my explanation are interviews, news reports, and again, descriptive statistics. In total, 36 semi-structured interviews were conducted between May 2012 and April 2013 (Appendix A). Early interviews were

[6] There is, however, informative literature that deals with Turkish pharmaceutical policy before the shift in 2009 (Eren, 2002; Eren Vural, 2007a; 2007b; Güldal & Semin, 2008; Kırım, 1985; 1986).

exploratory in nature and primarily helped to understand the world of pharmaceuticals and to define the research question. Later interviews addressed more specifically the question why price controls were introduced in 2009 and how they were implemented so effectively. Interviews were conducted with a large variety of actors, with the important exception of the top-level economic regulators who arguably made the decision. Whenever possible I tried to corroborate the hypotheses developed through the interviews with publicly available records. For this purpose, I primarily used news reports. For some parts of the argument, however, interviews remained the only source. For instance, the claim that the AKP government had little concern for pharmaceutical profit interests and that, especially the multinational, pharmaceutical producers had limited access to the responsible regulators, is largely based on information gathered through the interviews. In addition, further descriptive statistics are used throughout the argument in order to provide evidence for central claims.

The remainder of this thesis proceeds as follows. Chapter 2 analyzes developments in Turkish politics as well as health and pharmaceutical policy in the 2002-2008 period, which facilitate an understanding of the rapid shift that was to occur. Chapter 3 provides an explanation of the policy regime change in 2009 and the effective implementation of drug price controls in 2009-2012. Chapter 4 offers some brief and cautious conclusions that go beyond the immediate case of Turkey in 2002-2012.

CHAPTER 2

SETTING THE STAGE: THE CHANGING POLITICAL AND POLICY CONTEXTS OF PHARMACEUTICAL PRICES, 2002-2008

In this chapter, I examine four areas of politics and policy that experienced important changes in the 2002-2008 period. I argue that in conjunction these changes set the stage for the transformation of Turkey's policy regime for pharmaceutical expenditure, prices and profits that began in 2009. The four transformations are the following. First, since 2002 Turkey is governed by a single-party government formed by the AKP, which has a unique constituency and over the years increased its control over state institutions. Second, from 2003 a health and social security reform was implemented, which brought single-payer public health care and near-universal coverage. Third, from 2004 the regulatory framework that governed the prices and public reimbursement of pharmaceuticals was reformed and strengthened. Fourth, since 2004 the relations between the Turkish government and pharmaceutical producers were altered by the Roche scandal and subsequent lawsuits against producers charged for excessive pricing. These changes were historically intertwined, but they merit separate examination.

Prologue: A Pre-AKP Attempt to Reduce Drug Prices

Before examining pharmaceutical price regulation in the AKP era, let me first take a small step back to consider an episode that occurred shortly before the AKP came to power. The 1999-2002 coalition government that was formed by the centre-left DSP,

the centre-right ANAP and the nationalist MHP under Prime Minister Bülent Ecevit had attempted to regulate pharmaceutical prices more strictly. I argue that in 2002 the coalition government (just as the AKP in 2009) had advanced plans to cut pharmaceutical prices, but that these had not been implemented with the planned stringency because multinational pharmaceutical producers made an effective intervention in the policy process. The policy episode I will describe to illustrate this point is of particular relevance for my analysis in the subsequent chapter because the situation in 2002 resembled the situation in 2009, when strict drug price controls eventually were introduced.

During the rule of the 1999-2002 coalition government, stricter price controls as a remedy for rising public pharmaceutical expenditure became a serious policy proposal in the aftermath of the 2000/2001 Turkish financial crisis. In order to recover from the financial-turned-fiscal crisis, the Turkish government launched a stand-by agreement with the IMF in February 2002 and committed itself to budget cuts and "structural reforms." As a result, savings in public health expenditure became a priority for the Ministry of Labor and Social Security, under which the three major social security funds operated. In particular, public spending on medicines was targeted, as the three funds then were together reimbursing 74% of total pharmaceutical expenditure (Monitor Group, 2003).

The specific institutional arrangements of the SSK had long allowed it to keep its drug spending lower than the other social security funds. By 2002, under the political leadership of Yaşar Okuyan (ANAP), then Minister of Labor and Social Security, the social insurance fund *Bağ-Kur* had implemented a reimbursement policy that favored cheaper generic drugs and a very similar reform was also

proposed for the social insurance fund *Emekli Sandığı*.[7] The policy, which became known as the "cheapest generic drug" (*en ucuz eşdeğer ilaç*) policy or the "purchase of the cheapest medicine" (*en ucuz ilaç alım*) policy, suggested reimbursing equivalent drugs (generics and off-patent originals) only up to the price of the cheapest among them, which would normally be a generic drug. The price differences of all other drugs would have to be paid out-of-pocket by patients and hence strongly dissuade patients from buying them. This policy was especially strict, as most similar policies (as that of the SSK) set upper reimbursement limits at some average market price.

This policy proposal became a direct issue of Turkey's stand-by agreement with the IMF. Like all IMF borrowers, the Turkish government was required to regularly submit so-called Letters of Intent, which "describes the policies that Turkey intends to implement in the context of its request for financial support," in order to continue to receive credit lines. In its 3 April 2002 Letter of Intent, Turkey's coalition government announced that, as a structural policy, "we will implement a generic drug purchase program in another [of our social security institutions] (Emekli Sandıgı) by end-April" (IMF, 2002a). In its 19 June 2002 Letter of Intent, it did not mention the progress of the generic drug purchase program, while on 30 July 2002 it found that "health spending pressures have emerged, largely as a result of higher medicine prices," but still did not comment on the progress of the reform plan (IMF, 2002c). On both Letters of Intent, the IMF commented that the "Ministry of Health now aims to finalize the generic drug purchase program by end-2002" (IMF, 2002b), a very long time-horizon, considering the government had originally planned to implement generic drug purchasing within less than a month. Eventually, the

[7] It is subject to pharmacological debate whether "equivalent" original and generic medicines are actually of the same medical quality. For the purposes of this thesis, I assume that they are.

coalition government never implemented the pro-generic reimbursement policy with Emekli Sandığı.

This story of a minor policy proposal's slow death is more interesting than it may seem at first sight. The evidence suggests that direct and open lobbying by the multinational pharmaceutical industry played a crucial role in it. In May 2002, one month after the initial Letter of Intent, Pfizer sent an eleven-member delegation under the leadership of global Vice President Mohand Sidi Said to Ankara. It was the delegation's pronounced aim to convince the government to repeal the policy for Bağ-Kur and not to implement it with Emekli Sandığı. Within a short time the delegation managed to arrange appointments with all relevant ministers, including Kemal Derviş, who then was the influential Minister of State for Economic Affairs in charge of the stabilization program (*Radikal*, 10.05.2002). Speaking with the press, Sidi Said claimed that the policy would harm the introduction of new medicines to the Turkish market (*Radikal*, 10.05.2002), and he announced that due to the new policy approach Pfizer had already cancelled investments worth 80 million USD (*Hürriyet*, 11.05.2002). Other multinational companies, such as Merck Sharp & Dome, were also making very similar predictions or threats (*Radikal*, 06.05.2002).

After his term in office, the responsible minister Yaşar Okuyan gave two interviews regarding the issue and stated that he had been pressured by the American ambassador in Turkey, Deputy Prime Minister Mesut Yilmaz, and Kemal Derviş to abandon the reform. Pfizer had apparently also managed to mobilize the IMF for their concern. According to Okuyan, the IMF negotiators told the Turkish policy-makers during a meeting that the generic drug policy was "creating problems" (*Radikal*, 16.08.2004; *Vatan*, 27.01.2003). It seems reasonable to conclude that the protest of the multinational pharmaceutical companies and, perhaps even more, the

IMF's apparent support for their cause, were the key reasons for the Turkish government to abandon the new reimbursement rules for Emekli Sandığı. After all, a similar policy had been introduced for Bağ-Kur and the same proposal for Emekli Sandığı had found its way into Turkey's Letter of Intent to the IMF. So there seemed to be sufficient support for the policy within the coalition government. Moreover, at the time there was no discussion of possible negative effects of the reform on patients, which could have otherwise motivated its withdrawal.

This episode is the literal point of departure for the relations between the AKP government and pharmaceutical producers. In August 2002, both Okuyan and Derviş left their offices. In November 2002, the AKP was elected to form the new government. In March 2003, Emekli Sandığı did introduce an upper-limit for reimbursement, but it was the average market price of equivalent drugs, and not the cheapest price, the radical solution proposed in 2002 (Top & Tarcan, 2004). In its early years, the AKP government did not implement any regulations that were extraordinarily strict on pharmaceutical prices or profits.

The AKP and Its Constituencies

The AKP's unexpected election victory in November 2002 opened a new chapter of Turkish history. Since then popular support for the AKP has increased. The party won 34% of the popular vote in 2002, 47% in 2007, and 50% in 2011.[8] As a result of this (and a restrictive ten-percent threshold to enter parliament) the AKP has commanded solid parliamentary majorities and governed Turkey as a single-party government for over a decade now. This stability is unique in Turkey's recent

[8] In addition to the three general elections, there were local elections in 2004 and 2009. In those the AKP won 42% and 39% of the vote respectively.

history. In contrast, between 1991 and 2002 Turkey had nine different governments, all of which were either coalition or minority governments. Against this historical background, it makes sense to consider the last decade as the (beginning of the) AKP era of modern Turkish history. But what are the characteristics of this party that has named an era which happens to coincide with quite remarkable changes in pharmaceutical policy?

Despite the party's origin in the Islamist Welfare Party, the moderate wing of which most of the party leadership used to belong to, the AKP is often considered as a typical centre-right party. From a comparative perspective, such a characterization may be misleading, as the labels "left" and "right" have very specific meanings in Turkish politics. Considering the AKP's support for active social policy, in particular focusing on millions of poor workers in the informal economy, but also its heavy reliance on say privatization, the party's social and economic policy agenda contains both right-wing and left-wing elements. While its electoral base has broadened since its initial success in 2007, the AKP has two core constituencies, namely the so-called "Anatolian" bourgeoisie and the rural and urban lower classes. As I will argue in this thesis, the distinct interests of these two groups go some way to explaining why the AKP government has successfully pushed for strict pharmaceutical price controls. For this reason, the relationship of the AKP with these two social clienteles should be specified.

Much has been made of the role of the "Anatolian" bourgeoisie in the rise of the AKP. This group of provincial entrepreneurs and merchants first arose during the period of export-led industrialization in the 1980s and has since then challenged the privileges of the older, mostly secularist and Istanbul-based industrial

conglomerates.[9] Indeed, when Tayyip Erdoğan and his political allies decided to split from the radical Islamist movement in 2001 and establish the AKP, crucial early support came from this group of Islamic, "Anatolian" business people. While it has been rightly argued that the old industrial elite, represented by TÜSIAD, has come to terms with the AKP and its governing of the economy (Demiralp, 2009, p. 331), the "Anatolian" bourgeoisie is different in that it is actively employing its capital to further the political power of the AKP. For instance, "Anatolian" business people have been investing in the media sector, bought newspapers and television channels, and in this way have had larger impact on public opinion (Buğra & Savaşkan, 2012, pp. 53-54, 57). Moreover, many of these provincial entrepreneurs have themselves been representatives for the AKP on the national or local level.

Besides this continuous support by the "Anatolian" bourgeoisie, another key constituency of the AKP, especially in electoral terms, has been the rural and urban lower classes, which have been "the traditional base of the Islamist movement" (Demiralp, 2009, p. 331). In fact, according to surveys "AKP voters are more religious, more rural, less educated and poorer" than the voters of the secularist main opposition party CHP (Hale & Özbudun, 2010, p. 41). Considering the perceived neoliberal character of the AKP's economic policies, the sustained support of the rural population and the urban poor have often been framed as somewhat paradoxical. By some this puzzle has been solved by suggesting that economic neoliberalism is covered by ideological populism. However, while ideological factors such as the AKP's Islamic-conservative pedigree should certainly not be ignored, there is evidence that much of the support that led to the AKP's reelections in 2007 and 2011 stemmed from the "economic pragmatism" of AKP voters evaluating both

[9] In has become a commonplace in the literature to identify these two groups of businessmen by reference to the two large associations TÜSIAD and MÜSIAD (Buğra, 1998).

Turkey's macroeconomic condition and their own financial situation (Çarkoğlu, 2008; 2012).

Indeed, Turkey's macroeconomic performance (in terms of GDP growth and inflation) under the rule of the AKP has been impressive (Öniş, 2012).[10] How far this boom has actually "trickled down" to the lower classes through the market is less clear. But even if the poor have not benefited from macroeconomic changes like low interest rates and low inflation (Demiralp, 2009, p. 331), an argument has been made that the AKP government actively used formal mechanisms of redistribution that substantially benefitted the lower classes. Ziya Öniş points to the large increases in public expenditure on health and education in the AKP era:

> The AKP's ability to increase social expenditures in these critical areas and its ability to improve the provision of public services, both at the level of the local and national governments, made a visible impact on the living standards of the middle and poorer segments of society and not surprisingly contributed to the party's steadily rising electoral fortunes. (Öniş, 2012, p. 141)

But there must also be no doubt that the AKP has been a staunch pro-business and pro-market party. Despite the AKP's firm roots in political Islam, it is in no way hostile toward global capital or a market economy, and therefore distinctly different from the parties of the Islamic *Milli Görüş* (National Outlook) movement that preceded it. Most analysts also consider the AKP as, in principle, sympathetic toward foreign multinational companies operating in Turkey (Aydın, 2010). Öniş argues that it was due to this combination of neo-liberal, pro-business economic policy with neo-populist, redistributive social policy – which he coins "social neo-liberalism"– that

[10] Öniş (2012) also points to the fact that the only loss in votes that the AKP suffered in five nation-wide (three general, two local) elections, i.e. when its share dropped to 38.8% in the 2009 local elections, came at the time when the global financial crisis was felt by the Turkish economy.

made it possible for the AKP to construct and sustain its cross-class coalition of supporters.

Health Care Reform

One particular field in which public expenditure increased in the first years of the AKP era was health care. The share of public health expenditure in GDP rose from 3.78% in 2002 to 4.43% in 2008 (and 4.56% in 2010). This rise in expenditure came with some significant improvements in public health indicators. For instance, the average number of annual doctor visits per capita increased from three in 2002 to seven in 2009.[11] Arguably, much of this change can be attributed to the Health Transformation Program (HTP), that is the major health care reform undertaken by the AKP government since 2003 (MoH, 2003). Making good on campaign promises, the newly-formed AKP government declared the slogan "Health for All" in 2002 (Ağartan, 2008, p. 267).

The HTP was to reform Turkey's hitherto inegalitarian corporatist health care system, where service provision was public, but also highly fragmented. This corporatist system distinguished three major occupational groups that were entitled to more or less comprehensive health care services; active and retired civil servants covered by the consolidated budget and the fund Emekli Sandığı, formal workers registered with the Social Insurance Institution (SSK), and the self-employed registered with Bağ-Kur (Buğra & Keyder, 2006, p. 213). While the latter two funds

[11] Despite these improvements in the numbers, the health care reform has been criticized by observers for, among other things, increasing privatization of service delivery, financing through premiums and co-payments, and strengthening the reliance on informal family networks. A rich collection of such criticisms can be found in the comment section of a recent article that praised the achievements of the Health Transfornmation Program (and that was written by some its administrators) (Baris, Mollahaliloglu, & Aydin, 2011).

were financed through employer and employee contributions, the civil servants fund was financed directly by the state.

In 2002, 67% of the Turkish population was covered by the public health care system (Ağartan, 2012, p. 461), while, as Buğra and Keyder write, "more than one-third of the population remains outside of health insurance coverage, having to pay for their needs themselves" (Buğra & Keyder, 2006, p. 215). This led some analysts to characterize Turkey's public health system as dualist, providing decent care to one part of the population, but excluding the rest (Buğra & Adar, 2008, p. 85). While the number of people that had no access to public health service providers was already high, the number of people who had to pay for their pharmaceutical needs themselves was even higher. Since the Green Card scheme for the very poor did not reimburse pharmaceutical consumption before 2005, the share of the population that was covered by public pharmaceutical reimbursement was only 58% (Ağartan, 2012, p. 461; author's calculation). In contrast, by 2010 the coverage for both health services and pharmaceutical reimbursement had reached a near-universal 96% of the population (Ağartan, 2012, p. 464).

It was against this historical background that the AKP adopted a reform proposal with the key objective of making the health care system more universalist and creating a single-payer national health system that included the entire population and did not leave anyone uninsured, but also with the aims of increasing efficiency, controlling public cost, financing the system via means-tested contributions, and, importantly, allowing for a much larger role of private provision of health care. The reform was, however, no novel idea of the AKP. Rather, a coalition supporting similar plans had been evolving before and it was eventually the AKP government that had sufficient political will and power to accomplish such a reform. Social

transformations such as rapid urbanization and the weakening of informal welfare mechanisms had put increasing pressure on the dualist health care system since the 1980s. Political responses such as the introduction of the Green Card scheme in 1992 by a coalition government are evidence of the early political recognition of the need to extend health care coverage.

The health reform was backed by Turkey's two most important business associations, the secularist TÜSIAD and the "Anatolian"-Islamic MÜSIAD. TÜSIAD was an early supporter of the idea of a single-payer fund, financed primarily through payroll premiums for those in the labor market, where the premiums of people with low incomes are paid by the government. But it also demanded a larger role for private providers and increased public expenditure on health, where the "public sector will be a payer rather than a provider" (TÜSİAD, 2005, p. 25). MÜSIAD also supported the government's reform, emphasizing the objective of providing equitable access to basic health services, "which the state is obliged to provide according to the notion of the social state" (Bolat, 2007, p. 4; author's translation[12]), rather than the organizational and financial problems of the old health system. MÜSIAD also supported private investment in health care and increased competition between public and private health care providers:

> The increase of foreign investments in [health] service provision is extremely important, also because it will promote competition between the private and the public sector. In this competition, the capital, which protects national values and *which believes that serving people is a service to God, also needs to increase its investments in the health care sector*. (Bolat, 2007, p. 5; author's translation; emphasis in the original).

[12] The original Turkish versions of all quotes translated by the author are presented in Appendix C.

It can be said that the business sector (both the secularist and the "Anatolian" bourgeoisie) supported the health care reform of the AKP government, because not only did it promise new and profitable opportunities for private investment in the health sector, but also because business had an interest in a more inclusive health policy that did not leave anyone uninsured. Whether that was the case because a universalist approach to social policy promised "maintaining social cohesion" (Buğra & Adar, 2008, p. 102), whether businessmen had a religious commitment to it, or whether tax-financed health care for the poor just represented a growing market remains open to debate.

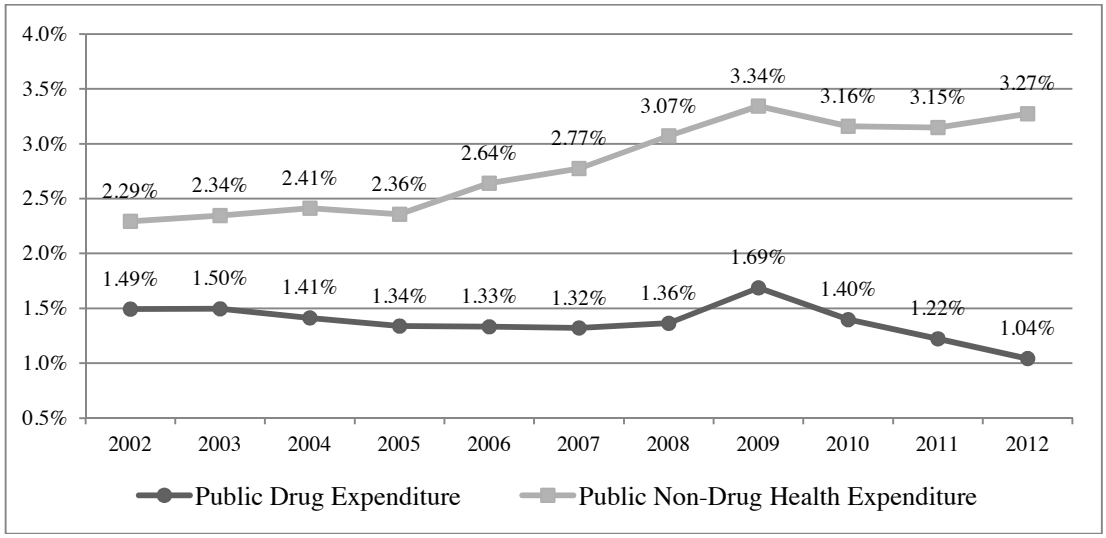
For whatever historical causes and coalitions of interests, the AKP's Health Transformation Program was eventually implemented. In 2008, in spite of a prior challenge in the Supreme Court (where it was brought by the opposition party CHP and Turkey's secularist president Ahmet Sezer), the three major social insurance funds were unified in the Social Security Institution (SGK). In 2010, the Active Civil Servants Scheme was also transferred, and with the transfer of the Green Card scheme in 2011 Turkey eventually had a single-payer system. Such broad institutional reforms did not leave public expenditure unaltered. Table 2 shows the development of public health and public pharmaceutical expenditure.

Table 2. Public Health and Pharmaceutical Expenditure, 2002-2012

	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Public Health Expenditure (bn TL)	13.3	17.5	21.4	24.0	30.1	34.5	42.2	47.9	50.1	56.7	61.1
Annual Growth (%)	57.3	31.6	22.5	12.1	25.6	14.7	22.1	13.6	4.5	13.3	7.8
Public Drug Expenditure (bn TL)	5.2	6.8	7.9	8.7	10.1	11.1	13.0	16.1	15.3	15.9	14.8
Annual Growth (%)	-	30.0	16.1	10.0	16.3	10.3	16.4	23.9	-4.5	3.4	-6.9

Notes: Values for 2012 are estimates.
Sources: AİFD (personal communication), MoD (2012), MoF (2012), TURKSTAT (2011), author's calculation

For the arguments in this thesis the distinction between public drug and public non-drug health expenditure is important. The assumption is that non-drug health expenditure includes primarily treatment and services. Figure 1 presents these two categories in terms relative to GDP. The figure shows that non-drug health expenditure relative to GDP increased by almost one-third within the first five years of the health care reform. After 2009, however, non-drug health expenditure slightly decreased again. Drug expenditure, on the other hand, has remained relatively stable during the first years of the health reform, and then made a jump in 2009 (in part because of the global financial crisis, due to which GDP decreased). After that the GDP share of public drug expenditure decreased significantly; in 2012 it was about one-fourth below the level of 2008.



Notes: Values for 2012 are estimates.
Sources: AİFD (personal communication), BUMKO (2013), MoD (2012), MoF (2012), TURKSTAT (2011); author's calculation.

Figure 1. Public Health and Pharmaceutical Expenditure (% GDP).

New Regulatory Framework

The health care reform and the restructuring of the social security system fundamentally transformed Turkey's social policy environment. The AKP's first term in government was characterized by political and policy entrepreneurship in response to Turkey's inegalitarian, corporatist health care system and the social problems it posed. In the lee of this broader reform movement more specific institutions of the welfare state also underwent transformation. Pharmaceutical price and cost regulations were radically reformed in the 2004-2008 period, in particular the systems with which the state controls legal price ceilings and public reimbursement. The regulation of pharmaceutical prices and public reimbursement is legally and organizationally separated. The regulation of maximum prices is carried out by the Ministry of Health and the İEGM (named TİTCK since 2012), Turkey's drug regulatory agency. The regulation of public reimbursement, on the other hand, is the responsibility of the Ministry of Labor and Social Security and its affiliated SGK since it became Turkey's single social insurance fund. In particular before the SGK was founded, the Ministry of Finance (through Budget Implementation Directives) made rules regarding the pharmaceutical reimbursement of the social security funds. Both mechanisms are, albeit not formally, under the substantial control of the Prime Ministry and the Economic Coordination Committee (EKK).

The 2004 Price Control System

The regulatory system for controlling the maximum market prices of pharmaceuticals was reformed with the introduction of a system of external reference

pricing in 2004. To evaluate the dimensions of this change, let us first examine Turkey's earlier price control systems. During the era of import substitution in the 1960s and 1970s, the official objective of price controls were "to provide cheap drugs to the public and prevent the over pricing activities of transnational corporations which caused the outflow of scarce foreign exchange" (Eren, 2002, p. 12). To that end both input costs and final prices were strictly regulated. The liberalization period of the 1980s then saw a shift to a strategy of export-led growth in the pharmaceutical industry. Hence, the official objective of the 1984 pricing system was to increase pharmaceutical exports and investments, which at the time implied for state regulators:

> the importance of allowing enough profits for the manufacturers to finance investments and R&D and of avoiding the long term detrimental effects of 'forcing producers to provide unprofitable public service' by insisting on cheap drugs (Eren, 2002, p. 142)

For that purpose, and similar to the PPRS in the United Kingdom, the 1984 "cost-plus" pricing system aimed at controlling the profit margins of producers instead of their sales prices. The scheme allowed producers to freely price their drugs within the range of two profit margins, namely a maximum profit margin of 20% for any single product's annual revenues, as well as a margin of 15% for a producer's total revenues (Council of Ministers, 1984). In practice, however, price-setting had never been that free and application of the scheme was largely replaced by discretionary political decision-making. In particular, the Ministry of Health frequently allowed producers to increase their sales prices by fixed and mostly equal rates. This choice appears to have had two primary reasons. First, drug prices were expected to increase even more if the pricing system was fully applied, which was likely to generate

popular resentment and hence political loss, and, second, the Ministry of Health simply did not have the administrative capacity to oversee and audit the cost structures of all pharmaceutical producers and products in the Turkish market (Eren, 2002, p. 143).

The difficulty of determining the cost structure of pharmaceutical production and hence of implementing the 1984 pricing system goes some way to explaining why reference pricing was introduced in 2004. When the issue of pharmaceutical cost-containment became politically more important during the years of the 1999-2002 coalition government and the early years of the AKP government the cost-plus pricing system proved inappropriate to effectively regulate drug prices. The coalition government, however, did not actually abolish the 1984 pricing system. Rather, as late as in February 2002, it amended the system, adding the clause that the profit margins (15-20% for producers, 9% for wholesalers and 25% for pharmacists) are only "maximum margins," but that lower margins could be decided by the Ministry of Health (Council of Ministers, 2002). This decree came into force in July 2002, just four months before the coalition government was swept out of office by the AKP.

Since the very beginning, the containment of public pharmaceutical expenditure and the need for reducing drug prices have been key rhetorical themes of the AKP government. In fact, it can be said that costs and prices have been the core of its pharmaceutical policy approach as it was outlined in the Health Transformation Program.

> Proportionally speaking, expenditures on pharmaceuticals are very high in Turkey. Because of the current policies of the social security institutions [high reimbursement rates], a large part of the population is increasingly insensitive to pharmaceutical prices. We know that the increases in drug prices do not rest on a scientific basis. As part of the

> Health Transformation Program, stakeholders will be brought together in dialogue and agreement, in order to solve according to scientific principles the longstanding problems with pharmaceuticals, one of the most important elements of health care. (MoH, 2003, pp. 34-35; author's translation)

In the same report, it was made explicit that the share of pharmaceutical expenditure in health expenditure is highest in Turkey among OECD countries. While the HTP did not spell out the details of a new pricing system, it made clear that the government wanted to address the problem of high pharmaceutical expenditure. It is interesting to note that the World Bank, in a report that has been considered as a blueprint for the HTP, also had identified pharmaceutical cost containment as an important element of health care reform in Turkey (World Bank, 2003, p. 33).

In January 2004 it became public that the Turkish government was working on a new price control system. In his first comments to the press, Turkey's Minister of Health, Recep Akdağ, stressed that the new price system should reduce the prices of particularly expensive pharmaceuticals such as cancer drugs and blood products, put on a par the profit rates of local and imported drugs, while not increasing the "burden" on public pharmaceutical expenditure (*Hürriyet*, 11.01.2004; 18.01.2004, 29.01.2004). The particular choice of a system of external reference pricing was apparently in response to an internal ministerial report evaluating alternative pricing systems (personal communication, interview 11). The AKP government formally introduced external reference pricing as Turkey's new pharmaceutical pricing system with a February 2004 cabinet decree (revised in June 2007) that set out the logic of the new system (Council of Ministers, 2004a; 2007), which has since then evolved

very dynamically. The two pricing decrees were frequently amended, which is important because these amendments often introduced new price cuts.[13]

The logic of external reference pricing is simple. The legally permitted maximum ex-factory sales price of a product (that is, the price for which the wholesaler buys the product from the producer) in the Turkish market is determined by the prices of the same product in a group of reference countries. According to the 2004 pricing decree, these reference countries have to be a group of five to ten European Union member countries and ever since the first decree these have been France, Greece, Italy, Portugal and Spain. In addition to these, there are two more *de facto* reference countries, as the countries were the reference product was produced and from where it was imported are also included if they are not one of the actual reference countries.[14]

The reference price of any drug product (original or generic) in the Turkish market is the lowest ex-factory list price (excluding possible discounts) of its corresponding original drug product in any of the five reference countries. After the reference price of a product is established, the legal price ceiling of that product in the Turkish market is determined by multiplying the reference price with a reference price factor of less than or equal to 100%. As of 2012, for instance, the reference factor for on-patent original drugs is 100%, whereas the reference factor off-patent original as well as generic drugs is 60%. Maximum prices in Turkey change then either when the government changes the reference factor (most prominently in 2009 and 2011), or when their reference price abroad changes. It is the legal responsibility

[13] The 2004 pricing decree was amended twice (Council of Ministers, 2004c; 2004d). The 2007 pricing decree was so far amended four times (Council of Ministers, 2009a; 2009b; 2009c; 2011b).

[14] One of interviewees pointed out to me that this clause was particularly designed to prevent imports from India and China (personal communication, interview 25). In fact, as of November 2012 there were only ten Indian and two Chinese drug products in the Turkish market (İEGM, 2012b).

of the producers to monitor the reference price of their products and to report changes to the İEGM. Every Friday the İEGM publishes the current Drug Price List on its website, known as the "Friday list" or, at least among pharmacists, as the "Friday drops" (*cuma düşüşleri*), indicating the usual direction of the price changes (personal communication, interview 17).

Another innovation that came with the new pricing system is the creation of a category of so-called "20-year-old" products. This category grants special status to original as well as generic drug products that already were in the Turkish market prior to 1 August 1987. Until 2009 these 20-year-olds were entirely excluded from the reference pricing system. The purpose of creating this new product category, which only exists in Turkey, was for the government to be able to treat some products (older molecules) differentially. Indeed, companies much prefer to keep 20-year status for their products (personal communication, interview 28). For one, this status allows overall higher prices, but especially the list prices of these products are significantly higher, which is of particular importance for multinational firms, because that prevents price cuts from spreading to other markets.

The entire system of maximum price regulation is governed by executive decisions rather than parliamentary legislation. In legal terms, this places price controls in the domain of administrative law. It was criticized that the system had never been "authorized" by any law (personal communication, interview 6). In order to authorize the method of governing prices by cabinet decree, a decree-law was passed in 2011 with the pronounced aim to "put in order the organizational structure, functions, powers, and responsibilities of the Ministry of Health and its affiliated institutions" (Council of Ministers, 2011a; author's translation). However, this law,

too, was an executive decree, a so-called "decree with the power of law" (*kanun hükmünde kararname*), which is by no means unusual in the Turkish context.[15]

The role of the pharmaceutical regulatory agency and its degree of independence deserve some attention. The literature on regulatory capitalism and the regulatory state has made much of the world-wide rise of independent regulatory agencies (IRAs). When the AKP first came to power, there were plans to transfer regulatory authority over pharmaceuticals from the İEGM to a new IRA. The envisioned National Drug Agency (*Ulusal İlaç Kurumu*) was to be "independent from any kind of influence" (MoH, 2003, p. 35; author's translation). In 2008, a World Bank report remarked that "the process seems stalled for political reasons and it is not clear when these plans will be turned into reality" (Çelik & Seiter, 2008, p. 7). In 2012 (at the end of the period examined in this thesis), the İEGM was restructured and the Pharmaceutical and Medical Device Agency of Turkey (TİTCK) was established. While the TİTCK has certain characteristics of institutional independence, such as its own budget and public entity status (Council of Ministers, 2011a), it is still a subsidiary institution to the Ministry of Health. In practice, much of the pricing decisions made by the İEGM appeared to be influenced by the Prime Ministry and the EKK, which since May 2009 is coordinated by the Deputy Prime Minister (Responsible for the Economy) Ali Babacan. Hence, at least with regard to price regulation, the İEGM is *de facto* not independent, but on the contrary under strict political control. This is consistent with Işık Özel's (2012) analysis that, as a rule, Turkey has recently experienced "de-delegation" of regulatory authority, with

[15] The authority to pass decree-laws is granted to the Council of Ministers by the 1982 constitution. The increased usage of decree-laws is a legacy of the Özal period (Sönmez, 2011, p. 124n).

increased (formal and informal) political control of IRAs through ministries and an overall "decline of regulatory independence."

Public Reimbursement

Besides the setting of maximum market prices, the second major mechanism that the state can use to control drug prices and in turn its own drug expenditure is public reimbursement. Reimbursement refers to the practice of state institutions to refund the consumers of pharmaceuticals (often via pharmacists) for some share of their expenditure, where this share primarily depends on the consumer's insurance status and the type of the pharmaceutical consumed. The significance of this indirect form of price regulation hinges on the dominant role of the state as one of the largest buyers of pharmaceuticals. In the OECD, the state on average finances 61% of total pharmaceutical consumption (OECD, 2008, p. 38). In Turkey this "public share" has traditionally been even higher, estimated at 85% for 2008 (BCG, 2011, p. 124), one of the highest values in the world and constituting a quasi-monopsonistic market structure. While not quite as fundamental as the ones regarding maximum prices, the changes that were implemented as part of the general health care reform made the reimbursement mechanism potentially more effective in regulating prices.

The logic of pharmaceutical reimbursement is as follows. As part of a general political commitment to public financing of health care services, many states decide to pay for some of the population's pharmaceutical expenditure. Usually public reimbursement is restricted to prescription drugs, which are deemed more essential, but sometimes over-the-counter drugs are also reimbursed. According to different visions of "cost sharing," states require patients to pay for some of the cost of their

drugs. Patients pay a certain percentage of co-payment (*katılım payı*) for every drug purchase (currently 10-20% in Turkey). Some drugs and some patients may be exempted from co-payments (for instance drugs related to chronic illness in Turkey). Besides direct savings through cost sharing, co-payments are usually expected to make patients more price-sensitive when consuming drugs. Moreover, patients sometimes pay out-of-pocket payments (*katkı payı*) for drug products that are more expensive, for example, when consumers opt for more expensive original drug products that are not reimbursed above the price of a cheaper generic alternative.

Let us now turn to reimbursement specifically in Turkey. Before the unification of reimbursement procedures that was realized as part of the social security reform, Turkey's large social insurance funds had separate policies of pharmaceutical reimbursement. This led to both different reimbursement rates and to different overall spending. The Green Card did not at all cover pharmaceutical consumption of outpatients until January 2005, which means that some 13.5 million people had to fully cover their drug consumption (*Hürriyet*, 15.12.2004). The other four public social insurance institutions did fund pharmaceutical consumption, but they spent very different shares of their total budget on drug reimbursement. In 2003, this share was 45% for the SSK, 50% for active civil servants financed by the government budget, 58% for Bağ-Kur and even 60% for retired civil servants covered by Emekli Sandığı (Top & Tarcan, 2004).

Because of this financial burden, Emekli Sandığı was already experimenting with internal reference pricing (for determining reimbursement rates) between March 2003 and March 2004 and reportedly realized savings of TL 500 million in this period (Top & Tarcan, 2004). The SSK, on the other hand, has long had a reputation for purchasing its pharmaceuticals very efficiently. It operated its own pharmacies

outside of the free market and those insured with SSK could only get their prescriptions from SSK-affiliated pharmacies. While this arguably resulted in lower service quality, it was efficient financially. For its purchases it directly bought from producers in large volumes, through tenders or negotiation. Importantly, the abolition of SSK-pharmacies contributed to increasing public drug expenditure.

Even though the single-payer General Health Insurance (GSS) was not formally implemented until 2008, public reimbursement became increasingly centralized following the founding of a single reimbursement commission with the pricing decree of February 2004. The commission replaced the hitherto largely autonomous decision-making of the large social security funds regarding their pharmaceutical reimbursement.

The reform of public reimbursement continued when, in December 2004, state institutions (MoLSS, MoF, SGK), industry associations and the pharmacists association signed a Public Pharmaceutical Purchase Protocol (*Kamu İlac Alım Protokolü*) (*Hürriyet*, 15.12.2004). The protocol represents a deal between the state as the largest buyer of pharmaceuticals and pharmaceutical business. The state announced that it would begin to publicly reimburse the pharmaceutical consumption of approximately 13.5 million Green Card holders and would also allow the 35 million people insured by SSK to buy their pharmaceuticals in free-market pharmacies (and thus effectively ending the system of cost-efficient SSK-pharmacies). In return, producers agreed to grant special public discounts of 4%-11% to the social security funds, while the pharmacists granted 3.5% of public discounts. That the protocol really presented a deal between business and the state was pointedly put by the Minister of Finance Kemal Unakıtan, who commented that

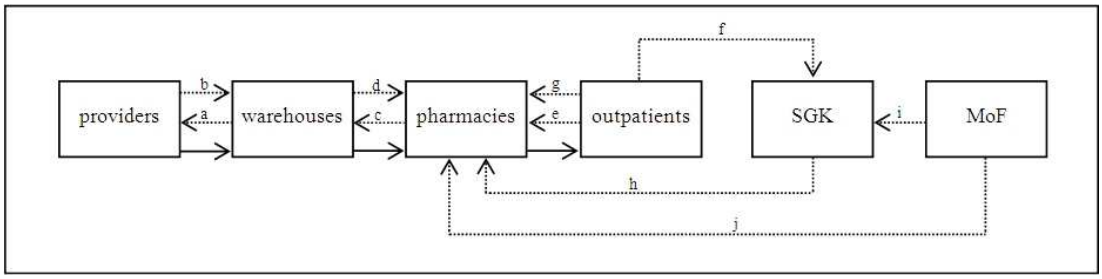
> The drug expenditure of the public sector is 10-12 billion lira per year. Considering this large volume, the state said "If I am buying so many drugs, then I also want something in return". This was a win-win situation. (*Hürriyet*, 15.12.2004; author's translation)

The protocol was formalized in a Budget Implementation Directive of the Ministry of Finance in February 2005, which set up the new architecture of public reimbursement (MoF, 2005). The directive introduced a positive list (*Bedeli Ödenecek İlaçlar Listesi*) that identified those pharmaceuticals eligible for public reimbursement, and it formalized the public discounts agreed in the December 2004 protocol. However, in May 2005 a drug co-payment of 20% was introduced for Green Card holders.

In 2006, public reimbursement was fully unified with the introduction of a single positive list. Since then public reimbursement has been governed centrally by the SGK (MoLSS), and reimbursement rates are determined by the Health Implementation Communiqué (*Sağlık Uygulama Tebliği*, SUT).[16] For products on the positive list, the SGK reimburses 100% of inpatient drug consumption and drug consumption related to chronic illness, 90% of drug consumption of retired people, and 80% of remaining drug consumption. Not only prescription drugs, but some OTC drugs such as aspirin, are also reimbursed. In September 2008, the public discounts from producers that had been 4% before were also raised to 11%. In addition to external reference pricing, since 2008 Turkey also uses a form of internal reference pricing. After application of external reference pricing, generic drug products cannot be priced more than 15% above the cheapest generic in the same group. In 2011, this rate was decreased to 10%.

[16] There have been three SUTs (SGK, 2007; 2008; 2010a). They have been frequently amended, more than thirty times until today.

The reforms described in this section have restructured the pharmaceutical market in Turkey, which is schematically shown in Figure 2.



Key: Solid lines represent product flows, dashed lines represent financial flows. (a) Warehouses buy drugs from providers, where (b) providers may grant in-kind discounts (extra products) to warehouses; (c) pharmacies buy drugs from warehouses, where (d) warehouses may grant in-kind discounts to pharmacies; (e) outpatients make residual out-of-pocket payments to the pharmacy as well as (f) statutory co-payments for prescription drugs and their general insurance premiums to SGK, and (g) purchase OTC drugs; (h) SGK reimburses pharmacies for prescription drugs; (i) MoF co-funds SGK out of the general budget and (j) reimbursed pharmacies for the prescription drugs of civil servants until 2010 and of Green Card holders until 2011.
Source: author's illustration

Figure 2. Financial and product flows in Turkey's pharmaceutical retail market, 2009

The Roche Scandal

In this last empirical section of the chapter, I want to examine a very particular phenomenon of the 2002-2008 period, what came to be known as the "Roche scandal" or the "Roche case." In July 2004, the "Roche scandal" became public (*Vatan*, 30.07.2004), which "changed everything" in the Turkish pharmaceutical industry, according to one of my interviewees (personal communication, interview 8). One week earlier, Veysi Mungan, a former sales manager of the Swiss multinational company Roche, had filed a complaint with the Istanbul Chief Public Prosecutor (*Hürriyet*, 10.08.2004). While the details of the case are complex and not too relevant for my purpose, Mungan accused Roche of having sold in late 2003 the cancer drug Neorecormon (at a time when the SSK pharmacy system was still separate from the open pharmacy market) at a much higher price to the SSK (230 TL) and to Başkent Hospital (173 TL) than to the private sector, namely the

warehouse Beşer Ecza Deposu (88 TL). The key accusations were that Roche had breached public procurement law, worked together with only one warehouse in order to avoid competition, charged the state an "exorbitant" (*fahiş*) price, and had therefore inflicted financial damage of several million TL on the state (*Radikal*, 08.08.2004; *Vatan*, 15.08.2004).

Reactions to the scandal were polarized. The media frequently and predominantly embraced the narrative of a scandal in which a private provider, and especially a multinational pharmaceutical company, had tricked naïve social security institutions into purchasing drugs at an exorbitant price. Subsequent newspaper interviews with the whistleblower reinforced this view (*Hürriyet*, 16.05.2010). Roche, on the other hand, presented the events as normal. In press statements the Swiss multinational claimed that SSK had not requested a lower price, and that the differential pricing was legal according to public procurement law. On 8 August Roche placed an ad in several newspapers.

> Since the Public Procurement Law came into effect in 2003, it is possible that from time to time price differences can occur in the tenders that are opened to meet public demand for medical products (*ntvmsnbc*, 10.08.2004; author's translation)

It is interesting that the Turkish Pharmacists Association did not come out against Roche, but basically supported the interpretation that the case was a product of public procurement rules and the differentiated regulatory framework for drug reimbursement (*ntvmsnbc*, 10.08.2004). Important for the argument of this thesis is, that the AKP government also did not contribute to the scandalization of the Roche case. The Minister of Health Recep Akdağ demanded a careful investigation of the case, but also stressed that the case reveals the need for institutional reform.

> I have worked as a purchasing manager in a hospital in Erzurum. […] Not only filthiness, but sometimes ignorance too can produce such results. […] These events will be conductive to improvements. […] In a sense, this was well-timed. […] Our aim is a modern, objective, and transparent pricing system. (*Milliyet*, 15.08.2004; author's translation)

And in fact, in December 2004 the government, producers and pharmacists signed a protocol that set up a single new reimbursement system, which abolished the SSK's drug purchase through tenders.

Despite this apparent settlement between the government and pharmaceutical providers, the Roche case intensified when it turned into a lawsuit in early 2005. Already in August 2004, Nazmi Okumuş, the Istanbul public prosecutor leading the case, had ordered a police unit from the Organized Crime Directorate to seize company records at Roche's corporate headquarters in Istanbul (*Hürriyet*, 13.08.2004). In February 2005, the police took several suspects under custody, including employees of Roche and Beşer, but also high-level civil servants of the SSK. Most prominently, Faruk Yöneyman, the CEO of Roche Turkey, was detained and handcuffed by the police (*Hürriyet*, 14.02.2005; 15.02.2005). The Foreign Investors Association (YASED), whose president Yöneyman had previously been, sharply criticized his detention and warned from the negative effects it will have on foreign investments (*Milliyet*, 16.02.2005). Yöneyman was released after a few days, and immediately retired from his position (*Radikal*, 19.02.2005).

In March 2005, the public prosecutor Okumuş opened a lawsuit at the High Criminal Court in Istanbul against 18 employees of Roche and Beşer as well as SSK managers.[17] The indictment charged them with having violated the Law on Prevention of Benefit-Oriented Criminal Organizations (*çıkar amaçlı suç*

[17] Okumuş used to be a public prosecutor at the State Security Court (*Devlet Güvenlik Mahkemesi*, DGM) (*Hürriyet*, 09.03.2005).

örgütleriyle mücadele kanunu) and for having rigged the bids for the SSK pharmaceutical tender (*İstanbul Cumhuriyet Başsavcılığı*, 2005). The SSK managers were also charged with abuse of office and for having purchased pharmaceuticals not via tender, but through direct supply channels (*Hürriyet*, 07.03.2005). For these crimes the public prosecutor demanded prison sentences between two and eleven years. Paradoxically, the indictment claimed that the Turkish state per year pays 6 billion USD too much for medicines. During the trial, Orhan Canpolat, one of the accused SSK managers, correctly pointed out that this was more than the total size of the Turkish market (*Hürriyet*, 10.06.2005). During the case it became clear that the lawsuit was driven by the judiciary and that the AKP government was not supporting the indictment. Okumuş directly criticized the government:

> Even though the state is robbed regarding pharmaceuticals in a systematic and organized manner, the Ministry of Health and the Ministry of Labor are not following the lawsuits. No steps have been taken to recover the damage. When the investigation report found that the events occurred "without the intention of the firms," it created an impression of cronyism. The covering up of facts leads to conviction. (*Sabah*, 30.05.2006; author's translation)

Moreover, it is notable that the AKP government, at least initially, did not dismiss the SSK managers under accusation, which would have been in its power as it was in control of all the relevant ministries. One of them, Hülya Özdemir, was even appointed to head the newly established Medical and Economic Evaluation Committee of the SGK in 2007 (*Hürriyet*, 05.12.2007).

After the accusations had become public several state institutions began to carry out investigations. In September 2004, the Turkish Competition Authority decided that Roche had not caused public damage (Yilmaz et al., 2012). In 2005 the

Prime Ministry Inspection Board undertook a comprehensive investigation of the case and issued three reports, all of which, by function, had to be approved by Prime Minister Erdoğan (Prime Ministry Inspection Board, 2005a; 2005b; 2005c). In sum, the reports found that there had been public damage that had to be compensated, and that the Competition Authority should revise its decision. In 2006, the Competition Authority reconsidered its unanimous decision of 2004 and fined Roche 4.4 million TL for distortion of competition (*Radikal*, 14.07.2006).

In 2008, the High Criminal Court acquitted Faruk Yöneyman and the 17 other defendants of having founded and participated in a "benefit-oriented criminal organization" and referred the remaining, less serious indictments to a lower criminal court (*Asliye Ceza Mahkemesi*). The court stated that its decision had taken into account a written statement it had received from the Prime Ministry Inspection Board which conceded that the there had been wrong information in its earlier reports (*Radikal*, 29.03.2008).[18] Nevertheless, in February 2010 Roche paid 5.2 million TL and the Turkish state recovered the incurred damage (*Hürriyet*, 16.05.2010).

Beyond the original lawsuit, which investigated the over-pricing of one particular product sold to the SSK in December 2003, the Roche case generated a larger spin-off case. We recall that Turkey introduced a new pricing system in January 2004. As a result of its investigations into the pricing practices of Roche, the Prime Ministry Inspection Board found that Roche and other producers were not complying with the rules of the external reference pricing system, that is, that they were not setting their prices in Turkey according to the lowest price in the reference countries. This led to the opening of a multi-defendant lawsuit in May 2007 against 30 pharmaceutical producers that were accused for having incurred "public damage"

[18] In 2009 the Court of Appeals (*Yargıtay*) repealed the decision (with the exception of Veysi Mungan's acquittal) and the case is currently being reopened (*Hürriyet*, 04.08.2009).

by setting illegally high maximum prices. The list of defendants included basically all large foreign and local producers (*Hürriyet*, 08.02.2007). The case is not closed yet, but several producers appear to have settled claims with the state.

The case of Roche's cancer drug Neupogen may be illustrative of how the state used its position as the largest buyer to increase the compliance of producers with the new pricing system. In September 2006, the Ministry of Finance took Neupogen off the public reimbursement list (*Hürriyet*, 13.09.2006). A few weeks later, Roche's new CEO George Hadjiev told the media that the company had paid 1.4 million TL to the Ministry of Health to recover the damage created by announcing a too high reference price for the drug (*Medimagazin*, 18.10.2006). Just about a week later, the Ministry of Finance, on request of the Ministry of Health, included Neupogen again to the public reimbursement list (*Hürriyet*, 27.10.2006).

For the purpose of this thesis (that is, to explain why Turkey shifted to strict price controls in 2009), the Roche case is especially relevant for two reasons. First, the scandal and its ramifications appear to have helped the AKP government to implement the new regulatory framework for pharmaceutical pricing. The Roche case pointed to the institutional deficiencies of Turkey's fragmented pharmaceutical reimbursement system. Instead of firing SSK managers for malpractice, the government unified public reimbursement rules and abolished SSK drug tenders just half a year after the scandal had become public. Certainly, the AKP's prior plans for health and social security reform suggest that this reform would have been proposed even if the Roche scandal had never happened. But it is likely that the scandal helped the AKP reformers to implement their ideas. One may want to add that there is some irony in the fact that the Roche scandal, which revealed one instance of SSK purchasing at exorbitant cost, may have helped the AKP government in abolishing

the SSK system of drug purchasing and provision that had until then been the most cost-efficient of all the public institutions.

Moreover, the subsequent multi-defendant lawsuit over pricing behavior appears to have aided the implementation and institutionalization of the new pharmaceutical pricing system. In particular, the lawsuit increased private compliance with pricing regulations. One of the industry insiders that I interviewed expressed that the Roche case, and especially the arrest of the Roche CEO, had greatly reduced corruption in the Turkish pharmaceutical industry; companies decided to increase compliance out of fear of facing legal action (personal communication, interview 8).[19] Hence, the Roche-Beşer-SSK case does not seem to have been an anomaly. While the Roche scandal was neither produced nor especially nurtured by the AKP, one interviewee suggested that the government has been using the case a means of intimidation (*gözdağı*) to implement its pharmaceutical reforms (personal communication, interview 11).

A second way in which the case is likely to have affected the course of events examined in this thesis, relates to the policy-makers' knowledge about the cost structure of the pharmaceutical industry. The three reports written by the Prime Ministry Inspection Board most probably only revealed small parts of the information gathered, and the documents secured in the first police raid most likely revealed otherwise classified company data. Indeed, one of my interviewees believed that through the investigations "the government found out the real average price of production" (personal communication, interview 5). Hence, the government's direct confrontation with the high level of profitability rendered the pharmaceutical

[19] Here I refer exclusively to compliance with pricing and reimbursement regulations. Corruption may be more prevalent in the pharmaceutical hospital market, which operates under public procurement law, and in areas such as the producers' direct drug promotion to doctors.

industry as a field in which price regulation is economically feasible. In addition, public opinion was affected by the case, which made stricter control of pharmaceutical profits politically, too, more feasible and perhaps even attractive. This was to turn out relevant when the government urgently wanted to cut health care spending in 2009. The government's knowledge about the high profits of multinational drug producers and the public scandalization of those are likely to have decreased the concern of the AKP's political leadership to help sustain those profits.

Conclusion: The Changed Contexts of Pharmaceutical Prices

As the aim of the subsequent chapter is to explain Turkey's shift to strict drug price controls in 2009-2012, what can be said, by means of conclusion of the present chapter, about the contexts of pharmaceutical prices going into 2009? First and foremost, no one seemed to see the shift to stricter regulations coming. While a company like Roche had disinvested after the arrest of its CEO, it was quick to return and pledge to make Turkey one of its local hubs (*Hürriyet*, 08.02.2009). The Turkish market was predicted to annually grow by 11-14% until 2013 and to be one of the world's seven "pharmerging" markets (Hill & Chui, 2009). For the multinational pharmaceutical companies, Turkey seemed particularly attractive during the "global economic crisis [as] growth in publicly funded markets is likely to ameliorate some of the stress" (Hill & Chui, 2009, p. 7). In February 2009, a foreign executive stated that Turkey's pharmaceutical sector had been the sector "least affected by the crisis" for which he saw a "bright future" (*Hürriyet*, 03.02.2009).

In Turkey, the growth of the "publicly funded market" came in form of the AKP's health care and social security reform. As a result, the share of the population

that was eligible for public reimbursement of medicine consumption has increased from only 58% in 2002 to near-universal 96% in 2010. While public drug expenditure has decreased in terms relative to GDP and public health expenditure, in absolute terms it has increased continuously at high rates. From 2002 to 2009, the average annual growth of public drug expenditure was 17.5%. Aware of the burden this creates for the social security system and public finance, the AKP government has since the very beginning emphasized the need to contain public expenditure on medicines and to achieve this especially by means of stricter price regulations. However, despite this rhetorical commitment and some minor policy instruments to keep the growth rate of public drug expenditure under control, the AKP government implemented no policy in the 2002-2008 period that seriously confronted the interests of pharmaceutical producers in rising drug expenditure and continuously high prices.

What the AKP government did implement, on the other hand, was a comprehensive reform of the regulatory framework for drug pricing and reimbursement. This reform began in early 2004 as a component of the AKP's health care reform, was probably facilitated by the Roche scandal that hit the industry in the same year, and was fully implemented by 2008. While this very comprehensive reform eased the bureaucratic administration and political oversight of price regulation, it was in the final analysis neutral on public expenditure and prices. Besides, the AKP government also introduced data exclusivity rules in 2005 that strengthened the implementation of the global regime of intellectual property rights in Turkey, and which were believed to weaken local generic industry and to increase public pharmaceutical expenditure.

It is difficult not to conclude that the major policy changes in health care and pharmaceutical regulation implemented in 2002-2008 were essentially pro-business and pro-market. Certainly, they also improved population health and the equity of the public health care system among social groups (perhaps at the cost of formerly privileged groups), but the profitability of the pharmaceutical industry (and arguably many other sectors of the health care economy) was not seriously compromised in this period. Price regulation remained lenient despite the new regulatory framework. From this perspective, it appears that the AKP's pharmaceutical price policy in the 2002-2008 was both populist and neoliberal.

However, beneath the surface of these *policy* changes that did not seriously challenge the profit interests of pharmaceutical producers, there occurred deeper *political* changes that prepared the ground for the subsequent policy change toward stricter state regulation of pharmaceutical prices. First, with the AKP's accession to power in 2002, the Turkish government in electoral terms came to be primarily supported by the poorer segments of society. This continued to be a fact going into 2009, whether the lower classes had materially benefited from the AKP's previous policies or not. Second, in 2002-2008 the AKP's governing capacity was substantially strengthened. In the area of pharmaceutical policy this is represented in form of a reformed regulatory framework and the industry's increased compliance with it. Third, while the AKP's political leadership apparently chose not to scandalize it, the Roche case left pharmaceutical producers vulnerable to being targeted in the future. Trough the Prime Ministry's investigations the AKP government gained insight into the price structure of producers, and the extensive media coverage gave the pharmaceutical industry a reputation for fraudulent overpricing.

The contexts examined in this chapter made the government's subsequent shift to strict pharmaceutical price controls by no means inevitable. But they set the stage in important ways. Eventually, the shift appears to have been brought about by a combination of these policy and political contexts, and by more specific events and political choices that happened in 2009. It is to those events and choices that the subsequent chapter turns to.

CHAPTER 3

TIGHTENING THE REINS: THE SHIFT TO STRICT PHARMACEUTICAL PRICE CONTROLS, 2009-2012

This chapter turns to the years 2009-2012, the period in which the phenomenon this thesis seeks to explain occurs. While the regulatory framework for the governance of drug prices had been reformed comprehensively since 2004, this early period of AKP rule had seen relatively little actual regulation (i.e., reduction) of pharmaceutical expenditure or prices. Only after the introduction of the Pharma Budget in September 2009 did public pharmaceutical expenditure and average prices begin to decrease significantly. The purpose of this chapter is to explain why and how this episode of substantial regulation of prices came about. To this end I will first attempt to evaluate the magnitude and significance of the 2010-2012 decreases in pharmaceutical costs and prices, and then put forth an argument regarding the political-economic sources of this regime change in pharmaceutical price policy.

Measuring the Shift

In 2009, the Turkish government introduced a "global budget" for public pharmaceutical expenditure as part of its medium-term financial program. This budget capped total government spending on pharmaceuticals at 46.8 billion TL for the 2010-2012 period.[20] The global budget proposed annual expenditure figures for

[20] The global budget excludes the pharmaceutical expenditure of hospitals for inpatients, which is defined as treatment cost.

this period. Table 3 shows the prescribed Pharma Budget for 2010-2012 and actual public pharmaceutical expenditure over the last decade.

Table 3. Pharmaceutical Expenditure and Pharma Budget, 2002-2012

	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Public Drug Expenditure (bn TL)	5.2	6.8	7.9	8.7	10.1	11.1	13.0	16.1	15.3	15.9	14.8
Annual Growth (%)	-	30.0	16.1	10.0	16.3	10.3	16.4	23.9	-4.5	3.4	-6.9
Pharma Budget (bn TL)	-	-	-	-	-	-	-	-	14.6	15.6	16.7
Annual Growth (%)	-	-	-	-	-	-	-	-	-	6.6	7.1

Sources: AİFD (personal communication), MoF (2012), SGK (2010), TURKSTAT (2011), author's calculation.

The purpose of the Pharma Budget was to bring down public pharmaceutical expenditure substantially at once (some 9% from 16.1 billion TL in 2009) and to thereafter limit expenditure growth (some 7% annually). The budget was to be enforced over the three-year period, that is, overshooting in one year would lead to further budget cuts in the subsequent year, which explains why actual expenditure changed at rates very different to those prescribed by the budget.[21]

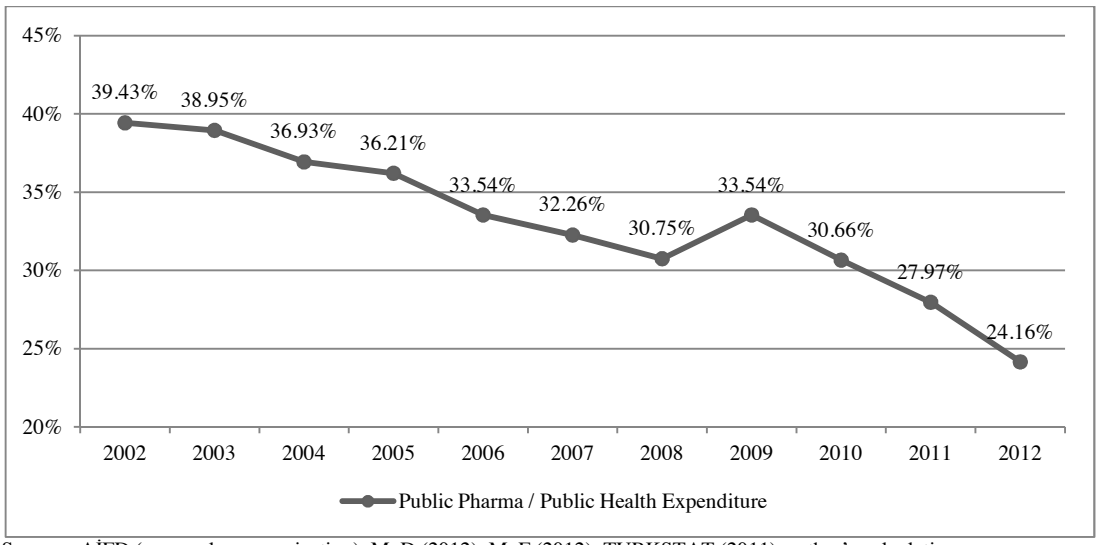
The evolution of nominal expenditure figures suggests prima facie that global budgeting was highly effective in limiting public expenditure. In 2012 public drug expenditure was an estimated 14.8 billion TL and therewith some 8% below its peak in 2009. One way to assess the impact of the Pharma Budget is by speculating how the world may have been without it. For instance, one can extrapolate from the growth of public expenditure before 2010. The compound annual growth rate (CAGR) of 2004-2009 was 15.3%.[22] If public expenditure had grown at this previous rate, then drug expenditure in 2010-2012 would have totaled 64.5 billion TL (18.5,

[21] The Turkish government continued global budgeting for public pharmaceutical expenditure beyond 2012. For 2013 a global budget of 15.6 billion TL has been announced (*Eczacının Sesi*, 06.02.2013). One important change is that no three-year budget has been announced this time, but the government is believed to have one (personal communication, interview 35).

[22] 2004 was picked as the base year for the estimate to be relatively conservative. 2004 yielded the lowest CAGR when compared to the alternative base years 2002-2008.

21.3 and 24.6) instead of the actual 46.0 billion TL. From this perspective, one can argue that a total of 18.5 billion TL in public drug expenditure was saved during (but not necessarily all by) the implementation of the Pharma Budget.

Public pharmaceutical expenditure was contained even more significantly in relative terms. This is because in the period from 2009 to 2012 the growth rate of public pharmaceutical expenditure (-8%) was well below the respective growth rates of total public health expenditure (+28%) and the GDP of Turkey (+49%). As a result the share of public pharmaceutical expenditure in GDP fell swiftly from 1.69% in 2009 to 1.04% in 2012, while the share of public health expenditure did not fall significantly (2009: 3.34%, 2012: 3.27%) in the same period (Figure 1). One result of this is that the share of public drug expenditure in total public health expenditure has been falling significantly over the last decade, as shown in Figure 3.



Sources: AİFD (personal communication), MoD (2012), MoF (2012), TURKSTAT (2011), author's calculation.

Figure 3. Public pharmaceutical expenditure (% public health expenditure).

The only exception was 2009, when Turkey was hit by the negative repercussions of the global financial crisis. While the "pharma share" had already been declining in

2002-2008, this was mostly due to the stronger growth of public non-drug health expenditure (Figure 1). In contrast, the declining pharma share in 2010-2012 was driven by the nominal decline in pharmaceutical expenditure. The declining pharma share in Turkey over the last decade per se is certainly not extraordinary. The pharma share of countries' public health expenditures tends to decline with rising GDP. What is remarkable about the Turkish case is the short period of time in which the pharma share decreased.

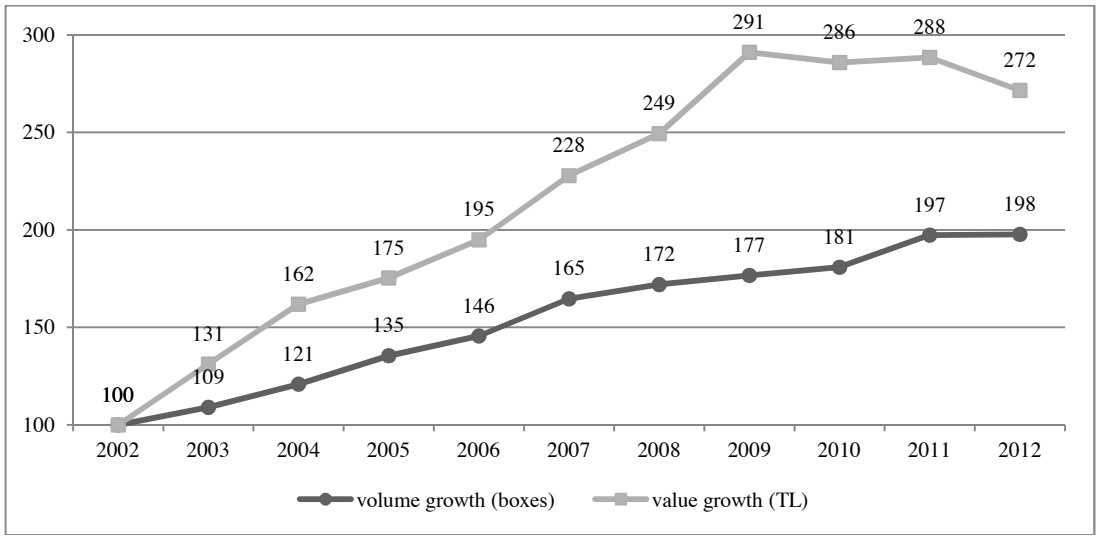
Having established the fact that public pharmaceutical cost containment was relatively effective in the AKP era, the question arises how these expenditure savings were realized. In theory, public health care systems have two basic options to bring down their pharmaceutical cost. First, they can, via some form of state regulation, reduce the average price and hence total cost of the pharmaceutical volume they are covering. Alternatively, they can decrease total public coverage of private pharmaceutical consumption, by, among other things, increasing patients' out-of-pocket payments (including co-payments), pursuing an OTC-strategy and hence a reduction of reimbursed prescription medicines, or through attempts to bring down prescription rates in the first place.

The AKP government has predominantly relied on the first of these two options. It quite successfully attempted to regulate drug prices in order to contain the cost of public health care without having to cut public financing significantly. While it did start a campaign to promote "rational drug use," it – at least until recently – avoided to implement an OTC-strategy or to increase out-of-pocket payments substantially. The proposition that decreasing prices were driving public pharmaceutical cost containment is confirmed when analyzing indicators of market growth (Table 4, Figure 4).

Table 4. Pharmaceutical Market Size, 2002-2012

	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Market Volume (bn boxes)	0.8	0.9	1.0	1.1	1.1	1.3	1.4	1.4	1.4	1.6	1.6
Market Value (bn TL)	4.8	6.2	7.7	8.3	9.3	10.8	11.9	13.9	13.6	13.7	12.9
Average Price (TL/box)	6.03	7.26	8.08	7.81	8.08	8.35	8.75	9.94	9.54	8.82	8.29

Note: Prescription drug market; at nominal ex-manufacturer prices, including public discounts.
Source: İEİS (2013); author's calculation.



Notes: Prescription drug market; at nominal ex-manufacturer prices, including public discounts; 2002 = 100.
Source: İEİS (2013); author's calculation.
Figure 4. Pharmaceutical market growth, 2002-2012.

Nominal Market value began to stagnate in 2010 and even decreased in 2012, while market volume continued to increase at a relatively constant rate. The average price of drugs in the market increased by 65% between 2002 and 2009, but began to steadily fall thereafter. For the pharmaceutical market this was a large change. The period until 2009 had seen very high market growth, to the extent that Turkey was considered one of the world's seven "pharmerging markets" (Hill & Chui, 2009).[23]

Another important indicator of the way in which pharmaceutical cost containment was achieved in Turkey is the "public share" in expenditure. The concept of cost sharing refers to the relative distribution of cost among private and public sources. In Turkey, the public share in health financing was at 73% in 2008

[23] The other six "pharmerging markets" were Brazil, China, India, Mexico, Russia and South Korea.

(OECD, 2012), while the public share in pharmaceutical cost was well above that, at an estimated 85% (BCG, 2011, p. 120).[24] In contrast, in the OECD the pharmaceutical public share was at 61%, while the total health public share was at 72% (data from 2005; OECD, 2008, p. 38). Hence, Turkey is quite unique in two aspects. It has one of the highest public shares in pharmaceutical financing among all OECD countries and is one of the few countries whose public share in pharmaceutical cost is higher than in total health expenditure (OECD, 2008, p. 39).

When examining variation in public share over time, a decreasing public share could be interpreted as a "retreat of the state" from pharmaceutical financing. For instance, this happened in Italy during the 1980s and 1990s, when the government reduced its public share in the cost, while total cost was rising (Carone, Schwierz, & Xavier, 2012; Guillén & Cabiedes, 2003). Such a process of state retreat cannot quite be observed in Turkey over the 2002-2012 period. Admittedly, there were signs in 2012 that the Turkish state planned to increase the average out-of-pocket payment somewhat and therefore the private share in pharmaceutical financing, especially through reducing the number of drugs which are reimbursed at 100% (*Bugün*, 25.02.2012; *Hürriyet*, 24.02.2012). However, these are developments beginning at the end of the period under study here.

Broadly speaking, 2002-2012 was a period of extension of the public financing of pharmaceuticals with two critical factors being the granting of pharmaceutical reimbursement to Green Card holders in 2005 and the extension toward universal health insurance (including pharmaceutical coverage) since 2004. One can say that, while other areas of Turkey's health care system became increasingly privatized in

[24] Hard data on Turkey's pharmaceutical public share are not available, primarily due to insufficient statistics on private pharmaceutical expenditure (state expenditures naturally are better monitored). However, I came across several estimates of the public share in my interviews, ranging from 80-95%.

the 2002-2012 period, the financing of the population's pharmaceutical consumption remained firmly in the hands of the state. Turkey achieved pharmaceutical cost containment then through a sharp reduction in pharmaceutical prices and not trough retreat from public financing.

But how exactly did Turkey manage to reduce pharmaceutical prices, and how much of this change in average prices can really be attributed to political control? In order to answer this question we should examine in more detail the regulatory changes that were implemented since 2009. Most prominently, in 2009, 2010 and 2011 reference factors used in maximum pricing were decreased and mandatory public discounts were increased. Table 5 shows the evolution of reference factors and public discounts since the introduction of this pricing system in 2004.

Table 5. Reference Factors and Public Discounts for Producers, 2004-2013

		Original drugs without generics	Original drugs with generics	Generics drugs	20-year drugs above 6.79 TL
Feb. 2004	Reference Factor	90	90	70	-
	Public Discount	-	-	-	-
	Total Price Factor	90	90	70	-
Apr. 2004	Reference Factor	100	100	80	-
	Public Discount	-	-	-	-
	Total Price Factor	100	100	80	-
Feb. 2005	Reference Factor	100	100	80	-
	Public Discount	4[a] / 11[b]	4[a] / 11[b]	11	-
	Total Price Factor	89[a] / 96[b]	89[a] / 96[b]	71.2	-
Sep. 2008	Reference Factor	100	100	80	-
	Public Discount	11	11	11	-
	Total Price Factor	89	89	71.2	-
Sep. 2009	Reference Factor	100	60	60	-
	Public Discount	24	11	11	-
	Total Price Factor	76	53.4	53.4	-
Dec. 2009	Reference Factor	100	66	66	100
	Public Discount	23	11	11	89
	Total Price Factor	77	58.74	58.74	89
Dec. 2010	Reference Factor	100	66	66	100
	Public Discount	32.5	20.5	20.5	20.5
	Total Price Factor	67.5	52.47	52.47	79.5
Nov. 2011	Reference Factor	100	60	60	80
	Public Discount	41	28	28	28
	Total Price Factor	59	43.2	43.2	57.6
Mar. 2013	Reference Factor	100	60	60	80
	Public Discount	41	28	28	20.5[c] / 28[d]
	Total Price Factor	59	43.2	43.2	63.6[c] / 57.6[d]

Notes: All values in percent. The table only includes product groups to which external reference pricing is applied. The total price factor is derived by multiplying the reference factor with (100 - public discount). (a) Products older than 6 years; (b) products younger than 6 years; (c) products between 6.79 TL and 10.21 TL; (d) products above 10.22 TL.
Sources: Council of Ministers (2004a; 2004c; 2009b; 2009c; 2011b), MoF (2005), SGK (2008; 2009a; 2009b; 2010c; 2011; 2013).

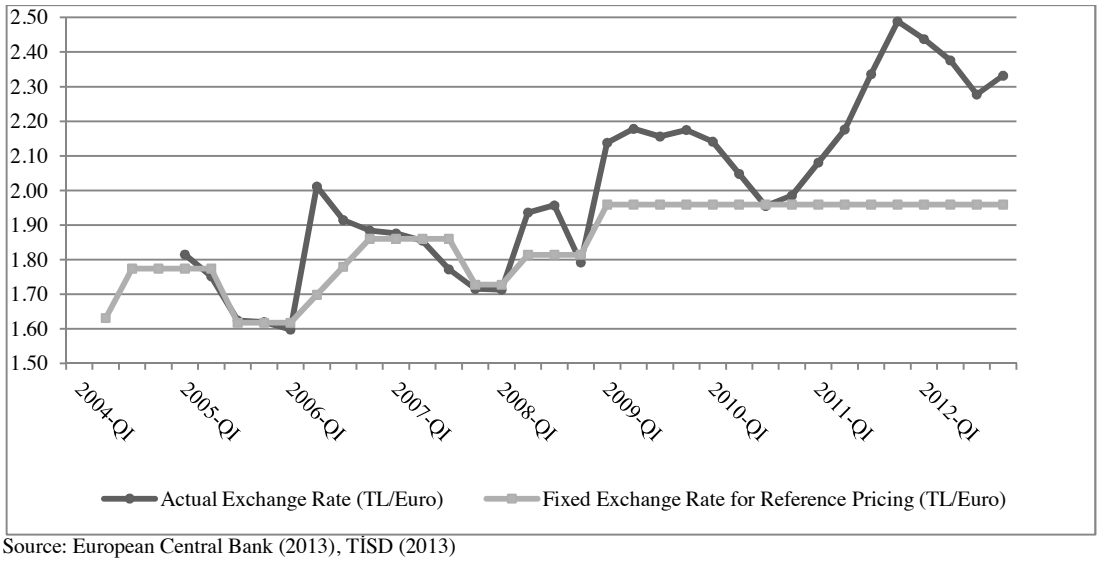
The "total price factor" that is derived in Table 5 combines the impact of reference factor and public discount and hence represents the proportion of actual prices in Turkey (after the application of discounts) to list prices (before the application of discounts) in the respectively cheapest reference country. Let us consider an example of an original drug without a generic alternative in early 2009. Among the reference countries, the drug is cheapest in Greece, where it conveniently costs 100 Euro. Say the exchange rate was 2.00 TL/Euro at the time, then the reference price of the drug is 200 TL. Because it is a proprietary drug, the maximum price in the Turkish market is 100%, so exactly these 200 TL. The producer is then allowed to sell the drug for 200 TL in Turkish pharmacies. But if the producer wants to enter the product on the positive list, that is, if it should be eligible for public reimbursement, then the producer needs to grant a 24% mandatory discount and thus reduce the price of the product to 148 TL.

The figures in Table 5 provide an overview of how prices changed after the introduction of the Pharma Budget. The change of the total price factor is a good indicator of how actual prices of the different product groups have changed in relation to list prices abroad. In any case, if reference prices (list prices) have not increased abroad, which they hardly did in the period under observation, then a reduction of the total price factor (for off-patent originals) from 89% in early 2009 to 43.2% in early 2012 means that this drug's price was about halved. However, these figures must also be treated with caution. While maximum prices derived through external reference pricing are universally applied, the official public discounts are only benchmarks, exceptions to which are granted by the SGK. This last point is important because many such exceptions were granted, after long negotiations with producers, when the SGK had last increased public discounts in 2011.

It is unfortunately difficult to compare actual prices in Turkey with actual prices in other countries, because the discounts granted by producers (and distributors) vary even within countries when social security funds separately negotiate different levels of discounts. For instance, this is the case in Germany and the United States, but was also the case in Turkey until 2005. Negotiated discount levels are sometimes even kept secret, as published low price agreements in one market may create price pressure in other markets (*Tageszeitung*, 17.05.2012). For this reason it is difficult for countries to take discounted actual prices as reference prices.

Not illustrated in Table 5 are the regulations regarding internal reference pricing (*eşdeğer ilaç uygulaması*), which had already been introduced in 2008 to regulate the reimbursement rates for generic drugs with equivalent active ingredients. Accordingly any generic drug could only be reimbursed up to 15% above the price of the cheapest equivalent generic. In 2011 this margin was reduced to 10%. As has been discussed above, reimbursement rates of competitive drugs can function as de facto maximum prices.

Possibly the single most effective instrument of drug price control of the period, however, was a rather unusual one. Since April 2009 Turkey has been using a fixed exchange rate of 1.9595 TL/Euro for translating the reference prices in European reference countries into maximum prices for the Turkish market. Figure 5 illustrates the development of the actual exchange rate vis-à-vis the exchange rate used to determine pharmaceutical price ceilings.



Source: European Central Bank (2013), TİSD (2013)
Figure 5. Real exchange rate and fixed pharmaceutical exchange rate, 2004-2012.

The impact of this measure must have been significant. Let us consider an example. In August 2011, the exchange rate peaked at 2.58 TL/Euro. When the reference price (that is the cheapest price in any reference country) of an original-without-generic drug product was 100 Euro, then the maximum price in Turkey was 195.95 TL, while it would have been 258 TL according to current exchange rates.

In a crude attempt to quantify the impact of the fixed exchange rate on drug prices in Turkey, one can compute the average actual exchange rate, which was 2.2150 TL/Euro from 2010 through 2012. Hence, the actual exchange rate was on average 25.55% above the fixed exchange rate used for the translation of reference prices. Everything else being equal and assuming that all pharmaceuticals were actually priced at allowed maximum prices and that all pharmaceuticals reimbursed by the government were included in the external reference pricing system (both of which was not the case), the fixed exchange rate may have translated into cost containment of 11.8 billion TL over the three-year implementation of the Pharma Budget. In December 2011, the industry estimated its own loss due from the fixed exchange rate at 2.5 billion TL (AİFD, İEİS, & TİSD, 2011). In any case, the

expenditure effect of this regulatory instrument was likely several billion TL and it must have been stronger in 2011 and 2012 when the average actual exchange rate was higher.

Another indicator of the significance of the fixed exchange rate is the fact that the pharmaceutical industry has made exchange rate adjustment one of its central political demands (AİFD, İEİS, & TİSD, 2011, *Eczacının Sesi*, 06.02.2013). For one thing, this certainly points to the financial magnitude of the measure. In addition, it is likely that the pharmaceutical industry perceives exchange rate adjustment as a *relatively* promising area where public cost containment could be relaxed. In fact, existing regulations do prescribe adjustment, which allows industry representatives to employ a language of "we want compliance with existing regulations" (*Akşam*, 22.04.2012).

One further measure of success of the Turkish pricing regime is that a rising number of other emerging political economies that are attempting to control drug prices are using Turkey as a reference country in their own reference pricing systems. As of November 2012, a total of nine countries was referencing Turkey, namely Russia, South Korea, Saudi Arabia, Egypt, Macedonia, Morocco, Iran, Oman, and Colombia (personal communication, interview 32).

The Turkish government's active use of the three instruments of drug price control (reference price factors, mandatory public discounts, and exchange rate fixing) since 2009 has without doubt driven the decrease of average prices and public expenditure. This does not mean, however, that pharmaceutical prices should be considered as fully determined by domestic political sources. There are important non-political, non-domestic sources of pharmaceutical prices which should briefly be considered here. For instance, one major international source of falling drug prices in

Turkey has been Europe's financial-turned-fiscal crisis. Austerity measures in countries such as Greece and Spain have included extensive cuts to pharmaceutical budgets and in turn led to falling average prices of drugs in those countries. Because of the way external reference pricing works, maximum prices in Turkey fall either when reference factors are lowered by regulators, or when the reference price abroad decreases by a certain margin.

In January 2012, the current reference price of a combined 22% of drug products in the Turkish market came from Spain or Greece (İEGM, 2012a; author's calculation). Through this mechanism, decreasing drug prices in Greece and Spain have spilled over to the Turkish market. This example suggests that one important reason why public drug expenditure in Turkey decreased in the 2010-2012 period was the European fiscal crisis. But this does not mean domestic regulation had no part in this. In fact, Turkey's external reference pricing system functioned as the crucial interface between foreign and domestic drug prices. The pre-2004 cost-plus pricing system would not have transmitted falling international drug prices. Thus, it was the 2004-2008 reform of the regulatory framework which made this "non-political" source of cost containment possible in the first place.

Besides the European fiscal crisis, a phenomenon known as the "patent cliff" has put pressure on the average price of pharmaceuticals. In recent years, many "blockbuster" drugs have gone off patent, leading to the entrance of generic competition and often rapid decrease in prices. Most famously, perhaps, Pfizer's best-selling, cholesterol-lowering drug Lipitor lost its patent protection in November 2011. As a result Pfizer's revenues from Lipitor dropped from 9.5 billion US$ in 2011 to 3.9 billion US$ in 2012. The process has been described as the pharmaceutical industry "going generic." It is uncertain if it has come to stay or if a

wave of new blockbuster drugs (possibly in biotechnology) will again increase average drug prices. But in the 2010-2012 period this process certainly put pressure on prices.

So far, this thesis has considered drug prices and the pharmaceutical market from an aggregate perspective. While this is a useful simplification for many aspects of the issue, the pharmaceutical market is in reality highly fragmented, producing several distinct and rigid submarkets. This fragmentation stems primarily from the nature of pharmaceuticals. In contrast to most other products, most pharmaceuticals are not substitutable with each other. After all, a diabetic would not buy an antibiotic instead of insulin, no matter how much cheaper or better it is. Recognizing the fragmentation of the pharmaceutical market is important for understanding the reasons behind effective price and cost regulation. It seems that political attempts to reduce prices tend to be more successful in some submarkets. In other submarkets again, the political will behind cost containment may be smaller.

Indeed, price decreases in the 2009-2012 period in Turkey were not homogenous across products. Table 6 illustrates this by providing data of the 30 top-selling (according to revenues) drugs in 2009. Together these 30 drugs accounted for 2.4 billion TL in revenues, or for more than 17% of the total prescription drug market (most of the drugs on the list are prescription drugs). This translates into higher expenditure for the state, as SGK additionally pays mark-ups to warehouses, pharmacists and value-added tax to the treasury. Based on revenue and sales data, the average price of these 30 drugs in 2009 and in 2012 is calculated. No data is available (-) for 8 drugs, because in 2012 those were not among the 50 top-selling anymore, most likely because their price decreased so much, or possibly because they were taken off the market.

Table 6. Top 30 Pharmaceuticals, 2009-2012

Drug (Producer)	Group	Revenue (rank)		Revenue (mn TL)		Boxes (mn)		Average Price (TL)		
		2009	2012	2009	2012	2009	2012	2009	2012	Δ (%)
Seretide (GSK)	2	1	9	159	89	2.3	2.4	69.84	36.67	-48%
Spiriva (Boehringer)	1	2	2	123	103	2.4	3.3	50.59	31.54	-38%
Glivec (Novartis)	2	3	27	113	55	0.03	0.03	3635.50	1896.41	-48%
Foradil Combi (Novartis)	4	4	17	107	65	2.3	2.3	45.90	28.78	-37%
Co-Diovan (Novartis)	2	5	21	101	64	4.5	6.0	22.46	10.58	-53%
Herceptin (Roche)	1	6	1	101	132	0.1	0.2	995.65	799.49	-20%
Augmentin (GSK)	4	7	4	96	99	10.9	15.2	8.78	6.51	-26%
Lansor (Sanovel)	3	8	3	89	99	6.2	9.7	14.29	10.22	-28%
Lantus (Sanofi)	1	9	6	86	96	1.0	1.7	81.98	57.04	-30%
Cefaks (Deva)	4	10	43	83	41	4.2	6.0	20.05	6.85	-66%
Novomix 30 (Novo Nordisk)	1	11	7	82	95	1.6	2.4	50.89	40.50	-20%
Lipitor (Pfizer)	2	12	-	78	-	1.5	-	50.65	-	-
Octagam (Berk)	1	13	-	77	-	0.1	-	1106.92	-	-
Arveles (Ulagay)	2	14	35	75	48	10.1	12.8	7.46	3.73	-50%
Cipralex (Lundbeck)	2	15	-	73	-	3.2	-	23.15	-	-
Taxotere (Sanofi)	2	16	-	72	-	0.2	-	455.45	-	-
Symbicort (Astra Zeneca)	4	17	33	70	48	1.2	1.3	55.97	37.64	-33%
Beloc (Astra Zeneca)	4	18	8	68	95	14.7	18.9	4.61	5.04	+9%
Enfexia (Bilim)	4	19	-	68	-	3.6	-	19.04	-	-
Remicade (MSD)	1	20	13	64	70	0.1	0.1	799.24	559.27	-30%
Humira (Abbvie)	1	21	10	64	82	0.0	0.1	1732.73	1068.48	-38%
Infex (Celtis)	3	22	-	63	-	2.8	-	22.54	-	-
Enbrel (Pfizer)	1	23	14	60	70	0.1	0.2	678.58	465.22	-31%
Crestor (Astra Zeneca)	2	24	-	59	-	1.7	-	35.06	-	-
Neurontin (Pfizer)	2	25	38	58	43	1.6	2.3	36.10	19.00	-47%
Plavix (Sanofi)	2	26	-	58	-	1.2	-	48.72	-	-
Atacand Plus (Astra Zeneca)	2	27	45	57	41	2.6	3.1	22.28	13.16	-41%
Nexium (Astra Zeneca)	1	28	5	56	98	2.7	7.5	20.98	13.04	-38%
Amoklavin (Deva)	4	29	18	55	65	7.5	10.1	7.34	6.38	-13%
Baraclude (BMS)	1	30	40	54	43	0.1	0.1	631.33	355.92	-44%

Note: at ex-manufacturer prices, including producer discounts; 2009 is March 2009-February 2010, 2012 is March 2012-February 2013; group key: 1=original without generic, 2=original with generic, 3=generic, 4=20-year product (İEGM, 2012a); hyphens indicate that the drug was not among the Top 50 drugs according to revenue in 2012 (which was the available data).
Source: IMS

When analyzing the date in Table 6, it turns out that the average prices of all but one drug have decreased, and the (unweighted) average price decrease has been 35%. Let us look at the six drugs that showed the lowest reductions in average price. Three of them, Augmentin (-26%), Beloc (+9%) and Amoklavin (-13%), were already among the cheapest drugs in 2009, with average prices below 10 TL. All three of these also happen to be "20-year old" drugs, whose prices have been less affected. Lansor (-28%) is a generic drug that also was not too expensive to begin with. The remaining two drugs that lost relatively little are Herceptin (-20%) and Novomix 30 (-20%). Herceptin is an on-patent biotech drug (biologic) for treating breast cancer, and Novomix is an on-patent drug for diabetes. Herceptin was the best-selling drug in 2012. This pattern is fairly representative. The average price for antineoplastic cancer drugs (ATC3 L01X, which includes Herceptin) fell by only 7% between 2009 and 2012. The average price for insulins (A10C) fell by only 20% in the same period. Moreover, only 2 out of 10 proprietary products in the 2009 top-revenue list, that were still patent-protected in 2012, had dropped in the 2012 top-revenue list.

While the interest of this study is primarily with the AKP government's general policy position to reduce drug prices, this intra-market data suggest data that prices in some pharmaceutical submarkets are significantly less regulable than in others. I will return to this issue when discussing the ways in which the government coped with availability problems of critical cancer drugs in 2010-2012. But it would seem that competitive (generic) submarkets show the highest potential for effective price cuts via political regulation, while submarkets that are both non-competitive (mostly on-patent) and perceived as critical by the public have a much lower potential for price regulation.

Explaining the Shift

The previous section has dealt with the economic aspects of stricter expenditure and price regulation in the 2009-2012 period. I have shown how the introduction of an upper limit for public pharmaceutical spending in conjunction with stricter price cuts led to significant savings in pharmaceutical expenditure. However, the Pharma Budget and the stricter price controls are only the proximate causes of decreasing average prices and industry profitability. The government's decision to implement this set of regulations had deeper political-economic reasons, the analysis of which is the purpose of the remainder of this chapter.

The political process through which stricter price controls and lower public expenditure came into existence can be best understood by answering two distinct questions, the first of which is: Why did the AKP government develop the political will to strictly regulate drug prices? I argue that the development of this political will was primarily driven by two characteristics of the AKP government, namely its commitment to fiscal discipline in times of rapidly rising health expenditure and financial crisis, and its populist use of health policy as a key instrument to generate popular support. The shift to stricter drug price controls was hence a historical product of the AKP's fiscal discipline and its health policy populism in 2009. It is in this sense that lower drug prices were an instrumental political objective of the AKP, whose actual purpose was to contain public expenditure and to maintain public satisfaction with health care.

But political will is not sufficient to explain why this policy idea could actually be implemented and maintained. Hence, the second question: Why was the AKP government able to act on its political will and successfully implement strict price

controls (a policy idea with a track-record of implementation failure)? I argue that two factors were of particular importance in accommodating the AKP government's implementation of strict drug price controls. First, effective political implementation was made possible by a new regulatory framework and a powerful and assertive political executive. Second, the government's political commitment to low drug prices was not diluted by competing policy goals in other policy areas.

Fiscal Discipline

Let me now first examine how public pharmaceutical cost containment became a policy priority of the Turkish government in 2009. Here I emphasize the interplay of the AKP government's "learned fiscal discipline," the long-term problem of making social security and health expenditure "sustainable," and the short-term requirements to budget-making in the context of the global financial crisis and ongoing negotiations with the IMF over a new stand-by agreement.

In a recent article, Ziya Öniş and Ali Burak Güven (2011) analyze how Turkey's public expenditure regime has transformed during the rule of the AKP. In the AKP government's early years, its economic policy-making was characterized by very strict fiscal discipline. This was primarily an effect of Turkey's 2000/2001 financial crisis, "which ingrained Turkey's liberal bureaucrats and politicians with the unshakeable belief that all evil came from fiscal imprudence and financial instability" (Öniş & Güven, 2011, p. 596). It is debatable to what degree the AKP's inheritance of budgetary prudence was shaped by such ideational factors as the memory of the crisis experience, or if the equally inherited stand-by agreement with the IMF was more consequential in shaping the AKP government's attitude toward

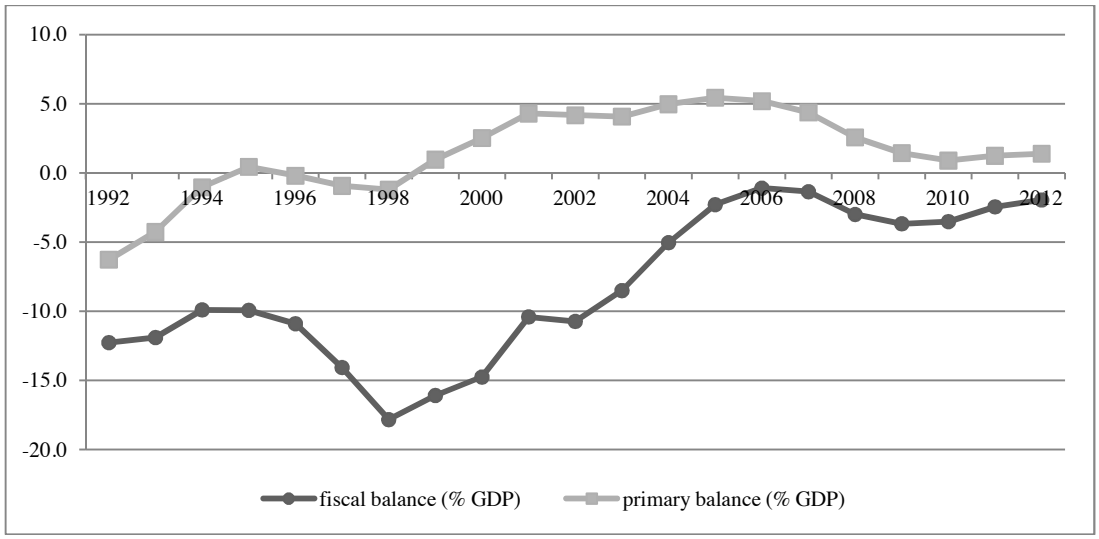
fiscal discipline in its initial years (the program lasted from 2002 to 2005 and was then extended until 2008). In any case, the AKP government (as in the area of health policy) did initially not deviate from the prudent public expenditure regime of the preceding coalition government. One result of this "learned obsession with […] financial stability" (Öniş & Güven, 2011, p. 586) was a sharp reduction of fiscal and primary deficits in the first four years of AKP rule. Öniş and Güven continue to argue that, over time, the fiscal discipline of the AKP government relaxed.

> Content with the overall economic performance, the party's attention from 2006 onward shifted toward consolidating its power by defending and expanding its coalitional base. […] By the election year of 2007, a new policy approach had matured that centred on more open deviations from the reformist path, but without endangering what the AKP leadership understood to be the foundations, however fragile, of the rapid growth status quo. (Öniş & Güven, 2011, pp. 592-593)

This new policy approach of the post-2006 AKP government has been conceptualized as "controlled populism" (Öniş & Güven, 2011; Öniş, 2012).[25] According to this interpretation, the AKP government should be considered as controlled populist, because it uses fiscal expansion and redistribution in some policy areas to generate public support (health, education, housing), but it concomitantly safeguards macroeconomic stability by governing in a neoliberal instead of populist manner in other policy areas (banking regulation, privatization, monetary policy). The concept of controlled populism is very useful for the analytical purpose of this thesis, that is, to understand the shift to strict drug price controls. It is crucial, however, to notice that fiscal discipline did not deteriorate substantially after 2006.

[25] The concept of controlled populism implicitly adopts the economic and not the political definition of populism (Piquet Carneiro, 2011).

Figure 6 illustrates the historical development of fiscal and primary deficits in Turkey.



Notes: Depicted values are three-year moving averages; underlying values for 2012 and 2013 are estimates.
Sources: 1991-1999: Kaya & Yılar (2011), 2000-2013: BUMKO (2013), author's calculation.
Figure 6. Fiscal and primary balance, 1992-2012.

Due to the populist fiscal expansion in social policy, the primary balance declined between 2006 and 2008. Since 2009, however, the government's fiscal discipline did not deteriorate further and deficits were at moderate levels (especially when compared to the "crisis-ridden" member states of the European Union). One reason behind this fiscal stabilization was the 2008 financial crisis, which renewed worries about macroeconomic stability and thus reinvigorated Turkey's "fisco-financial stability paradigm" (Öniş & Güven, 2011, p. 598).

Despite the AKP's general fiscal discipline, it vastly expanded public spending in some policy areas. One of them, public health expenditure, is of particular interest, as I want to argue that in 2009 the general need for budget cuts coincided with the more particular attempt of the government to make public health spending sustainable, that is, to reduce its rate of growth. We recall from the previous chapter, that the Health Transformation Program had been expanding public health insurance

to reach near-universal coverage, while increasing benefits for most of the insured. As a result, nominal public health expenditure more than tripled between 2002 and 2008 (Table 2). The largest and ever-increasing share of these health expenditures was managed by the country's single-payer social security fund, the SGK. Besides health, the SGK is also responsible for pension payments. In principle, it runs a premium-financed system, but since its inception the SGK always received transfers from the general budget to cover its revenue deficit. Table 7 displays the evolution of this deficit.

Table 7. SGK Expenditures and Revenues, 2002-2012

	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Expenditures (bn TL)	28	41	51	60	72	82	93	107	122	141	-
Annual Growth (%)	57	48	22	18	20	14	14	15	14	15	-
Revenues (bn TL)	20	28	35	41	54	57	67	78	95	124	-
Annual Growth (%)	50	39	24	19	31	6	18	16	22	31	-
Deficit (bn TL)	8	13	16	19	18	25	26	29	27	16	
Deficit (%)	28	32	31	31	25	31	28	27	22	12	-

Sources: SGK (2012), author's calculation.

After 2002, the nominal budget transfer to the SGK continuously rose and peaked at 29 billion TL in 2009. Because of this, a debate regarding the "sustainability" of social security ensued among policy-makers. Even though pensions accounted for a larger share of the SGK's expenditures than health care, discussions regarding the sustainability of social security financing often focused on health expenditure (*Hürriyet*, 07.08.2009). It is not surprising then, that policy proposals how "savings in health" (*sağlıkta tasarruf*) could be realized are just as old as the "transformation in health" program itself. Let me consider one example that is instructive about the difficulties to implement "savings in health." In 2006, under pressure of the IMF stand-by agreement, the AKP government made an attempt to cut health care

expenditure by 1.4 billion TL (*Hürriyet*, 05.06.2006). On 1 July 2006, the Ministry of Finance passed a communiqué that introduced the controversial "package pricing" (*vaka başına ödeme*) for outpatients (MoF, 2006). Public and private health care institutions were to be paid fixed prices for patient treatment. The policy was eventually repealed by Turkey's higher administrative court (*Danıştay*) in October 2006 (*Hürriyet*, 18.11.2006).

What is interesting in this regard is what the AKP government did *not* do in 2006 to contain health care expenditure. The IMF had explicitly proposed to reduce public pharmaceutical expenditure by implementing stricter price controls, specifically by expanding the pool of reference countries by adding some new member states of the European Union (Hürriyet, 05.06.2006). This would have likely reduced drug prices and hence the drug bill of the state. But the Turkish government did not implement this proposal. This suggests that, in 2006, pharmaceutical price controls had not yet come into the explicit focus of the AKP government as a tool to achieve "savings in health." But this also suggests that in this period the IMF was more interested in the budgetary discipline of its client Turkey, than in supporting private interests of the pharmaceutical industry.

"Savings in health" again came onto the government's agenda in 2009 (never having disappeared entirely, of course). The AKP government began negotiating with the IMF in December 2008, but a new stand-by agreement never materialized, as negations were eventually called off in March 2010. Instead, Turkey had "used the process as a quasi-anchor to steer market sentiment" (Öniş & Burak, 2011, p. 589). In the second half of 2009, Turkey was drafting its medium-term financial program for 2010-2012. And since the government was still negotiating a stand-by agreement at that time, the budget draft effectively needed to be approved by the IMF. By that

time it had become relatively obvious that Turkey was negotiating with the IMF for the "psychological effect" on investors more than for the credit line itself. But this did not change the fact that the 2010-2012 budget needed to be IMF-conform and therefore had to implement structural reforms and, as a result, savings in public health expenditure. As a matter of fact, the thee-year budget did eventually gain the approval of the IMF (*Hürriyet*, 18.09.2009).

It was in this environment of multi-layered political concern about fiscal stability and public health expenditure, when serious pharmaceutical cost containment came onto the agenda of Turkey's economic policy-makers. When health in general had already been identified as a policy area that needed to generate savings, pharmaceutical cost attracted particular attention. In 2009 the state's total pharmaceutical expenditure peaked at 16 billion TL, up from 13 billion TL in 2008. This annual increase of 24% was by far the highest in six years (Table 2). It was also reported to regulators that drug expenditure in Turkey had been growing faster than in any OECD country (*Medimagazin*, 14.09.2009).

This development became foreseeable by mid-2009. I propose that it was at this complex political-economic conjuncture, when public pharmaceutical expenditure was politically chosen as one of the central budget items through which the "savings in health" were to be realized. It was in late July 2009 when it was first reported that Deputy Prime Minister Ali Babacan was planning to introduce an upper spending-limit not only for hospital expenditures, but also for the state's total pharmaceutical expenditure (*finanstrend.com*, 31.07.2009). From this first conception of the policy idea, things proceeded quickly and apparently without much consultation with the pharmaceutical sector. In late August, the Minister of Finance Mehmet Şimşek announced that separate "global budgets" would be introduced for

private, state and university hospitals, as well as for total (outpatient) public pharmaceutical expenditure (*Hürriyet*, 31.08.2009).[26]

In mid-September 2009 then, the global pharma budget was announced as part of the 2010-2012 Medium-Term Financial Program (the "IMF budget" discussed above). Turkey's Minister of Labor and Social Security Ömer Dinçer announced that 3 billion TL of savings should be realized in public health expenditure in 2010, 1.5 billion TL or half of which would be in pharmaceutical expenditure alone (*Hürriyet*, 16.09.2009b). At that point, the specific size of the pharma budget over the next three years was not yet announced, but apparently already agreed upon internally. The question is why Turkey's economic policy-makers chose pharmaceuticals to carry such a disproportionately high share of the total cost containment in health. After all, what the budget suggested was a 9% cut in public pharmaceutical expenditure.

Reasons behind this targeting of pharmaceutical expenditure were the facts that pharmaceutical expenditure made up a very significant part of total health expenditure and that, in 2009, it was growing at a much higher rate (24%) than the total public health expenditure (14%), which was an absolute exception over the entire 2002-2012 period (Table 2). Economic policy-makers perceived savings in pharmaceutical expenditure to be most promising (personal communication, interview 21). One can conclude then that strict pharmaceutical cost containment arose as a serious policy proposal in Turkey at a time when substantial health budget cuts had to be made somewhere and drug spending due to its size and perceived

[26] The pharmaceutical consumption of hospital patients (inpatients) is not included in the state's pharmaceutical expenditure (and hence the Pharma Budget), but is considered as treatment cost.

elasticity presented itself as the best solution relative to other items in the health are budget.

Health Policy Populism

Let me now turn to the political process through which the AKP government decided that it was the producers (and, to a lesser degree, the distributors) of pharmaceuticals that were to carry the lion's share of the cost containment measures. In other words, why did the government decide to implement the agreed Pharma Budget predominantly through price cuts? In answering this question I use the AKP's characteristic "health policy populism" to explain why alternative solutions to the problem of pharmaceutical cost containment were not chosen.

Before I return to the historical process, it may be useful to make some counterfactual considerations. For analytical purposes, Turkey's shift to a strict regime of drug price controls can be separated into two political decisions, one to contain public drug spending and another one to achieve this via price cuts. The analytical separation is useful to understand that, in theory, Turkey could have contained its drug spending in a different manner. Had the AKP government been more convinced by neoliberal ideology, more considerate of pharmaceutical industrial interests, or less worried about popular (electoral) response, then the AKP's economic policy-makers could have contained public drug spending by substantially increasing (from around just 15%) the private share in drug expenditure. One key strategy could then have been to convert prescriptions drugs into not reimbursed over-the-counter drugs. Such a strategy shifts the financing of these drugs to patients. Also, it is often preferred by producers as public discounts do

not apply to OTC drugs (leading to higher prices) and promotion is allowed (leading to higher sales). As a case in point, even painkillers such as aspirin have reimbursement and prescription drug status in Turkey, while producers would usually prefer to sell them as OTC drugs (personal communication, interview 33).

But the AKP government did not choose this "neoliberal" solution to the problem of pharmaceutical cost containment. Instead it chose to implement much stricter price controls in order to achieve the envisioned cost containment without having to reduce the public provision of pharmaceuticals. I argue that this policy choice followed a distinct political logic. The AKP government used health policy in general and pharmaceutical policy in this particular case, primarily to generate popular support. In this process it focused on the needs of its own social base, willing and capable to ignore the loud, public dissent of groups not belonging to its own support coalition. Strict price controls, then, were the populist, instead of the neoliberal, solution to the fiscal problem of cost containment. It should be noted that I consider the price controls as populist primarily because they allowed the AKP government to continue to reimburse most private drug consumption and to avoid stricter cuts to non-drug health expenditure. I do not think that the fact that low drug prices could be popular in and of themselves was a major reason for the policy choice of stricter drug price controls. It was, though, a welcome side effect, and the AKP government politically exploited the situation afterwards.

In order to demonstrate how the AKP's populist use of health care and the introduction of stricter price controls were related, we need to zoom in and examine the policy debate in September 2009. The first public proposals regarding the implementation of the envisioned pharma budget were made by Turkey's top economic policy-makers at the time, Deputy Prime Minister Ali Babacan and

Minister of Finance Mehmet Şimşek.[27] These initial proposals focused on increasing generic substitution, promoting "rational drug use" (*Sabah*, 03.09.2009), and – importantly – increasing private out-of-pocket payments for pharmaceuticals (*ntvmsnbc*, 04.09.2009). At the same time cost containment measures for other areas of health expenditure were discussed, equally involving the option of higher private out-of-pocket payments. It seemed likely that the government then planned to implement savings in pharmaceutical expenditure through some mixture of price cuts and "privatization" of cost.

At that point an intervention occurred that placed the upcoming solution to the problem of drug spending control between the poles of fiscal policy and social policy. A conflict, whether genuine or staged, between Prime Minister Erdoğan and his ministers of the economy became public. At a public event, Erdoğan commented on the proposed health budget cuts:

> In the history of the Turkish Republic, never was as much money spent on social security as in the current era. [...] This is priceless. 'Sir, the budget has a deficit'. You cannot foreclose this, you cannot stop this by saying the the budget has a deficit, whatever it is. Because this project is priceless, we will do whatever it takes. From time to time I disagree on this topic with my ministers. There are some steps we need to take, because we are in a race and we need to succeed. (*Milliyet*, 03.09.2009; author's translation)

Erdoğan hence publicly rejected the idea of making cuts to the health care budget. Later he was also quoted to have said that, "we will not cut from the people's medicines" (*Hürriyet*, 01.10.2009; author's translation). A few days after Erdoğan's intervention, Şimşek responded and claimed that Erdoğan had been misunderstood.

[27] It is interesting to note that Babacan and Şimşek are the technocrats of the AKP government. Both received graduate degrees abroad in the areas of business and finance, and both had relatively long careers in private business before they entered politics in 2001 (Babacan) and 2007 (Şimşek).

The "condition" of the Prime Minister had been that the access to and the quality of health care must not suffer, not that its cost could not be reduced.

> Our dear Prime Minister, of course, supports our work, under the condition that there is no deterioration in access to health services and the quality of health services we provide. I think the message there has been misunderstood. Our dear Prime Minister supports us within that frame. You will see that we will make very serious savings in health care. We are more or less finished with the health sector reform. In recent years public health expenditure has risen from 9 billion lira to almost 38 billion lira. This is a serious increase. With pharmaceutical expenditure it is the same. (*Milliyet*, 07.09.2009; author's translation)

It appears that, at a time when it was politically uncertain how exactly the "savings in health" would be implemented, but the increase of private out-of-pocket payments was at least one of the options, the AKP's political leadership, in the person of Prime Minister Erdoğan, intervened in the until then technocratic policy process and placed a political constraint on the way in which cost containment in pharmaceuticals could be achieved. If the "savings in health" were to be realized, the economic policy-makers needed to find a way that would not reduce popular access to pharmaceuticals.

When Turkey's medium-term financial program for 2010-2012 was announced on 16 September 2009, it became clear where this political compromise was leading. The 1.5 billion TL of envisioned savings in pharmaceutical expenditure were to be realized through reducing supply sector profitability. Labor and Social Security Minister Ömer Dinçer announced at the presentation of the OVP that "nothing will change in the way citizens receive their health service. But we will negotiate with the service, drug and device sectors from which we purchase" (*Hürriyet*, 16.09.2009b; author's translation). Dinçer added that the primary policy tools will be to reduce

manufacturer prices and implement public discounts. What followed were two and a half months of negotiations with the three large pharmaceutical industry associations, who eventually had to accept severe price cuts to implement the global pharma budget (more on these negotiations below).

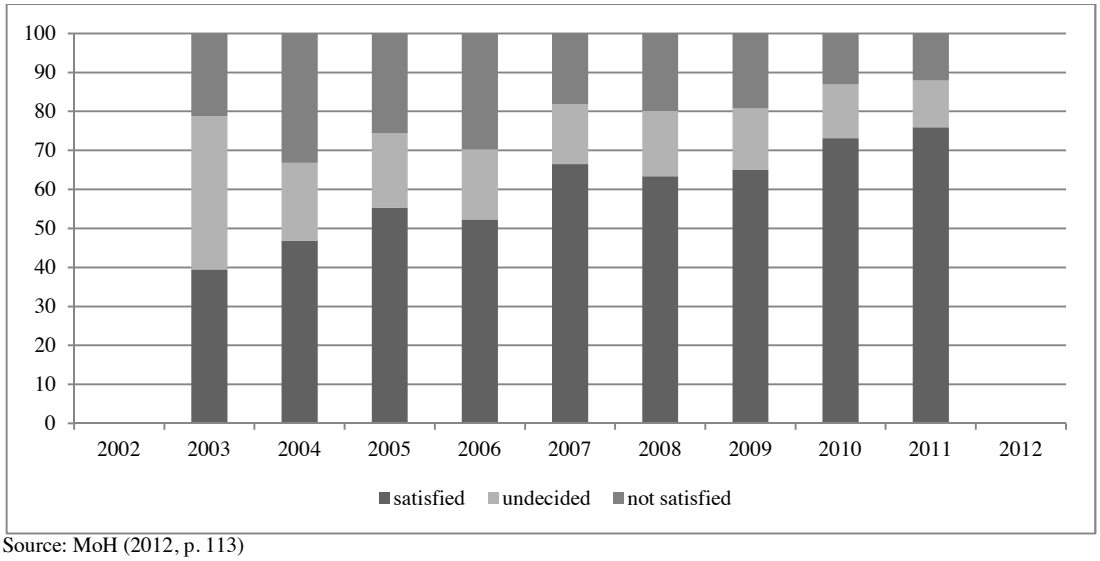
The political process that produced strict drug price controls can then be summarized as follows. In 2009, in a context of fiscal and financial crisis, Turkey's technocratic economic policy-makers were convinced that savings in public pharmaceutical expenditure were an important instrument in stabilizing Turkey's economy. They seemed willing to implement those savings through a mixture of policy instruments, leading to a reduction of prices, but also to a reduction of public reimbursement. Aware of the electoral importance of health policy, the AKP's political leadership demanded that public reimbursement could not be reduced. Determined to realize the envisioned budget cut, the technocrats pushed through very comprehensive price cuts (and remained just as determined in 2010 and 2011, implementing even stricter price cuts).

This interpretation of the events has a couple of implications. First of all, it seems that the concept of "controlled populism" helps to explain why pharmaceutical policy generated price cuts. The AKP government was committed to the expansion of public health services (to the particular benefit of the poor), but also committed to macroeconomic stability in times of recurring crisis. Taking a controlled populist middle-path, it decided to maintain the level of public reimbursement and reduce the profit margins of pharmaceutical producers. Öniş and Güven (2011) argue that controlled populism is a characteristic feature of the AKP when comparing its performance *across* policy fields. My analysis of the pharmaceutical expenditure and price policy suggests that the AKP may also be considered controlled populist *within*

policy fields. Moreover, my analysis of this particular policy process suggests that the controlled populism may be only an aggregate characteristic of the post-2006 AKP government. The case of pharmaceutical pricing policy seems to suggest that a controlled populist outcome was the result of a compromise between the fiscal prudence of one part of the government (motivated by worries about the macroeconomy) and the keen populist senses of another part (motivated by worries about upcoming elections).

Moving out of this immediate context, one should consider the phenomenon of the AKP's health policy populism in some more detail. After all, one key assumption made in the analysis above is that Erdoğan's intervention was driven more by political calculation. I do not reject the idea that the AKP government pursued its health policy agenda – with its focus on extending public health services to lower classes – at least in part out of ideological conviction. But especially after the general elections of 2007, the main driver behind the AKP's health policy choices appears to be the concern to generate and maintain social support for its political rule. One characteristic of the AKP's health policy populism is that it is almost exclusively directed at the final consumers of health services (that is patients), and especially at the group of new public health service users from the lower classes that had emerged due to the health reform and that constitutes an important part of the AKP's electorate. At the same time, the AKP government has been much less sensitive to the demands of the providers of health services and products, including health sector employees such as doctors, nurses or pharmacists. Many health employee organizations officially oppose the AKP's Health Transformation Program (Akinci et al., 2012). This has produced polarization among the stakeholders in health policy.

On the one hand, popular satisfaction with health services has substantially increased during the rule of the AKP, from just 40% in 2003 to 76% in 2011 (Figure 7).



Source: MoH (2012, p. 113)

Figure 7. Popular satisfaction with health services, 2002-2012.

Public satisfaction with the government's health policy has apparently paid off substantially for the AKP at the polls. Surveys by pollster Adil Gür have suggested that a majority of voters considers health policy as the most successful policy area of the AKP government. Gür also argued that health policy had been the most important factor in the AKP's second election victory in 2007 (Çakkal, 2011; *Taraf*, 15.09.2008). There have been estimates that 10 percentage points of the AKP's 47% in 2007 could be attributed to popular support for the government's health policy. Whether this actually was the case does not matter much for the purpose of this study. What is important is that the AKP – which does have a reputation for meticulous popular opinion polling (*Sabah*, 05.01.2012) – perceives its health policy performance as important for its political success and has embraced health policy as one of its key political projects. This seemed to be especially the case in the period

after the 2007 election, that is, the time period in which strict drug price controls were introduced.

As with regard to the more specific popular preferences for pharmaceutical policy, no systematic evidence is available. But it seems plausible that pharmaceutical policy as a large element of health policy followed a similar dynamic. In addition, anecdotal evidence supports the assumption. During the 2011 election campaign, the AKP presented its various "achievements" in a series of elections posters, several of them related to health policy. One of them displayed a woman next to the statement "I buy my pharmaceuticals from the pharmacy I want, and, on top of that, for 80% cheaper." The rest of the poster shows Prime Minister Erdoğan and the following statements: "We realized record price cuts for pharmaceuticals. It was a dream, it became reality. AK Party. Yes" (Figure 8; author's translation).

Source: AKP (2011)

Figure 8. AKP election poster, 2011.

My interviews supported the interpretation that the AKP's primary motivation to not increase private financing, but to cut producer prices, was a populist political calculation. The pharmaceutical industry itself was convinced that it had contributed to the AKP's electoral success. Nezih Barut, CEO and joint owner of Turkey's largest pharmaceutical producer Abdi İbrahim, said he had told Turkey's Minister of Health:

> My dear Minister, research has shown that 10 percent of your party's votes come from health care. A large share in this 10 percent belongs to the pharmaceutical producers. The fact that we are still providing medicines at these low prices, making a large sacrifice, has increased your votes. (*Bugün*, 25.12.2012; author's translation)

In conjunction this evidence supports the argument that Erdoğan's intervention in the 2009 policy debate over "savings in health" was motivated by his understanding of the electoral importance of health policy for his government. Any solution to the cost containment problem that would have substantially restricted the lower classes' access to health services and pharmaceuticals (or rather their perception thereof) could have risked the AKP's electoral performance and political rule in the future. It was hence the government's health populism that prevented a looming neoliberal solution of containing public pharmaceutical expenditure by increasing private financing. The only option left then to the economic policy-makers was to contain pharmaceutical and therefore health care expenditure by sharply reducing the price the state pays producers and distributors when reimbursing the population's private drug consumption.

In summary, the material in the previous two sections has demonstrated how, in the context of economic crisis, the combination of two distinct characteristics of

the AKP government, namely its fiscal discipline and its populist use of health policy, has produced the policy idea of stricter drug price controls. This production was accidental in the sense that the tough regulation of pharmaceutical prices and profits was not a characteristic demand of the AKP government before 2009. But once produced, the government had the political will to implement the price controls. However, political will is hardly ever enough to implement a policy idea. There were two important political factors that allowed the AKP government to implement and maintain its policy of strict drug price controls.

Implementing Price Cuts

Let us now examine how the price cuts were implemented politically. First, details of the global budget for public pharmaceutical expenditure were announced during a press conference given by Ali Babacan, Ömer Dinçer, and State Minister Cevdet Yılmaz on 15 September 2009, which presented the Medium-Term Financial Program 2010-2012, the "IMF budget" discussed above (*Hürriyet*, 16.09.2009a). At this press conference, Minister of Labor and Social Security Dinçer announced that public discounts would be increased and the reference factor that determines the legally allowed maximum price would be substantially decreased (*Hürriyet*, 16.09.2009b). Just three days later the details of the new and stringent price regulations were published in the state's official gazette (*Resmi Gazete*, 18.09.2009). By a decision of the Council of Ministers that had been taken on 10 September 2009, the reference factor for generic drugs was reduced from 80% to 60%, and the reference factor for original drugs with generics (that is, most off-patent originals) was reduced from 100% to 60%. While the reference factor of on-patent originals

remained at 100%, the mandatory discount that producers need to grant to the SGK was increased from 11% to 24% (Table 5). These changes were to go into effect after 45 days, on 2 November 2009.

These changes were not negotiated with the pharmaceutical industry. Instead the sector was presented with a fait accompli. But as the new regulations were to directly reduce the revenues of both producers and distributors, both groups began to protest the measures and to demand their partial repeal (*Hürriyet*, 17.09.2009; 19.09.2009). Pharmacists and warehouses were obviously going to be affected by a reduction of producer prices, as their sales prices are determined by fixed mark-ups. Moreover, as pharmacists keep large amounts of medicines in stock, they opposed to having to cover "stock damages" (*stok zararları*) created by reduced sales prices after having filled their stocks at the old, higher producer prices. While a separate analysis of the relations between the government and pharmacists is beyond the scope of this thesis, it can be said that the pharmacist associations resisted more and arguably more successfully than producers.

Only after the government had passed the price decrees, did it begin to negotiate with the three industry associations AİFD, İEİS, and TİSD to mutually agree on a set of implementation measures. With the days to the implementation counting down, the Ministry Health and industry representatives met very frequently, but could not reach an agreement. As a result, on 1 November 2009, the Ministry of Health announced that the changes were to now go into effect on 4 December 2009. At some point, the influential EKK joined the negotiations (*Eczacinin Sesi*, 06.02.2013; *Hürriyet*, 01.10.2009). While the pharmacists were preparing a massive strike for the day when the price decree was to come into effect, the pharmaceutical industry eventually gave in to the demands of the government. The Turkish

Pharmacists Association harshly criticized the pharmaceutical industry for having remained "apathetic" (*duyarsiz*) regarding the price cuts of the government (*Hürriyet*, 04.12.2009).

On 1 December 2009 the three producer associations signed a protocol that accepted the strict global budget, while having gained some miniscule concessions on price controls. The government agreed to raise the reference factor for generics and originals with generics from 60% to 66% and to reduce the public discount for originals from 24% to 23%. The protocol also conceded that additional price cuts would be implemented, if the original cuts do not suffice to stay within the three-year global budget. An industry representative I spoke to thought that the signing of the protocol had been the industry's "biggest mistake," as it legitimized future price cuts (personal communication, interview 25). However, it appears that the producers thought that they did not have much choice, considering that otherwise even stricter price cuts would have come into force. In a recent report to the American government (known as the "Special 301 Submission"), the influential American lobby group PhRMA paid special attention to the reason why the industry agreed to sign the protocol:

> The 2010 Government pharmaceutical budget was set at 10 percent less than actual Government spending in 2009, but allows for 7 percent growth per annum for 2011 and 2012. In the event that these caps are exceeded, additional price cuts are anticipated based on an unofficial protocol to which the industry agreed under the threat of more severe price cuts and measures. (PhRMA, 2013, p. 24)

Despite the 2009 price cuts, public pharmaceutical expenditure in 2010 did not decrease as much as the global budget had prescribed. As a result public discounts were increased for both original and generic drugs in October 2010 (*Hürriyet*,

22.10.2010). These price cuts, too, were "ratified" by the industry with another protocol (AİFD, İEİS, & TİSD, 2010). When the global budget was again overshooting in 2011, the government introduced another round of tough price cuts in early November 2011. However, this time the industry associations did not agree to sign a "voluntary" protocol, but instead revolted against the new price cuts. Industry representatives were repeating their mantra that "the knife has reached bone"; further price cuts could lead companies to pull drugs out of the market. This time some producers simply refused to adapt the new additional public discounts. These drugs were mostly original and essential, including cancer and diabetes drugs. Ignoring the new price cut, firms like Pfizer and Roche continued to sell their medicines to the pharmacies, but the SGK would only reimburse on the basis of the new 41% public discount. The difference had to be paid out-of-pocket by patients at that time, and many of these drugs experienced shortage in those weeks (*Zaman*, 11.12.2011).

After a few weeks, the AKP government gave in and removed the additional public discounts for critical 365 drugs (*Hürriyet*, 18.12.2011). In addition, value-added tax on pharmaceutical raw materials was reduced from 18% to 8%, which had been a long-standing demanded of local producers (*Hürriyet*, 16.12.2011). Despite this, the 2011 price cute was considered to have hit generic producers particularly hard. At that time, the winner seemed to be the multinational companies that used their monopoly command over patent-protected critical drugs to gain concessions from the government. However, price regulations may continue more subtly, and the victory of the multinationals in December 2011 may turn out to have been pyrrhic. Apparently, the companies that resisted adopting the additional public discounts were threatened at the time that a "black list" would be kept of those who resisted the new

discount levels, and their new (non-essential) drugs may be excluded from the positive list for reimbursement. There is evidence that the government has been making good on this promise (personal communication, interview 33).

Many of the sector insiders I interviewed thought that the price cuts of 2011 are likely to mark a temporary end of the tightening regulations (personal communication, interview 1). And despite the concessions that multinational producers were able to gain from the government in December 2011, public pharmaceutical expenditure did significantly decrease in 2012. Recently, in March 2013, the government relaxed public discounts for cheap products slightly (SGK, 2013). The 4% public discount on products cheaper than 3.55 TL (which had been introduced in 2005) was removed entirely, and the discount for a low-price subgroup of 20-year products was slightly reduced. This measure was taken to pay back the surplus that the 2010-2012 global budget had eventually produced (some 800 million TL). However, no further steps were taken toward relaxing the price controls. As of today, the AKP government appears determined to keep in place beyond 2012 the pharmaceutical price regulations that were a distinct product of the "crisis economy." All in all, while the further tightening of price and profit regulations may have come to and end after the November 2011 price cuts, the 2009-2012 global budget has without doubt seriously impaired the profitability of the pharmaceutical industry in Turkey and has placed drug prices under public control that was unknown before September 2009.

When considering the effective implementation of the spending limit and the price cuts, one needs acknowledge the high degree of executive control and in particular the role of the EKK and the Prime Ministry. Many of my interviewees pointed out the central and assertive role of Ali Babacan in the process (personal

communication, interviews 2; 35; 36). Prime Minister Erdoğan, on the other hand, does not appear to be involved closely with the negotiation of global budgets and implementation of price cuts. While reimbursement decisions were formally taken by the SGK (MoLSS) and pricing decisions by the İEGM (MoH), de facto control over these, at least since 2009, has been exerted by the EKK. While the ministries may well have a higher degree of bureaucratic autonomy in other areas (e.g. licensing), the decision over budget, reimbursement and price cuts appears firmly centralized in the EKK under the leadership of Ali Babacan.

The EKK and Babacan appeared to be relatively autonomous from the interests of the pharmaceutical industry. For example, the association of multinational producers (AİFD) had prepared a comprehensive strategy report for the development of the Turkish pharmaceutical industry. One key function of the report was to convince the government to relax pharmaceutical price and reimbursement regulations (personal communication, interview 35). While the AİFD could present the report to the SGK, the association was so far unable to get an appointment with the EKK. Especially when comparing this with the 2002 episode, where a delegation of Pfizer was able to meet with Turkey's top-level economic regulators on short notice, pharmaceutical producers appear now to have considerably less access to the regulators in charge of drug price controls. In sum, the EKK was important in effectively implementing the planned drug price controls, because it located the authority over global budgeting and pharmaceutical price regulation directly with the Prime Ministry. Moreover, the EKK appeared to remain relatively autonomous, at least from multinational drug producers.

Besides this high degree of centralized and assertive control over the price cuts, the successful regulation of drug prices in 2009-2012 also was aided by the existence

of an effective regulatory framework. This framework, as described in the second chapter of this thesis, had been fundamentally reformed in the 2004-2008 period. Both of its main components – external reference pricing and public reimbursement – were powerful mechanisms in the governance of drug prices, as they allowed to politically reduce prices in an effective and efficient manner.[28] In this sense, this regulatory framework may also be understood as a "social technology." This point becomes clearer when comparing the new regulatory framework with Turkey's previous cost-plus pricing system. Such a system makes it very hard to control drug prices against the will of producers, as it is they who report their input costs and regulators have little opportunity for control. This system was never fully applied in Turkey, but one of the reasons it was eventually replaced was its large administrative complexity that could not be burdened by the small drug regulatory agency (İEGM).

The introduction of external reference pricing in 2004 made systematic price regulation easier. The maximum prices for large groups of drug products could since be changed by a simple adjustment of the reference factor. In 2009, as a case in point, the reference factor for all generic and off-patent original drugs was reduced from respectively 80% and 100% to 66% (after the Pharma Budget Protocol). Price controls in such a framework can hence be introduced much less incrementally. Moreover, the highly effective fixing of the exchange rate, which I examined in the previous section, also functioned through the reference pricing system. And, again, the decreasing drug prices in Greece and Spain did only transmit to Turkey thanks to external reference pricing. Despite the government's use of external referencing to decrease prices since 2009, it should be emphasized that there is no necessary link between external reference pricing and the strictness of price controls. In fact, before

[28] As the reform of the regulatory framework has been described in detail in Chapter 2, no references are provided in this section.

the interests of the AKP government in drug prices shifted in 2009, Turkey's external reference pricing system was criticized for being too loose as it set prices according to much wealthier European Union member countries (Güldal & Semin, 2008, p. 388).

The centralized mechanism of public reimbursement is the second element of the regulatory framework that helped the AKP government to control prices. Interestingly, when the Public Pharmaceutical Purchase Protocol was signed in December 2004, it was considered to have reduced the state's capability to buy pharmaceuticals inexpensively. Indeed, the SSK previously was able to purchase at prices lower than other social security funds, because by reimbursing its insurance members only in affiliated pharmacies it created a market fragment that producers could only reach by selling directly to the SSK through tenders and price negotiations. When the pharmacy market was liberalized in 2004, the state lost this instrument of using a special distribution channel to increase its monopsonistic power. Since 2005 only hospital pharmacies can make use of tenders, and they do seem to be able to purchase below market price. It should be added that the abolition of the SSK pharmacy system is an instance where the AKP's pro-business, pro-privatization reforms harmonized well with its health policy populism, as the system was unpopular among the insured (Figure 8).

In spite of the loss of the SSK pharmacy system, the 2004-2008 reforms of public reimbursement seem to have also strengthened the ability of the government to control prices. The Public Pharmaceutical Purchase Protocol unified public reimbursement rules, and at the same time the scope of reimbursement was extended to millions of Green Card holders. If one also takes into account the move to general health insurance since 2006, these reforms have created one monolithic public

reimbursement mechanism that covers almost the entire population. Through this mechanism the SGK and economic policy-makers can efficiently change reimbursement rules for virtually the entire prescription drug market. This stands in contrast to much more fragmented systems of public reimbursement, as for instance in the United States, Germany or Turkey prior to 2004.

To be clear, I consider the prior reform of the regulatory framework as less important than those examined below. Even with a less suitable framework, the AKP government could probably have come up with a set of ad-hoc measures to control prices to similar effect. External reference pricing and centralized reimbursement may not have made the drug price controls of 2009-2012 possible, but certainly easier.

Countervailing Policy Goals

So far, this chapter has examined how, in the context of the global financial crisis, the AKP government began to regulate pharmaceutical prices more strictly. The analysis focused on how the need to contain rising health expenditure in conjunction with an evaluation of the likely political consequences of the available implementation measures, led the government to adopt the policy goal of low drug prices. This analysis remains incomplete as an explanation, since most democratic states with public health care systems, especially in times of fiscal crisis, would identify the reduction of drug prices as a policy goal. While the AKP's decision to let producers instead of patients pay the bill of pharmaceutical cost containment has been especially resolute due to the AKP's particular use of public health policy to

connect with its electorate, it alone does not explain why low drug prices have become such a *dominant* policy goal.

I want to argue in this section that the AKP government's choice of very strict drug price controls and its subsequent ability to implement it, were importantly facilitated by the relative absence of countervailing policy objectives, which if present could have prevented or significantly diluted pharmaceutical price regulation. The assumption here is that all health care states do at some point consider policies to control drug prices. What varies across cases is the concern of politicians for other policy goals that seem to require less strict control of drug prices. I identify four such countervailing policy goals that may prevent the implementation or even the proposal of strict drug price controls: Future medical innovation, availability of existing medicines, local production, and catering to special interest groups. Since producers tend to actively support the adoption of these policy goals in order to avoid stricter regulations, this issue also relates to questions of the constructedness of policy ideas and (who constructs?) to the autonomy of the government when considering competing policy goals. However, I believe that even if special interest groups partake in constructing policy goals, they are still based on some objective interests (of the government).

In the following I will examine how the AKP's political leadership stood with regard to these four policy goals in 2009-2012. The idea, of course, is that none of them were of consequential importance. First, a policy goal which is especially in advanced economies often enlisted to justify high drug prices is the innovation of new medicines in the future. The argument is that in a private market economy, producers need sufficient capital and financial incentive to engage in costly research and development. Innovative new drugs, in turn, would improve public health. While

the argument is sound and often employed by originator companies, future innovation for medical purposes does not seem to be a consequential policy goal in developmental contexts. If anything, the goal of medical innovation usually occurs concomitant with the goal of being the economy which develops, produces and exports this innovation (see the preamble of the British PPRS cited in the introduction). In fact, the Turkish government did very recently adopt the goal of developing a "national medicine" (*milli ilaç*), but the motivation behind appeared primarily economic-industrial.

Second, the availability of medicines in the market and avoiding shortages seems to be a much more influential policy goal to dilute the objective of low drug prices. Whether politicians are concerned with direct health effects or worry about public opposition, they may oppose stricter regulation in order to avoid problems with availability. The concern is justified. Pharmaceutical producers frequently decide to launch a product later, to pull it out of, or to never introduce it to a national market if they consider the allowed price and hence profit margin as too low. In fact, multinational pharmaceutical companies often define price floors for their products. National representations are instructed to take a product off the market if its price, due to regulations, falls below the price floor. Strict price controls can also lead to drug shortages in the off-patent market, as only a small number of companies may decide to produce at a given low price level. As there is such a positive relationship, it seems reasonable for national governments to not regulate prices "too much" if they want to avoid problems with availability.

The issue of availability of medicines has been very relevant in the Turkish case. Due to the relatively low profitability of the Turkish market, multinationals launch their new products either late or never in Turkey. Much more controversial,

however, has been that some drugs which doctors and patients had already been using were pulled from of the market by producers or from the reimbursement list by the government. Both created serious availability issues for patients, as they either could not find the medicines in pharmacies or had to pay for them out-of-pocket. The latter was the case in November and December 2011, when some multinational producers were refusing to apply additional discounts to their prices. This created a "medicines crisis" that received wide media coverage. Eventually, the SGK official Murat Karaşen announced that

> As a result of the new prices, some companies applied to us for withdrawal of drugs from the market. It was unacceptable for us that these [medicines] are not on the market. Otherwise our patients could be the victims. Because of this, we removed the public discount last implemented. (*Hürriyet*, 19.12.2011; author's translation)

It was this crisis of medicines availability that halted the AKP government's attempts to implement ever new additional price cuts. It represents a prioritization of the policy goal of availability at expense of the policy goal of cost containment, with the implication that the government's (auxiliary) goal to of reducing drug prices was also revised at this point.

However, December 2011, when several multinational producers were consciously creating availability problems in order to protest and resist new price cuts, appears to be an, albeit important, exception. Since the beginning of the strict price controls in 2009, there have been problems of availability and shortage with many drugs (*Hürriyet*, 07.10.2012). The media very frequently reports these problems and usually discusses explicitly how they are related to the pricing and

reimbursement regulations implemented by the government. Yet, the government has in principle not diluted its policy of strict drug price controls.

One important reason for this may be that especially poorer patients that are the AKP's social clientele do not blame the government for these problems of availability. During a visit to a large state hospital in Istanbul that was frequented primarily by poor and religiously conservative patients, I talked to doctors and patients in the oncology unit and also discussed the issue of non-available medicines. While the people waiting in line to see a doctor acknowledged that there are non-available drugs, this did not lead them to criticize the price regulation policies of the government. A pharmacist working in the same hospital told me that patients experiencing drug shortage usually criticize the pharmacists (personal communication, interview 30). What this suggests is that the AKP government does not pay a high political price for the availability and shortage problems incurred by its strict price and reimbursement regulations; this allows the policy goal of cost containment to remain dominant. Moreover, in Turkey there are hardly any organized patients associations that would channel the interest in drug availability into political demands for less strict price regulation.

Recently, the Turkish Pharmacists Association (TEB) with permission of the SGK has began to alleviate some problems of availability by directly importing pharmaceuticals from Europe which cannot be found in the Turkish market. The SGK reimburses these imported drugs, often at a price much higher compared to the price granted to producers if they sell the product to the state (*Milliyet*, 07.03.2013; *Sabah*, 07.03.2013). This agreement between SGK and TEB solves some of the regulation-induced availability problems and therefore may stabilize the

government's policy of strictly controlling producer prices. However, whether this pays off in terms of overall cost containment is an open question.

The third policy goal that may countervail strict price controls and hence public cost containment is the support of local industrial development. In a globalized world economy, it is today possible for national economies to import most innovation in medical technology and even to import a large share of finished drug products. Indeed, while 95% of Turkey's pharmaceutical demand was met by domestic production in the early 1980s, this shared had fallen to 50% by 2008 (Semin & Güldal, 2008, p. 385; İEİS, 2013). Albeit possible, many developing states may prefer to increase the level of local production, and perhaps even development, of pharmaceuticals. While the issue of supply security is sometimes invoked to justify the need for domestic production, the primary rationale for the policy goal of increasing local pharmaceutical production is of an economic-developmental nature.

The pharmaceutical industry (including biotechnology) is particularly attractive, as it is considered a high-value sector that can generate wealth and high-quality employment. Countries like South Korea, Taiwan and Singapore have in recent years increased public investments to forge the development of innovative domestic biotechnology firms "to gain first-mover advantages in a cutting-edge, science-based industry" (Wong, 2011, p. 1). In addition, Taiwan and Korea have sizeable generic industries manufacturing for the domestic market. India, on the other hand, has developed a large industry that produces primarily generic drug products and active pharmaceutical ingredients for the domestic market and for export (Wadhwa et al., 2008). What the two strategies have in common is that they seek to move up to higher levels of the global value chain of pharmaceutical and biotechnology production.

Whatever success these strategies yielded, institutional arrangements played an important role, but pricing regulations were by no means irrelevant. If national regulators (in the context of a market economy) want to increase investments in domestic production, they need to ensure that these investments generate a certain amount of profit. If price regulation becomes stricter, then foreign direct and domestic investments become, other things being equal, less likely. This leaves public health care system inevitable with an industrial policy part to play. If a national economy seeks to increase domestic pharmaceutical production, then the ministries of health and social security cannot design pricing and reimbursement regulations with the sole aim of reducing prices.

For Turkey's AKP government, the policy goal of increasing local production has gained importance in recent years, but it did not challenge the logic of extant pricing and reimbursement regulations. Historical experience may have taught regulators that loose price regulations alone do not attract investments in local production. For many years, before 2009, profitability in the sector was much higher, but local production was declining in relatively terms. One should specify here what local production means, as it is internally diverse. It includes some "classical" domestically-owned companies that locally produce generic versions of off-patent drugs. But it also includes local producers that engage in in-licensing and toll-manufacturing, and hence locally produce the patented or generic drugs or foreign companies, foreign multinational companies that produce locally themselves, and local producers that have been bought up and become subsidiaries of foreign multinationals. In 2008, these four groups accounted for a combined 50% of the 11.9 billion TL market for prescription drugs (İEİS, 2013). It is unlikely that local capital

(the first two groups) accounted for more than half of this, that is, 25% of the total market.

Many local producers were bought in the years before the shift to strict price controls. Attracted by the "pharmerging future" of the Turkish market (Hill & Chui, 2009) pharmaceutical multinationals and capital investors acquired Biofarma and Deva in 2006, Eczacıbaşı in 2007 and Mustafa Nevzat in 2012 (*Medimagazin*, 22.10.2012; PricewaterhouseCoopers, 2009). Abdi İbrahim and Bilim İlaç remain the last two large and locally-owned ("classical") companies, with a combined market value share of 11.4% in 2010 (IMS, 2011). But have been quite successfully over recent years. Abdi İbrahim, owned by the Turkish dollar billionaire Nezih Barut, has been the Turkish market leader for several years. Privately owned and apparently profitable, both Abdi İbrahim and Bilim İlaç have resisted foreign takeover.

When multinational pharmaceutical companies invest in Turkey by buying up local producers, then this itself does not increase local production, but only diverts pharmaceutical revenues and profits. In fact, so-called green-field investments appear to have been relatively low in Turkey, when compared with other "pharmerging" markets (personal communication, interview 36). Considering the historical record of allowing pharmaceutical producers to make large profits, increasing local production may not have functioned as a countervailing policy goal for the AKP government, precisely because it understood that allowing for higher prices will not achieve that goal.

Despite the dominance of cost containment in the making of pricing and reimbursement regulations, the AKP government has in recent years become more concerned with increasing local production. The change appears to have been primarily motivated by Turkey's high current account deficit, which was 6.4% of

GDP in 2010, and 9.9% of GDP in 2011 (BUMKO, 2012). As the pharmaceutical sector's trade deficit (3.9 billion USD in 2010, 4.1 billion USD in 211) significantly contributed to the "current account crisis", it was soon targeted to contribute to the alleviation of the problem. In 2011 the government began to adopt the policy goal of increasing local production and reducing imports. The pharmaceutical industry was defined as "strategic" and the Ministry of Science, Industry and Technology received more responsibility. It founded a small Pharmaceutical and Medical Device Industry Department (*İlaç ve Tıbbi Cihaz Sanayi Şubesi*) in September 2011, which began preparing a sectoral strategy (Çayci, 2012; Sayar, 2012). Parallel, the government already took some measures. In April 2012, the Ministry of Economy passed an incentive, which identified, among others, the pharmaceutical sector as strategic.

More attention has been attracted by the Ministry of Health's decision in March 2010 to not recognize foreign GMP certificates anymore (unless the country of origin has signed a mutual recognition agreement to accept Turkish GMP certificates, which they do not in practice), which are required for licensing in Turkey. Hence, Turkish inspectors need to visit the abroad factories before a new product receives import permission (IMS, 2011). This lengthens the process of licensing and has apparently increased the use of toll-manufacturing in Turkish factories. It has been acknowledged by the government that the purpose of the policy is to prevent imports. In 2012, pharmaceutical imports declined from 4.7 to 4.0 billion USD, while exports rose from 0.57 to 0.66 billion USD (İEİS, 2013). The decrease in imported value may be a result of the GMP measure, but was certainly also affected by declining average prices.

These policy measures to support domestic production, driven by the government's macroeconomic worries over the large current account deficit, can be

interpreted as a slight shift toward pharmaceutical industrial policy. So far this did not lead to a change of pharmaceutical pricing and reimbursement regulations. This may change in the future. The sectoral strategy document prepared by the Ministry of Industry includes the clause that the public pharmaceutical reimbursement of the SGK should support local production. The strategy document is currently still under review of the EKK. If accepted, it is likely to become much more consequential than currently as a ministerial document (personal communication, interview 36). In the 2009-2012 period, however, which is the object of analysis in this study, the AKP government's industrial policy interests have not motivated any dilution of strict price controls and hence did not have any countervailing effect.

The fourth and last policy goal that may countervail strict pharmaceutical price regulation, and which I want to consider here, is the privileged support of business groups close to the government. In my case, this would be the "Anatolian" bourgeoisie that is close to the AKP government. In short, the idea is that the policy goal of strict cost containment and price regulation may be countervailed if business groups that have particularly close relations with the government would be substantially harmed. A similar argument has been put forth by Monica Prasad, who examines the 1987 reform of the German health care system. She argues that the reform aimed to regulate pharmaceutical prices, but the proposal failed, because the Free Democratic Party, the junior partner in the conservative-liberal coalition government, acted as the "political protector" of the pharmaceutical industry and resisted stricter drug price controls (Prasad, 2006, p. 191).

Privileged treatment of particular groups of business people is in no way a specific characteristic of contemporary Turkey, but one can argue that in the AKP era the pairing of the government with on specific group of business people, namely

the "Anatolian" bourgeoisie, has been more pronounced and palpable than in other contexts. Buğra and Savaşkan (2012, p. 27) argue that "the political authority continues to mobilize a series of legislative and administrative mechanisms for the privileged treatment of those business people with the right political and sectarian affiliations." Many of these "Anatolian" business people have come to wealth thanks to privileged treatment in the government's discretionary public purchase decisions, especially the sectors of social housing and public health (Buğra and Savaşkan, 2012, p. 36).

In the pharmaceutical industry, however, the presence of "Anatolian" business people has been very limited in the 2009-2012 period. At the time when the AKP government shifted to strict drug price controls, the market was dominated by multinational companies. Abdi İbrahim and Bilim İlaç, the remaining large domestic companies, can hardly be considered as part of the "Anatolian" bourgeoisie. While the privileged treatment of "Anatolian" business people has not functioned as a countervailing policy goal in the period under study, this may well change in the future. "Anatolian" capital appears to have begun investing into local generic production. Most prominently, the Sancak family founded the company Pharmactive in November 2010, built a large production plant near Istanbul that will began production in 2013, and aims to become one of Turkey's five largest generic manufactures within just five years. The industry representatives with whom I talked expressed a lack of understanding of such large new investments in a low-profitability environment, where some domestic producers are even running deficits (personal communication, interview 36). Whether this implies that the pharmaceutical industry, after three rounds of price cuts, is still more profitable than it makes the public believe, or whether "Anatolian" investors have more trust in the

future, government-business relations may be up for an interesting change once these producers grow larger.

Conclusion: The Accidental Emergence of Strict Regulation

At the end of Chapter 2, I argued that going into 2009, Turkey's upcoming shift to strict drug price controls was hardly foreseeable. The Turkish political economy and the AKP government in particular were not the most likely candidates to squeeze the profits of private pharmaceutical business in order to spare the common population from high out-of-pocket payments and to be able to continue spending public resources on health services instead. After all, it was the AKP government that had liberalized the pharmaceutical market and willingly given up the institutional instruments that had allowed the SSK to keep drug prices low. But it happened. Under the impact of a severe economic crisis, the interplay of several characteristics of the AKP's political leadership and its constituency produced a set of pharmaceutical price regulations more effective and more anti-business than in many other countries whose public health care systems were under similar strain. In it is this sense, that the policy regime change was accidental (or contingent).

In order to explain why Turkey shifted to a policy regime of strict drug price controls in 2009-2012, this chapter answered two questions. First, why did the Turkish government decide that it wanted to reduce prices? The Turkish health care system has for long reimbursed the lion's share of private drug consumption, which is why pharmaceutical cost containment has been a long-standing policy problem. This problem was aggravated under the pressure to present a budget that would please the IMF, a pressure to which the fiscally disciplined AKP was ready to

submit. Reducing excessive public health care spending was one of the "structural reform" requirements of the fund, so policy-makers began looking for a health budget item from which several billion could be slashed. Drug spending appeared as the most viable. Aware though of the crucial importance of popular health policy for its political success, the AKP's political leadership constrained economic regulators as to slash health cost at low political cost. Under the dual pressure to uphold fiscal discipline and health policy populism, the EKK chose to drive down drug prices by tightening pricing and reimbursement rules. Almost overnight, the AKP became committed to strict price controls and new policy regime arose. On the other side, pharmaceutical producers now cynically admit that they became the "ATM of the government" (personal communication, interview 32).

As for the second question this chapter answered, why was the Turkish government subsequently able to effectively implement its new political commitment to low drug prices? A new regulatory framework increased the compliance of the private sector, and a high degree of centralized executive authority allowed for effective political-technical implementation. An important condition for sustained implementation, though, was that the government's political commitment itself was not compromised. Crucially, it did not adopt policy goals that could have countervailed the "cost containment via strict price controls" strategy by requiring a higher level of prices. By and large, the AKP's regulation of pricing and reimbursement remained relatively unaffected by the desire to support medical innovation, to avoid drug availability problems, to support domestic industrial development, or to allow wealth creation by specifically favored businesspeople. While these competing policy goals, that is, their broad absence, explain why the implementation of drug price controls has been in principle so effective, they also

explain at what point it ceased to be effective. When the third round of price cuts in late 2011 generated serious problems with the availability of medicines, in particular of on-patent drugs that were perceived as essential and had no alternative, the government needed to halt its attempts to further reduce prices, especially of the still expensive and imported proprietary drugs.

CHAPTER 4

CONCLUSION

This thesis set out to study how national political economies regulate pharmaceutical prices within the constraints of the global regime of intellectual property rights. The case study of Turkey demonstrated that substantial national policy space to reduce the average price of drugs exists even when patent and data exclusivity rules are not seriously challenged. Since 2009, Turkey has used three policy instruments to reduce drug prices, namely legal price ceilings, public reimbursement rules, and (more ad hoc) exchange rate fixing for determining price ceilings. These policy instruments helped to reverse a historical trend of increasing average prices; the average price of prescription drugs fell by 17% from 2009 to 2012.

Turkey's shift to more stringent drug price controls had many context-specific reasons, the analysis of which is at the core of this study. It is possible, however, to draw from this case some more general conclusions. The regulation of drug prices seems to gain political relevance to the degree that free pricing strains public budgets and harms access to medicines that are rendered as social rights rather than consumer choice. The reduction of drug prices by political intervention is instrumental to the more immediate goals of public health care systems, to improve access, and to reduce cost. The political economy of pharmaceutical prices then becomes an issue of welfare state politics, just as it is an issue of private business regulation. One key reason why drug price regulation turned against business interests in Turkey is that health policy was electorally so consequential (or was thought to be so). Put simply,

health policy and politics mattered. In this sense, Turkey's shift to strict price controls was also a result of democratic politics.

This study focused on the sources of the policy change, at the expense of its consequences. It became clear, though, that national price regulation in the era of globally enforced intellectual property rights comes at serious cost. The late launch of new medicines and drug shortages are an unsurprising outcome of price controls when intellectual property rights prevent the market entry of competing products. Price controls in Turkey were effective, among other things, because politicians proved to be relatively insensitive to problems with drug shortage and unavailability. On the other hand, the time when these unintended consequences became too severe marked the point when the "tightening of the reins" was halted. The economic consequences of drug price controls therefore had a feedback effect on their social and political sources. Whether a national regime of tightening pharmaceutical price regulation proves stable then depends on the response of drug producers to reduced profit margins, the response of society to the resulting health care consequences, and eventually the response of the polity to social attitudes. This multi-level feedback is contingent on the social-political formation of a particular national context.

In the introduction, the issue of drug price controls was situated between the competing goals of social policy and industrial policy (Jacobzone, 2000), where pharmaceutical reimbursement of public health care systems generates an interest of the state in low drug prices, while domestic production of pharmaceuticals leads to a political interest in higher drug prices and hence dilute the policy goal of low drug prices. In particular the cases of the United Kingdom and Ireland supported this economic two-factor model of national drug price regulation, driven by public health expenditure management and domestic industry support.

My analysis of the Turkish case is compatible with this hypothesis made in the literature, but draws at the same time a more complex picture of how price regulation, public expenditure and industrial structure are interrelated. Indeed, I argued that rising public expenditure motivated the introduction of stricter price controls. But I also emphasized that the political will to contain health expenditure does itself not lead to strict regulation of pharmaceutical prices and profits, as a reduction of the public share in total pharmaceutical cost also achieves the goal of cost containment. The Turkish case suggests that social structure and political institutions play an important and contingent role in translating the burden of public pharmaceutical expenditure into a particular set of cost containment measures.

Moreover, my analysis of countervailing policy goals found that a small domestic industry created insufficient political leverage to dilute the policy goal of low drug prices, and thus corroborated the hypothesis that the size of the pharmaceutical industry is a factor that influences national regimes of price regulation. However, the support of domestic production was found to be only one among multiple policy goals that may dilute the political will to reduce drug prices. The degree of social and political sensitivity toward problems of drug shortage and availability, as well as the specific relation between pharmaceutical producers and the government in power were found to be important in explaining why Turkey introduced and maintained strict drug price controls. The question whether these factors are of systematic significance, however, can only by answered by an explicitly comparative study.

Taking a glance at the future, it appears uncertain how long Turkey will maintain the current regime of pharmaceutical price regulation. On the one hand, if problems with availability persist and popular opinion begins to turn against

government regulations, then price controls especially of drugs experiencing shortage may be relaxed. Moreover, if recent developments in industrial structure continue, that is, if Turkey's "Anatolian" business people are entering the pharmaceutical sector, then the political incentives of the AKP government may change. International pressure may also increase, as the American lobby organization PhRMA has recently proposed to the United States Trade Representative to designate Turkey as a so-called Priority Foreign Country. This status, under the well-known Section 301 of the United States Trade Act, is usually given to countries with "inadequate" intellectual property rights or to those which deny "fair and equitable market access." PhRMA specifically cited the Turkish government's "draconian" price controls and "confiscatory" discounts in its 2013 submission, suggesting that the price regulations deny market access (PhRMA, 2013, p. 20). It will be interesting to see how the Trade Representative responds to this proposal.

On the other hand, price regulations may also prove sticky. International pressure on Turkey may not be as high as in other policy areas. In fact, most countries around the world are implementing similar price controls and the international financial organizations have become supportive of them. The international political climate regarding drug price controls appears to have changed. In Turkey, producers are still attempting to frame the 2009 price cuts as emergency measures that were necessary to deal with the global financial crisis, to which the industry was "willing to contribute." But the Turkish government seems happy enough with the savings to make the policy measures permanent. The longer they stay in effect, the more normalized they are likely to become. If multinationals continue to operate in Turkey and local producers like Abdi İbrahim continue to thrive, then a systematic relaxation of price controls seems less likely.

APPENDIXES

A. Interviews

This thesis draws on a series of 36 original interviews that were conducted by the author between May 2012 and April 2013. All interviews were anonymous and announced as such beforehand. Interviews were semi-structured. Notes were taken by the author, while only two interviews were recorded. Table 8 provides an overview of the conducted interviews.

Table 8. List of Interviewees

Number	Date	Duration	Place	Description
1	17.05.2012	1.0h	Istanbul	pharmaceutical sector consultant
2	23.05.2012	0.5h	Istanbul	pharmaceutical sector consultant
3	24.05.2012	1.0h	Istanbul	pharmaceutical sector consultant
4	25.05.2012	0.5h	Istanbul	pharmaceutical sector lawyer
5	29.05.2012	1.0h	Istanbul	pharmaceutical sector lawyer
6	31.05.2012	1.0h	Istanbul	pharmaceutical sector lawyer
7	30.07.2012	0.5h	Istanbul	pharmaceutical industry employee
8	15.08.2012	2.0h	Istanbul	pharmaceutical sector consultant
9	23.08.2012	1.5h	Istanbul	pharmaceutical industry employee
10a (6)	29.08.2012	2.0h	Istanbul	pharmaceutical sector lawyer
10b	29.08.2012	2.0h	Istanbul	medical device industry employee
11	06.09.2012	1.0h	Istanbul	pharmaceutical sector lawyer
12	14.09.2012	3.0h	Istanbul	medical device industry representative
13	14.09.2012	1.5h	Istanbul	pharmaceutical industry employee
14	17.09.2012	2.0h	Ankara	pharmaceutical sector regulator
15	18.09.2012	1.5h	Ankara	academic
16	18.09.2012	1.5h	Ankara	pharmacist
17	18.09.2012	1.0h	Ankara	pharmacists representative
18	19.09.2012	0.75h	Ankara	medical device industry executive
19	19.09.2012	1.0h	Ankara	medical device industry representative
20	19.09.2012	1.0h	Ankara	pharmaceutical sector regulator
21	20.09.2012	0.5h	Ankara	academic
22	20.09.2012	1.0h	Ankara	medical device industry representative
23a	21.09.2012	0.5h	Ankara	pharmaceutical sector regulator
23b	21.09.2012	0.5h	Ankara	pharmaceutical sector regulator
24a	24.09.2012	1.25h	Istanbul	pharmaceutical industry employee
24b	24.09.2012	1.25h	Istanbul	pharmaceutical industry employee
25	04.10.2012	1.25h	Istanbul	pharmaceutical industry executive
26	10.10.2012	1.50h	Istanbul	pharmaceutical industry executive
27 (8)	18.10.2012	1.75h	Istanbul	pharmaceutical sector consultant
28 (24b)	18.10.2012	1.75h	Istanbul	pharmaceutical industry employee
29a	15.11.2012	1.0h	Istanbul	oncologist at a university hospital
29b	15.11.2012	1.0h	Istanbul	pharmaceutical industry sales representative
30	15.11.2012	0.5h	Istanbul	pharmacist at a university hospital
31	15.11.2012	0.5h	Istanbul	purchasing manager at a university hospital
32	19.11.2012	email	Istanbul	pharmaceutical industry employee
33	22.01.2013	1.0h	Istanbul	pharmaceutical industry executive
34	06.02.2013	1.0h	Ankara	pharmaceutical sector regulator
35	07.02.2013	1.0h	Ankara	pharmaceutical industry representative
36	09.04.2013	1.0h	Istanbul	pharmaceutical industry representative

Notes: Interview numbers followed by lower-case letters indicate that the interview was conducted with multiple persons. Interview numbers in parentheses indicate that the same person was interviewed before.

B. Statistical Data

The numbers used in the text and tables are rounded substantially for easier comprehension. Calculations are based on more detailed numbers. Table 9 below shows those numbers, including those that are not readily publicly available.

Table 9. Selected Indicators in Detail, 2001-2012

(#)	Indicator	2001	2002	2003	2004	2005	2006
(a)	Nominal GDP (mn TL)	240.224	350.476	454.781	559.033	648.932	758.391
(b)	Current Account Balance (mn USD)	3.760	-626	-7.515	-14.431	-22.309	-32.249
(c)	Pharmaceutical Import (mn USD)	-	1.439	2.019	2.710	2.849	3.036
(d)	Pharmaceutical Export (mn USD)	-	145	179	248	283	313
(e)	Pharmaceutical Trade Balance (mn USD)	-	-1.294	-1.840	-2.462	-2.566	-2.723
(f)	Fiscal Balance (mn TL)	-28.556	-40.184	-40.208	-29.128	-6.903	-4.643
(g)	Primary Balance (mn TL)	12.482	11.544	18.319	27.363	38.777	41.320
(h)	Prescription Drug Market Value (mn TL)	2.743	4.762	6.243	7.708	8.344	9.279
(i)	Prescription Drug Market Volume (mn boxes)	735	789	860	954	1.069	1.149
(j)	Public Health Expenditure (mn TL)	8.438	13.270	17.462	21.389	23.987	30.116
(k)	Public Drug Expenditure (mn TL)	-	5.232	6.801	7.899	8.685	10.101
(l)	Public Non-Drug Health Expenditure (mn TL)	-	8.038	10.661	13.490	15.302	20.015
(m)	Pharma Budget 2009 (mn TL)	-	-	-	-	-	-
(n)	SGK Expenditures (mn TL)	17.831	27.982	41.336	50.622	59.941	71.867
(o)	SGK Revenues (mn TL)	13.361	20.018	27.917	34.689	41.249	53.831
(#)	Indicator	2007	2008	2009	2010	2011	2012
(a)	Nominal GDP (mn TL)	843.178	950.534	952.559	1.098.799	1.298.062	1.416.817
(b)	Current Account Balance (mn USD)	-38.434	-41.524	-13.370	-46.643	-76.986	-47.476
(c)	Pharmaceutical Import (mn USD)	3.524	4.361	4.080	4.410	4.697	3.996
(d)	Pharmaceutical Export (mn USD)	358	421	429	558	567	662
(e)	Pharmaceutical Trade Balance (mn USD)	-3.166	-3.940	-3.651	-3.852	-4.130	-3.334
(f)	Fiscal Balance (mn TL)	-13.708	-17.432	-52.761	-40.081	-17.783	-28.791
(g)	Primary Balance (mn TL)	35.045	33.229	440	8.217	24.448	19.625
(h)	Prescription Drug Market Value (mn TL)	10.844	11.872	13.854	13.609	13.732	12.927
(i)	Prescription Drug Market Volume (mn boxes)	1.299	1.357	1.394	1.427	1.557	1.560
(j)	Public Health Expenditure (mn TL)	34.530	42.159	47.904	50.060	56.740	61.145
(k)	Public Drug Expenditure (mn TL)	11.140	12.964	16.068	15.347	15.868	14.772
(l)	Public Non-Drug Health Expenditure (mn TL)	23.390	29.195	31.836	34.713	40.872	46.373
(m)	Pharma Budget 2009 (mn TL)	-	-	-	14.600	15.563	16.669
(n)	SGK Expenditures (mn TL)	81.915	93.159	106.775	121.997	140.715	-
(o)	SGK Revenues (mn TL)	56.875	67.257	78.073	95.273	124.480	-

Sources: (a, b) 2001-2012: BUMKO (2013); (c, d) İEİS (2013); (e) author's calculation; (f, g) 2001-2012: BUMKO (2013), (h, i) İEİS (personal communication, 2013); (j) 2000-2008: TURKSTAT (2011), 2009-2012: MoD (2012); (k) 2002-2004: AİFD (2013), 2005-2011: MoF (2012, p. 237), 2012: AİFD (personal communication, 2013); (l) author's calculation; (m) SGK (2010), (n, o) SGK (2012).

C. Original Quotes

In the following the quotes translated by the author are listed in their original Turkish version in order of appearance.

"Sosyal devlet anlayışına göre devletin sağlamakla yükümlü olduğu temel hizmetlerin sunumunda her zaman ciddi sorunlar ve adaletsizlikler yaşanmıştır." (Bolat, 2007, p. 4).

"Özellikle hizmetlerin sunumunda yabancı yatırımların artması, özel sektör ve kamu arasındaki rekabetin kızışması acısından da son derece önemli bir hale gelmiştir. Bu rekabet alanında milli değerlerine sahip çıkan, *insanlara hizmeti Hakk'a hizmet sayan bir inanca sahip sermayenin sağlık sektöründe de yatırımlarını artırması gerekmektedir*." (Bolat, 2007, p. 5; emphasis in the original).

"Oransal olarak Türkiye'de ilaçlara ve farmasotik ürünlere yapılan harcamalar çok yüksektir. Sosyal güvenlik kurumlarının mevcut politikaları yüzünden nüfusun çok büyük bir bölümü ilaç fiyatlarına karşı oldukça duyarsızdır. İlaç fiyat artışlarının bilimsel bir temele oturmadığını biliyoruz. Sağlıkta Dönüşüm Programı çerçevesinde, sağlık hizmetlerinin en önemli girdilerinden olan ilaçla ilgili uzun yıllardır yaşanan sorunların bilimsel esaslar çerçevesinde, tarafların karşılıklı diyalogu ve uzlaşmacı yaklaşımları ile çözülmesine yönelik bir platform oluşturulacaktır." (MoH, 2003, pp. 34-35)

“Sağlık Bakanlığı ve bağlı kuruluşlarının teşkilat, görev, yetki ve sorumluluklarını düzenlemektir” (Council of Ministers, 2011a)

“Bu kurum, her türlü etkiden uzak olarak bağımsız bir şekilde ulusal politikalar doğrultusunda uygulamalarda bulunacaktır.” (MoH, 2003, p. 35)

“Kamunun yıllık ilaç maliyeti 10-12 katrilyon lira. Bu kadar büyük alım söz konusu olunca devlet, ‘Ben bu kadar çok ilaç alıyorsam; o zaman bir kıyak da isterim’ dedi. Bundan tüm taraflar kazançlı çıktı” (*Hürriyet*, 15.12.2004)

“Kamu İhale Kanunu'nun 2003 yılında yürürlüğe girmesinden sonra kamunun tıbbi ürün ihtiyacı için düzenlenen ihalelerde zaman zaman fiyat farklılıkları ortaya çıkabilmektedir. [...] Çözüm devletin ihale uygulamalarının tek bir sistem dahilinde yapılmasından geçmektedir” (*ntvmsnbc*, 10.08.2004)

“Ben eskiden Erzurum’da bir hastanede satın alma müdürü olarak çalışmıştım. [...] Sadece kirlilik değil, bazen bilgisizlik de bu tür sonuçlar doğurabiliyor. [...] Sonuçları itibariyle daha iyi olaylara vesile olacağı. [...] Bir bakıma isabet oldu. [...] Hedefimiz çağdaş, objektif, şeffaf bir fiyatlandırma sistemi.” (*Milliyet*, 15.08.2004).

“Devlet ilaçta sistemli ve organize bir şekilde soyulduğu halde, Sağlık Bakanlığı da Çalışma Bakanlığı da davaları takip etmiyor. Zararın tahsili için de harekete geçilmiyor. Soruşturma Raporu'nda 'firmaların kasıtları bulunmadığı' ibaresi bir kayırma intibaı uyandırmıştır. Olayların örtbas edildiği kanaati doğurmaktadır.” (*Sabah*, 30.05.2006)

“Türkiye Cumhuriyeti tarihinin, sosyal güvenceye harcadığı para, bu dönemde olduğu gibi hiçbir zaman olmamıştır [...] Bunun bedeli yok. ‘Efendim, bütçe açık veriyor’. Ne verirse versin, bütçe açık veriyor diye bunu önleyemezsiniz, bunu durduramazsınız. Çünkü bu işin bedeli olmaz, ne gerekiyorsa bunu yapacağız. Zaman zaman ben, bakanlarımla bu konuda anlaşmazlıklara düştüğüm de oluyor. Bu konuda atmamız gereken adımlar var çünkü yarış halindeyiz, bunu başarmamız lazım.” (*Milliyet*, 03.09.2009)

“Halkın ilacından kesinti yapmayız” (*Hürriyet*, 01.10.2009)

“Sayın Başbakanımız sağlık hizmetlerine erişim ve verdiğimiz sağlık hizmetinin kalitesinde bir geriye gidiş olmaması koşuluyla tabii ki bizim yaptığımız çalışmalara destek veriyor. Bence oradaki mesaj yanlış anlaşıldı. Sayın Başbakanımız bize o çerçevede destek veriyor. Göreceksiniz sağlıkta çok ciddi tasarruflar yapacağız. Sağlık sektörü çalışmasını aşağı yukarı bitirdik sayılır. Son yıllarda kamu sağlık harcamaları 9 milyar liradan neredeyse 38 milyarlara çıktı. Ciddi bir artış yaşandı. Aynı şekilde ilaç harcamaları da öyle.” (*Milliyet*, 07.09.2009)

“Vatandaş, sağlık hizmetini nasıl alıyorsa, aynı şekilde almaya devam edecek. Ancak hizmet, ilaç ve ürün aldığımız sektörlerle görüşmeler yapacağız” (*Hürriyet*, 16.09.2009b).

“Sayın Bakanım, oylarınızın yüzde 10'unun partinize sağlıktan geldiği araştırmalarda ortaya çıkmış. Bu yüzde 10'da da en büyük pay ilaççıların. Hala bu düşük fiyatlarla,

çok büyük fedakarlık yaparak ilacı veriyor olmamız, sizin oy potansiyelinizi artırdı" (*Bugün*, 25.12.2012)

"Firmaların yeni fiyattan dolayı bu ilaçları piyasada bulunduramadıklarına dair bize müracaatları vardı. Bunların piyasada bulunmaması bizim için kabul edilemez bir durumdu. Aksi takdirde hastalarımız mağduriyet yaşayabilirdi. Bu nedenle yapılan son kamu kurumu iskontosunu kaldırdık." (*Hürriyet*, 19.12.2011)

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