



WHO Collaborating Centre
for Pharmaceutical Pricing
and Reimbursement Policies

Short PPRI / PHIS Pharma Profile

TURKEY 2013



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The data provided in this document by the members of the PPRI/PHIS network and other authors represent the current situation. The data have no legally binding value and are meant especially for the information of PPRI/PHIS network members who are committed to sharing information on pharmaceutical pricing and reimbursement.

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Abbreviations

AIFD	Arařtırmacı İlaç Firmaları Derneđi / Association for Research Based Pharmaceutical Companies
COPD	Chronic Obstructive Pulmonary Disease
GDP	Gross Domestic Product
GÖG:	Gesundheit Österreich GmbH / Austrian Health Institute
HIG	Health Implementation Guideline
HTA	Health Technology Assessment
IEIS	İlaç Endüstrisi İşverenler Sendikası / Pharmaceutical Manufacturers Association
IVF	In-vitro Fertilisation
MEEC	Tıbbi ve Ekonomik Deđerlendirme Komisyonu / Medical and Economic Evaluation Commission
MoDef	Milli Savunma Bakanlıđı / Ministry of Defence
MoDev	Kalkınma Bakanlıđı / Ministry of Development
MoF	Maliye Bakanlıđı / Ministry of Finance
MoH	Sađlık Bakanlıđı / Ministry of Health
OECD	Organisation for Economic Cooperation and Development
PHC	Primary Health Care
RC	Ödeme Komisyonu / Reimbursement Commission
SSI	Sosyal Güvenlik Kurumu / Social Security Institution
SSK	Sosyal Sigortalar Kurumu/ Social Security Agency for blue collar workers before the SSI
THE	Total Health Expenditure
TITCK	Türkiye İlaç ve Tıbbi Cihaz Kurumu/Turkish Pharmaceutical and Medical Device Agency

TL	Turkish Liras
TUIK	Turkish Statistics Institute
USD	United States Dollar
VAT	Value added tax
WHO	World Health Organization

Introduction

PPRI / PHIS Pharma Profiles: national reporting systems on pharmaceutical pricing and reimbursement

The need for accurate and up-to-date country information has been broadly acknowledged. Information about specific issues of a country is of key importance for decision makers and researchers, even if their needs with regard to the level of detail may vary.

Within the framework of the PPRI (Pharmaceutical Pricing and Reimbursement Information) research project (2005 – beginning of 2008), the project consortium, consisting of the Austrian Health Institute (Gesundheit Österreich GmbH / Österreichisches Bundesinstitut für Gesundheitswesen) and the World Health Organization (WHO) developed the so-called “PPRI Pharma Profiles” as a tool for understanding, collecting and analyzing pharmaceutical pricing and reimbursement information. A key principle of the PPRI Pharma Profiles was that the Profiles were written by national country experts, usually staff of competent authorities for pharmaceutical pricing and reimbursement (Ministries of Health, Medicines Agencies, Social Health Insurance institutions) represented in the PPRI network and that they were critically reviewed by project consortium members.

PPRI Pharma Profiles, which primarily focused on the out-patient pharmaceutical sector, for 23 countries were published within the years 2007 to 2009. Even if the PPRI project officially ended at the beginning of the year 2008, the PPRI network members continued contributing by updating the PPRI Pharma Profiles.

The PHIS (Pharmaceutical Health Information System) project surveyed, for the first time, information about the in-patient pharmaceutical sector. The PHIS project consortium, including the Austrian Health Institute, the International Healthcare and Health Insurance Institute (IHII) in Bulgaria and the Slovak Medicines Agency (SUKL), developed the PHIS Hospital Pharma report about medicines management in the hospital sector and the PHIS Pharma Profile as a comprehensive report about the pharmaceutical out-patient and in-patient sectors. The principle of involving national experts as authors remained the same. As of mid-2014, 19 PHIS Hospital Pharma reports and 8 PHIS Pharma Profiles were published. All published country reports and profiles are publicly accessible at the website of WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies at <http://whocc.goeg.at/Publications/CountryReports>.

Additionally, in order to allow information at a glance, posters about pharmaceutical systems and policies were produced. They are also available at the WHO Collaborating Centre's website at <http://whocc.goeg.at/Publications/CountryPosters>.

In order to support the production of the PPRI and PHIS Pharma Profiles, templates were made available to the authors. In the course of the years, the templates for the profiles (now called “PPRI/PHIS Pharma Profiles”) were revised, further developed and updated.

The PPRI/PHIS Pharma Profile 2013 is designed to comprise up-to-date information as of 2013 about pharmaceutical pricing and reimbursement in both the out-patient and in-patient sectors and data for the latest available years.

Templates, glossaries and indicators

All PPRI and PHIS Pharma Profiles are based on a template which provides a homogenous outline for reporting. The templates were developed in the PPRI and PHIS projects, were circulated for review and feed-back to the PPRI/PHIS network members, were tested by the authors of the profiles and afterwards revised by consortium members, taking into account the experiences made.

The uniform reporting outline provided by the Pharma Profile Templates provides the benefit that the national reports can easily be used for comparative analyses. The indicators in the PHIS (Pharmaceutical Health Information System) database (<http://phis.goeg.at/index.aspx?alias=phisDatabase>) are derived from the PPRI and PHIS Pharma Profiles. The Pharma Profiles Templates of recent years included references to the relevant PHIS indicators.

Editorial guidelines provide advice to authors and reviewers and aim to increase the readability of the profiles. Readers can expect a universal approach with regard to citations, data presentations, spelling etc. across the PPRI / PHIS Pharma Profiles.

To achieve clarity for authors, reviewers and reader and thus to create a common understanding of the concepts and terms used, a glossary was developed in the early times of the PPRI project. It has been regularly updated since. The most updated version of the Glossary of WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies can be found at the WHO Collaborating Centre's website at <http://whocc.goeg.at/Glossary/About>. Authors of the PPRI/PHIS Pharma Profiles are requested to adhere to the Glossary.

PPRI, PHIS, and WHO Collaborating Centre

Pharmaceutical Pricing and Reimbursement Information (PPRI) was originally a research project, co-funded by the European Commission, Directorate-General Public Health and Consumers. It was performed from 2005 till early 2008. In the course of the project the PPRI network was established, and a set of pharmaceutical indicators, filled with real data from 27 PPRI countries, as well as more than 20 country reports (PPRI Pharma Profiles) and brief overviews on the pharmaceutical systems (country information) were produced.

Today, Pharmaceutical Pricing and Reimbursement Information (PPRI) is a networking and information-sharing initiative on burning issues of pharmaceutical policies from a public health perspective. The PPRI network involves representatives from around 70 institutions: These are public authorities and third party payers from 40 countries (mainly European countries, including all 27 EU Member States) as well as European and international institu-

tions such as European Commission services and agencies, OECD, WHO (HQ and Regional Office for Europe) and World Bank.

In the on-going PPRI initiative, the networking of the public authorities continues via regular networking meetings and continuous sharing of relevant information for decision-making, including up-dates of country-specific information. The PPRI secretariat is hosted at the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (see below).

The PPRI project was selected by the Executive Agency for Health and Consumers, in collaboration with the Health Programme's National Focal Points (NFP) and the Directorate General for Health and Consumers (DG SANCO), as a good practice example of EU Public Health projects with an important impact for EU Member States (http://whocc.goeg.at/Literaturliste/Dokumente/FurtherReading/EAHC_NFP_EUHealthProgramme_ImpactProjects.pdf).

Pharmaceutical Health Information System (PHIS) was a European Commission co-funded project which ran from September 2008 to April 2011. The project aimed to increase knowledge and exchange of information on pharmaceutical policies, in particular on pricing and reimbursement, in the EU Member States, covering both the out-patient and the in-patient sectors. A special focus of the project was on Hospital Pharma, with a European survey of medicines management in hospitals in the EU Member States and an investigation and analysis of official and actual prices of medicines in hospitals in selected case study countries. Methodology tools, in particular with regard to terminology, indicators and reporting tools, were further developed based on work started in PPRI.

The Health Economics Department of the Austrian Health Institute was nominated as WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies in summer 2010 and re-designated in 2014. The Centre continues methodology work started under the framework of the PPRI and PHIS projects: One of the Centre's explicit tasks is to develop the tool for describing and analyzing national pharmaceutical pricing and reimbursement systems ("Pharma Profiles"). WHO Collaborating Centre staff are also involved as experts in the development of the WHO Pharmaceutical Country Profiles by supporting to expand the current tool of the PPRI/PHIS Pharma Profiles for the European countries, and adapting it so that it can describe the pharmaceutical sector in other health system arrangements.

Within the PPRI and PHIS projects, websites were established. Policy makers, researchers and the interested public are thus offered open access to our findings and methodological tools developed. The PPRI and PHIS project websites are no longer maintained, all relevant PPRI and PHIS information was integrated in the website of the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies: <http://whocc.goeg.at>. The website of the Centre is designed to serve as an information platform about pharmaceutical policies, and it includes published profiles, indicators of the PHIS database, glossaries and templates for reporting of pharmaceutical pricing and reimbursement information.

About this short profile

This short profile aims at providing a concise overview of the pharmaceutical system of the given country. The report is structured in 6 sections:

- 1 Health care system
- 2 Pharmaceutical system
- 3 Pricing, reimbursement and volume control in the out-patient sector
- 4 Pricing, reimbursement and volume control in the in-patient sector
- 5 Interface management and developments
- 6 Pharmaceutical data fact sheet

1 Health care system

The Turkish population was 75,627,384 with a female population of 49.8% in 2012. The population increase rate has dropped from 1.35% in 2011 to 1.2% in 2012. The age structure of the country characterises a young and dynamic population but the decreasing trend of the population increase rate and increasing share of the population aged 65 and over reflect that this outlook is changing. In 2012, the 15-64 age group formed 67.6% of the population. The share of the 0-14 age group was 24.9% and the “65 and over age” group was 7.5%. The median age for 2012 was reported at 30.1 (Türkiye İstatistik Kurumu, 2013). The total age dependency rate was 48,4 and total fertility rate was 2.1 for 2011 (Ministry of Health, 2012).

The health care indicators of the country have improved considerably in the last ten years both with the influence of the changes in the health care system and in the socioeconomic indicators. For instance, the overall life expectancy has increased from 70 in 2000 to 75 in 2009 (72 for males and 77 for females). Similar improvements were also observed for other major indicators such as the infant mortality rate, under five mortality rate and maternal mortality rate. The infant mortality rate per thousand decreased from 31.5 in 2002 to 7.7 in 2011, under five mortality rate per 1000 live births decreased from 40 in 2002 to 11.3 in 2011 and the maternal death rate per 100,000 live births decreased from 64 in 2002 to 15.5 in 2011 (Ministry of Health, 2012).

The Turkish health care system has been undergoing a radical reform process since 2003 with radical changes both in the organisation and financing of the system. Before 2003, there were three major social security organisations covering around 60% of the population with varying benefits packages. After the implementation of the reforms, all previous health coverage schemes were gradually merged in the Social Insurance Institute (SSI). The fragmented nature of the health care system was also the same for the organisation of the health care system as well. There were various public providers of health care with varying quality and standards of health care. After the implementation of the reforms, the majority of the public providers were merged under the Ministry of Health (MoH) except the facilities of the Ministry of Defence (MoDef) and the university hospitals.

The health care system is based on social health insurance principles. There are two main actors in the health care system: The Social Security Institution (SSI) and the Ministry of Health (MoH). The SSI is the main financier of the system and the principle purchaser of health care services both from public and private sector. The SSI covers 98.2% of the population (Sosyal Güvenlik Kurumu, 2012) and it is compulsory to be a member.

The health care expenditure trends in Turkey are presented in Table 1.1 below.

Table 1.1: Health Expenditure Trends in Turkey, 1999 - 2013

Years	GDP %	Per Capita Health Expenditure (USD)	Public expenditure (% of THE)	Out-of-Pocket Payments (% of THE)
1999	4.8	186	61.1	29.1
2000	4.9	204	62.9	27.6
2001	5.2	154	68.1	22.8
2002	5.4	188	70.7	19.8
2003	5.3	242	71.9	18.5
2004	5.4	310	71.2	19.2
2005	5.4	382	67.8	22.8
2006	5.8	441	68.3	22.0
2007	6.0	553	67.8	21.8
2008	6.1	624	73.0	17.4
2009	6.1	521	81.0	14.1
2010	5.6	563	78.6	16.3
2011	5.3	556	79.6	15.4
2012	5.4	566	76.8	15.4

GDP = Gross Domestic Product, THE = Total Health Expenditure

Source: Turkish Statistics Institute 2011, 2013

The reforms had an impact on both the demand and supply side and changed the behaviour of both patients and providers. Access to health care services has improved for all segments of the society. For instance, the annual physician visit per patient has increased from 3.0 in 2002 to 8.2 in 2011 (Ministry of Health, 2012). A performance based system was adopted for public sector physicians mainly rewarding the increase in patient care activities.

The main source of funding is social insurance contributions. The premiums are based on the employer and employee contributions. The share of total health expenditure in Gross Domestic Product (GDP) has increased from 4.8% in 1999 to 5.4% in 2012. The share of government expenditures in total health expenditures was 22.2% whereas the SSI's expenditures constituted 54.6% of the total expenditures. In other words 77% of the health care expenditures were made out of public purse. Out-of-pocket expenditures formed 15.4% of total health expenditures with a declining trend. (Turkish Statistics Institute, 2011, 2013).

There are co-payments and user charges at different levels of the health care system for different purposes. The co-payment and user charge rules and amounts are determined by

the SSI and published in the Health Implementation Guideline (HIG) that sets the rules of reimbursement. These are summarised below:

1. Co-payments in out-patient care
 - a. There are no co-payments at public primary health care facilities.
 - b. 5 TL (1.73 €) in public secondary and tertiary care out-patient departments.
 - c. 12 TL (4.15 €) in private hospital out-patient departments having contract with the SSI.
 - d. If the patient refers to another provider with the same specialisation branch within ten days of his/her first visit, an additional 5 TL (1.73 €) is asked in addition to the payments above.
 - e. There is a 10% co-payment for retired members of the SSI and their dependents and 20% co-payment for active workers and their dependents from the total amount of prescription.
 - f. In addition to the above item, there is an additional 3 TL (1.03 €) payment for each prescription up to three items and 1 TL (0.34 €) for each additional item.
 - g. There is a 10% co-payment for retired members and their dependants for medical devices and prosthesis and 20% for active workers and their dependants. However, the total amount for this type of co-payment cannot exceed 75% of the minimum wage.
 - h. There is a co-payment for in-vitro fertilisation (IVF) treatment. The rate is 30% of the SSI tariff in the first attempt and 25% in the second attempt
2. Exemptions from out-patient co-payments
 - a. Emergency care services
 - b. Treatment of occupational diseases and accidents
 - c. Chronic diseases (such as tuberculosis, hepatitis, cancer, metabolic diseases, congenital diseases, hypertensive diseases, cardiovascular diseases, transplantation, asthma, chronic obstructive pulmonary disease (COPD), chronic renal failure and similar diseases)
 - d. Medicines used in in-patient care and laboratory and diagnostic tests
3. User charges
 - a. Foundation University and private hospitals having contract with the SSI can charge an extra out-of pocket payment from patients based on their total invoice amount. This cannot exceed 200% of the total amount.
 - b. Public universities can provide health care after official hours and in this case they can charge the patient an extra amount for both out-patient and in-patient services. For out-patient care this charge cannot exceed 100% (for other services more than 50%) of the invoice amount. The total amount cannot be more than twice the minimum wage in any case.
 - c. If the prescribed medicine is above 10% of the brand price determined by the SSI equivalent groups and if the patient insists on having the prescribed

medicine rather than a substitute medicine then the difference is paid by the patient.

- d. There are also exceptional health care services listed by the SSI and providers can ask maximum three times of the SSI amount from patients. Examples are vaginal delivery epidural, penil prosthesis, laser treatment of prostate, operations with robotic surgery.
4. Exemptions from user charges
 - a. Emergency care services, intensive care, burn treatment, cancer, newborn health care services, organ, tissue and root cell transplantations, surgeries for congenital anomalies, cardiovascular surgeries
 5. Health care providers (both public and private) can ask additional payment from patient rooms with TV, telephone and en-suit bathroom. The amount can be at maximum 1.5 times of the standard bed tariff for rooms with 2 beds and 3 times for single beds.

The Ministry of Health is the main provider of out-patient and in-patient care in addition to its responsibilities in public health domain. Out-patient care is given at the family health centres of the MoH, out-patient departments of the public and private hospitals and private out-patient offices of doctors. The family practitioners scheme, replacing the previous primary health care (PHC) system based on socialised medicine principles, started as a pilot project in 2004 and covered the whole country in 2010. Family health centres are the backbones of the MoH PHC system. Family practitioners are responsible from the population under their list and are paid by capitation payment system. The payment is also linked to some selected performance indicators to motivate preventive activities such as immunisation and maternal and child health care. The remuneration of the health care professionals in these centres is made from the MoH budget. Out-patient care is also given at the out-patient departments of public and private hospitals as well. Public facilities can be both the MoH and university hospitals. The SSI pays a global budget to the MoH for all services provided by the MoH facilities. The MoH then allocates the budget among the hospitals based on their number of visits and diagnosis and treatment procedures. The SSI has a price tariff determining the price of each procedure or treatment. The tariff is either based on package price that pays a fixed price for a visit covering all the procedures undertaken during an out-patient episode or on a fee for service payment. The SSI also purchases out-patient services from private hospitals as well based on the same price tariff. Public hospitals doctors are paid a salary plus an extra payment based on the performance of the doctor in the previous month. Performance is determined as the activities of the doctor in terms of patient care. University hospitals also provide out-patient care based on the same rules for other public hospitals, however, the price tariff is different from public hospitals taking into account the more complex case mix of university hospital patients. As there is not a compulsory referral system, a patient can directly refer to an out-patient department of secondary or tertiary care facility and can avoid the family practitioner level.

The government is the main provider in the in-patient sector. MoH hospitals dominate the system with 121,297 (62% of the total) beds in 2011 compared to 31,648 (16% of the total) beds in the private sector. Both public and private universities have 18% of total beds. However, the reform period since 2003 has resulted in a considerable increase in the share of the private sector in the health care system. In 2003 the share of private beds in total beds was 7% (Ministry of Health, 2012). The main payer in the in-patient sector is the SSI. The MoH hospitals are remunerated by a global budget from the SSI to the MoH. Every year the MoH and SGK negotiate on the global budget of the next year. The MoH allocates the budget through its facilities mainly based on the quantity of the health care services provided. University hospitals, on the other hand, are remunerated by each episode of the in-patient care. Some services and activities are under the package payment system. The SSI has determined the types of services that will be remunerated based on a package price. The episodes of treatment of these diseases are paid a fixed price regardless of the real cost of the treatment and procedures undertaken during care. The rest are paid based on the fee for service system. The SSI has determined a price tariff for these services as well. There are no co-payments for in-patient care in the MoH and university hospitals except user charges for rooms with special facilities. The SSI also purchases in-patient care from private hospitals based on the same principles which hold for public facilities. However, as stated earlier, private facilities can ask extra payment from patients with certain exceptions explained above.

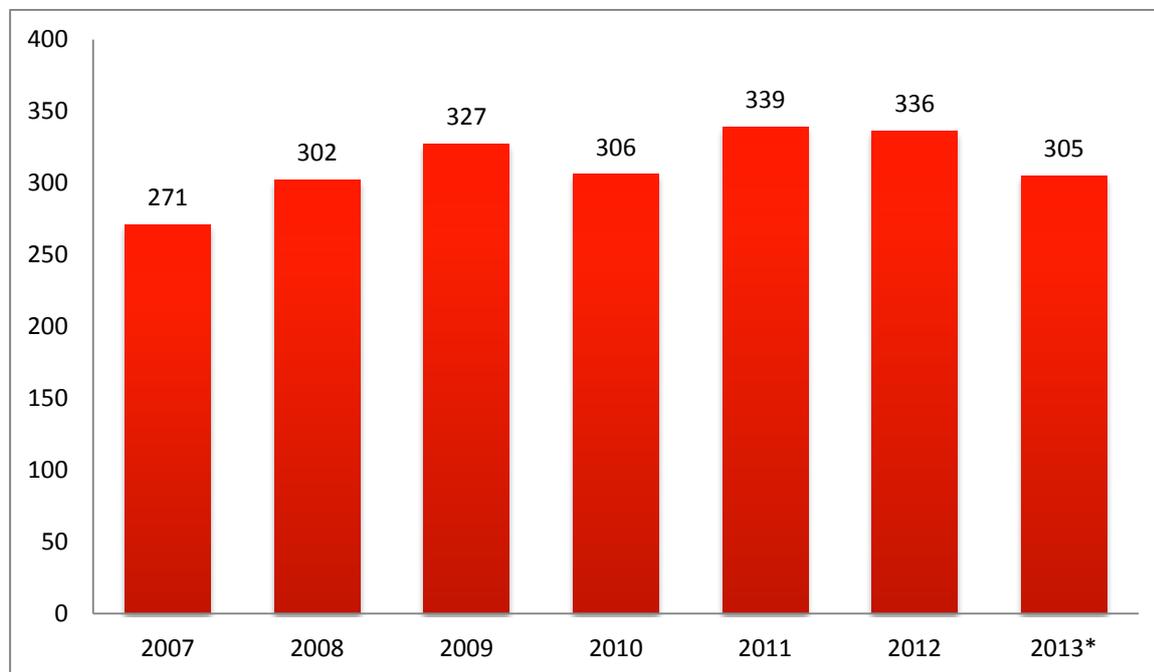
The number of healthcare staff has increased over the years in Turkey. The total number of health care staff has increased from 378,551 in 2002 to 670,092 in 2011 (Ministry of Health, 2012). Of the total number, 19% are physicians, 3% are dentists, 3.8% are pharmacists and 19% are nurses. The number of physicians per 100,000 population has increased from 169 in 2002 to 169 in 2011. However, the figure is still low compared to number of physicians in upper middle income countries (171), upper income countries (277), European Union (326) and the WHO European region (332) (Ministry of Health 2012). A similar trend is observed in all health care staff groups. Physicians work predominantly in the MoH facilities (58.2%), followed by universities (20.9%) and private sector (20.8%). Pharmacists are predominantly in the private sector (91.8%) whereas nurses are in the public sector (77%). The government has a policy of increasing the number of staff especially in areas with chronic shortages (physicians and nurses).

2 Pharmaceutical system

Various organisations and players shape pharmaceutical policies in Turkey. In the public sector, the Ministry of Health (MoH) and the Social Security Institution (SSI) are the key actors. The MoH is the main regulatory body in market authorisation, pricing, legal classification and inspection. In 2012 the organisation of the MoH was revised and the Turkish Pharmaceuticals and Medical Devices Agency (TITCK) was established instead. The agency replaced the former General Directorate of Pharmaceuticals and Pharmacies (IEGM) with extended roles and responsibilities. Currently, all policies and regulations for pharmaceuticals and medical devices are made and observed by this Agency. The second key actor in the public domain, the SSI, is the reimbursement agency for all health care including pharmaceuticals. There is a Reimbursement Commission with members from different public organisations and other sub-commissions supporting this commission in the SSI. The Reimbursement Commission gives the final decision about the reimbursement price and rules and conditions of reimbursement.

The cost containment policy in the health care system in general, and in the pharmaceutical system in particular, is still on the agenda of the Government. Rational use of medicines and measures to support this policy have long been discussed at the government quarters but there is still a long way to go especially in terms of changing the behaviour of both patients and providers. The use of clinically effective, safe, high quality, cost-effective and affordable medicines is stated as the main policy goal for pharmaceuticals. Since 2003, a number of policies and measures have been introduced in all spheres of pharmaceutical policy including marketing approval, pricing and reimbursement. These will be detailed in the following sections.

Accessibility to health care has considerably increased in the health care system with the Transformation Program after 2003. The program reformed both the organisation and financing of the health care system. Comprehensive coverage of the population was achieved with equal benefits to each member of the system. The inequities among different groups of the society, inherited from the previous system, were abandoned gradually and at the beginning of the 2013 all financial schemes were merged under the SSI umbrella with same benefits packages and similar rules. As a result of the changes in the health care system, the number of visits to a physician per person per year has increased from 3.0 in 2002 to 8.2 in 2012. This also meant an increase in the number of prescriptions and an inevitable increase in the volume of medicines prescribed over the years (Figure 1).

Figure 2.1: Number of prescriptions (millions), 2007 - 2012

* Excluding December 2013

Source: <http://www.aifd.org.tr/en/Sektorel-Bilgiler/Veri-Merkezi.aspx>

The following policies have contributed to the increased access and utilisation of health services:

- General health insurance
- Family practitioner scheme
- Performance based payment system
- Use of private facilities in health care provision

The total consumption of pharmaceuticals in terms of units reached to 1,769 million units and to 14,450 million TL (5 billion €) in 2012. The market growth over the years is presented in Table 2. The figures presented in Table 2.1 and Table 2.2 and Figure 2.2 and Figure 2.3 cover the out-patient sector only. In-patient figures are not publicly available. The SSI makes a total payment for each in-patient episode in hospitals, hence the breakdown of the figures for pharmaceuticals is not available.

Table 2.1: Market Size in Terms of Volume and Value in Turkey, out-patient sector only, 2006 - 2012

Years	Volume (million packs)	Value (million TL)
2006	1,292	9,962
2007	1,399	11,588
2008	1,477	12,726
2009	1,527	14,844
2010	1,570	14,790
2011	1,721	15,813
2012	1,769	14,450

Source: www.aifd.org.tr/DataCenter/Table.aspx?p=594 and www.aifd.org.tr/DataCenter/Table.aspx?p=595

The market value of the pharmaceutical sector was 6.64 billion TL (2.29 billion €) in 2005 and reached to 9.1 billion TL (3.1 billion €) in 2011 with 5.4% growth rate. In terms of units, the market size was 1.21 billion units in 2005 and reached to 1.72 billion units in 2011 with 6% growth rate. Although the market has grown by 22% in terms of units and 48% in terms of value between 2005-2009 the increasing trend has slowed down after 2009 with global budget and other cost containment measures. The growth rate in terms of units dropped to 16% between 2005-2011. Whereas the sector has downsized by 8% between 2009-2011 in terms of value (AIFD, 2013). Table 2.2 and Figure 2.2 and Figure 2.3 present the market value of the sector in terms of units and value by breakdown of generics and original medicines.

Table 2.2: Division of market shares between generics and original medicines in value in Turkey (%), out-patient sector only, 2007 - 2012

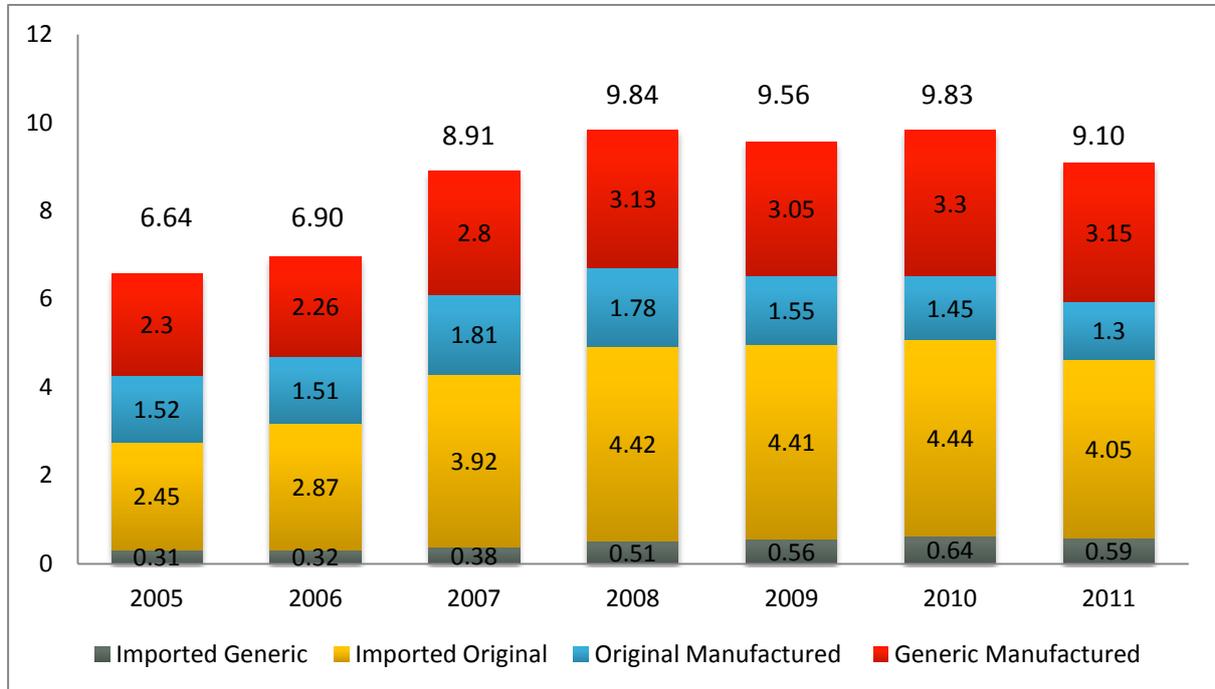
Years	Generics	Original medicines
2007	35.7	64.3
2008	36.8	63.2
2009	37.5	62.5
2010	39.8	60.2
2011	41.2	58.8
2012	41.4	58.6

www.aifd.org.tr/DataCenter/Table.aspx?p=602

www.aifd.org.tr/DataCenter/Table.aspx?p=912

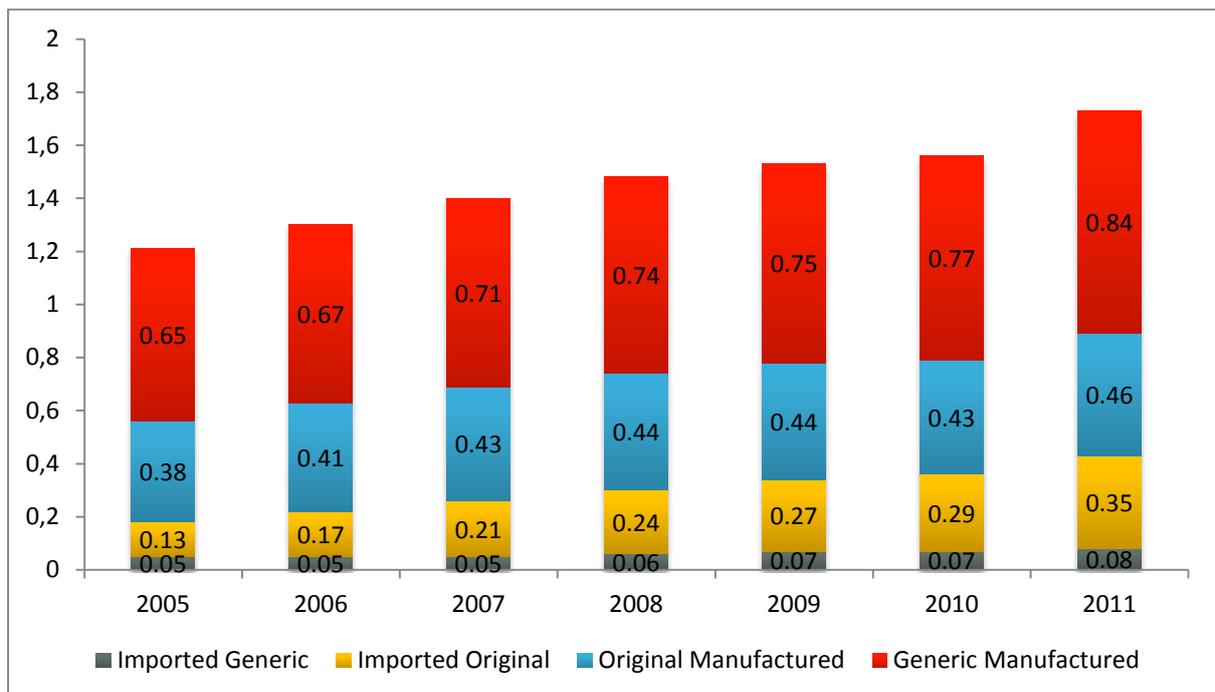
Turkey

Figure 2.2: Total Pharmaceutical Sales Value (million USD), 2005 - 2011



Source: AİFD, 2013

Figure 2.3: Total Pharmaceutical Sales – Volume (million boxes)



Source: AİFD, 2013

The major market players in the pharmaceutical sector are the industry, wholesalers and retailers. The Turkish pharmaceutical industry is comprised of both research based and generic manufacturers. The generic companies either manufacture or import generic pharmaceuticals. Research based companies are organised under the Association of Research Based Pharmaceutical Companies (Araştırmacı İlaç Firmaları Derneği- AIFD) whereas the generic manufacturers are organised under the Pharmaceutical Manufacturers Association (İlaç Endüstrisi İşverenler Sendikası, IEIS). Pharmaceuticals are distributed from manufacturers to wholesalers and then to pharmacies. For hospitals, pharmaceuticals can either be distributed via wholesalers or from manufacturers directly

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 5,000 outlets in Bursa, Izmir and Istanbul (IMS). Pharmaceuticals can only be distributed by wholesalers to pharmacies (Law no 6197). 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 routinely supplied by wholesalers but they are also available on call.

In Turkey pharmacies are private entities, and hospitals have their own pharmacies only to serve in-patients. Until 2005, the SSK (the social security agency for blue collar workers before the SSI) 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 fill 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.

In the out-patient sector, there are two major sources of funding of medicines: the SSI and out-of-pocket payments. The SSI is the main source of funding. Patients purchase their prescriptions from private pharmacies and the SSI reimburses the pharmacies based on their claims. As stated and detailed earlier, there are co-payments for out-patient pharmaceuticals.

In the in-patient sector the major source of fund is the SSI. There are no co-payments for in-patient medicines.

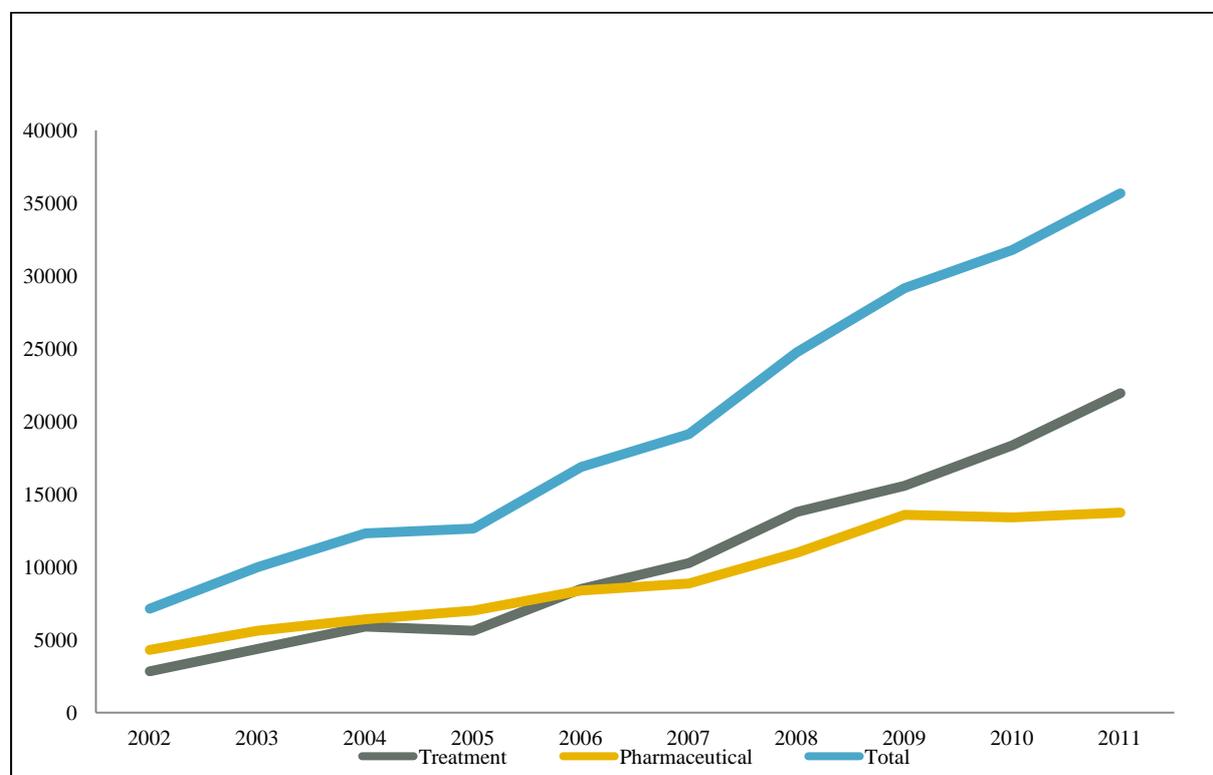
The size of pharmaceutical expenditures has been extensively debated especially at the beginning of the reform initiatives and the discussions have been the driving force behind cost containment measures introduced over the years. The impact of these policies can clearly be seen from the breakdown of the SSI expenditures (Table 2.3 and Figure 2.4).

Table 2.3: Health Expenditure, expressed in TL, of the SSI, 2003 - 2012

Years	Treatment		Medicines		Other		Total
	TL	%	TL	%	TL	%	TL
2003	4,363	40.9	5,615	52.7	685	6.4	10,757
2004	5,906	44.9	6,399	48.7	845	6.4	13,244
2005	5,626	41.3	7,001	51.4	981	7.2	13,701
2006	8,490	48.1	8,372	47.4	805	4.6	17,762
2007	10,268	51.4	8,858	44.3	858	4.3	20,080
2008	13,953	55.0	10,717	42.3	667	2.7	25,444
2009	15,129	52.5	13,161	45.7	521	1.8	28,909
2010	18,469	56.8	13,547	41.7	493	1.5	32,607
2011	21,848	59.9	14,414	38.8	508	1.4	36,599
2012	29,206	66.2	14,300	32.4	605	1.4	44,210

Source: Sosyal Güvenlik Kurumu, 2012

Figure 2.4: Total Health Care and Pharmaceutical Expenditures of the SSI (million TL), 2002- 2011

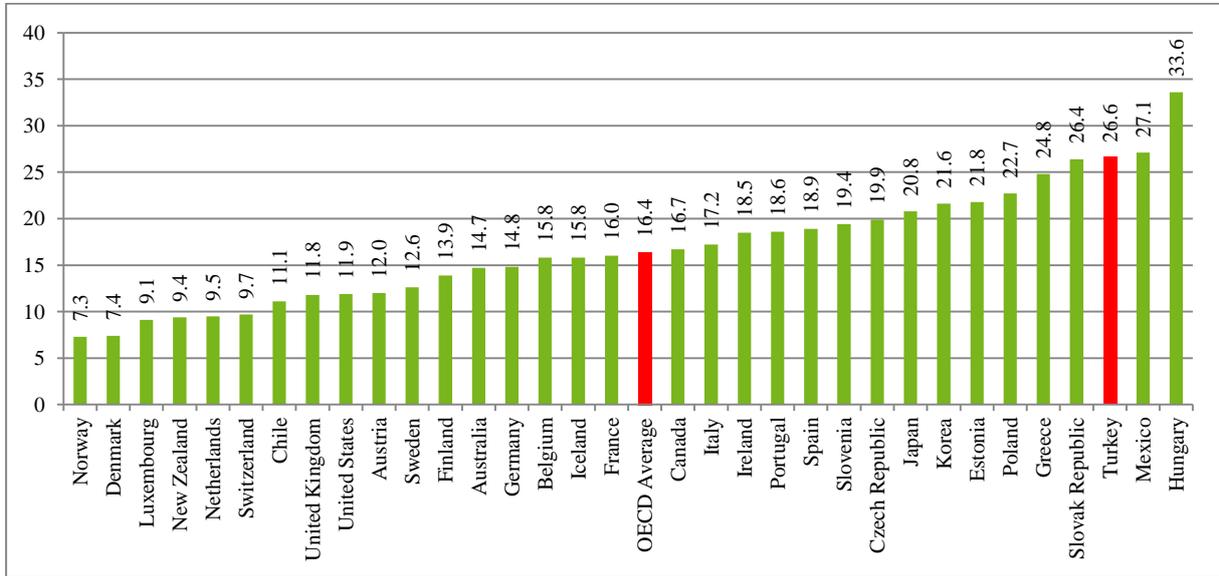


Source: Sosyal Güvenlik Kurumu, 2012

The government determined a global budget for pharmaceuticals in 2010 and increased the pressure on the pharmaceutical sector. The budgets were determined as 14.6 billion TL (5.05 billion €) for 2010, 15.6 billion TL (5.39 billion €) for 2011 and 16.7 billion TL (5.77 billion €) for 2012. According to the protocol signed with the industry and the government, exceeding these amounts resulted in extra measures to contain costs. The government increased rates of discounts and also took other measures in pricing and reimbursement to compensate the exceeding budget in all three years. As a result of these policies, although it is still high compared to OECD countries (Figure 2.5), the share of pharmaceutical expenditures in total health expenditures has decreased over the years (Figure 2.6 and Figure 2.7).

Turkey

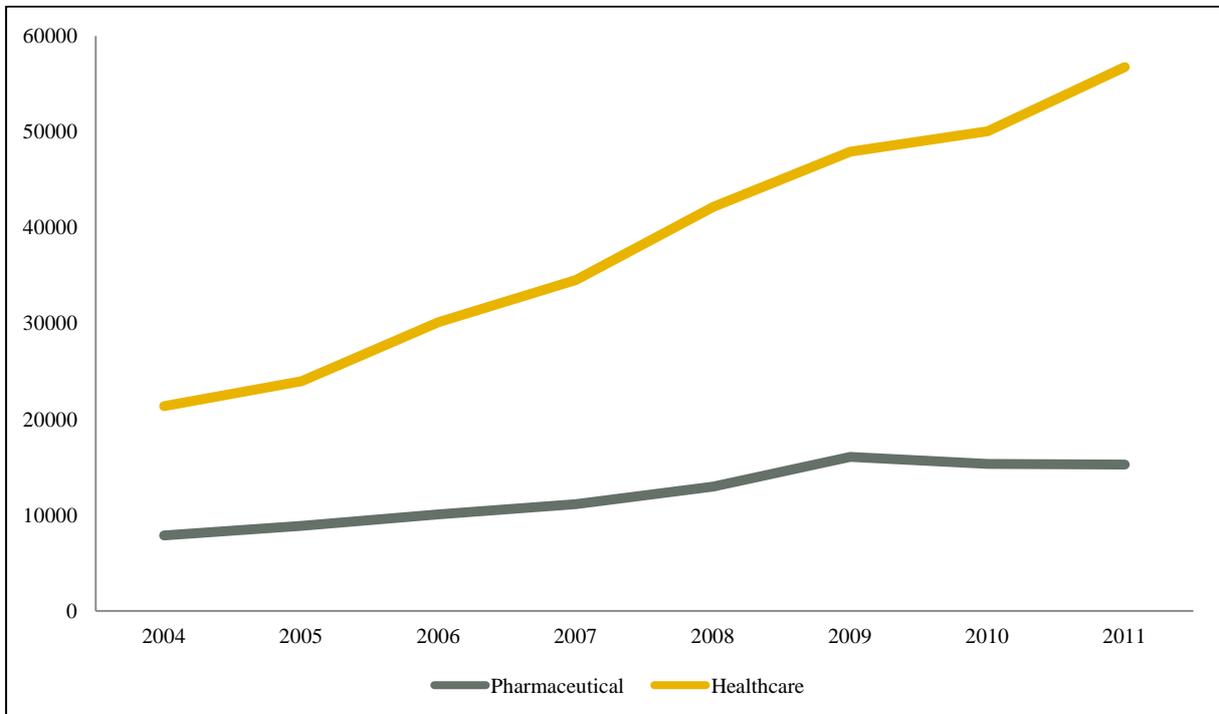
Figure 2.5: Shares of Pharmaceutical Expenditure in % of Total Health Expenditures in OECD country comparison, 2010 or the Latest Available Year



OECD = Organisation for Cooperation and Development

Source: OECD, 2012

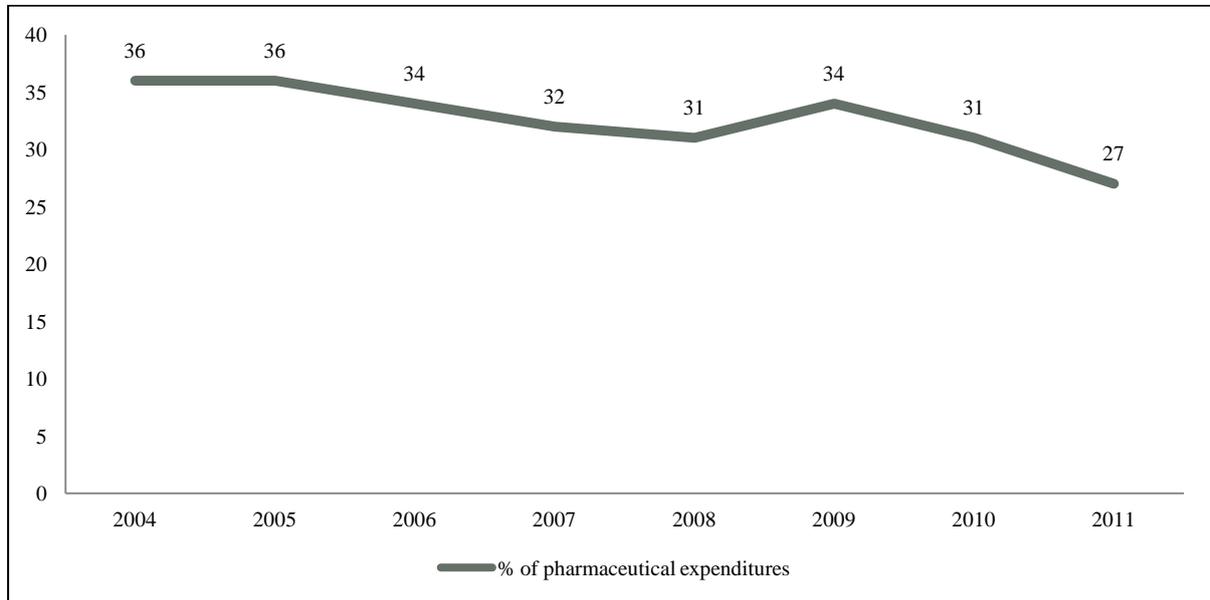
Figure 2.6: Total Health Care and Total Pharmaceutical Expenditures, 2004 - 2011



Source: Sosyal Güvenlik Kurumu, 2012

Turkey

Figure 2.7: Percentage of Pharmaceutical Expenditures in Total Health Care Expenditures in Turkey, 2004 and 2011



Source: Sosyal Güvenlik Kurumu, 2012

3 Pricing, reimbursement and volume control in the out-patient sector

There are two relevant prices for medicines in Turkey: the pharmacy retail price and reimbursement price. The former is determined by the Ministry of Health (MoH) and the latter is determined by the SSI. The MoH is the only authority in determining the ex-factory prices of medicines. The pricing system has changed radically since 2004 from a cost plus approach to external reference pricing. All companies have to apply for marketing approval first and after getting the approval should continue with the pricing procedures in the MoH – no matter whether they market reimbursable, non-reimbursable medicines, prescription only medicines or Over-the-Counter (OTC) medicines). There is a Pricing Commission comprised of members from the MoH, Ministry of Finance (MoF), Ministry of Development (MoDev), Treasury and SSI. The commission meets trimonthly and whenever needed. The commission also decides on the Euro exchange value that will be applied to reference prices. Pricing decisions are made at the manufacturer level and wholesale and pharmacy mark ups and Value Added Tax (VAT) are added later.

The government introduced external reference pricing for new (on-patent) medicines in 2004 with the Decree No 2004/6781. The most recent revision to the Decree was made in 2011. Currently, the ex-factory price of a medicine is the cheapest price in a basket of five countries, namely, France, Greece, Italy, Portugal and Spain. Although the Decree has authorised the government to increase the reference countries up to ten, no change has been made since the inception of the system. The lowest price in these reference countries is taken as the maximum ex-factory price of the original product.

If there is not an ex-factory price for a product in the reference countries then the price of the product could at maximum be the pharmacy purchasing price 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 from which the product is imported, the price in the country of importation is taken as the reference price. If the product is authorised 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 authorised 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 authorised in the 28 EU Member States at all then the original country of importation is taken as a reference. For products that are not available and authorised 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 statutorily regulated fixed mark-ups for wholesalers and pharmacies plus 8% VAT. Table 3.1 below presents the wholesale and pharmacy mark-ups.

Table 3.1: Wholesale and Pharmacy Mark-Ups, 2013

Up to ----	Maximum mark-up in % on the Ex-Factory Price	Maximum mark-up in % on the wholesale price
<10 TL / 3.46 €	9	25
10-50 TL / 3.46 €- 17.3 €	8	24
50-100 TL / 17.3 €- 34.6 €	7	23
100-200 TL / 34.6 €- 69.2 €	4	16
> 200 TL / 69.2 €	2	10

Source: Resmi Gazete, 2007

For generics, prices are determined as 60% of the reference price of the original product. Once a generic enters the market the price of the original also decreases to 60% of the reference price. There is no further decrease in prices of medicines with the entrance of other generics. The medicines marketed before 1.08.1987 are classified as twenty-year medicines. These medicines can be priced up to 80% of the reference price.

For biosimilars, 100% of the cheapest price in reference countries or other EU countries (if the bio-similar is not available in reference countries) is taken as the reference price. For hospital medicines, the price is the cheapest of the 5 reference countries. The price of the original hospital medicine does not drop to 60% of the reference price until a generic enters the market.

The SSI as the main public reimbursement authority is the main actor in deciding on the reimbursement of medicines. Reimbursement rules for all health care interventions are published in the Health Implementation Guideline (HIG), which is binding both for the private and public sector. The Guideline sets the rules for co-payment, reimbursable and non-reimbursable health care interventions, rules of use of certain pharmaceuticals and medical devices and so on.

After getting the price from the MoH, the company applies to the SSI with a dossier covering information about the clinical effectiveness, cost-effectiveness and budget impact of the product. There is a positive list of medicines, and the inclusion to the list is a prerequisite in order to be reimbursed by the SSI. There are two committees deciding on the reimbursement status of the medicines: The Medical and Economic Evaluation Committee (MEEC) and the Reimbursement Commission (RC). The former undertakes the assessment and the latter undertakes the appraisal functions. Both committees are formed by representatives from the SSI and other public organisations such as the MoH, Ministry of Finance and the Treasury. In the Medical and Economic Evaluation Committee, the industry is represented by members from the Association for Research Based Pharmaceutical Companies (AIFD) (original medicines) and Association for Pharmaceutical Industry Employer Organisations (IEIS) (generics). The reimbursement application dossier of the firm is first assessed by the Medical and Economic Evaluation Committee. There is a guideline for firms to follow in preparation of

these documents. The dossier contains three main sections. In the first section the clinical effectiveness data for the pharmaceutical is presented with special reference to the results of clinical trials, efficacy and effectiveness of the medicine and adverse effects. The second section contains information about the economic value of the product and cost effectiveness studies are undertaken. The third section covers information about the expected budget impact of the product. The Medical and Economic Evaluation Committee presents its assessment results to the Reimbursement Commission and the final decision is made by the Commission. The Reimbursement Commission is comprised of members from the Ministry of Finance, Ministry of Health, Treasury, and Ministry of Development. The final decision is based on a combination of the evidence from clinical studies, economic models and budget impact. However, the final verdict is not transparent, in other words, the reasons for inclusion in or exclusion from the list are not made public.

As stated earlier, the reimbursement price of medicines is different from the retail price. There are statutory discounts determined granted by pharmaceutical industry to the SSI for different categories of medicines. Table 3.2 below presents the discount rates. These discounts are based on the ex-factory price of the medicine determined by external reference pricing by the MoH.

Table 3.2: Statutory Discount Rates of the SSI, 2013

Ex-factory price	SSI Discount Rate (%)
General rule	
Medicines with ex-factory price ≤ 3.55 TL (1.25 €)	-
Medicines with ex-factory price ≥ 3.56 TL (1.26 €)	7 or 11 basic discount
Medicines with 20 years label	
Ex-factory price between 3.56 TL (1.26 €) - 6.78 TL (2.40 €)	7
Ex-factory price between 6.79 TL (2.41 €) -10.21 TL (3.62 €)	20 (basic 11+additional 9)
Medicines with 10.22 TL (3.62 €) or more reference ex-factory price	28 (basic 11+17)
Medicines with 10.22 (3.62 €) or more ex-factory price but without reference price. The discount is until a reference price is determined.	40 (basic 11 +29)
Originals without generic	
Ex-factory price between 3.56 TL (1.26 €) - 6.78 TL (2.40 €)	20 (basic11+9)
Ex-factory price 6.79 (2.41 €) TL and more	41 (basic 11+30)
Originals with generics and generics	
Ex-factory price between 3.56 TL (1.26 €) - 6.78 TL (2,40 €)	20 (basic 11+9)
Ex-factory price 6.79 TL (2.41 €) and more	28 (basic 11 + 17)

All pharmaceuticals on the positive list are grouped in pharmaceutical equivalent groups. The groups and list of pharmaceuticals are determined by the Reimbursement Commission based on the advice from the Technical Commission. 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 agency pays the cheapest price plus 10%. The reference pharmaceutical should have been 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. Generic substitution is voluntary.

There are also statutory discounts at the pharmacy level as well. The discount rates are determined according to the annual retail income of the pharmacy. Table 7 shows the current rates.

Table 3.3: Pharmacy Discount Rates in Reimbursement, 2013

Pharmacy turnover	Pharmacy discount (%)
Pharmacies with annual revenue up to 350,000 TL (124,113 €)	1
Pharmacies with annual revenue between 350.000TL (124,113 €) - 600.000 TL (212,765 €)	2
Pharmacies with annual revenue between 600.000 TL (212,765 €) - 900.000 TL (319,148 €)	3
Pharmacies with annual revenue more than 900.000 TL (319,148 €)	4

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 is reimbursed. In-patient pharmaceuticals are fully reimbursed. The rules of reimbursement are determined by the Reimbursement Commission. Reimbursement eligibility depends on the status of the patient, but no citizen is 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.

The reimbursement policy and internal reference pricing motivates the use of generics when they are available.

There are no claw-backs and risk sharing schemes in Turkey. Pharmacoeconomic analysis is required in the application for reimbursement. The analysis is made by the applying firm and assessed by the Medical and Economic Evaluation Committee. Health Technology Assessment (HTA) entered the Turkish health care system within the context of reimbursement of pharmaceuticals. Starting from 2008, HTA started to be discussed both at the MoH and SSI quarters. An HTA department was established within the MoH with the revision of the organisation structure of the MoH. The department published its first HTA report in 2014 about obesity surgery (Sağlık Araştırmaları Genel Müdürlüğü, 2014).

4 Pricing, reimbursement and volume control in the in-patient sector

Hospitals in Turkey are remunerated from the government budget, by the public reimbursement agency, private insurance companies and households. Public hospitals, both state and university hospitals, have a dual budget. All public hospitals receive a line-item budget from the State through the MoH for state hospitals, and the Ministry of Education (for university hospitals). These allocations are made through the routine budget allocation process and mainly cover salary payments and other current and capital expenses.

Payment rules by public reimbursement agencies are determined by the Health Implementation Guideline (HIG) issued by the SSI. The HIG covers rules of payments for all health goods and services ranging from out-patient to in-patient care and pharmaceuticals to medical devices. The HIG is binding for both the public and the private sector. Reimbursement of in-patients are made either by payment per case or by fee for service system. The guideline classifies health care interventions that should be paid by case (Attachment 9) and any other intervention outside the list is paid by fee for service. Attachment 9 of the Guideline covers both the interventions to be paid by case payment system and their fees. These fees consist of bed fees, all consultations and examinations, operations and invasive interventions, anaesthetics, medicines (except blood products), blood components (erythrosine suspensions, full blood, trombocytes, plasma etc), disposable goods, anaesthetic fees, laboratory, pathology and radiology tests and feeds for the accompanying person. Under the fee for service system, all fees are determined by the HIG. The SSI pays the MoH hospitals through a global budget determined annually at the beginning of the year. Other remuneration sources for hospitals are private insurance companies and patients. The private insurance companies pay for their beneficiaries based on their contracts with the private hospitals. Private hospitals are also allowed to ask for a co-payment from publicly covered patients up to a percentage determined by their classification by the SSI explained above. In-patient treatments under the SSI are fully reimbursed. Currently there is no co-payment for patients in MoH hospitals. However, patients who are treated in private hospitals but reimbursed by the SSI can be asked to contribute up to 200% of the original bill as user charge.

The pricing principles do not differ between hospital medicines and others. Statutory pricing is binding for all pharmaceuticals authorised by the MoH at all price levels. Prices are determined by the Department of Pharmaceutical Pricing in the Turkish Medicines and Medical Devices Agency (Türkiye İlaç ve Tıbbi Cihaz Kurumu -TITCK). External price referencing is used in the pricing process. Prices of hospital-only medicines are determined the same way in Turkey, however, hospitals can have discounts during the purchasing process. Public hospitals purchase their medicines through a tendering process (open tendering, tendering among predetermined competitors, bargaining and direct purchasing) and private hospitals apply their own procedures and rules in the tendering process.

The retail prices of hospital medicines are determined by the MoH by using the external reference pricing system but the purchasing prices of hospitals can be different because of the tendering system and a price difference can occur for the same medicine among different hospitals.

Hospital prices are either the ex-factory or wholesale prices as both can supply hospitals. An 8% VAT is added to this value. This rate is fixed for all pharmaceuticals. Normal mark-ups mentioned above are applied to the prices. Discounts can be given in the tendering process. In general it is known that hospital prices are lower than the retail pharmacy prices. First of all there are no pharmacy mark-ups in hospitals and also there are discounts in the tendering process. Public information on the actual prices of pharmaceuticals is not available.

There are four ways of purchasing medicines for hospitals.

Open tendering: In open tendering, the process is open to everyone meeting the requirements determined by the administration.

Tendering among predetermined competitors (procurement by invitation): In cases where the good or service has some specific characteristics and not everyone can produce, the administration can invite these firms to the tendering process. So this is not open to everyone but to those invited only.

Bargaining Negotiations: Bargaining can be used in cases where the monetary value of the good or service is under TL 50,000 (18,382 €). In this case, the administration does not have to announce the purchasing decision but invite those firms that can provide the service.

Direct purchase: In cases where the value of the good or service is less than TL 45,000 (16,544 €, 1 € = 2.72 TL 10.11.2013) the administration can directly purchase from the market.

In the final decision to purchase, the cheapest offer has to be selected. This whole purchasing process is overlooked by a committee established of members of the institution. The hospital pharmacist has a crucial role in purchasing medicines from the beginning to the end. The need for medicines (type, amount etc.) is determined by the pharmacist who is also responsible for administering the stocks. The pharmacist has an important role making the last decision as well. Only pharmaceutical firms and wholesalers can enter the bidding process. Retail pharmacies are not allowed. As the offer with the cheapest price wins the bid the price of the medicine can be cheaper than the price determined by following the external reference pricing system detailed above.

Hospitals carry out their own procurement procedures. Each hospital has its own procurement commission comprised of members from the hospital (5 people) and their decision is the last verdict. The offered price is the main criteria for accepting a tender. As stated above the offer with the cheapest price wins the tender. Pharmaceuticals are not mixed with other goods and services and are purchased alone. The frequency of the procurement process is

determined entirely by the hospital itself. The tender is published in the official gazette, local papers and other media depending on the estimated value of the tender. In procurements by invitation the tender is not published but special letters are sent as invitations. Hospitals do not share information about the procurement process and its results. There are no pharmacoeconomic evaluations required and no HTA.

The main task of a hospital pharmacist is to manage the hospital pharmacy as effectively and efficiently as possible and serve the needs of the in-patients. The pharmacist is responsible for provision of medicines timely and correctly to the wards. She/he is also responsible for controlling stocks and preparing list of medicines to be purchased.

There are two positive lists in place. One for out-patient medicines and one for hospital-only medicines. These lists are declared as attachments to the HIG (http://www.sgk.gov.tr/wps/portal/tr/mevzuat/yururlukteki_mevzuat/tebligler). If the medicine used in the hospital is not listed in the hospital-only-medicines list then the medicines are purchased from the out-patient medicine list. In other words, both lists are used in hospitals. These lists are published as attachments to the HIG. The attachment 2/B lists the hospital-only medicines that are reimbursable by social security agencies. Currently there are around 50 active ingredients on this list. The same procedures as for out-patient medicines are followed regarding the inclusion of hospital-only medicines on the list.

Hospital medicines are fully reimbursed with no co-payments. Hospital pharmacies serve only to in-patients with no exceptions. When a patient is hospitalised his/her medicines are supplied from the hospital pharmacy. The bill includes all expenditures including pharmaceutical expenditures. The SSI or the MoF (in case of active civil servants and the Green Card holders – the latter is a specific scheme to access health services for low-income people, see (Tatar, 2010) and (Tatar, 2007) reimburses the hospital based on the total amount on the bill. If the hospital pharmacy does not have the ordered medicine in the pharmacy then, upon certification of this case by the pharmacists, the medicine can be purchased from retail pharmacies.

5 Interface management and developments

Interface management or integrated care is not organised in Turkey yet. As described above, Turkey has undergone a global health care reform process and the pharmaceutical sector has been subject to substantial changes in terms of licensing, pricing and reimbursement. As the majority of the systemic changes have occurred in the past there is not any further expectation for a major change under these topics. Incremental changes will be in place in the future instead of a radical shift from the current system. There are signs that the SGK is considering to insert some risk sharing arrangements in future, however, these are at an early stage of discussion.

6 Pharmaceutical data fact sheet: TURKEY

		2012	2013	Source	Notes
Demography					
Population	total	75,627,384		TUIK	Data as of 31 December
	0-14 years	18,857,179		TUIK	
	15-64 years	51,088,202		TUIK	
	> 64 years	5,628,003		TUIK	
Life expectancy	at birth				
	at age 65				
Economic data in TL (millions)					
Gross domestic product		1,415,786		TUIK	
Health expenditure	total	76,278		TUIK	
	public	58,560		TUIK	
	private	17,718		TUIK	
Health expenditure in the out-patient sector	total			TUIK	
	public			TUIK	
	private			TUIK	
Health expenditure in the in-patient sector	total			TUIK	
	public			TUIK	
	private			TUIK	
Prescriptions					
No. of prescriptions	in volume (Thousands)	336,023	305,879	AIFD	Prescription in volume = number of items prescribed. Excl. December
Prescriptions	in value (millions)	13,865	13,506	AIFD	Prescription in value = public expenditure of prescribed medicines.

Short PPRI/PHIS Pharma Profile 2013

Turkey

		2012	2013	Source	Notes	
Pharmaceutical consumption						
Total	In packs	1,709,000,000	1,778,000,000		DDD = defined daily doses	
	In DDD					
Out-patient sector	In packs					
	In DDD					
In-patient sector	In packs					
	In DDD					
Generic shares						
Shares in % of total market (in-patient/ out-patient)	In volume	52.7	52.4	AIFD		Volume: Expressed in number of prescriptions Value: Expressed in expenditure
	In value	41.2	40.2	AIFD		
Shares in % of total out-patient market	In volume					
	In value					
Shares in % of out-patient reimbursement market	In volume					
	In value					
Shares in % of out-patient off-patient market	In volume					
	In value					
Shares in % of the in-patient market	In volume					
	In value					
Retailers of medicines						
No. of community pharmacies	private	24,406	TUIK		Data as of 1 January Hospital pharmacies dispensing to out-patients are not included in this figure	
Pharmaceutical expenditure TL (millions)						
Pharmaceutical expenditure	Total	16,390	17,160		Data as of 31 December	
	Public	14,772	15,726			
	Private	1,618	1,434			

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