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Pharmaceutical Pricing and Reimbursement Information

TURKEY

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Pharma Profile

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Executive Summary

Turkey is at the verge of critical health care reforms where radical changes are introduced both in the provision and financing side. The proposed system will have an impact on utilization patterns and provision modes of health care services. In line with the global tendencies, the reforms are focused on purchaser-provider split, extending coverage to the whole population by introducing a general health insurance scheme based on social insurance principles and organizing the primary level of care through family practitioners. In recent years, in line with an active health care policy environment major changes have been accomplished in the pharmaceutical sector as well. This profile provides broad information on the outlook of the pharmaceutical sector.

Pharmaceutical policy is collectively shaped by various authorities in Turkey. The MoH General Directorate of Pharmaceuticals and Pharmacies (GDPP) is the main authority in market authorization, pricing, legal classification and inspection. Reimbursement policies, on the other hand, are determined by an inter-ministerial commission under the coordination of the Ministry of Finance.

There is not a comprehensive policy but a set of policies and legislation that governs the pharmaceutical sector. As stated earlier, Turkey had witnessed major policy reforms in the last 4 years influencing the pharmaceutical sector as well. In the last policy document "Transformation in Health", establishment of a National Institute of Medicine is proposed. It is envisaged that this institution will be a platform for dialogue and consensus for all stakeholders in the pharmaceutical sector. The institution will be responsible for making policies and market authorization and will be the regulatory body for production, promotion, marketing and research and development activities.

The Turkish pharmaceutical industry is comprised of both research based and generic manufacturers. In 2005 there were 50 research oriented companies and 200 generic manufacturers. As there are no unbranded generics in the market, there are only branded original and generic products. The distribution channel of pharmaceuticals starts from manufacturers to wholesalers and to pharmacies. There were 491 wholesalers on the market in 2005. However, 70 % of the market is represented by two wholesalers. There is a multi-channel distribution system. Pharmacies are serviced routinely by wholesalers but they are also available on call. Pharmacies are private entities in Turkey and hospitals have their own pharmacies only to serve in-patients. Pharmacies are remunerated by social security organizations, state and private out-of-pocket payments. They receive free goods from wholesalers and the amount of free goods may be quite influential in their decisions to replace prescriptions.

Doctors are organized predominantly around the Turkish Medical Association. The Association does not have an official role in pharmaceutical policy-making. Their influence is restricted to voicing their opposition and referring to courts for cancellation of arrangements made by the government. Patients do not have an active role in deciding which pharmaceuticals will be prescribed. However, they have a certain role in pharmaceuticals dispensed as they can purchase pharmaceuticals that are above the reference price level by paying the difference. If they do not accept to pay the pharmacist replaces the prescribed pharmaceutical by a reimbursable one in

the equivalent group. Prices are determined by the MoH and are fixed so there is not an incentive for patients to shop around for pharmaceuticals.

The level of pharmaceutical expenditures has been subject to fierce debates in the last three years in Turkey. Pharmaceutical expenditures have been the most speculated area of health expenditure estimations ranging from 40-60% of total health care expenditures. The debate around the issue has been fuelled by the IMF demands to curtail public expenditures including health. Pharmaceutical expenditures, especially public pharmaceutical expenditures are an area where expenditures can be calculated relatively easily compared to other components of health expenditures. In addition to this, concrete measures can be taken with solid outcomes in a short period of time. With the impetus provided by these arguments, Turkey embarked on several initiatives to regulate pharmaceutical pricing and reimbursement issues.

The main funding source of public pharmaceutical expenditures is the funds from social insurance organizations and the state. It is believed that the following policy changes had various impact on pharmaceutical spending. First of all, in general, access to health care has improved since 2004 with radical changes in the provision side. In the past, the Social Insurance Organization (SSK) had its own hospitals with restricted access to its members and in many cases low standard facilities. In 2005, as part of the ongoing reforms, the competence of these facilities were transferred to the Ministry of Health (MoH) and all MoH hospitals were opened to the SSK members increasing the opportunities of access. Second, access to prescriptions was also improved after allowing SSK enrollees to obtain pharmaceuticals from private pharmacies. In the past, the SSK members were only allowed to buy pharmaceuticals from their hospitals' pharmacies. After the transfer of these hospitals to the MoH, the SSK beneficiaries also started to purchase their prescriptions from private pharmacies as well. Last but by no means the least, in the past, the Green Card Scheme for the poor covered only in-patient care hence excluded out-patient care and prescriptions. In 2005 the scheme was extended to cover all health care expenditures easing access of the poorest segments of the society.

OOP expenditures are mainly made for pharmaceuticals. (41.4% of total OOP health expenditures were made to buy pharmaceuticals in 2003). Some part of this is caused by co-payment arrangements in the social security organizations but a considerable amount is made for self-medication. Private health insurance sector is not developed in Turkey. In 2000 only 3.6% of the total health care expenditures were made by private health insurance companies.

The MoH has the sole responsibility in pricing decisions. The Pricing Department under the MoH GDPP determines the price of each pharmaceutical sold in the country with the Pricing Commission following the external price referencing criteria. The Pricing Commission meets quarterly under the coordination of the MoH. The commission comprises of members from the Ministry of Finance, State Planning Organization, Ministry of Labor and Social Security and the Treasury. The Commission can be called for urgent meeting in cases of changes in economic indicators, exchange rate etc. The pricing criteria and methodology in Turkey has radically changed since 2004 in line with attempts to reform the Turkish health care system and to control rising pharmaceutical expenditures. In the past, prices of pharmaceuticals were determined upon the application of the firm based on a cost-plus approach. However, increasing concerns about the share of pharmaceutical expenditures in total health care expenditures and pressures from outside to contain public expenditures have resulted in reviewing and regulating the process. Free pricing is not allowed in Turkey. Prices are determined by statutory pricing. The cur-

rent pricing system started to be implemented from 2004. Price setting procedures are same for all pharmaceuticals. Pricing decisions are made at the manufacturer level and wholesale and pharmacy mark ups and VAT are added later. Price change is not possible unless there are changes in the criteria used. Statutory pricing is binding for all pharmaceuticals at all price levels. External price referencing is used in the pricing process. The pricing procedures are written in law and enforceable. It is impossible to replace the procedures by other ways of pricing.

The prices of original products are determined by using the prices in a basket of five EU countries (Italy, France, Spain, Portugal and Greece) at the time of writing the profile (May 2007). Reference countries are determined annually but there has not been any change since the inception of this model. The lowest price in these reference countries is taken as the maximum ex-factory price of an original product. If there is not an ex-factory price for a product in the reference countries the wholesale price calculated by deducting any mark ups and VAT from the pharmacy retail price is used. In cases where the ex-factory price of a product is lower in the country that the product is imported, the price in the country of importation is taken as the reference price. If the product is authorized and available only in one of the reference countries, the ex-factory price in that country is taken as a reference. In cases where the product is not authorized in any of the reference countries then the cheapest ex-factory price in the 25 EU Member States is taken as a reference. If the product is not authorized in the EU at all then the original country of importation is taken as a reference. For products that are not available and authorized in other countries but only in Turkey then the price is set by negotiations between the MoH and the company. The pharmacy retail price is determined by adding mark-ups for wholesalers and pharmacies plus VAT.

For generics, prices are determined as 80% of the price of the original product. Rules are same as original products if the ex-factory price of a product in the importation country is lower than the price of the product in any of the reference countries. The final product price is determined by adding wholesale and pharmacy mark-ups and VAT. The prices of generics can not be higher than the original's reference price and the highest price of the equivalent generic in the market.

The reimbursement price is different from the pharmacy retail price. This is the price applied to purchases of public sector i.e. social security funds and the state. The price is determined by applying a public sector discount to the ex-factory price of the product. Currently the rate is 4% for pharmaceuticals newer than 6 years and 11% for pharmaceuticals older than 6 years. Wholesalers and pharmacies are reimbursed by mark-ups for all pharmaceuticals.

In the past, different social insurance organizations had their own reimbursement rules and procedures but in line with the move towards a more united system since 2003 all public agencies follow the same legal arrangements. At the time of writing all social security funds have one common positive list and they reimburse pharmaceuticals based on the rules set in the Budget Implementation Guidelines (BIG) prepared annually and modified as deemed appropriate throughout the year by the Ministry of Finance. This Guideline sets the rules and principles for spending public funds. The Reimbursement Commission is the key body in the preparation of the BIG reimbursement decisions and positive list. The commission's working procedures and principles were detailed in 2006. At first all pharmaceuticals reimbursed by the social security organizations were added to the list but in time some OTCs were excluded. The scheme covers all public reimbursing agencies.

The commission has the sole power in reimbursement decisions. The inclusion/exclusion principles to the positive list are not clear and the roles of participants in this process are not transparent as well. There are concerns that the budget impact has been the overriding criteria so far in reimbursement decisions. The intention, by the introduction of the positive list was to carry out cost-effectiveness analysis for all new pharmaceuticals to be reimbursed, but thus far no such assessment has been performed. The members of the commission can influence the reimbursement decisions. In the past there were instances where the decisions to exclude some pharmaceuticals from the positive list were taken to the court by non governmental organizations and some of these attempts succeeded in including the pharmaceutical on the list again. However the decisions made by these courts are subjective and not based on scientific evidence as well.

In the working procedures of the commission, it is stated that pharmaco-economic assessments can be requested both from the company and other international organizations for reimbursement decisions. It is widely believed that budget impact and economic considerations play a major role in the process. The changes in the list are made regularly in six month intervals during the regular meetings but the Commission can convene upon the call of the Ministry of Finance for urgent action. For reimbursement of pharmaceuticals used in an in-patient episode in hospitals, the price is determined by applying the manufacturer discount plus a pharmacy discount of 3.5%.

Based on the information provided in this report, the following points can be considered as the future challenges in Turkey:

- First of all, in order to make evidence based policies, there is an urgent need to review the information available in the health sector in general and pharmaceutical sector in particular. Without sound information on health care expenditures, pharmaceutical expenditures, utilization of health care services and other related topics, it will not be possible to make sound policies. The NHA study carried out for 1999 and 2000 was a good starting point to generate detailed health expenditure data but as the study is not repeated in the following years there is an important information gap in this area.
- Reasons of rising pharmaceutical expenditures should be given special attention as Turkey specific conditions may be the underlying reason. Claiming that pharmaceutical expenditures are too high in the country and should be curtailed undermines the specific reasons and creates an obstacle before making policies benefiting the public in general.
- Health economics and pharmaco-economics capacity should be developed both in the companies and public sector. Improvement of this capacity in the public sector would help decision-makers both in their pricing and reimbursement decisions.

Establishment of a National Drug Agency as proposed in recent reforms should be accelerated

Table of content

Executive Summary	1
Table of content.....	5
List of tables and figures	8
List of abbreviations	9
Introduction.....	1
1 Background.....	2
1.1 Demography.....	2
1.2 Economic background.....	3
1.3 Political context	5
1.4 Health care system	5
1.4.1 Organization.....	5
1.4.2 Funding	7
1.4.3 Access to health care	8
1.4.3.1 Out-patient care	8
1.4.3.2 In-patient care	9
2 Pharmaceutical system	11
2.1 Organisation.....	11
2.1.1 Regulatory framework.....	13
2.1.1.1 Policy and legislation.....	13
2.1.1.2 Authorities	14
2.1.2 Pharmaceutical market.....	16
2.1.2.1 Availability of pharmaceuticals.....	16
2.1.2.2 Market data	17
2.1.2.3 Patents and data protection	18
2.1.3 Market players	18
2.1.3.1 Industry	18
2.1.3.2 Wholesalers	19
2.1.3.3 Pharmaceutical outlets / retailers.....	20
2.1.3.3.1 Pharmacies	20
2.1.3.3.2 Other pharmacy outlets	22
2.1.3.3.3 Internet pharmacies	22
2.1.3.3.4 Dispensing doctors	22
2.1.3.4 Hospitals	22
2.1.3.5 Doctors.....	23
2.1.3.6 Patients	23
2.2 Funding	23

2.2.1	Pharmaceutical expenditure	23
2.2.2	Sources of funds	25
2.3	Evaluation.....	26
3	Pricing	28
3.1	Organisation	28
3.2	Pricing policies	28
3.2.1	Statutory pricing	29
3.2.2	Negotiations	30
3.2.3	Free pricing	30
3.2.4	Public procurement / tendering.....	30
3.3	Pricing procedures	31
3.3.1	External price referencing.....	31
3.3.2	Internal price referencing	32
3.3.3	Cost-plus pricing	32
3.3.4	(Indirect) Profit control	32
3.4	Exceptions.....	32
3.4.1	Hospitals-only	32
3.4.2	Generics.....	33
3.4.3	Over-The-Counter pharmaceuticals	33
3.4.4	Parallel traded pharmaceuticals	33
3.4.5	Other exceptions.....	33
3.5	Margins and taxes	33
3.5.1	Wholesale remuneration.....	33
3.5.2	Pharmacy remuneration	34
3.5.3	Remuneration of other dispensaries.....	34
3.5.4	Value-added tax.....	34
3.5.5	Other taxes	34
3.6	Pricing related cost-containment measures.....	35
3.6.1	Discounts / Rebates.....	35
3.6.2	Margin cuts	35
3.6.3	Price freezes / Price cuts	35
3.6.4	Price reviews.....	35
4	Reimbursement	36
4.1	Organization	36
4.2	Reimbursement schemes	37
4.2.1	Eligibility criteria	37
4.2.2	Reimbursement categories and reimbursement rates	37
4.2.3	Reimbursement lists	38
4.3	Reference price system	39
4.4	Private pharmaceutical expenses	39

4.4.1	Direct payments	40
4.4.2	Out-of-pocket payments	40
4.4.2.1	Fixed co-payments	41
	There are no fixed co-payments in Turkey	41
4.4.2.2	Percentage co-payments	41
4.4.2.3	Deductibles	41
	Reimbursement in the hospital sector	41
4.5	Reimbursement related cost-containment measures	41
4.5.1	Major changes in reimbursement lists	42
4.5.2	Introduction / review of reference price system	42
4.5.3	Introduction of new / other out-of-pocket payments	42
4.5.4	Claw-backs	42
4.5.5	Reimbursement reviews	42
5	Rational use of pharmaceuticals	43
5.1	Impact of pharmaceutical budgets	43
5.2	Prescription guidelines	43
5.3	Information to patients / doctors	44
5.4	Pharmaco-economics	44
5.5	Generics	45
5.5.1	Generic substitution	45
5.5.2	Generic prescription	45
5.5.3	Generic promotion	45
5.6	Consumption	46
6	Current challenges and future developments	47
6.1	Current challenges	47
6.2	Future developments	47
7	Appendixes	49
7.1	References	49
7.2	Further reading	50
7.3	Detailed description of authors	51

List of tables and figures

Table 1.1:	Turkey - Demographic indicators 1995, 2000 - 2005	3
Table 1.2:	Turkey - Macroeconomic indicators 1995, 2000 - 2005	4
Table 1.3:	Turkey- Health expenditure, 1995, 2000 - 2005	8
Table 1.4:	Turkey - Out-patient care 1995, 2000 - 2005	9
Table 1.5:	Turkey - In-patient care 1995, 2000 - 2005	10
Table 2.1:	Turkey - Authorities in the regulatory framework in the pharmaceutical system 2006	14
Table 2.2:	Turkey - Number of pharmaceuticals 1995, 2000 - 2006 ¹	16
Table 2.3:	Turkey - Market data 1995, 2000 - 2005	17
Table 2.4:	<i>Top 10 best selling pharmaceuticals, by active ingredient, 2005 or latest available year.....</i>	18
Table 2.5:	Turkey - Key data on the pharmaceutical industry 1995, 2000 – 2005	19
Table 2.6:	Turkey - Key data on pharmaceutical wholesale 1995 – 2005	20
Table 2.7:	Turkey - Retailers of pharmaceuticals 1995, 2000 - 2006 ¹	22
Table 2.8:	Turkey- Total pharmaceutical expenditure 1995, 2000 - 2005	25
Table 3.1:	Turkey - Ways of pricing of pharmaceuticals.....	29
Table 3.2:	Turkey - Pricing procedures.....	31
Table 3.3:	Turkey - Regulation of wholesale and pharmacy mark ups 2006	33
Table 3.4:	Turkey - Wholesale mark-up scheme 2007	34
Table 3.5:	Turkey - Pharmacy mark-up scheme 2006	34
Table 4.1:	Turkey - Reimbursement of pharmaceuticals	38
Table 4.2:	Turkey- Reimbursement rates and patient co-payment rates, 2006	40
Table 5.1:	Turkey - Development of the generic market in the out-patient sector, 2000 - 2005	45
Figure 2.1:	Turkey - Flowchart of the pharmaceutical system	11

List of abbreviations

ATC	Anatomic Therapeutic Chemical classification
BIG	Budget Implementation Guide
BoD	Burden of Disease
COPD	Chronic Obstructive Pulmonary Disease
CPP	Characteristics of Pharmaceutical Product
EMA	European Agency for the Evaluation of Medicinal Products
EU	European Union
FDA	Food and Drug Administration
GDP	Gross Domestic Product
GDPP	General Directorate of Pharmaceuticals and Pharmacies
GERF	Government Employees Retirement Fund
GGE	General Government Expenditure
GHIS	General Health Insurance Scheme
GP	General Practitioner
HE	Health Expenditure
HiT	Health systems in Transition
HOM	Hospital-Only Medicine
IEIS	Turkish Association of Pharmaceutical Manufacturers
IMF	International Monetary Fund
IMR	Infant Mortality Rate
Mio.	Million
MoH	Ministry of Health
NCU	National Currency Unit
NGO	Non-governmental Organization
NHA	National Health Accounts

NHS	National Health Service
NTL	New Turkish Lira
OECD	Organisation for Economic Co-operation and Development
OOP	Out-Of-Pocket payment
OTC	Over-The-Counter pharmaceuticals
PE	Pharmaceutical Expenditure
POM	Prescription-Only Medicines
PPP	Pharmacy Purchasing Price
PPPa	Purchasing Power Parity
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy Retail Price
SHA	System of Health Accounts
SHI	Social Health Insurance
SSK	Social Insurance Organization
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
VAT	Value Added Tax
VHI	Voluntary Health Insurance
WHO	World Health Organization

Introduction

The Pharmaceutical Pricing and Reimbursement Information (PPRI) project is a 31 month-project (2005-2007) commissioned by the Health and Consumer Protection Directorate-General (DG SANCO) of the European Commission and co-funded by the Austrian Federal Ministry of Health, Family and Youth (Bundesministerium für Gesundheit, Familie und Jugend, BMGFJ). The project was coordinated by the main partner Gesundheit Österreich GmbH / Geschäftsbe-reich ÖBIG (GÖG/ÖBIG) and the associated partner World Health Organisation (WHO) Regional Office for Europe. The PPRI project has established a network of 46 participating institutions (competent authorities and other relevant organisations) in the field of pharmaceuticals.

The PPRI project seeks to increase transparency and knowledge and facilitate the exchange of experience in the field of pharmaceuticals by

- establishing and maintaining a network of relevant institutions in the field of pharmaceuticals in the enlarged European Union (EU), in order to facilitate a regular exchange of information and allow a process of learning from each other,
- producing country reports on pharmaceutical pricing and reimbursement systems, the “PPRI Pharma Profiles”,
- developing indicators for the comparison of pharmaceutical pricing and reimbursement information,
- providing a comparative analysis on pharmaceutical pricing and reimbursement in the European Union (EU) and,

disseminating the outcomes of the project.

The PPRI Pharma Profiles are country-specific reports that provide detailed descriptions of the countries pharmaceutical systems and policies. The profiles are written by PPRI participants (country experts from competent authorities, Medicines Agencies, Social Insurance Institutions, research institutes) and edited by experts of the PPRI project coordination.

This Pharma Profile is one of the many PPRI Pharma Profiles, which all are available on the PPRI website at <http://ppri.oebig.at>. The information and data provided in the PPRI Pharma Profiles refer, in general, to the year 2006.

In order to improve readability and allow for comparisons between countries, the structure of the Pharma profiles follows a template, which was developed by the project coordination team and the PPRI participants. The template is based on a large needs assessment of both national and international stakeholders. In addition to the template a glossary was developed to facilitate the writing process and the readability. The 70-page PPRI Pharma Profile Template and the PPRI Glossary are available at the PPRI website.

1 Background

1.1 Demography

Turkey had 73 million inhabitants in 2005 with a population density of 9.4 persons per km². The capital is Ankara with 4 million populations and Istanbul is the most populous city is with 11.5 million inhabitants. The Eastern part of the country is sparsely populated whereas the most populous region of the country is the Marmara Region (198 per km² and 36 per km² respectively).

Although the percentage of people over 65 years is increasing in Turkey, in general the population is very young posing both opportunities and challenges. In 2005 29.2% of the population was under 15 and 65.4% was between 15-49 years. As infant mortality rate (IMR) is still quite high compared to the development level of the country (24.6 years in 2004) (OECD, 2005), life expectancy at birth is also lower compared to European Union (EU) countries standing at 68.8 years for males and 73.6 years for females (71.1 for the whole population) in 2004 (OECD, 2005). Between 1960-2000, Turkey gained 20 years in life expectancy which is well above the OECD average for the same period (OECD, 2004).

According to the Burden of Disease Study (BoD), in 2004 ischemic heart disease was the major cause of death (21.7% of total deaths) followed by cerebrovascular diseases (15% of total deaths). Perinatal causes and lower respiratory infections and Chronic Obstructive Pulmonary Disease (COPD) were among the first five major killing diseases (Ministry of Health, 2004a).

Table 1.1: Turkey - Demographic indicators 1995, 2000 - 2005

Variable	1995	2000	2001	2002	2003	2004	2005
Total population (thousands)	61,763 ¹	67,420 ¹	68,407 ¹	69,388 ¹	70,363 ¹	71,332 ¹	72,005 ¹
Population density per km ²	79.2	86.4	87.7	88.9	90.2	91.2	94.1
Population aged 0-14 (in % of total)	32.9 ²	30.0 ¹	29.7 ¹	29.5 ¹	29.2 ¹	28.8 ¹	29.2 ²
Population aged 15-64 (in % of total)	62.6 ²	64.6 ¹	64.9 ¹	65.0 ¹	65.2 ¹	65.5 ¹	65.4 ²
Population aged > 64 (in % of total)	4.5 ²	5.4 ¹	5.4 ¹	5.5 ¹	5.6 ¹	5.7 ¹	5.4 ²
Life expectancy at birth, total	67.9 ³	70.5 ³	70.6 ³	70.8 ³	71.0 ³	71.2 ³	71.4 ³
Life expectancy at birth, females	70.2 ³	72.8 ³	73.0 ³	73.2 ³	73.4 ³	73.6 ³	73.8 ³
Life expectancy at birth, males	65.6 ³	68.1 ³	68.2 ³	68.4 ³	68.6 ³	68.8 ³	68.9 ³

¹ Source: www.ekutup.dpt.gov.tr/ekonomi/gosterge/tr/1950-04/esg.htm

² Source : www.un.org/esa.population/publications/wpp2004/POP_R2004_DATA_Web.xls³

³ Source: OECD, 2006

1.2 Economic background

In 2005, Turkey had a Gross Domestic Product (GDP) of 487.2 billion New Turkish Liras (NTL) (302.6 billion €) and a GDP per capita of 6,760 NTL (4,198 €). The GDP per capita in Purchasing Power Parity was 8.141 \$ in 2003. Table 1.2 shows the improvements in the Turkish economy between 1990-2004.

Table 1.2: Turkey - Macroeconomic indicators 1995, 2000 - 2005

Variable	1995	2000	2001	2002	2003	2004	2005
GDP in NTL (millions)	7,762 ¹	124,583 ¹	178,412 ¹	277,574 ¹	359,762 ¹	430,511 ¹	487.202 ¹
GDP / capita in NTL	125,7	1,847	2,608	4,000	5,112	6,035	6,760
GDP / capita in PPPa	5,561 ¹	6,814 ¹	6,153 ¹	6,550 ¹	6,808 ¹	7,529 ¹	8,141 ¹
Growth rate from 1995-2005 ²	8.0 ²	6.1 ²	-7.3 ¹	3.1 ¹	4.9 ¹	9.6 ¹	8.3 ¹
General government expenditure (GGE)(millions NTL)	3,966 ³ (1996)	53,159 ³	102,765 ¹	146,281 ¹	179,525 ¹	198,896 ¹	212,420 ^{1*}
GGE in % of GDP	n.a.	42.7	57.6	52.7	49.9	46.2	43.6
Exchange rate (NTL per €), annual rate	n.a.	591,643 ⁴	1,063,35 ³	1,560,35 ⁵	1,609,50 ³	1,796,93 ⁸	1.61 ^{4,*}

GDP = Gross Domestic Product, GGE = General government expenditure, NCU = National Currency Unit, NTL = New Turkish Lira; PPPa = Purchasing Power Parity

¹ Source: Devlet Planlama Teşkilatı, 2007

² Source: www.dtm.gov.tr/ead/gosterrge/baslica.xls

³ Source: www.who.int/nha/country/TUR.xls

⁴ Source: www.tcmb.gov.tr

* In 2005 Turkey erased 6 zeros from its currency i.e. 1.000.000 TL became 1 NTL. The improvement between 1995-2000 is mainly because high inflation rate (over 60%) during that period.

The General Government Expenditure (GGE) was 212,420 million NTL (131,938 million €) in 2005 and this was 43.6% of the GDP for the same year.

The Turkish economy experienced major crises in the last two decades resulting in diminishing economic wealth and decrease in the pace of economic development. After the most recent crisis in April 2001, tight fiscal and monetary policies and a flexible exchange rate regime were adopted with the guidance of the International Monetary Fund (IMF). Since 2003, along with the impetus provided by the possibility of becoming an EU member, a number of reforms were introduced in various sectors including health. Inflation rate, a long-standing problem of the Turkish economy, decreased considerably (from 63.8% in 2001 to 9.8% in 2006). However, there are still severe problems such as high unemployment rate (10.5% in 2005) and high current account deficit (30.1 Billion US\$, 7.5% of GDP in 2006). Privatization has long been a priority agenda item where concrete attempts have been made since the early 1990s with various privatization examples from sectors such as energy, transportation, telecommunication etc. Since 2003 concrete attempts have also been made to increase the role of the private sector in health care.

1.3 Political context

Turkey is a parliamentary democracy where the executive, legislative and judiciary powers are separated exclusively. The 1982 Constitution has described Turkey as a democratic, secular and social state governed by the rule of law.

In the last general elections of 2003 only two political parties could enter the parliament, namely, The Justice and Development Party and the Republican Populist Party. Currently, as a result of internal changes in the composition of the parliament, other parties are also represented. The distribution of parliamentary seats is as follows: Justice and Development Party (65.4% of total chairs), Republican and Populist Party (28.2% of total chairs), Mainland Party (3.8% of total chairs) and others (including independent members) (2.6% of total chairs).

Administratively, Turkey is divided into 81 provinces headed by provincial governors appointed by the center. The State is highly centralized however; at the moment there are attempts to move to a more decentralized public management system. Provincial governors appointed by the centre represent all ministers and the head of the State. All ministries, including health, have their own local organizations at the province and the heads of these organizations (Provincial Directorate of Health) are responsible to the governor. Provinces are divided to districts (ilçe) and villages according to their population and geographical location. The heads of districts (kaymakam) are also appointed by the center and the organization at the district level is the same as the provincial level. The heads of districts are responsible to the provincial governor that they are geographically attached. Each geographical area has a municipality and city mayors and municipality council members together with provincial council members and village heads are elected in local elections. Municipalities are responsible from various tasks ranging from environment to health and economic development to transportation. They can raise their own revenues through economic activities and can collect certain taxes. However, a considerable number of municipalities are dependant on funds from the central government jeopardizing their independence from the central control. Decentralization has long been on the political agenda and since 2003 a special emphasis is made on empowering municipalities and decentralizing the government functions. The legislative arrangements are prepared for decentralization but not discussed and ratified by the Parliament yet.

1.4 Health care system

1.4.1 Organization

The Turkish health care system is neither a National Health Service nor a Social Health Insurance System but both. The system is still very fragmented both in terms of finance and organization although concrete reforms have been made since 2003 to reduce fragmentation. The current reform initiatives are directed towards introducing a General Health Insurance Scheme (GHIS), a family practitioner scheme and establishing autonomous hospitals.

The Ministry of Health (MoH) is the dominant actor in terms of provision of health care services with 67.9% of hospital beds followed by university hospitals (14.6% of hospital beds) and other public hospitals (8.3% of hospital beds). Private sector is flourishing in the provision side with explicit incentives inherent in the reforms after 2003 (8.6% of hospital beds) (Sağlık Bakanlığı, 2005).

At the central level, the MoH is the main authority in the provision of primary, secondary and tertiary care. Turkey has a deconcentrated public administration governance mechanism i.e. the lowest level of decentralization. Provincial administrators appointed by the head of the state represent all ministries and other central organizations within their provinces. Provincial Health Directorates are accountable to the MoH for all health related activities within the boundaries of their provinces. The provincial level has restricted responsibility for regulation, provision and finance as the centre makes the majority of the decisions.

The legal basis of the system is very fragmented in line with the general outlook of the system. Major Acts that are the backbones of the current health care system are General Public Health Act (Act No 1593), Ministry of Health Organization Act (Act No 181), Socialization of Health Care Services Act (Act no 224), Basic Health Services Act (Act no 3359).

The level of coverage in Turkey is a contentious topic. Official figures state that 91.7% of the population was covered by one of the schemes outlined in section 1.4.2. in 2005 (Devlet Planlama Teşkilatı, 2007). The household survey carried out as part of the National Health Accounts (NHA) study revealed that in contrast to the official rhetoric that around 80% of the population is covered by one of the schemes in 2004, only 67.2% was covered. (Ministry of Health, 2004b). This figure was later supported by the findings of another household survey for the Burden of Disease and Cost Effectiveness Study (Ministry of Health, 2004a). The underlying reason for overestimation of the covered population is the assumptions made in calculation of the dependant population.

The Turkish health care system has been undergoing a reform process since the early 1990s with themes of purchaser-provider split, introduction of a GHIS, introduction of a family practitioner scheme and autonomous hospitals. However, despite some policy documents (with no implementation) and some research and training activities, no concrete attempts were made until 2003. After the 2003 elections, a strong single party government took the office with full enthusiasm to reform all spheres of economic and social life including health. The government issued a 'Health Transformation Program' (Ministry of Health, 2003) and the following revolutionary steps were taken since 2003:

- All Social Insurance Organization (SSK) hospitals and other public hospitals that were out of the control of MoH were transferred to the MoH. So the MoH became the major actor in health care provision followed by universities.
- The GHIS Act was enacted from the Parliament to merge all schemes outlined in section 1.4.2 under one umbrella.
- The family practitioner scheme was introduced in pilot provinces with the aim of extending the scheme to the whole country in 2008.
- Access of Green Card holders to health care services was extensively improved. As detailed in Section 1.4.2, Turkish citizens, upon the proof that they are under the poverty level deter-

mined by the State are issues a Green Card to cover their health expenditures. Before 2003, the Green Card holders were entitled only to in-patient care and expenses for out-patient care and prescriptions were not included in the scheme. At the moment Green Card holders are fully covered except for co-payments for prescriptions (20%).

- Access of SSK members was extended to private pharmacies.
- Purchasing health care services from the private sector was extended to whole schemes.

1.4.2 Funding

The main sources of funding for the health care are social insurance contributions, taxes and out-of-pocket payments. A National Health Accounts (NHA) study was conducted for the years 1999 and 2000 in line with the System of Health Accounts (SHA) methodology of the OECD. This study, for the first time provided a detailed account of health care expenditures in terms of financing agents, providers, health care functions and socio-economic indicators such as age, gender, region and income. Despite the official rhetoric that the NHA will be continued after 2000, in practice this was not achieved. For this reason, health care expenditure estimations after 2000 are not fully reliable especially for private expenditures. It is easy to collect information from social insurance organizations and the government for public health expenditures. However, as the estimates for private expenditures are not based on sound estimations and research, health care expenditures should be treated cautiously. The current financing schemes are elaborated briefly below.

Currently there are five schemes financing health care services. The largest is the SSK covering private sector employees and blue-collar public workers and their dependants (56.8% of the population in 2005) (Devlet Planlama Teşkilatı, 2007). The scheme is financed by the contributions from the employees and employers based on the salary of the employee. The second actor in the financing side is the Government Employees Retirement Fund (GERF) financing health care services of the retired civil servants and their dependants. In 2005 12.8% of the population was covered by GERF (Devlet Planlama Teşkilatı, 2007). The scheme is financed by contributions of the active civil servants and transfers from the Government budget. The third scheme, Bağ-Kur finances the health care services of the self-employed, agricultural workers, artisans etc. In 2005 14.2% of the population was covered by Bağ-Kur (Devlet Planlama Teşkilatı, 2007). The scheme is financed by contributions of the participants. All three schemes are subsidized by the State in case of deficit between their revenues and expenditures. The fourth scheme is for active civil servants and their dependants and their health care services are financed by the state budget i.e. tax funded. Last but by no means is the least, the fifth scheme is the Green Card scheme for the health care services of the poor (14% of the population). Upon the proof that a person is under a pre-determined level of income, his/her health care expenditures are financed by the state. Membership is mandatory to these schemes, except for Green Card, but it is a well known fact that because of the existence of an informal employment market, a number of people go unrecorded.

As stated earlier, current reform initiatives aim at merging all financing arrangements under the GHIS umbrella. At the time of writing (March 2007), all schemes purchase health care services both from the public and private sector. Although the new system was planned to be active from

January 2007, as the Supreme Court cancelled some very vital articles of the GHIS law, its implementation is now postponed to January 2008.

Out-of-pocket payments (OOP) have a significant share in total health expenditures in Turkey (27.5% in 2000 according to the NHA study) (Ministry of Health 2004b). As stated earlier, since 2003, major reforms were introduced influencing the utilization and financing of the health care system. The impact of these changes on the funding arrangements is not assessed anywhere. That is why it is envisaged that these figures should have changed substantially. However there is no evidence to support this claim. Voluntary health insurance schemes only had a share of 3.6 % in total health care expenditures in the same study.

Total health expenditures in Turkey are estimated as 37.027 million NTL/ € 22,998 million in 2005 totaling to 7.6% of GDP. The level of public health expenditures is estimated as 71.4% of total health care expenditures. Table 1.3 below summarizes the health care expenditures.

Table 1.3: Turkey- Health expenditure, 1995, 2000 - 2005

Health expenditure	1995	2000	2001	2002	2003	2004	2005
THE in NTL (millions)	262 ¹	8,248 ¹	13,337 ¹	20,450 ¹	27,259 ¹	33,005 ¹	37,027 ²
THE in % of GDP	3.4 ¹	6.6 ¹	7.5 ¹	7.4 ¹	7.6 ¹	7.7 ¹	7.6 ²
THE per capita in NTL	4 ¹	122 ¹	195 ¹	295 ¹	385 ¹	460 ¹	514 ²
Public HE in % of THE	70.3 ¹	62.9 ¹	68.2 ¹	70.4 ¹	71.6 ¹	72.1 ¹	71.4 ²
Private HE in % of THE	29.7 ¹	37.1 ¹	31.8 ¹	29.6 ¹	28.4 ¹	27.9 ¹	28.6 ²

GDP = Gross Domestic Product, HE= Health Expenditure, THE = Total Health Expenditure, NCU = National Currency Unit, NTL = New Turkish Lira

¹ Source: OECD, 2006

² Source: www.who.int/nha/country/TUR.xls

The sharp increase of THE from 1995 to 2000 can mainly be attributed to methodological reasons. As stated earlier, Turkey has internationally comparable health expenditure figures only for 1999 and 2000. The figure for 1995 in the above Table comes from an MoH Study that had different health care expenditure definitions and methodology. In addition to this, it should be stated that the level of PHE is an estimation after 2000.

1.4.3 Access to health care

1.4.3.1 Out-patient care

Out-patient care in Turkey is provided in health houses, health centers, out-patient clinics of hospitals, private health care centers and private clinics. Health centers and health houses are public facilities attached to the MoH. Doctors in Turkey can practice both in the public and private sector on part time basis. That is why the majority of the specialists in out-patient clinics of public hospitals also practice in their private clinics. General practice as a medical specialty was established in 1983 and there are not enough general practitioners in the country. The graduates of medical schools can practice as 'practitioners' immediately after graduation and out-patient services in health centers are generally provided by them. Specialists usually provide

services in hospitals and private facilities. Patients are free to choose from practicing doctors. As the referral system does not work effectively, in many cases patients jump the primary level of care and attend directly to secondary or tertiary care. This results in direct access to specialist care even in cases where health needs can be met at the primary level. Under the proposed health care system, family practitioners will be the gatekeepers for out-patient care. As stated earlier, the scheme started to be implemented on pilot basis in selected provinces and will be enlarged to the whole country in 2008. Current practitioners without specialties will be trained for a year to perform as family practitioners under the new system.

Public sector out-patient doctors are paid by salaries determined according to the state salary scheme. Doctors and other health personnel are also paid an extra amount from the revolving funds of their institutions calculated according to their performance in the previous month. Performance covers number of patient visits, operations etc. This amount can in some cases be more than salary. In private sector, fee-for-service is the dominant payment method. The envisaged system proposes that family practitioners will be paid on per capita basis.

If a patient is covered by any scheme outlined above, there are no charges for out-patient care in public facilities except for prescriptions (20 % and 10% co-payment for active workers and retirees respectively). In private facilities, a supplement payment determined by the facility may be asked.

Table 1.4: Turkey - Out-patient care 1995, 2000 - 2005

Variable	1995	2000	2001	2002	2003	2004	2005
Total number of doctors	69.349 ¹	85.117 ¹	90.757 ¹	95.190 ¹	97.763 ¹	99.304 ¹	102.500 ¹
Number of doctors per 1,000 inhabitants ²	1,1	1,3	1,3	1,4	1,4	1,4	1,4
Total number of out-patient doctors	NA	NA	NA	NA	NA	NA	NA
<i>thereof General Practitioners</i> ³	49,341 ¹	56,032 ¹	60,505 ¹	63,153 ¹	63,613 ¹	62,144 ¹	64,264 ¹
<i>thereof dentists</i>	11.717 ¹	16.002 ¹	15.868 ¹	17.108 ¹	18.073 ¹		
Number of out patient doctors per 1,000 inhabitants	NA	NA	NA	NA	NA	NA	NA
Number of out-patient clinics departments ("ambulatories")	NA	NA	NA	NA	NA	NA	NA

NA = not available

¹ Source: Sağlık Bakanlığı, 2007

² Source: www.tuik.gov.tr/PrelstatistikTablo.do?istab_id=14

1.4.3.2 In-patient care

In-patient care is provided by both public and private facilities. There were 177,820 beds in public hospitals (92.4 of total beds) and 13,541 beds in private facilities in 2005 (7.6% of total beds)

(Sağlık Bakanlığı, 2005).. Hospitals are predominantly attached to the MoH (65.9% of total beds) and are organized as secondary (MoH hospitals) and tertiary care (university hospitals and selected MoH hospitals) levels. However, as the referral system is not working effectively, under the current system even university hospitals operate as primary level of care.

In theory there are not any OOP payments for in-patient care if a patient is covered. However, recent research in this area showed that in reality patients purchase some of the services that should be provided by the hospital (pharmaceuticals, foods, medical devices) from outside (Tatar et al, 2007).

Doctors in hospitals are employees of the hospital and are paid on salary basis. The hospital personnel are also paid extra allowances from the revolving fund (i.e. the income generated by the hospital) of the hospital according to their performance in the previous month. Performance based payment allows doctors and other health care personnel to earn extra money from services provided in the hospital. As this is basically a fee for service system, there are concerns that this has led to unnecessary utilization of health care services.

Hospitals are remunerated by annual fixed budgets and fee-for-service. The budget allocated from the government usually covers personnel costs and costs of some amenities. Social insurance organizations make fee for service payments based on the Budget Implementation Guidelines (BIG). The Ministry of Finance publishes the fees for services in the BIG annually and payments in the public sector are made according to this tariff. The BIG covers rules of payment and fees for health care services in the public sector. Funds for hospitals come from central government, social health insurance and patients.

Table 1.5: Turkey - In-patient care 1995, 2000 - 2005

Variable	1995	2000	2001	2002	2003	2004	2005
Number of in-patient doctors	NA	NA	NA	NA	NA	NA	NA
Number of in-patient doctors per 1,000 inhabitants	NA	NA	NA	NA	NA	NA	NA
Number of hospitals ¹	1,009	1,184	1,158	1,114	1,126	1,175	1,198
Number of acute care beds ¹	136,072	156,549	159,290	162,235	164,897	171,888	176,785
thereof in private sector ¹	8,934	14,257	14,682	14,729	14,700	14,558	13,541
Acute care beds per 1,000 inhabitants	2.2	2.3	2.3	2.3	2.3	2.4	2.4
Average length of stay in hospital ²	NA	5.9	5.8	5.8	5.8	5.7	5.4

NA = not available

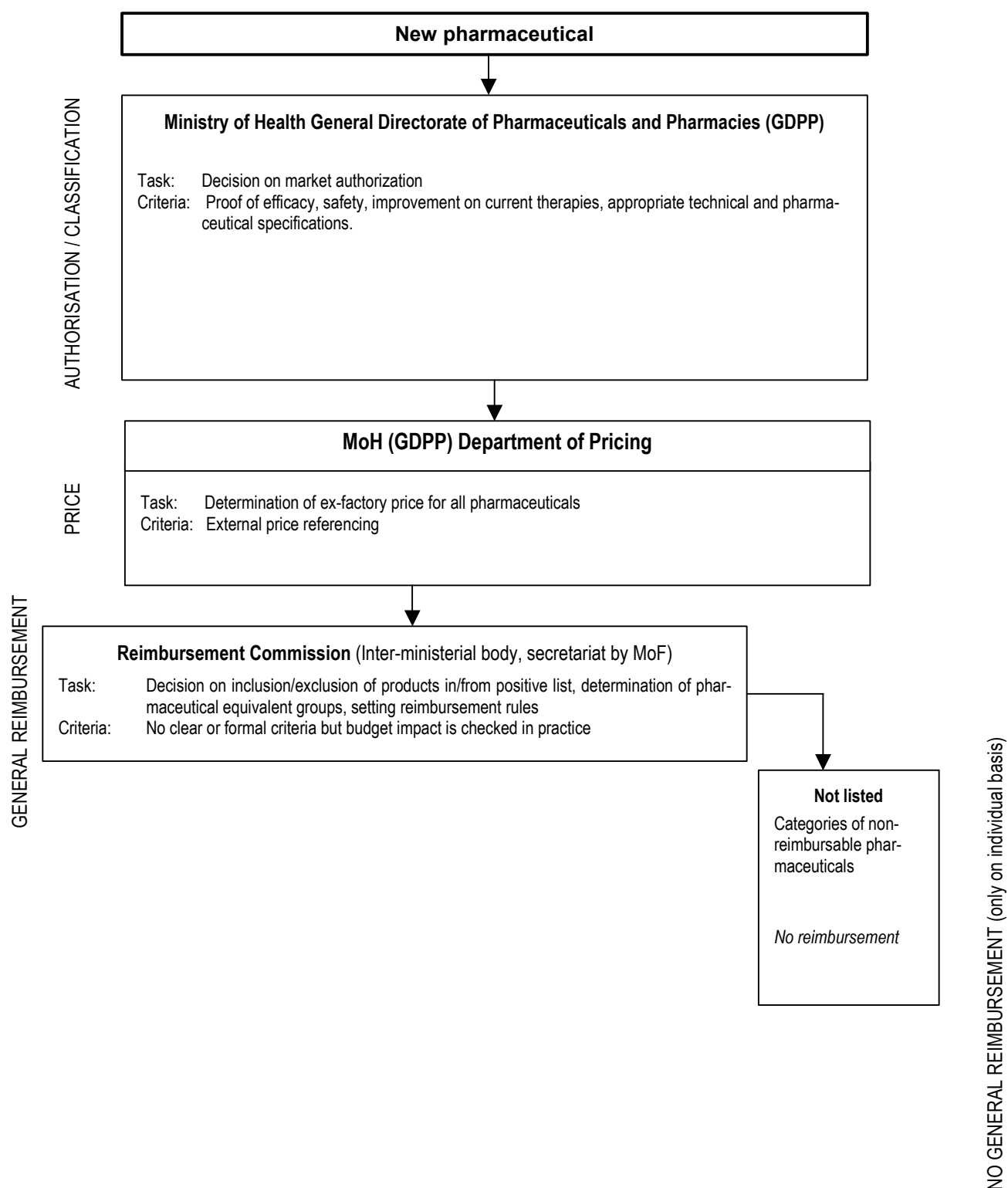
¹ Source: www.tuik.gov.tr/PrelstatistikTablo.do?istab_id_13

² Source: Sağlık Bakanlığı, 2005

2 Pharmaceutical system

2.1 Organisation

Figure 2.1: Turkey - Flowchart of the pharmaceutical system



2.1.1 Regulatory framework

2.1.1.1 Policy and legislation

Pharmaceutical policy is collectively shaped by various authorities in Turkey. The MoH General Directorate of Pharmaceuticals and Pharmacies (GDPP) is the main authority in market authorization, pricing, legal classification and inspection. The basic rules and regulations for all medicinal products are set in the Act on Medicinal Products for Human Use (Act No 1262, Official Gazette No 809, 26.05.1928). Various articles of the Act are amended to meet the requirements in time but the Act is still in effect.

Reimbursement policies are determined by an inter-ministerial commission under the coordination of the Ministry of Finance. The GDPP's responsibilities and working arrangements are explained in Act on the Organization and Duties of the MoH (Official Gazette, 14.12.1983) and the Basic Health Care Services Act (Act No 3359, Official Gazette, 14.05.1987). The Directorate is supported by a number of committees in undertaking its responsibilities which will be detailed in the next section. The duties and working procedures of these commissions are regulated in the Regulation on Setting the Duties of Scientific Advisory Board and Commissions for Medicinal Products for Human Use (Official Gazette No 25254, 9.10.2003). The market authorization approval requirements for pharmaceutical products are declared in the Licensing Regulations for Pharmaceuticals (Official Gazette No 25705, 19.1.2005). This Decree lays down all the information, documents and other related materials that should be submitted to the GDPP for authorization.

The National Patent Act is effective since January 1, 1999. The Act is implemented retrospective from January 1 1995. In line with other departments of the MoH, the GDPP also initiated arrangements for harmonization of EU procedures as Turkey is a potential member state. During this process, modifications for authorization regulations were made on January 19, 2005 to allow a 6-year marketing exclusivity under certain conditions. Accordingly, protection is provided only for new molecules authorized in Turkey after January 1, 2005 and the protection term will effectively begin from the first authorization date in any of the EU Customs Union Zone countries. This protection term is limited with the patent term of the concerned molecule and is applicable to molecules authorized from January 1, 2001 only if there is not a generic application as of December 31, 2004 for these molecules (Kanavos et al, 2005)

There is not a comprehensive policy for pharmaceuticals but a set of policies and legislation that governs the sector. As stated earlier, Turkey had witnessed major health policy reforms in the last 4 years influencing the pharmaceutical sector as well. In the last policy document "Transformation in Health" (Ministry of Health, 2003), establishment of a National Institute of Medicine is proposed. It is envisaged that this institution will be a platform for dialog and consensus for all stakeholders in the pharmaceutical sector. The institution will be responsible for making policies and authorization and will be the regulatory body for production, promotion, marketing and research and development activities.

Decisions on reimbursement are made by the "Reimbursement Commission" under the coordination of Ministry of Finance. The Commission was established in 2004 with the Decree No

2004/6781. The working principles and procedures of this commission are detailed in Chapter 4 Reimbursement section.

2.1.1.2 Authorities

Table 2.1: Turkey - Authorities in the regulatory framework in the pharmaceutical system 2006

Name in local language (Abbreviation)	Name in English	Description	Responsibility
Sağlık Bakanlığı	Ministry of Health	Regulatory body	Overall planning and legislative authority In charge of market authorization and pricing
İlaç ve Eczacılık Genel Müdürlüğü	Directorate of Pharmaceuticals and Pharmacies	Division for pharmaceuticals and pharmacies (a directorate of the MoH)	In charge of market authorization, pricing, legal classification and inspection
Beşeri Tıbbi Ürünler Ruhsatlandırma Danışma Komisyonu	Advisory Commission for the Authorization of Medicinal Products for Human Use	Consulting body. Coordinated by the Directorate of Pharmaceuticals and Pharmacies	Evaluates the submitted approval documents for pharmaceuticals and decides to continue with the next step or not.
Teknoloji-Farmakoloji Danışma Komisyonu	Advisory Commission for Technology and Pharmacology	Consulting body. Coordinated by the Directorate of Pharmaceuticals and Pharmacies	Technical assessment of dossiers
Fiyat Belirleme Komisyonu	Pricing Commission	Coordinated by the Directorate of Pharmaceuticals and Pharmacies	Determines the ex-factory price of a pharmaceutical based on the current external price referencing system.
Biyoyararlanım ve Biyoeşdeğerlilik Değerlendirme Komisyonu	Advisory Commission for bio-availability and bio-equivalence	Consulting body. Coordinated by the Directorate of Pharmaceuticals and Pharmacies	Review and approval of documents for bio-availability and bio-equivalence
Farmakoekonomi Danışma Komisyonu	Advisory commission on Pharmacoeconomics	Consulting body. Coordinated by the Directorate of Pharmaceuticals and Pharmacies	Evaluates and analyzes pharmaceuticals by using pharmacoeconomics analysis such as cost-effectiveness and, cost-minimization.
Geri Ödeme Komisyonu	Reimbursement Commission	Regulatory body for reimbursement decisions. Coordinated by the Ministry of Finance	Decides to include or exclude pharmaceuticals from the positive list. Determines the pharmaceutical equivalent groups.

Source: Ministry of Health, Ministry of Finance

GDPP is the main authority for market authorization, pricing, legal classification and inspection of pharmaceuticals. The directorate is supported by a number of commissions. These commissions are comprised of academicians, pharmacologists, clinicians, other related experts and representatives of the Ministry and other related organizations. The commissions evaluate the documents provided by pharmaceutical manufacturers and their decisions form the basis for marketing and approval. In order to proceed with the next step, each commission should give an approval for the application.

Market authorization is granted only if the company is registered in Turkey. foreign importers can only import their pharmaceuticals through a company registered in Turkey that follows the rules and regulations of Commercial laws. The company should prepare a detailed dossier containing information on safety, efficacy, bio-equivalence (for generics), bio-availability (for originals) and active ingredient information. Since 2005, submission of CPP (Characteristics of Pharmaceutical Product) is obligatory to inform about other countries that the pharmaceutical is authorized.

Application documents are first reviewed by the Advisory Commission for Authorization of Medicinal Products for Human Use. The commission is comprised of approximately 20 permanent experts and additional experts are invited if and when needed for certain pharmaceuticals. Review process for this commission is generally 3-4 months.

After the approval of the first commission, the second commission, Advisory Commission for Technology and Pharmacology evaluates the technical aspects of the product. The prospectus prepared for the product is evaluated in comparison with FDA and EMEA approved prospectus. The commission may request additional data for pharmaceutical safety. Evaluation process usually takes between 6-8 months.

The third stage in pharmaceutical approval process is under the responsibility of the Department of Pricing attached to the GDPP. Pricing is a part of the market authorization process and a prerequisite for completion of the process. There is a Pricing Commission that determines the prices of pharmaceuticals. The commission is comprised of members from the Ministry of Finance, Ministry of Labor and Social Security, State Planning Organization and Treasury and meets quarterly. The commission makes proposals to the MoH about the changes in the prices of the products. If there is a change more than 5% in the exchange rate for more than 30 days, then, upon the invitation of the MoH, the commission meets out of schedule and makes necessary adjustments. Pricing of pharmaceuticals is determined according to the external price referencing system outlined in Section 3. Pricing procedures approximately take 3-6 months.

After completion of the pricing procedures, the commission for bio-equivalence and bio-availability evaluates the information on bio-equivalence (for generics) and bio-availability (for originals). Following the decision of the commission, the application is sent back to the Commission for the Authorization of Medicinal Products for Human Use with approvals given at all stages. The company is given marketing authorization within 2-4 weeks after this process. A barcode is given to the product after registration and after the verification that the product meets the appropriate labeling regulations, a sales permit is issued approximately in 14 days. According to the notice issued by the MoH on December 3, 2003, the market authorization of products are to be completed in 210 days.

If further data and tests are requested from the company, the period for 210 days is halted until the completion of the necessary procedures. If the application is rejected, the company is informed about the decision with justification. The company can object to rejection within 30 days and this objection should be finalized by the MoH within 90 days. The decision reached after this period is the final decision and is not subject to objection.

Reimbursement decisions are made by the Reimbursement Commission. This is an interministerial commission under the coordination of the Ministry of Finance. The commission comprises of members from the Ministry of Health, State Planning Organization, Treasury, Social Insurance Organization, GERF, Bağ-Kur and Ministry of Labor and Social Security. Responsibilities and working procedures of the commission is detailed in the reimbursement section. Market authorization licenses are valid for 5 years and the firm has to apply for renewal of the license 3 months before the deadline.

2.1.2 Pharmaceutical market

2.1.2.1 Availability of pharmaceuticals

As will be seen throughout the profile, lack of data is a major challenge in the pharmaceutical sector. This hinders the attempts to outline the current situation of the sector and also impedes the attempts to make evidence based policies. The available information shows that there were 3,390 pharmaceuticals on the market in 2003 but distribution of these by subcategories as in Table 2.2 is not available. In another report it is stated that in 2005, there were 138 active ingredients and 3,667 products in different forms (approximately 7000) (Kanavos, 2005). The GDPP and the Reimbursement Commission are the main actors in classification of pharmaceuticals.

Table 2.2: Turkey - Number of pharmaceuticals 1995, 2000 - 2006¹

Pharmaceuticals	1995	2000	2001	2002	2003	2004	2005	2006
Authorized								
On the market		2,658	3,162	3,316	3,390			
POM								
Reimbursable								
Generics								
Parallel traded	NA	NA	NA	NA	NA	NA	NA	NA
Hospital-only								
Others (please include further lines if necessary)								

NA = not available, POM = Prescription-Only Medicines

¹ as of 1 January

Source: Ministry of Industry and Trade, 2005

2.1.2.2 Market data

Table 2.3: Turkey - Market data 1995, 2000 - 2005

Pharmaceutical industry in million NCU / €	1995	2000	2001	2002	2003	2004	2005
<i>Prescriptions</i>							
No. of annual prescriptions by volume							
No. of annual prescriptions by value							
<i>Pharmaceutical sales</i>							
Sales at ex-factory price level							
Sales at wholesale price level							
Sales at pharmacy retail price level							
Sales at hospitals							
Sales of generics							
Sales of parallel traded pharmaceuticals							
<i>Exports and imports</i>							
Total pharmaceutical exports (million USD)		140	149	157	246	248	282
raw material		69	72	78	77	67	65
finished product		71	77	79	169	181	217
Total pharmaceutical imports		1,511	1,534	1,716	2,419	2,710	2,845
raw material		828	836	874	1,231	1,380	1,409
finished product		683	698	842	1,188	1,330	1,436

Source: IEIS

The pharmaceutical market data as required by the table is not available. Data on exports and imports are available from the Turkish Association of Pharmaceutical Manufacturers. Accordingly, in 2005, 282 million US \$ worth pharmaceuticals were exported and 2,895 million US\$ worth were imported.

Table 2.4: Top 10 best selling pharmaceuticals, by active ingredient, 2005 or latest available year.

Position	Pharmaceutical, by active ingredient
1	Fluticasone+Salmeterol
2	Imatinib
3	Flurbiprofen
4	Etodolac
5	Hydrochlorothiazide+Valsartan
6	Tiotropium Bromide
7	Docetaxel
8	Olanzapine
9	Atorvastatin
10	Amoxicillin+Clavulonic Acid

Source: IMS

2.1.2.3 Patents and data protection

Issues around intellectual property rights protection have been at the centre of fierce debates in the pharmaceutical sector. The Turkish Patent Act was endorsed in January 1, 1999, valid retrospectively from January 1, 1995. This Act did not have provisions for marketing exclusivity or Supplementary Protection Certificate (SPC). The MoH has, after long negotiations and consultations with all stakeholders, has introduced a 6 year period of marketing exclusivity under certain conditions on January 19, 2005.

According to the new arrangements, marketing exclusivity provides protection only for new molecules registered from January 1, 2005 excluding the molecules registered before the deadline. The protection term begins from the first registration date in any of the EU Customs Union Zone Countries and the protection term is limited with the patent term of the concerned molecule. Marketing exclusivity also covers molecules registered from January 1, 2001 if there is not a generic in the Turkish market or no generic application was made as of 31 December 2004 for these molecules.

2.1.3 Market players

2.1.3.1 Industry

The Turkish pharmaceutical industry is comprised of both research based and generic manufacturers. In 2005 there were 50 research oriented companies and 200 generic manufacturers. The generic companies either manufacture or import generic pharmaceuticals. As there are only branded original and generic products. Research based companies are organized under the Association of Research Based Pharmaceutical Companies (Araştırmacı İlaç Firmaları Derneği) whereas the generic manufacturers are organized under the Pharmaceutical Manufacturers Association (İlaç Endüstrisi İşverenler Sendikası-IEIS). The industry is not involved directly in pricing.

ing and reimbursement commissions but implicit contribution to policy-making is made by informal initiatives.

Pharmaceuticals are distributed from manufacturers to wholesalers and then to pharmacies. For hospitals, pharmaceuticals can either be distributed via wholesalers or from manufacturers directly.

Table 2.5: Turkey - Key data on the pharmaceutical industry 1995, 2000 – 2005

Pharmaceutical industry	1995	2000	2001	2002	2003	2004	2005
Total no. of companies							
- research-oriented							50 ²
- generic producers							200 ²
- biotech							
Number of persons employed ¹		10,871 ³	10,826 ³	11,554 ³	12,734 ³	14,707 ³	18,466 ^{3,4}

¹ counted per head

² Source: IMS

³ Source: Devlet Planlama Teşkilatı, 2007

⁴ Estimate

2.1.3.2 Wholesalers

The distribution channel of pharmaceuticals starts from manufacturers to wholesalers and to pharmacies. There were 491 wholesalers in the market in 2005 (Devlet Planlama Teşkilatı, 2007). However, 70% of the market is represented by two wholesalers (Hedef Alliance and Selçuk Ecza). Alliance Unichem owns 50% of Hedef Alliance. It is envisaged that in the future, with stringent pricing policies and increasing competition in the market, there will be a decline in the number of wholesalers (Kanavos, et al, 2005).

Regional pharmacy co-operatives command an estimated 10-12% share of the wholesale market, serving some 5000 outlets in Bursa, Izmir and Istanbul (IMS). Pharmaceuticals can only be distributed by wholesalers to pharmacies. Hospitals can purchase pharmaceuticals both from wholesalers and companies directly after a tendering process. According to the Public Tendering Act, public hospitals purchase pharmaceuticals from entities that offer the lowest price after a competitive bidding process.

There is a multi-channel distribution system. Pharmacies are serviced routinely by wholesalers but they are also available on call.

As explained in Section 2.1.3.3.1, until February 2005 SSK members were not allowed to buy their prescriptions from community pharmacies and their prescriptions were dispensed from SSK hospitals' pharmacies. In February 2005, after the transfer of the competence of these hospitals to the MoH, SSK prescriptions were also directed to private pharmacies which resulted in an increase in the market size. Despite the increase in the market size it is envisaged that

the pressures on pricing, changes in the reimbursement policies and poor payment conditions will have an adverse impact on the distribution sector. As competition intensifies and working conditions deteriorate, local wholesalers are increasingly seeking joint ventures with foreign companies. The Turkish wholesaler Hedef is already in a 50/50 partnership with the pan-European wholesaler AllianceBoots. Most pharmaceutical manufacturers deal with three or more wholesalers in order to minimize logistical costs and maximize customer access. The co-operatives are making concerted efforts to increase their share to 15% in order to compensate for falling prices, as well as to capture the new business deriving from retail dispensing of SSK and Green Card out-patient pharmaceuticals. With the changes in SSK dispensing rules, delays in payments to pharmacies were experienced. The shift in SSK dispensing and subsequent payment delays suffered by pharmacies has caused knock-on financial problems for the wholesale sector. Wholesalers have proposed that the government should be financially responsible for payment delays of over one month, and they are also seeking alternative financial protection, including a cost-sharing scheme involving pharmacies, distributors and pharmaceutical companies.

Table 2.6: Turkey - Key data on pharmaceutical wholesale 1995 – 2005

Wholesalers	1995	2000	2001	2002	2003	2004	2005
Total number of whole-sale companies							491 ¹
Total number of outlets							5,000 ²

¹ Source: Devlet Planlama Teşkilatı, 2006

² Source: IMS

2.1.3.3 Pharmaceutical outlets / retailers

Pharmaceuticals can in general be dispensed through pharmacies. Doctors are allowed to dispense only if there is not a pharmacy within reach of the community. In case of establishment of a pharmacy within the area, these doctor led entities are closed. Drug stores and supermarkets are not allowed to sell pharmaceuticals and this is valid both for POMs and OTCs. Pharmacy chains and mail order/internet pharmacies are forbidden as well.

2.1.3.3.1 Pharmacies

Pharmacies are private entities in Turkey and hospitals have their own pharmacies only to serve in-patients. Until 2005, the SSK owned its own hospitals and the beneficiaries of this scheme were obliged to purchase their prescriptions from hospital pharmacies for out-patient care as well. With the transfer of these hospitals to the MoH in 2005, the scheme beneficiaries were also allowed to buy their prescriptions from private pharmacies.

Activities of pharmacies and establishment and ownership rules are regulated by Act on Pharmacists and Pharmacies (Act No 6197) and Decree on Pharmacies and Pharmacy Services. Only Turkish citizens with a diploma from a Faculty of Pharmacy can open a pharmacy. Although pharmacies can only be owned by a pharmacist, this does not guarantee the presence of a pharmacist at all times. Pharmacists can hire their degree (Muvazaa) to third parties and a

technician can run the facility. It is envisaged that this system is more widespread in the Eastern and South-Eastern part of the country (Kanavos et al, 2005). A pharmacist can open only one pharmacy and pharmacy chains are not allowed. This issue has been on the agenda recently with strong opposition especially from pharmacists

Pharmacists are organized around the “Turkish Pharmacists Association”. This is a strong and powerful NGO organized in 81 provinces. The provincial branches have a role in the approval of opening new pharmacies within the boundaries of the province. The association is also an active stakeholder within the health policy-making framework.

Pharmacies are remunerated by social security organizations, state and private out-of-pocket payments. They receive free goods from wholesalers and the amount of free goods may be quite influential in their decisions to substitute prescriptions. These issues are explained in detail in relevant sections.

There aren't any incentives to open pharmacies in rural areas. There is not an explicit policy on regulating location hence geographical distribution of pharmacies. There were 22,600 pharmacies in 2005 with 0.3 pharmacies per 1000 habitants. About 500 new pharmacies open each year.

The new pricing legislation hit pharmacies directly, through price cuts, and indirectly, through losses on pre-purchased stock. Stocks bought at prices set before the price reduction was sold to the public at a loss, with most manufacturers refusing returns, and the government refusing to provide compensation (although the wholesale sector received some rebates). Pharmacists also had to absorb some of the rebates introduced to ease the transition of SSK dispensing to private retail pharmacies. Pharmacists are now carrying much smaller stocks. On the other hand, retail pharmacies saw a dramatic upturn in sales from February 2005, when the SSK hospital system was reorganized and SSK institutions no longer dispensed pharmaceuticals to outpatients. In practical terms, however, the change caused operational difficulties as pharmacies were caught unprepared and the government failed to provide sufficient technical and financial support. The merger of the state health insurance funds will reduce some of the operational costs and difficulties for pharmacies, as they will no longer have to run three different systems for reimbursement.

Table 2.7: Turkey - Retailers of pharmaceuticals 1995, 2000 - 2006¹

Retailers	1995	2000	2001	2002	2003	2004	2005	2006
Number of community pharmacies ²							22,600	
No. of private pharmacies								
No. of public pharmacies								
Number of hospital pharmacies for out-patients	NA	NA	NA	NA	NA	NA	NA	NA
Number of other POM dispensaries: _____	NA	NA	NA	NA	NA	NA	NA	NA
Total number of POM-dispensaries ¹	NA	NA	NA	NA	NA	NA	NA	NA
No. of internet pharmacies	NA	NA	NA	NA	NA	NA	NA	NA
No. of OTC dispensaries, like drugstores: _____	NA	NA	NA	NA	NA	NA	NA	NA

NA = not available; No. = number OTC = Over-The-Counter Pharmaceuticals, POM = Prescription-Only Medicines

¹ as of 1 January

² incl. branch pharmacies

2.1.3.3.2 Other pharmacy outlets

Dispensing of pharmaceuticals is not allowed in outlets other than private and hospital outlined above.

2.1.3.3.3 Internet pharmacies

Distance selling of pharmaceuticals through internet is not allowed in Turkey.

2.1.3.3.4 Dispensing doctors

Doctors are allowed to dispense pharmaceuticals only if there is not a community pharmacy within the reach of the community. This is usually the case for the rural parts of the Eastern and South Eastern regions of the country. However, there is not any published data regarding the extent of this practice. Given the surplus of pharmacists in recent years it is believed this is restricted to small number of practitioners. The "Pharmaceutical Cupboard" (İlaç Dolabı) as labeled in the Act should be approved by the Provincial Health Director. These facilities are closed if a pharmacy is opened in that community,

2.1.3.4 Hospitals

Hospitals can have pharmacies only for their in-patients. Dispensing out-patients is not allowed in hospitals with certain exceptions. Hospital pharmacies can dispense pharmaceuticals to out-patients from its retail price if:

- There isn't a pharmacy within reach of the community
- There is an emergency report of a doctor

- A pharmacy reports that the prescribed pharmaceutical is not available in the market.

All hospitals should have a pharmacy. Hospitals purchase pharmaceuticals according to public procurement regulations. Payments for purchased pharmaceuticals are made from the Revolving Funds of the hospital i.e. the money earned from provision of services or from the budget. Pharmaceuticals that should be available in a hospital pharmacy are determined by hospital pharmacists periodically and the hospital administrations purchase these pharmaceuticals after a competitive bidding process. Hospitals can get further reductions on the prices of pharmaceuticals especially in cases where bulk purchasing is made. However, reimbursement prices are used in reimbursement from patients and reimbursement agencies. This means that, even if a hospital gets a substantial discount, the patient is charged the reimbursement price.

2.1.3.5 Doctors

Doctors are organized predominantly around the Turkish Medical Association. The Association does not have an official role in pharmaceutical policy-making. Their influence is restricted to voicing their opposition and referring to courts for cancellation of arrangements made by the government.

In recent years, radical changes have been made as regards to prescription practices of doctors. Accordingly, reimbursement of certain pharmaceuticals is restricted to only prescription by certain specialties. Detailed information on this is given in section 5.2

2.1.3.6 Patients

Patients do not have an active role in deciding which pharmaceuticals will be prescribed. However, they have a certain role in pharmaceuticals dispensed as they can purchase products that are above the reference price level by paying the difference. If they do not accept to pay difference between the reimbursement price and the price of the product then the pharmacist replaces the prescribed pharmaceutical by a reimbursable one in the equivalent group. Prices are determined by the MoH and are fixed so there is not an incentive for patients to shop around for pharmaceuticals. There is not a mechanism that patients can follow the prices of pharmaceuticals. Although there are patient NGOs they are not actively lobbying on pharma issues at the moment.

2.2 Funding

2.2.1 Pharmaceutical expenditure

Total pharmaceutical expenditures were estimated as 1,728,745 NTL / 2,921,939 € in 2000. For the same year, the share of public pharmaceutical expenditures in total public health expenditures was 40.2%.

The level of pharmaceutical expenditures has been subject to fierce debates in the last three years in Turkey. Pharmaceutical expenditures have been the most speculated area of health expenditure estimations ranging from 40-60% of total health care expenditures. The debate around the issue has been fuelled by the IMF demands to curtail public expenditures including health. Pharmaceutical expenditures, especially public expenditures are an area where expenditures can be calculated relatively easily compared to other components of health expenditures. In addition to this, concrete measures can be taken with solid outcomes in a short period of time. With the impetus provided by these arguments, Turkey embarked on several initiatives to regulate pharmaceutical pricing and reimbursement issues. All these measures are explained in detail in relevant sections.

The most accurate figures for pharmaceutical expenditures and its share in health care expenditures in line with international standards were provided by the NHA study carried out for 1999 and 2000. The study concluded that Turkey spent 25% of its total current health care expenditures on pharmaceuticals in 2000 and 64% of these expenditures were made from public purse. Compared to other OECD countries, Turkey seems to spend a higher share of its resources for pharmaceuticals (for the same year this figure was 9% for Denmark, 12% for Luxemburg, 15% for Greece and 20% for France) (OECD,2004). However, conditions peculiar to Turkey should be included in any analysis attempting to compare international figures. This was done by a study in 2005 aiming at analyzing health and pharmaceutical expenditures in Turkey (Liu et al,2005). The study concluded that there is no reason to be concerned about “out of control” cost escalation in pharmaceutical expenditures. The reasons for relatively high share of pharmaceutical expenditures in health expenditures were listed as follows:

- In the Turkish health care market, domestic prices of pharmaceuticals reflect international market prices, whereas labor costs are normally based on national wage structures indicating that other elements of health care expenditures are underestimated.
- Public facilities are highly subsidized in Turkey. According to the NHA Study 35% of MoH hospital revenue comes from general budget meaning that social security organizations have been paying less on hospital services than the actual service costs. However pharmaceutical spending is not subsidized.
- Turkey has fewer physicians and hospital beds than other OECD countries indicating less chance to spend on services than on pharmaceuticals. One clear consequence of this is the high level of self medication. According to the NHA Household Survey, 30% of the people who assessed themselves in need of health care choose to purchase pharmaceuticals and other medical goods without prescription. This means that pharmaceuticals are the most easily accessible goods as they can be bought without a prescription. This is also in contrast to the situation in countries with well established health care.
- Turkey's relatively high percentage of pharmaceuticals in total health expenditure compared to OECD countries could be related to the methodology of the SHA. In the SHA under the pharmaceuticals category only the retail sale of pharmaceuticals i.e. pharmaceuticals sold in pharmacies are included. Pharmaceuticals used during an in-patient or out-patient episode in a hospital are classified under either ‘in-patient’ or ‘out-patient’ category. In Turkey there is evidence both from the NHA Household Survey and other surveys (Tatar et al, 2007) that patients are asked to purchase their prescriptions from pharmacies even when they are hospitalized. In the NHA survey it was found that 29.7% of the people purchased their in-

patient pharmaceuticals in this way. This practice artificially increases the ratio of pharmaceutical expenditure category in the SHA.

- In addition to the above comment, in the OECD countries the majority of health care spending occurs for in-patient services indicating that quite a large amount of pharmaceutical expenditures are absorbed in the “in-patient expenditures” category. In contrast to this, the mode of spending is intensive for out-patient care in Turkey and prescriptions have a higher share in the treatment of patients.

Unfortunately, there is no reliable information on TPE in Turkey. As stated earlier, the most accurate estimations were made by the NHA study for 1999 and 2000 (Ministry of Health, 2004b). The problem lies with the private pharmaceutical expenditures. Public pharmaceutical expenditures are easily estimated from the expenditures of the reimbursement organizations. These were; 1,728,745 NTL / 2,921,934 €, 3,067,062 NTL / 2,884,331 €, 5,231,754 NTL / 3,352,925 €, 6,800,738 NTL / 4,225,365 €, 7,760,420 NTL / 4,318,691 € and 8,779,000 NTL / 5,452,795 € for 2000, 2001, 2002, 2003, 2004 and 2005 respectively. However, without accurate estimations as regarding the total health expenditures and private pharmaceuticals it is not possible to complete the following table.

Table 2.8: *Turkey- Total pharmaceutical expenditure 1995, 2000 - 2005*

Pharmaceutical expenditure	1995	2000	2001	2002	2003	2004	2005
TPE in NCU		2,043					
TPE in % of Total Health Expenditure		24.8					
TPE per capita in NCU		30					
Public PE in % of THE		15.5					
Private PE in % of THE		9.3					

NCU = National Currency Unit, GDP = Gross Domestic Product, TPE = Total Pharmaceutical Expenditure, PE = Pharmaceutical Expenditure

Source: OECD Health Data, 2006

2.2.2 Sources of funds

The main funding source of public pharmaceutical expenditures is the funds from social insurance organizations and the state. As stated in the previous section, the increasing share of pharmaceutical expenditures in public health care expenditures is a contentious issue. It is believed that the following policy changes had various effects on pharmaceutical spending. First of all, in general, access to health care is improved since 2004 with radical changes in the provision side. In the past, the SSK had its own hospitals with restricted access to its members and in many cases low standard facilities. In 2005, as part of the ongoing reforms, these facilities were transferred to the MoH and all MoH hospitals were opened to the SSK members increasing the opportunities of access. Second, access to prescriptions was also improved after allowing SSK enrollees to obtain pharmaceuticals from private pharmacies. In the past, the SSK members were only allowed to buy pharmaceuticals from their hospitals' pharmacies. After the transfer of these hospitals to the MoH, the SSK beneficiaries also started to purchase their prescriptions from private pharmacies as well. Last but by no means the least, in the past, the

Green Card Scheme for the poorest covered only in-patient care hence excluded out-patient care and prescriptions. In 2005 the scheme was extended to cover all health care expenditures easing access of the poorest segments of the society.

Self medication is widely practiced in Turkey. The NHA household survey in 2003 revealed that 28% of the Turkish population purchased pharmaceuticals from pharmacies directly when they felt that they were in need of medical care (Ministry of Health, 2004). A similar result was found in another study aimed at exploring informal payments in the health care sector. (Tatar et al, 2007). The main reason behind this phenomenon is the fact that pharmaceuticals are the most easily accessible health goods in the country. Ironically many of the PoMs can be bought without any prescription from pharmacies. In addition to this, underinsurance, i.e. payment for health care services OPP, is also widely practiced in Turkey due to problems of access in health care.

OOP expenditures are mainly made for pharmaceuticals. (41.4% of total OOP health expenditures were made to buy pharmaceuticals in 2003) (Liu, et al, 2005). Some part of this is caused by co-payment arrangements in the social security organizations but a considerable amount is made for self-medication. Private health insurance sector is not developed in Turkey. In 2000 only 3.6% of the total health care expenditures were made by private health insurance companies (Ministry of Health, 2004).

It is envisaged that the restrictions imposed on prescriptions, reference pricing and exclusion of certain pharmaceuticals from the positive list have resulted in a change for OOP payments for pharmaceuticals. However, at the moment there is no supporting evidence to assess the impact of these policy changes.

Informal payments in health care are also a widely discussed topic in Turkey. A study was carried out in one of the provinces to find out the extent and nature of informal payments in the health care sector in 2003 (Tatar et al, 2007). The study concluded that informal payments comprised of 25% of total OOP payments indicating the need for immediate attention. It was also found that in the public sector, the majority of both formal and informal payments were made for pharmaceuticals. Informal payments for pharmaceuticals were defined in two forms in the study. A payment for a pharmaceutical was accepted as informal, if the patient was forced to buy his/her prescription from a private pharmacy during hospitalization. By law, these pharmaceuticals should be provided from the hospital pharmacy. Also, OOP payments for pharmaceuticals were considered as informal if the patient was fully covered by one of the social security schemes but bought a reimbursable pharmaceutical from OOP.

2.3 Evaluation

There are no specific programs to evaluate the pharmaceutical policy and the system in Turkey. This results in lack of information to assess the impact of policy changes on health, access to pharmaceuticals and cost-containment. There are ad hoc studies carried out to explore certain pharmaceutical policy issues mainly by foundations, associations and industry. For example two studies were carried out in 2005 by the Hope in Health Foundation on pharmaceutical expenditures and reimbursement policies (Kanavos, et al, 2005; Liu, et al, 2005).

As stated earlier, in the Transformation Program, establishment of a National Drug Agency is proposed. When this institution is established, all evaluation issues will be under the responsibility of this institution.

3 Pricing

3.1 Organisation

The MoH has the sole responsibility in pricing decisions. The Pricing Department under the MoH (GDPP) determines the price of each pharmaceutical sold in the country with the Pricing Commission following the external price referencing criteria outlined below. The Pricing Commission meets quarterly under the coordination of the MoH. The commission comprises of members from the Ministry of Finance, State Planning Organization, Ministry of Labor and Social Security and the Treasury. The Commission can be called for urgent meeting in cases of changes in economic indicators, exchange rate etc. The pricing criteria and methodology in Turkey has radically changed since 2004 in line with attempts to reform the Turkish health care system and to control rising pharmaceutical expenditures. In the past, prices of pharmaceuticals were determined upon the application of the firm based on a cost-plus approach. However, increasing concerns about the share of pharmaceutical expenditures in total health care expenditures and pressures from outside to contain public expenditures have resulted in reviewing and regulating the process. This change was first made by the MoH Decree on Pricing of Medicinal Products for Human use on 6 February 2004 (No 2004/6728).

The pharmacy retail price and reimbursement price are different. The rules applied for reimbursement price are outlined in the Reimbursement Section. Pricing and reimbursement responsibilities are not under the same institution. Reimbursement issues are determined by an inter-ministerial Reimbursement Commission detailed in the next section. Pricing decisions are given upon completion of the approval process from the Commission for the Authorization of Medicinal Products for Human Use and Commission for Technical and Local Product Documents (See Section 2.1.1.2. Authority). On average, pricing decisions take approximately 90 days. Reimbursement decisions are given after authorization and pricing of the pharmaceutical.

3.2 Pricing policies

Free pricing is not allowed in Turkey. Prices are determined by statutory pricing.

Table 3.1: Turkey - Ways of pricing of pharmaceuticals

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	Free pricing is not allowed in Turkey		
Statutory Pricing	Statutory pricing at all levels (price setting at manufacturer level, mark-ups at wholesale and pharmacy level)		
Price Negotiations	Not applied except for case where the ex-factory price cannot not be determined via external price referencing due to lacking data		
Discounts / re-bates	Yes	Yes	Yes
Public Procurement	➤ Only for products used in public hospitals		➤ Not applied
Institution in charge of pricing	➤ Ministry of Health		
Legal Basis	➤ Decree no 2004/6781		

Source: Decree on Pricing of Medicinal Products for Human Use (No 2004/6728)

The current pricing system started to be implemented from 2004. Price setting procedures are same for all pharmaceuticals authorized by the MoH. Pricing decisions are made at the manufacturer level and wholesale and pharmacy mark ups and VAT are added later. Price change is not possible unless there are changes in the criteria used.

Requests to change prices can be made both by the MoH and industry. The MoH can call the Pricing Commission if there is a 5% change in the exchange rate for 30 days or in cases where a re-evaluation is needed. The industry can apply for price changes if there is a change in the reference country prices or if there is a change in the exchange rates. The industry has the sole responsibility in informing the prices of the same pharmaceutical in the reference countries. Price changes are determined by the MoH.

3.2.1 Statutory pricing

Statutory pricing is binding for all pharmaceuticals authorized by the MoH at all price levels. Prices are determined by the Department of Pharmaceutical Pricing in the GDPP of MoH.

External price referencing is used in the pricing process. The system started to be implemented from 2004 with the Decree no 2004/6781. The pricing procedures are written in law and enforceable. It is impossible to replace the procedures by other ways of pricing.

The prices of original products are determined by using the prices in a basket of five EU countries (Italy, France, Spain, Portugal and Greece) at the time being (May 2007). Reference countries are determined annually but there has not been any change since the inception of this model. The lowest price in these reference countries is taken as the maximum ex-factory price of an original product. If there is not an ex-factory price for a product in the reference countries then the price of the product could maximum be the sale price to the wholesaler calculated by deducting any mark-ups and VAT from the pharmacy retail price. In cases where the ex-factory price of a product is lower in the country that the product is imported, the price in the country of importation is taken as the reference price. If the product is authorized and available only in one of the reference countries, the ex-factory price in that country is taken as a reference. In cases

where the product is not authorized in any of the reference countries, then the cheapest ex-factory price in the EU countries is taken as a reference. If the product is not authorized in the 25 EU Member States at all then the original country of importation is taken as a reference. For products that are not available and authorized in other countries but only in Turkey then the price is set by negotiations between the MoH and the company. The pharmacy retail price is determined by adding mark ups for wholesalers and pharmacies plus VAT.

For generics, prices are determined as 80% of the price of the original product. Rules are same as original products if the ex-factory price of a product in the importation country is lower than the price of the product in any of the reference countries. The final product price is determined by adding wholesale and pharmacy mark ups and VAT. The prices of generics can not be higher than the original's reference price and the highest price of the equivalent generic in the market.

The reimbursement price is different from the pharmacy retail price. This is the price applied to purchases of public sector i.e. social security funds and the state. The price is determined by applying a public sector discount to the ex-factory price of the product. Currently the rate is 4% for pharmaceuticals newer than 6 years and 11% for pharmaceuticals older than 6 years.

Manufacturers and importers apply to the MoH when there is a need to determine or revise the price of their product. The company is obliged to document the information required for pricing and the procedures are subject to be completed within 90 working days following the application date. If the MoH does not accept the requested price, the period will be frozen until the company submits the required documents. If the company does not submit valid documents for pricing then the MoH price will be valid for the product. The MoH can extend the 90 days period to additional 60 days with prior notification to the company. If the MoH fails to determine the price and notify the company within the given time limits then the price requested by the company will be valid. If the price of the product decreases by 5% in the reference country, the company is obliged to apply the MoH within 3 months to revise the price.

3.2.2 Negotiations

All prices are determined according to the rules outlined above, there are no negotiations. The only case where the price may be determined via negotiations between the MoH and the company is when a product is not authorized in other countries but only in Turkey (See section 3.2.1).

3.2.3 Free pricing

Free pricing is not allowed in Turkey.

3.2.4 Public procurement / tendering

Tendering for pharmaceuticals is carried out in public hospitals. Hospitals purchase pharmaceuticals directly from companies or wholesalers after a tendering process. The procedures and

rules are set in the Public Tendering Act (Act No 4734) elaborating the steps to be followed in any public procurement attempt. All pharmaceuticals used in hospitals should be purchased by following these rules. Tendering process guarantees the purchase of pharmaceuticals from the cheapest offer and the experience shows that hospitals can purchase pharmaceuticals much cheaper than their set prices. However, there are no empirical studies to verify this point.

3.3 Pricing procedures

Turkey used to price pharmaceuticals by cost-plus pricing method until 2004 but the system changed to external price referencing with the Pricing of Medicinal Products for Human Use Decree (No 2004/6781). The Decree was modified later but the basic principles were retained.

Table 3.2: Turkey - Pricing procedures

Pricing procedure	In use: Yes / no	Level of pricing	Scope
Internal price referencing	Not for pricing, however for reimbursement decisions (reference prices system, cf. Section 4.3.)	Manufacturer	Reimbursable
External price referencing	Yes	Manufacturer	All
Cost-plus pricing	No (abolished in 2004)		
Other, e. g. indirect profit control	No		

Source. Decree on Pricing of Medicinal Products for Human Use (No 2004/6728)

3.3.1 External price referencing

External price referencing is applied to all pharmaceuticals (POM, OTC and generics) in Turkey. The prices are determined at ex-factory level, later wholesaler and pharmacy mark ups and VAT are added to reach the pharmacy retail price. This is the only procedure in pharmaceutical pricing except in cases where the product is authorized only in Turkey, see Section 3.2.1..

As stated above, the principles of external price referencing were set by the Decree on Pricing of Medicinal Products for Human Use (No 2004/6781). Accordingly, prices of original products are determined by taking the cheapest price of the product in a basket of five EU countries. At the time of writing the profile (March 2007) these countries were France, Greece, Italy, Spain and Portugal. The price of the original product can only be the maximum of the cheapest ex-factory price in the reference countries. If there is not an ex-factory price of the product, the wholesale price calculated by deducting any mark ups and VAT from the pharmacy retail price is used. In cases where the ex-factory price in the importation country is lower than the designated price, then the price in the importation country is used as reference. The pharmacy retail price is determined by adding the wholesaler and pharmacy mark ups and VAT.

For generics, the price is determined as 80 % of the reference price of the original product. Same rules apply in cases where the price in the importation country is lower than the reference prices and in determining the pharmacy retail price (Section 3.2.1).

The country price information is provided by the company applying for authorization and pricing. A company applying for pricing has to fill the “Price Declaration Form for Human Used Medicinal Products” developed by the MoH. The company provides information on the product, on the prices of the product in reference countries and relevant information if the product is not marketed in the reference countries or the country of importation. The form has to be certified by an authorized person in the headquarter of the company and then stamped by the health or commercial authority in the country. If the form cannot be certified by these authorities, then it should be certified by an authorized attorney or representatives from the Turkish Embassy. The form also has to be signed by an authorized company representative in Turkey.

If there is a decrease of 5% or more in one of the reference countries in the basket, the company manufacturing or importing the product has to apply to the MoH within 3 months to revise the price.

3.3.2 Internal price referencing

There is no internal price referencing for pricing decisions in Turkey; however, Turkey uses internal price referencing (reference price system) in reimbursement (see section 4.3).

3.3.3 Cost-plus pricing

There is no longer cost-plus pricing in Turkey. It was abolished in 2004.

3.3.4 (Indirect) Profit control

There is no profit control in Turkey.

3.4 Exceptions

3.4.1 Hospitals-only

Prices of the hospitals-only medicines are determined the same way outlined above. However, hospitals can achieve price reductions by using the advantages of bulk buying from the market. Hospitals carry out their own procurement through their procurement departments. The procurement procedures for all public entities are outlined in the Public Procurement Act (Act No 4734). Accordingly, hospitals declare the list of pharmaceuticals intended to buy with detailed specifications and companies or wholesalers offer their prices for the products. All proposals are opened at the same day in front of the bidders and the cheapest bid is accepted. There isn't an

established system to monitor or evaluate the prices. Information on prices of pharmaceuticals in hospitals is not readily available as hospitals carry out this process on their own.

3.4.2 Generics

As stated in section 3.3.1, generic prices are determined as 80% of the price of the original product determined by external price referencing.

3.4.3 Over-The-Counter pharmaceuticals

The system for pricing the OTC pharmaceuticals are same as outlined above.

3.4.4 Parallel traded pharmaceuticals

There are no parallel traded pharmaceuticals in Turkey.

3.4.5 Other exceptions

There are no other exceptions.

3.5 Margins and taxes

In Turkey, all pharmaceuticals are regulated via regressive mark up schemes for wholesalers and pharmacies.

Table 3.3: Turkey - Regulation of wholesale and pharmacy mark ups 2006

	Wholesale mark up			Pharmacy mark-up		
	Regulation (yes/no)	Content	Scope*	Regulation (yes / no)	Content	Scope
Turkey	Yes	Regressive mark-ups	All pharmaceuticals	Yes	Regressive mark-ups	All pharmaceuticals

Source: Decree No 2004/6781

3.5.1 Wholesale remuneration

Wholesalers are remunerated via regressive mark-ups with margins being regulated by Decree No 2004/6781. These regulations are binding for all pharmaceuticals. The government regulates the margins strongly by regressive scheme.

Table 3.4: Turkey - Wholesale mark-up scheme 2007

Ex-Factory Price in NCU	Maximum Mark-up in % of Ex-factory price
< 10 NTL	9%
10-50 NTL	8%
50-100 NTL	7%
100-200 NTL	4%
> 200 NTL	2%

Source: Decree No 2004/6781

3.5.2 Pharmacy remuneration

Pharmacies are remunerated via mark-ups determined by the same Decree (No 2004/6781). Regulations cover all pharmaceuticals.

Table 3.5: Turkey - Pharmacy mark-up scheme 2006

Turkey	
Pharmacy purchase price (PPP) from ... to... in NCU/€	Pharmacy mark-up coefficient in % of PPP
<10 NTL / 5.5€	25%
10-50 NTL / 5.5€- 27.7€	24%
50-100NTL / 27.7€ - 55.5€	23%
100-200NTL / 55.5€ - 111.1€	16%
> 200 NTL / 111.1 €	10%

NCU = National Currency Unit

Source: Decree No. 2004/6781

3.5.3 Remuneration of other dispensaries

There are no other dispensaries in Turkey.

3.5.4 Value-added tax

The VAT for all pharmaceuticals is 8%. The percentage used to be 18% before March 2004. The reason for this reduction was mainly to reply the pressures from the market and the state to reduce the costs and prices of pharmaceuticals. The standard VAT is 18% for other goods and services.

3.5.5 Other taxes

There are no other taxes on pharmaceuticals.

3.6 Pricing related cost-containment measures

3.6.1 Discounts / Rebates

Discounts can be both in cash and in kind. These discounts are not based on legal grounds but are commercial. In kind discounts are made both from manufacturers to wholesalers and wholesalers to pharmacies as free goods. In-cash discounts are also a strong determinant of the competitiveness of the offers in hospital procurement. Unfortunately as these discounts are not documented it is not possible to comment on the scope and extent.

As stated earlier there is a public sector statutory discount determined at the time of pricing and this discount is both at the manufacturer and pharmacy level. For original products, the manufacturer discount rate is 4% for pharmaceuticals less than 6 years of authorization in Turkey and 11% for those more than 6 years of authorization. These discounts are made on pharmacy retail price. The rate is 11% for generics. Pharmacy discount is applied on the price determined after manufacturer discount with changing rates. Pharmacy discounts are calculated based on the previous year's sales revenue excluding VAT. The rates are 3% for pharmacies with 220,000 NTL / 122,222 €) annual revenue, 3.5% for annual revenue between 220,000 - 440,000 NTL / 122,222 € - 244,444 € revenue, 4% for 440,000 - 550,000 NTL / 244,444 € - 305,555 € and 4.5% for pharmacies with 550,000 NTL / 305,555 € and over annual revenue. For pharmaceuticals with less than 3.56 NTL retail price a 4% discount is made at the manufacturer level and then the pharmacy reduction is applied. Companies can apply to the Reimbursement Commission for further reductions.

3.6.2 Margin cuts

There hasn't been a change in the mark-ups or margins recently.

3.6.3 Price freezes / Price cuts

There are no price freezes in Turkey.

3.6.4 Price reviews

The pricing procedures are reviewed by the MoH relevant departments and the Pricing Commission but this evaluation does not take place systematically. At the time of writing (March 2007) there are signs that some amendments will be made to the current system by adding new countries to the basket and changing the percentages applied to generics and reimbursement price.

Prices of pharmaceuticals can be adjusted to reflect currency fluctuations. In 2006, there were three price increases, each of 5%, for this reason, while in 2005 prices were reduced to take into account fluctuations in foreign currency and the revaluation of the local currency.

4 Reimbursement

4.1 Organization

In the past, different social insurance organizations had their own reimbursement rules and procedures but in line with the move towards a more united system since 2003 all public agencies follow the same legal arrangements. At the moment all social security funds have one common positive list and they reimburse pharmaceuticals based on the rules set in the Budget Implementation Guidelines (BIG) prepared annually and modified as deemed appropriate throughout the year by the Ministry of Finance. This Guideline sets the rules and principles for spending public funds. The Reimbursement Commission, established by Decree No 2004/6781 in February 2004, is the key body in the preparation of the BIG reimbursement decisions and positive list. The commission's working procedures and principles were detailed in 2006¹. At first all pharmaceuticals reimbursed by the social security organizations were added to the list but in time some OTCs were excluded. The scheme covers all public reimbursing agencies.

The commission is comprised of members from the Ministry of Health, State Planning Organization, Treasury, SSK, GEF and Bag-Kur under the coordination of the Ministry of Finance. Representatives from the Ministry of Labor and Social Security are also invited when needed. There is also a technical commission comprised of experts from academic institutions or related branches that provide consultation and advice. The commission has the sole power in reimbursement decisions. The inclusion/exclusion principles to the positive list are not clear and the roles of participants in this process are not transparent as well. There are concerns that the budget impact has been the overriding criteria so far in reimbursement decisions. The intention, by the introduction of the positive list was to carry out cost-effectiveness analysis for all new pharmaceuticals to be reimbursed, but thus far no such assessment has been performed. The members of the commission can influence the reimbursement decisions. In the past there were instances where the decisions to exclude some pharmaceuticals from the positive list were taken to the court by non governmental organizations and some of these attempts succeeded in including the pharmaceutical on the list again. However the decisions made by these courts are subjective and not based on scientific evidence.

Companies apply to the Ministry of Finance, General Directorate of Budgetary and Fiscal Control (to the Reimbursement Commission) in order to determine the reimbursement status of a pharmaceutical. The written request should be supported by authorization, sales permit, barcode and price approval documents along with the patient leaflet. In addition to these documents the Commission may request, pharmaco-economic evaluation reports and/or information, documents or reports regarding sale and reimbursement requirements abroad.

The reimbursement status of the pharmaceutical can change over time. Some pharmaceuticals may be included or excluded from the list based on new evidence, change of policy, especially

¹ <http://www.bumko.gov.tr/upload/Saglik/GeriOdeme.htm>

for OTCs as government announced the decision on exclusion of nearly 120 OTC products from the Positive List in 2006.

4.2 Reimbursement schemes

The reimbursement scheme is named the Budget Implementation Guide and is published annually by the Ministry of Finance. In theory January 1 is the starting point for the new BIG but in practice some delays can be experienced. In this case, the previous year's BIG is in effect until the publication of the new one. The current scheme was introduced on 29.04.2006 (Official Gazette No 26153). The Guide is prepared by the Ministry of Finance based on the Act on Public Finance Management and Control (Act No 5018).

The scheme covers everyone under public schemes. In other words, the scheme sets all rules and procedures for reimbursement of health care services provided by public schemes. The Commission is obliged to make reimbursement decisions within three months following the application.

4.2.1 Eligibility criteria

Reimbursement decision is made by the Reimbursement Commission based on the recommendations from the technical committee. This committee is organized under the Ministry of Finance. As these procedures are not transparent the reimbursement eligibility criteria are not very clear as well. However, the practice so far indicates that product specific criteria (e. g. essential drug policy, medical & therapeutic value, safety, lack of alternative therapies, prescription status, patent status), economic criteria (e. g. reference price, budget impact), disease specific criteria (e. g. severity of illness, special medical needs) are taken into consideration. In the Decree determining the working procedures of the Commission it is stated that pharmacoeconomic reports can be required from companies or from internationally recognized organizations or institutions if and when needed. So pharmacoeconomic assessments are not used as inputs for reimbursement decisions. In the recent years there are concerns that the budget impact of reimbursement decisions can be the leading criteria during the process.

The same commission also decides on the reimbursement category of a single pharmaceutical. In recent years, it is envisaged that especially after decisions to exclude some widely used OTCs from the positive list, reference pricing system and rules applied to prescription behavior of doctors, OOP payments for pharmaceuticals have increased considerably. However, this claim is not supported by scientific evidence. Reimbursement eligibility depends on the status of the patient and as discussed below (4.2.2) chronically ill people are reimbursed 100%.

4.2.2 Reimbursement categories and reimbursement rates

Pharmaceuticals are fully reimbursed if a patient has a chronic disease certified by a medical report. For active workers 80% for the retired 90% of the reimbursement price are reimbursed. In-patient pharmaceuticals are fully reimbursed. The rules of reimbursement are determined by the Reimbursement Commission. As stated in Section 4.2.1, reimbursement eligibility depends

on the status of the patient. There are not any people excluded from access to reimbursable pharmaceuticals. In other words in the Turkish system the reimbursement rate depends on the population group but not on the pharmaceutical.

Table 4.1: Turkey - Reimbursement of pharmaceuticals

Reimbursement category	Reimbursement rate	Characteristic of category
Pharmaceuticals for active workers	80%	80% of the reimbursement price for active workers and their dependants are reimbursed
Pharmaceuticals for the retired	90%	90% of the prescriptions for the retirees and their dependants are reimbursed.
Chronic patients	100%	Based on the medical report of a group of doctors, pharmaceuticals for chronic diseases are fully reimbursed.
In-patient prescriptions	100%	In-patient prescriptions are fully reimbursed

Source: Budget Implementation Guide

4.2.3 Reimbursement lists

Turkey has a positive list indicating reimbursable pharmaceuticals. The list is administered by the Reimbursement Commission under the coordination of the Ministry of Finance. This is an inter-ministerial commission comprised of members from the Ministry of Health, State Planning Organization, Treasury, SSK (Social Security Institution), Emekli Sandigi (Retirement Fund) and Bag-Kur (Social Security Organization for Artisans and the Self-Employed).

The Commission convenes upon invitation from the Ministry of Finance. The Commission meets in the third week of March and September regularly with the aim of evaluating the general principles of reimbursement and performance in previous months. However, the Commission can convene for an unscheduled meeting upon the invitation of the Ministry of Finance in order to include or exclude pharmaceuticals introduced first time to the market, to revise the positive list, to evaluate the possible technical errors on the list and for other reasons.

The inclusion/exclusion principles for the positive list are not clear and the roles of participants in this process are not transparent as well. In the working procedures of the commission, it is stated that pharmaco-economic assessments can be requested both from the company and other international organizations for reimbursement decisions. It is widely believed that budget impact and economic considerations play a major role in the process. The changes in the list are made regularly in six month intervals during the regular meetings but the Commission can convene upon the call of the Ministry of Finance for urgent action. For reimbursement of pharmaceuticals used in an in-patient episode in hospitals, the price is determined by applying the manufacturer discount outlined in Section 3.6.1 plus a pharmacy discount of 3.5%.

4.3 Reference price system

The Reimbursement Commission outlined above is in charge of determining the principles of the price referencing system. The Ministry of Finance, based on the Act No 5234 is the final authority. The system started to be implemented from 2004.

All pharmaceuticals on the positive list are grouped in pharmaceutical equivalent groups. The groups and list of pharmaceuticals are determined by the Commission based on the advice from the Technical Commission. Currently there are 333 groups. Equivalent groups are based on price comparisons between similar dosages with same active ingredients for the same indication.

The reference price is calculated in comparison to the pharmaceutical with lowest price in equivalent groups. Accordingly, the reimbursement agencies pay the cheapest price plus 22 %. The reference pharmaceutical should be in the market at least for 5 months and should have a market share of at least 1% among the pharmaceuticals in the same equivalent group. If the patient opts for the prescribed pharmaceutical that is not reimbursable s/he has to pay the difference. In cases where the prescribed pharmaceutical is cheaper than the reference price then the pharmacy retail price is reimbursed. Doctors are free to prescribe a pharmaceutical above the reference price. If this is the case then the pharmaceutical is either replaced by a reimbursable one by the pharmacist or the patient pays the difference.

4.4 Private pharmaceutical expenses

Private pharmaceutical expenditures in Turkey can take several forms. Patients can pay OOP as part of the co-payment arrangements, as part of widely practiced self-medication and as the difference between the reference price and prescription. Co-payment percentages are determined by law but in other cases the patient decides whether to make OOP or not.

The NHA study in the year 2000 found that OOP payments for pharmaceuticals had the highest share in total OOP payments (41.4%) (Liu, et al, 2005) in line with the finding that self-medication is widely practiced in Turkey. However, as stated earlier there had been critical reforms and changes in the health sector since then with expected implications on access to health care and pharmaceuticals. It is envisaged that easing access to SSK members and enlarging the coverage for Green Card holders have resulted in more use of health care facilities hence more prescriptions. Also it is envisaged that this might have reduced the self-medication exercise as with extended coverage people are more likely to use health care services. This may mean a decrease in OOP expenditures for pharmaceuticals and a decrease for self-medication and an increase for co-payments would not be a surprise. However, there are not scientific studies to verify these assumptions at the moment.

There are exemptions from co-payments for the chronically ill. Upon a report from a hospital for chronic diseases all covered people are exempt from co-payments and their prescriptions cover a 3 months period i.e. the doctor can prescribe more. At the moment there are no mechanisms applied in order to promote rational consumption of pharmaceuticals aimed at patients.

The objectives of the cost-sharing policies can be stated as to reducing inappropriate demand, containing costs, shifting some responsibility to the consumers and raising revenue for the health sector.

4.4.1 Direct payments

As stated earlier, self medication is widely practiced in Turkey and this is the main reason of direct payments for pharmaceuticals. Pharmaceuticals are still the most easily accessible medical goods for the population. Pharmaceuticals which are under strict prescription rules in other countries can be bought without a prescription from a pharmacy. Prescription is a must for reimbursement but in cases of self-medication it is possible to buy a wide range of products without a prescription. Patients also pay the difference for the pharmaceuticals prescribed by a doctor but not included in the positive list. As stated earlier, in the past the list was very extensive including OTCs as well. Since 2006 some OTCs were excluded from the list gradually, increasing the possible share of direct payments.

4.4.2 Out-of-pocket payments

The co-payment rate in Turkey is 20 % of the reimbursement price for active workers and 10% for the retired. Co-payment is deducted from the salary of the beneficiary. This is valid for all social insurance schemes. For the Green Card holders the co-payment rate is 20%. When the Green Card coverage was extended to out-patient care and prescriptions in 2005, for a short time, no co-payment was asked from the beneficiaries as they are poor people by definition. However, the unprecedented upsurge of Green Card pharmaceutical expenditures resulted in introducing a co-payment for the Green Card holders as well.

The only exemption from co-payments is for the chronically ill. These include tuberculosis, cancer, chronic renal diseases, mental illness, transplantation, diabetes and other diseases with long term treatment. As stated earlier upon the report of a group of doctors, a patient might be exempt from all co-payment and their prescription covers an extended time (3 months). The report has to be renewed every two years.

Table 4.2: Turkey- Reimbursement rates and patient co-payment rates, 2006

Population groups ¹	Co-payment rate in %	Reimbursement rate in %
Active workers and dependants	20%	80%
Retired workers and dependants	10%	90%
Chronically ill	0%	100%
In-patient prescriptions	0%	100%

¹ Reimbursement / co-payment rates depend on the status of the patients, not on the pharmaceutical.

Source: Budget Implementation Guide

4.4.2.1 Fixed co-payments

There are no fixed co-payments in Turkey.

4.4.2.2 Percentage co-payments

There are percentage co-payments in Turkey. However, the percentage co-payments do not differ between pharmaceuticals, but depend on the status of the patients. As stated earlier the percentage is 20% for active workers and 10% for the retired. The only exemption is for the chronically ill and no co-payments are applied in this case.

4.4.2.3 Deductibles

There are no deductibles in Turkey.

Reimbursement in the hospital sector

Pharmaceuticals prescribed during an in-patient episode are fully reimbursed in Turkey. According to the BIG, all in-patient prescriptions should be provided by the hospital pharmacy. However, if the prescribed pharmaceutical is not available in the hospital stocks, upon the certification of the case by a hospital pharmacist the pharmaceuticals can be purchased from a private pharmacy. The maximum dose prescribed in these cases is restricted to five days. The prescription needs to be renewed after five days if the pharmaceutical still can not be provided by the hospital. The main payer of pharmaceuticals in hospitals is the social insurance organization. Hospitals calculate the price of pharmaceuticals used for their in-patients by applying the manufacturer discount outlined in Section 3.6.1 plus a pharmacy discount of 3.5%. For these pharmaceuticals that are not sold in pharmacies, only the manufacturer discount is applied. Even if a hospital gets further discounts from the wholesale or manufacturer at the end of the competitive bidding process, these rates are applied for reimbursement.

4.5 Reimbursement related cost-containment measures

As stated earlier, currently, cost-containment is high on the agendas of health policy makers and pharmaceutical expenditures are the major area of focus. That is why a number of arrangements have been made since 2005 most of them outlined above.

Co-payments have long been in practice in Turkey so it is not a contentious topic at the moment. At the inception of co-payment policy, the share of the patient was paid to the pharmacy. However, in practice after some time, the pharmacies waived this as part of competition among themselves. This meant no cost to patients which is against the underlying reason of introducing the scheme and also resulted in corruption as the covered beneficiaries started to use their benefits for their uncovered acquaintances. In order to avoid this, at the moment the co-payment shares of beneficiaries are directly taken from their salaries.

4.5.1 Major changes in reimbursement lists

There have been major changes in the reimbursement list. In 2004, when all social security schemes were merged under the same positive list, all pharmaceuticals reimbursed by these separate organizations were also merged. However, after the establishment of the Reimbursement Commission a number of changes were made to the list gradually. Turkey did not have a distinction between OTCs and prescription-only medicines until these arrangements. The Commission first determined a number of OTCs that should be excluded from the positive list. Despite fierce oppositions from doctors, pharmacists and patients these are still out of the list.

In addition to this a number of measures were taken for prescription rules of certain pharmaceuticals.

4.5.2 Introduction / review of reference price system

The reference price system is quite new in Turkey. As detailed in Section 4.3, the system was introduced in 2004. At the moment there are preparations to make some amendments but these are not in place yet.

4.5.3 Introduction of new / other out-of-pocket payments

The major change in OOP payments has been for the Green Card holders (poor people). Until 2005 the card was valid only for in-patient care excluding out-patient care and prescriptions. This meant purchasing of pharmaceuticals prescribed after an out-patient episode OOP by the poor people. In 2005 the Card benefits were extended to out-patient care and prescriptions as well. In line with this change the health care expenditures of Green Card upsurged rapidly.

4.5.4 Claw-backs

There are no claw-backs in Turkey.

4.5.5 Reimbursement reviews

As stated earlier, the Reimbursement Commission meets twice annually in order to review the reimbursement activities and decisions in the past. However the commission meets upon the invitation of the Ministry of Finance should the need arise. Both the manufacturers and Third Party Payers can ask for a review of a reimbursement decision. The decisions are published as amendments to the current BIG if an amendment is made.

5 Rational use of pharmaceuticals

5.1 Impact of pharmaceutical budgets

There are no budgetary constraints for prescribing doctors set by third party payers or the state in Turkey. Doctors are not evaluated about their prescribing habits. The prescriptions and other medical interventions are controlled by reimbursement agencies before reimbursement, resulting in some cases with the denial of payment.

5.2 Prescription guidelines

In 2003 a clinical practice guideline for primary care was developed by the MoH (Ministry of Health, 2003). The main aims of preparing the document were listed as: to form the basis for rational pharmaceutical utilization, to increase efficiency in the primary level of care, to increase quality of patient care and to develop scientific and evidence based general guidelines needed by physicians. The MoH took the leading role in developing the guideline. The first step in the preparation was to contact with the physicians working in the field, professional associations and international experts. Several working groups for diseases that are frequently diagnosed and treated in the primary level of care were established and these groups determined the basic rules in diagnosing, treating, monitoring and referral principles of each category. This information is available in a printed version and is also online¹. However, it should be noted that this guideline is not enforceable or in other words utilization depends on the physician and the system does not make any enforcement.

There isn't a regular clinical audit of doctors and there is not an information system used for monitoring prescribing patterns but there are rules of prescribing for reimbursement. In the following only some general rules are outlined.

- A diagnosis should be indicated in all prescriptions with the signature, stamp, specialty area and diploma number of the prescribing physician.
- Doctors can prescribe only 4 items with maximum 7 days dose in a prescription. The daily dose of the pharmaceutical should be indicated clearly. Chronic patients with health reports are exempt from this. If the smallest pack of the pharmaceutical in the market is more than 7 days dose then the prescription should be restricted to one pack. Multiple packs can be prescribed only when the 7 days treatment dose exceeds the smallest pack in the market. Maximum treatment dose is 3 months for chronic diseases with reports.
- A pharmaceutical can only be prescribed for the indication authorized by the MoH.
- In the last BIG a number of restrictions were introduced for prescription of selected pharmaceuticals. These included pharmaceuticals for rheumatological diseases (some of the pharmaceu-

¹ www.hm.saglik.gov.tr

tics could only be prescribed by rheumatologists and physiotherapists, immunologists and internists upon the report of the first two specialties), new age antidepressants and antipsychotics (can only be prescribed by psychiatrists, neurologists and urologists, gynecologists, internists, family practitioners or by other doctors upon the report of the first group).

- There are prescription guidelines for narcotic and psychotropic pharmaceuticals. These can be prescribed only on red and green prescriptions and are followed from manufacturer to patient.

5.3 Information to patients / doctors

Promotion of pharmaceuticals is regulated by the Decree on “Promotion of Medicinal Products” published in 2003. The Decree was prepared to implement the rules of [Directive 2001/83/EC](#). The Decree sets the rules for promotion of pharmaceuticals to the community and health care professionals. Promotion of pharmaceuticals to the community and their advertisement is strictly forbidden in Turkey.

Promotion activities to health care professionals are mainly made through company representatives and scientific meetings. The Decree for promotion also sets the rules of these activities. Accordingly, all printed materials for promotion of a pharmaceutical should have detailed information on the name of the pharmaceutical, active ingredient, name and address of the company. The information should reflect scientific evidence on therapeutic value of the pharmaceutical and proper citations to related printed evidence.

Companies can be sponsors to scientific meetings. In the Decree it is stated that these meetings could be organized in appropriate places with acceptable activities. However, the articles of the Decree are very loose in defining the boundaries of these meetings and promotion activities directed to health care professionals attending these meetings. It is stated that companies should inform all their sponsorship activities to the MoH and all documents should be retained for further investigation by the MoH should the need arise.

Pharmaceutical samples could be distributed to health care professionals but the companies should have a detailed information system recording all information about these products. Sample products should be the decreased versions of the marketed products if possible and should be labeled as “sample product not for sale”.

5.4 Pharmaco-economics

Health economics in general and phamaco-economics in particular are still in its infancy in Turkey. Lack of capacity in both fields poses a barrier before evidence based health and pharmaceutical policy. Health economics and phamaco-economic analyses are not required inputs in pricing and reimbursement decisions. Both in the pricing procedures and reimbursement decision procedures it is stated that pharmaco-economic analysis results may be required from firms and international organizations but this is not a prerequisite. There are also doubts that even if

such information is available to decision-makers, the lack of capacity to assess the results may hinder the attempts to use these analyses.

5.5 Generics

Generics are mainly seen as a cost containment tool. As can be seen from Table 5.1, in 2005, 35% of the total value was comprised of generics. As the local manufacturers are mainly involved in manufacturing or importing generics, this issue is also perceived as an important tool for empowering the local production of pharmaceuticals.

Table 5.1: Turkey - Development of the generic market in the out-patient sector, 2000 - 2005

Generic market share	2000	2001	2002	2003	2004	2005
Volume (number of prescriptions per year) %			49	51	50	51
Value %			31	32	34	35

Source: IEIS (Turkish Association of Pharmaceutical Manufacturers)

5.5.1 Generic substitution

Generic substitution is allowed in Turkey on voluntary basis. The rules of the reference price system are the key determinant in the decision to substitute (i.e. the cheapest in the pharmaceutical equivalent groups plus 22%). When a doctor writes a prescription to be reimbursed, the pharmacist first checks the reimbursement status of the pharmaceutical online. If the prescribed pharmaceutical is not reimbursable and if the patient does not want to pay the difference between the reference price and retail price then the pharmacist can substitute the prescribed pharmaceutical with other pharmaceuticals in the same group.

5.5.2 Generic prescription

Doctors are not obliged to write prescriptions generically. The doctor does not profit from prescribing generic pharmaceuticals and they have to prescribe a “brand” name.

5.5.3 Generic promotion

There aren't active, organized and systematic attempts to promote generics among patients, doctors and pharmacists. The reimbursement policy, by considering the cheapest alternative in the therapeutic group inevitably promotes generic use. Also, as stated earlier, the extent of free goods is an important ingredient in the decision of the pharmacists to replace prescriptions.

5.6 Consumption

Individual consumption data are not monitored in Turkey. There is also not an Essential Drug Policy in place.

6 Current challenges and future developments

6.1 Current challenges

As stated throughout the profile, policies related to pharmaceuticals have been at the core of fierce debates in the last 4 years in Turkey. External and internal influences to contain costs in the health care sector, rising pharmaceutical expenditures and concerns about pricing and reimbursement issues have resulted in reviewing all procedures and processes related to pharmaceuticals starting from registration to pricing and reimbursement. Details of these are outlined in relevant sections. It is evident that this trend will continue in the future but there are specific challenges for a pharmaceutical policy to be successful in Turkey. These can be listed as follows:

- First of all, in order to make evidence based policies, there is an urgent need to review the information available in the health sector in general and pharmaceutical sector in particular. Without sound information on health care expenditures, pharmaceutical expenditures, utilization of health care services and other related topics, it will not be possible to make sound policies. The NHA study carried out for 1999 and 2000 was a good starting point to generate detailed health expenditure data but as the study is not repeated in the following years there is an important information gap in this area.
- Reasons of rising pharmaceutical expenditures should be given special attention as Turkey specific conditions may be the underlying reason.
- Health economics and phamaco-economics capacity should be developed both in the companies and public sector. Improvement of this capacity in the public sector would help decision-makers both in their pricing and reimbursement decisions.
- A major challenge in the sector is related with the transparency of the policy-making environment. There seems to be a long way to go to meet the transparency criteria especially for the reimbursement policies.
- Establishment of a National Drug Agency as proposed in recent reforms should be accelerated.

6.2 Future developments

It seems that both the influence from outside and inside will keep the pharmaceutical policy-making environment under pressure in the foreseeable future. At the moment there is an ongoing debate on revising the external price referencing system. Adding new countries to the market, changing the ratios for generic prices (80% of the original's price at the moment) are high on the agenda.

There will also be changes in the long-run in the decisions of reimbursement as well. Especially more attention will be made to increasing the transparency of the decision-making process.

There will also be improvements in applying pharmaco-economics knowledge and information in the decision-making process as well.

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