WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

Short PPRI Pharma Profile

Turkey 2017

Gesundheit Österreich GmbH

PPRI Pharmaceutical Pricing and Reimbursement Information

Short PPRI Pharma Profile Turkey

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WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

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Introduction

PPRI 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 Public 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 analysing 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.

As a further development, information on the in-patient sector was integrated: 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 Public Health Institute, the International Healthcare and Health Insurance Institute (IHHII) 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. 19 PHIS Hospital Pharma reports and 5 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 matched and were made available to the authors. In the course of the years, the templates for the comprehensive profiles (in 2015 the "PPRI/PHIS Pharma Profiles were renamed again to "PPRI Pharma Profiles") were revised, further developed and updated.

The PPRI Pharma Profile 2017 is designed to comprise up-to-date information as of 2017 (or latest available year) about pharmaceutical pricing and reimbursement in both the out-patient and in-patient sectors and data for the latest available years.

Templates and glossaries

All PPRI 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.

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 Pharma Profiles.

To achieve clarity for authors, reviewers and readers 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 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 80 institutions: These are public authorities and third party payers from 46 countries (mainly European countries, including all 28 EU Member States) as well as European and international institutions 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 updates 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 Public Health Institute (GÖG) was nominated as WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies in summer 2010 and redesignated 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 for describing and analysing 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 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.

Since Sept. 2016 the Centre is located at the Pharmacoeconomics Department of the Austrian Public Health Institute (GÖG).

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Abbreviations

EMA : European Medicines Agency

EU : European Union

FDA : Food and Drug Administration

HIG : Health Implementation Guide

HTA : Health Technology Assessment

MEEC : Medical and Economic Evaluation Commission

MoH : Ministry of Health

MRC : Medicines Reimbursement Commission

NPP : Named Patient Program

SSI : Social Security Institution

THE : Total Health Expenditure

TITCK : Turkish Pharmaceuticals and Medical Devices Agency

TRY : Turkish Lira

TUIK : Turkish Statistics Institute

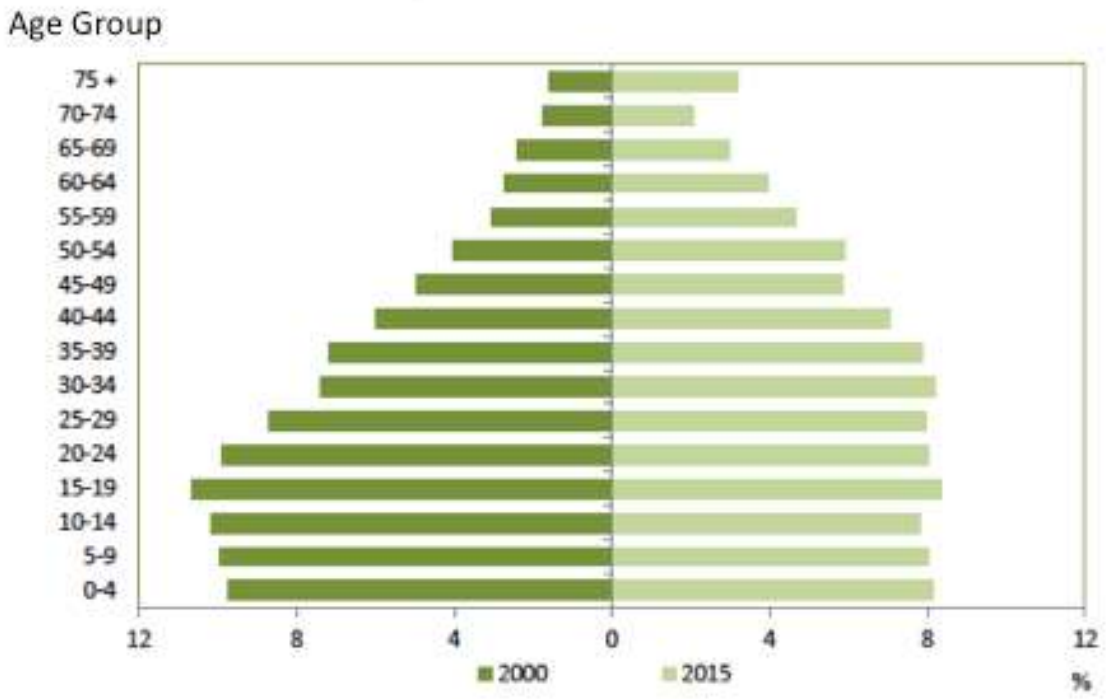
USA : United States of America

NME : New Molecular Entities

1 Health care system

The Turkish population was 78,741,053 of which 49,8% was female. The population increase rate was 13.4 in thousand in 2015 with a slight increase from 2014 (13.3). The median age was 31 in 2015 (Türkiye İstatistik Kurumu, 2016). Turkey is an ageing society with still a high proportion of younger ages in the total population. The figure 1 below compares the developments in the population pyramid of the country between 2000 and 2015 followed by a table on the demographic indicators.

Figure 1 Population Pyramid, Turkey (%)



Sağlık Bakanlığı, 2016

Table 1 Demographic Indicators, Turkey

	2000	2013	2014	2015
Total Population	67,803,927	76,667,864	77,695,904	78,741,053
Rural population (%)	40.8	13.3	12.8	12.4
Population aged 0-14 (%)	29.8	24.6	24.3	24.0
Population over 65 (%)	5.7	7.7	8.0	8.2
Annual population increase rate	18.3	13.7	13.3	13.4

Sağlık Bakanlığı, 2016

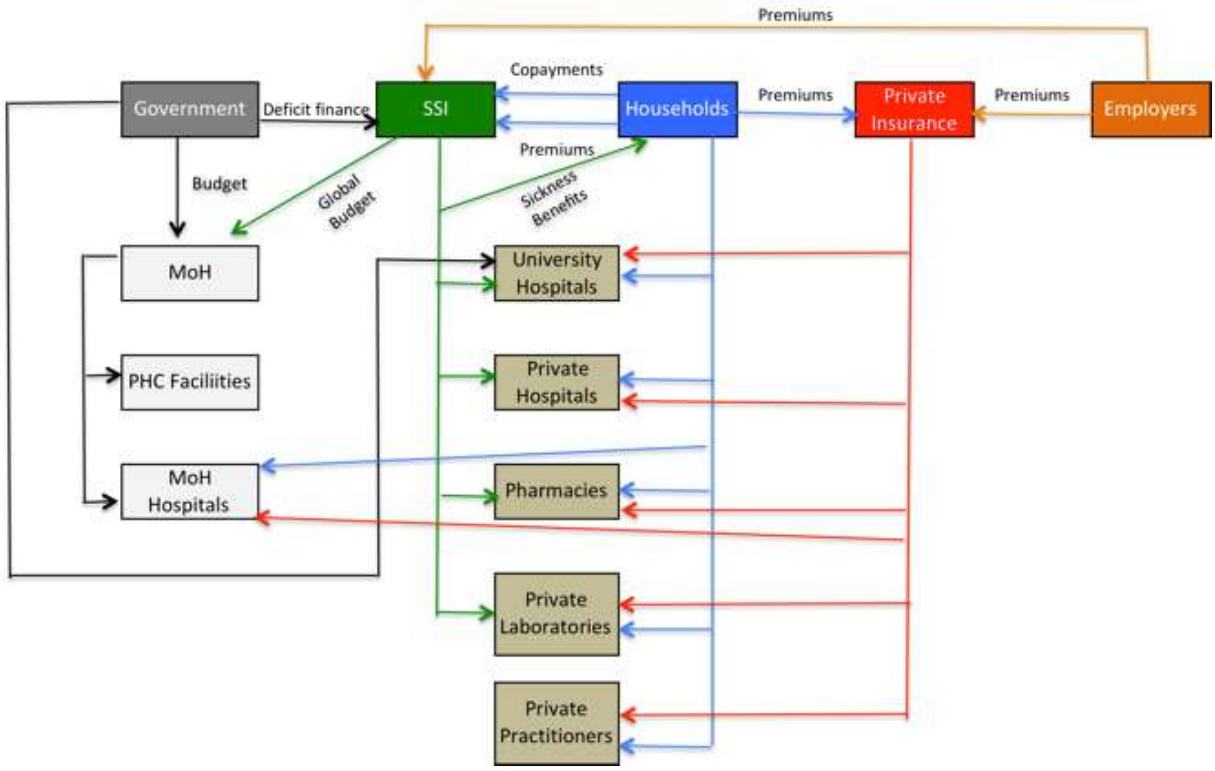
As can be seen from Table 1, the annual population increase rate is declining though in a slow pace. This is reflected in the distribution of age groups in total population. The percentage of 0-14 age group has declined from 35% in 1990 to 24% in 2015 and the percentage of over 65 age group has increased from 4.3% to 8.2% in the same period. In 2015 63.9% of the population was between 15-59 ages. The country's young age population creates an opportunity window for an economically and socially vibrant society but if these trends continue, Turkey will, in the medium term be facing the similar problems of the aged societies. Apart from the changes in the age distribution of the population, there is also a structural change as reflected in the urban/rural ratio of the population over years.

The Turkish health indicators have improved remarkably since 2002 due both to the changes in the health care system and improvements in socioeconomic indicators. The health care system is transformed from a segmented, low coverage and unequal benefits package schemes to a comprehensive, unified and same benefits package system for all residents. This has contributed to improvements in availability and accessibility of health care services. The life expectancy rate has increased to 78 in 2015 from 72.5 in 2002. The infant mortality rate has declined to 7.6 from 31.5 for the same period. Similarly, under five mortality rate per 1000 live births decreased from 40 in 2002 to 9.7 in 2015 and the maternal death rate per 100,000 live births decreased from 64 in 2002 to 14.7 in 2015 (Sağlık Bakanlığı, 2016).

Turkey has a social security based health care system and the Social Security Institution (SSI) is the key player in the financing side with a monopsonic power. The social security premiums are based on the employer and employee contributions and constitute the main funding source for the health care system. Any deficit both in the pension and general health insurance schemes are covered from public funds. In 2015, 98,7% of the population was covered by the universal health insurance (General Health Insurance) scheme (Act No 5510). The benefits package of the system is very generous enabling the Turkish people reaching decent and up-

to-date health care services. As the dominant payer in the system the SSI has an important role in developing and implementing health policies. The figure below displays the flow of funds in the Turkish health care system.

Figure 2: Flow of Funds in the Turkish Health Care System



On the provision side, the Ministry of Health (MoH) is the key actor with a network of primary, secondary and tertiary care facilities. The primary health care services are organized around the family practitioner centres headed by a family physician with a team of health professionals. Everyone in the country has to be registered to a family practitioner but in the absence of a compulsory referral system, patients may visit directly a secondary or tertiary care provider. The number of population per family practitioner is high (3,629 people per practitioner in 2015) and this is regarded as a main challenge to implementing a referral system. The government has declared that decreasing the number of people per a family practitioner is among the most important goals of Turkey in 2017 and beyond. The family practitioners are remunerated by capitation payment (The Decree on Family Practitioner Payment and Contracting- 5705). There are extra incentives for practitioners with good performance indicators measured mainly by preventive measures. There are also weights given to certain population sub-groups and family practitioners are given extra payment for pregnant women, prisoners, children between

0-59 months, and over 65 in their lists. There is also an adjustment on the payment based on the performance of the practitioner. The performance is measured by vaccination rates and follow-up activities in maternal and child health services. If the success rate for the population under this category in these indicators are below 98-97% 2% of the monthly payment to the practitioner is cut. The rates are 4% for rates below 95-96%, 6% for rates below 90-94%, 8% for rates below 85-89% and 10% for the rate below 85%. This system is designed to provide incentives to family practitioners for vaccination and monitoring maternal and child health services. The payments for family health centres are made from the MoH budget. The MoH also makes payments for the rent, amenities, Internet, medical supplies, official supplies and cleaning of family centres as well. Family practitioners are paid extra money for mobile services they provide.

The MoH is also the main provider of secondary and tertiary health care services. There are also university hospitals at the tertiary level and growing number private care providers. In 2015, there were 1,533 hospitals of which 865 were owned by the MoH (56.4%), 70 by universities (4.5%) and 562 by the private sector (36,7%). In terms of hospital beds, there were 209,648 beds of which 127.331 were owned by the MoH (60.7%), 38,361 (18.3%) by the universities and 43,645 (20.8%) by the private sector. As there isn't a referral system, secondary and tertiary care facilities can be the first point of contact for even minor complaints. SSI purchases health care services both from the public and private sector. There are multiple payment mechanisms depending on the type of the contract and ownership of the hospitals. For the MoH hospitals, the MoH and SSI agree on a global budget annually and the SSI transfers the agreed amount monthly to the MoH. The money is then allocated to the hospitals by a formulae developed by the MoH. The incoming year's global budget is negotiated depending on the last year's figures and performance. There are few university hospitals, which are paid by the same global budget system. These hospitals sign a contract with the SSI annually again based on the performance of the last year. However, the majority of the university hospitals are out of the global budget system and are remunerated by the services provided to the patients. There are also two payment methods at this level as well: fee for service and package price. The SSI has classified a number of health care services under a package price list. If this service is provided by the hospital the SSI pays a fixed price covering the whole services regardless of the length of stay of the patient. Some services are exempt from this package and they are paid on fee for service basis. Private hospitals sign a contract with the SSI. They can have a full service contract and give all health care services under the rules of the SSO. They can also sign a contract for certain specialties such as cardiovascular surgery, organ transplantation or oncology. In this case the SSI pays only the services provides under these specialties. Private hospitals can claim up to 200% of the SSI amount from the patient. The amount to be asked from the patient as co-payment differs from hospital to hospital encouraging a competition among hospitals.

Outpatient care is given both by family practitioners and by outpatient clinics of hospitals at the tertiary and secondary care. As stated earlier, as there isn't a compulsory referral system, hospitals' outpatient departments can be referred to as a first level of contact. The physicians at public hospitals are remunerated both from the budgets and revolving funds of hospitals.

There is a fix salary for each staff in the hospital allocated from the government, based on the type, education, experience, marital status etc. of the staff. In addition to this, the staffs in the hospital are remunerated from the revolving fund of the hospital based on their performance measured as number of procedures completed. In other words, the physicians are paid extra based on the number of patients examined, operated and tests completed in the previous month.

In 2015 the share of health expenditures in GDP was 5.4% of which 4.21% was public health expenditures and 1,15 was private expenditures. This was the lowest figure among the OECD countries (OECD average 8.9%). In terms of PPP the health care expenditure per capita was 1,063 USD for the same year. There has been a steady decrease in out-of-pocket (OOP) expenditures per capita due to increased coverage and accessibility to health care services. In 2015, the share of OOP in total healthcare expenditures has decreased to 16.6% from 22.8% in 2005 (OECD average 20.1%) (Sağlık Bakanlığı, 2016). The total health care expenditures were estimated as 104.568.000.000 TRY in Turkey of which 78.5% was from public sources. 49% of this amount was spent in hospitals, 11% was spent in outpatient centres and 25% were spent or medical devices and pharmaceuticals (Türkiye İstatistik Kurumu, 2015). The total health expenditure (THE) trends in Turkey are presented in Table 2 below.

Table 2: Health Expenditure Trends in Turkey, 1999-2015

Years	GDP (%)	Per Capita Health Expenditure (US$)	Public Expenditure (% of the THE)	Out-of Pocket Payments (% of the THE)
2000	4.9	204	62.9	27.6
2003	5.3	242	71.9	18.5
2010	5.6	563	78.6	16.3
2011	5.3	556	79.6	15.4
2012	5.4	566	76.8	15.4
2013	5.4	583	78.5	16.8
2014	5.4	583	77.4	17.8
2015	5.4	496	78.5	16.6

Sağlık Bakanlığı, 2016, Türkiye İstatistik Kurumu, 2016

There are co-payments and user charges at different levels of the health care system for different purposes. The rules and amount of co-payments and user charges are determined by the SSI and published in the Health Implementation Guide (HIG). These are summarized below.

1. Co-payments in out-patient care
    a. There are no co-payments at public primary health care facilities.
    b. 6 TRY (1.5€[1]) for public secondary care hospitals, 7 TRY (1.8€) for MoH tertiary care hospitals and 8 TRY (2.1€) for university hospitals. The patient has to pay an additional 5 TRY (1.3€) if he/she refers to another provider with the same specialization within 10 days of his/her first visit.
    c. 15 TRY (3.8€) in private hospital outpatient departments having contract with the SSI.
    d. 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.
    e. In addition to the above item, there is an additional 3 TRY (0.8€) payment for each prescription up to three items and 1 TRY (0.3€) for each additional item on the prescription.
    f. 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 this type of co-payment cannot exceed 75% of the minimum wage.
    g. There is a co-payment for in-vitro fertilization (IVF) treatment. The rate is 30% of the price in the SSI tariff in the first attempt, 25% in the second attempt and 20% in the third 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, chronic renal failure, HIV/AIDS etc.)
    d. Medicines used in in-patient care and laboratory and diagnostic tests.
3. User charges
    a. Foundation university hospitals 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 invoice.
    b. Public universities can provide health care after official hours and in this case, they can charge the patient an extra amount for both in-patient and outpatients

[1] 1€= 3.9299 TRY (Turkish Central Bank Exchange Rate on 14.02.2017)

services. For outpatient care this charge cannot exceed 100% of the invoice amount. The total amount cannot be more then twice the minimum wage in any case.

   c. If the prescribed medicine is above 10% of the band price determined by the SSI equivalent groups and if the patient insists on having the prescribed medicine rather than a substitute medicine in the same equivalent group then the difference is paid by the patient.

4. Exemptions from user charges
   a. Emergency care services, intensive care, burn treatment, cancer, newborn health care services, organ, tissue and stem-cell transplantations, surgeries for congenital abnormalities, cardiovascular services.
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.

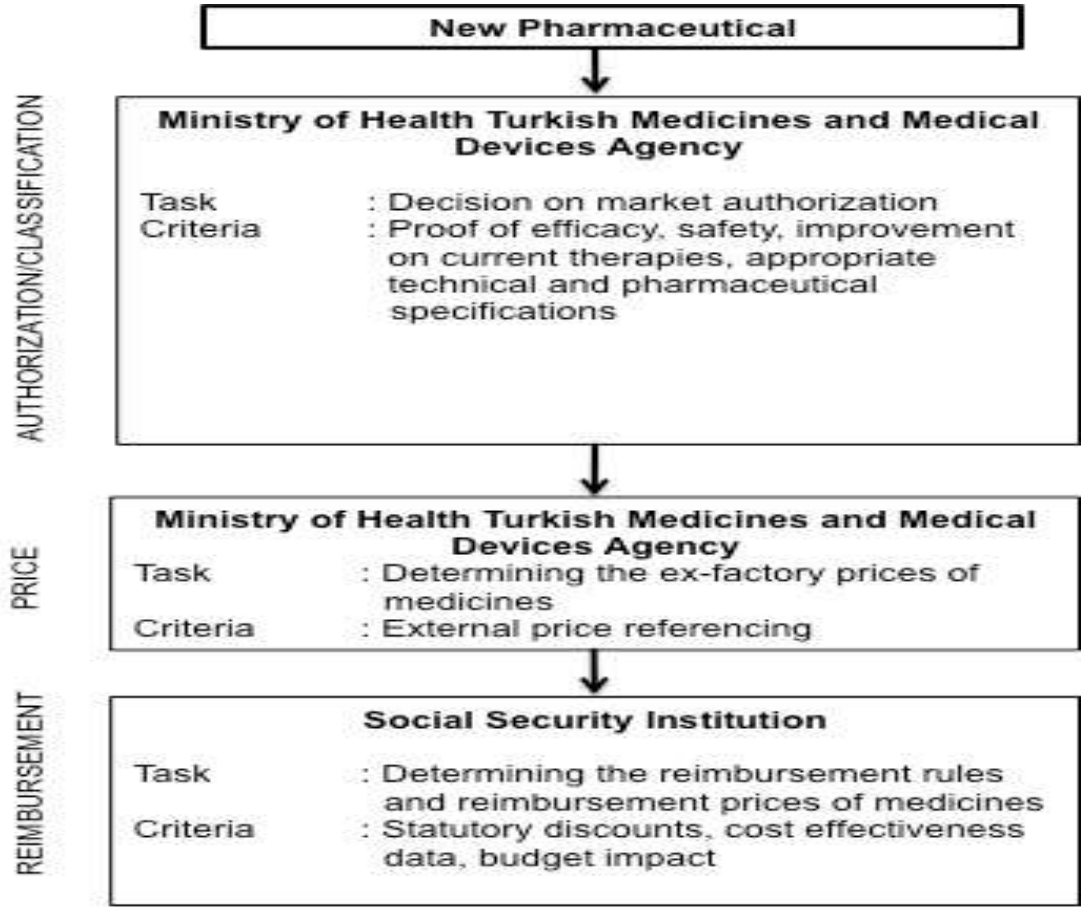
There is an increase in the number of physicians over the years. In 2015, the number of physicians per 100.000 population was 179 (138 in 2002). However, despite this increase, Turkey has the lowest number of physicians per 100.000 population among the OECD countries (OECD average 339). There is also a geographical inequality in distribution of physicians (273 per 100.000 in the West Anatolia compared to 131 in South Anatolia). However, the government has been taking steps to bridge the gap between regions but due to the fact that there is a long education time for physicians it will take time to reach a more equitable distribution. In terms of number of pharmacists, the number of pharmacists per 100.000 has not changed over time (35 per 100.000 in 2015 compared to 34 per 2002). This figure is again lower than the OECD average of 87 (Sağlık Bakanlığı, 2016).

2 Pharmaceutical system

The Turkish pharmaceutical sector is among the most regulated parts of the health care system. This regulation has been characterized by its emphasis on containing costs since the inception of the Health Transformation program in 2003. The share of pharmaceutical expenditures in total health care expenditures (around 40% at those times) and public health expenditures (around 60%) has attracted the attention of policy-makers as an area to intervene urgently. Regulations were introduced one after the other to contain and decrease pharmaceutical expenditures. First a pricing decree was issued introducing external reference pricing to a loosely regulated pricing environment. Second statutory discounts and cost-effectiveness data requirements were introduced in the reimbursement side with internal reference pricing as well. These attempts were followed by attempts at the market authorization side and GMP procedures were revised extensively. The last major policy change occurred with the introduction of a global budget for pharmaceuticals. Currently, the pharmaceutical policy is based on these systems with incremental changes from time to time. The details of these policies and implementation guidelines are explained in different sections below.

The two main actors in the pharmaceutical system are the MoH and the SSI (Figure 3). The MoH is the main regulatory body in market authorisation, pricing, legal classification and inspection. The Turkish Pharmaceuticals and Medical Devices Agency (TITCK) is responsible for the main policies and regulations for pharmaceuticals and medical devices except reimbursement. The second key actor in the public domain is the SSI which is responsible for reimbursement of all health care services including pharmaceuticals. The SSI has a Health Implementation Guide (HIG) covering all reimbursement rules for health care services, pharmaceuticals and medical devices. The health care providers both in the public and private sector have to follow the rules in the guideline for reimbursement. The rules for reimbursement of pharmaceuticals are also established in the Guideline. There is a positive list for pharmaceuticals revised continuously for both inclusion and exclusion of drugs from the list. There is a Reimbursement Commission with members from different public organizations and other sub-commissions supporting this commission in the SSI. The Reimbursement Commission gives the final decision about reimbursement, reimbursement price and rules and conditions of reimbursement. The figure below shows the route of a new medicine entering the market. The rules and procedures are explained below in relevant sections.

Figure 3: Route of a New Pharmaceutical Entering the Turkish Market



There were 11.233 products in the market in 2015 of which 8.104 were on the reimbursement list (Pharmaceutical Manufacturers Association of Turkey, 2016). Once on the reimbursement list there is generally no problem on access to medicines. There is a well-established distribution channel and a network of pharmacies delivering medicines to patients in any part of the country. The only concern may be the slowing pace of the new chemical entities entering the market due to stringent pricing and reimbursement policies. This tendency was observed in two recent study comparing the approval of new molecules in the USA, EU and Turkey (Lichtenberg et al, no date). The new molecular entity (NME) launches and access to drugs in Turkey were compared with the total number of compounds approved in the USA and the EU. It was found that 36 new molecules were approved by the FDA and 22 by the EMA between 2012 and 2013 (Q2) whereas only two of these were approved in Turkey during the same period. The rate of new drugs approved in Turkey was calculated as 4% for this period (Table 3) with a sharp decline from 29% between 2005-2011 (Kanzık, Hıncal, no date). This indicates that patients in Turkey benefit from many innovative drugs much later than their counterparts in the US or EU.

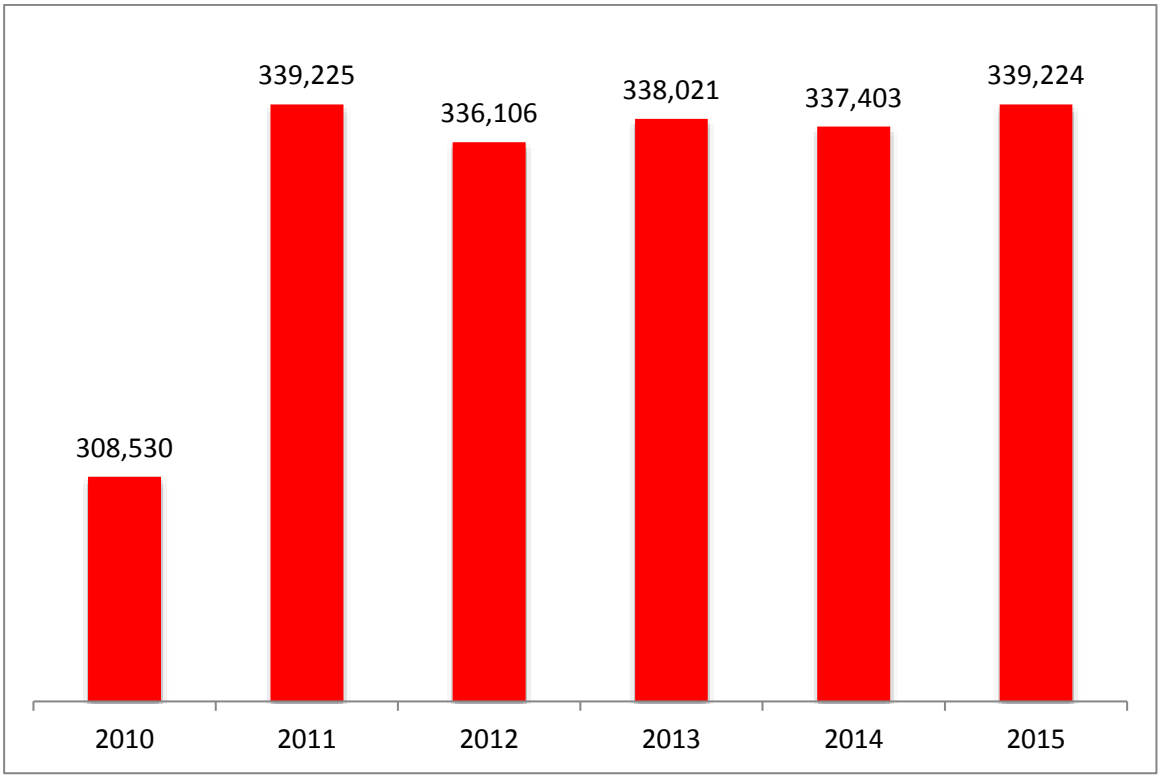
Table 3: Comparison of the New Molecular Entities Placed Upon the Market by USA-FDA and EU-EMA Between 2012 and 2013 (Q2).

Countries	NMEs in market between 2012-2013 Q2	NMEs available both in Turkey and the compared country	NMEs available in Turkey but not in the compared country	NMEs available in the compared country but not in Turkey	Access to Drug Index
ABD-FDA+EU-EMA	45	2	0	43	1
TR-TITCK	2				0.04
USA-FDA	36	2	0	34	0.8
EU-EMA	22	1	0	37	0.48

As stated above, since 2003 there have been extensive efforts to contain pharmaceutical expenditures and a number of policies have been adopted both by the MoH and the SSI. Apart from policies for market authorisation, pricing and reimbursement, rational use of medicines and measures to support this policy have also been discussed at different levels of the government health policy making environment. These policies mainly aim at changing the prescription and utilization 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.

The implementation of health care reforms had an impact on the coverage rate of the population that has increased from 67% to 97% and the benefits package has been equalized for all population regardless of their employment status. This has resulted in an increase in the number of visits to a physician per person per year from 3.1 in 2002 to 8.4 in 2015 (Sağlık Bakanlığı, 2016). This, coupled with the increase in the overall population during this period has resulted in an increase in the number of prescriptions and volume of medicines (Figure 4).

Figure 4: Number of Prescriptions (thousands), 2010-2015



Sosyal Güvenlik Kurumu, 2015

The total consumption of pharmaceuticals in terms of units reached to 2,113 million in 2015 of which 55.1% was for generics, 42.5% was for originals and 2.4% was for others. 78.1% of these units were produced locally whereas 21.1% were imported (Sağlık Bakanlığı, 2016). The market reached to 16.87 billion TRY (4.29 billion €) in 2015 in terms of value and 1,94 billion boxes in terms of units. The market growth over the years is presented in Figure 5. Table 4 displays distribution of value and units by sub-groups followed by Figure 6 showing the original versus generic distribution.

Figure 5: The Growth of The Turkish Pharmaceutical Market in terms of value and units

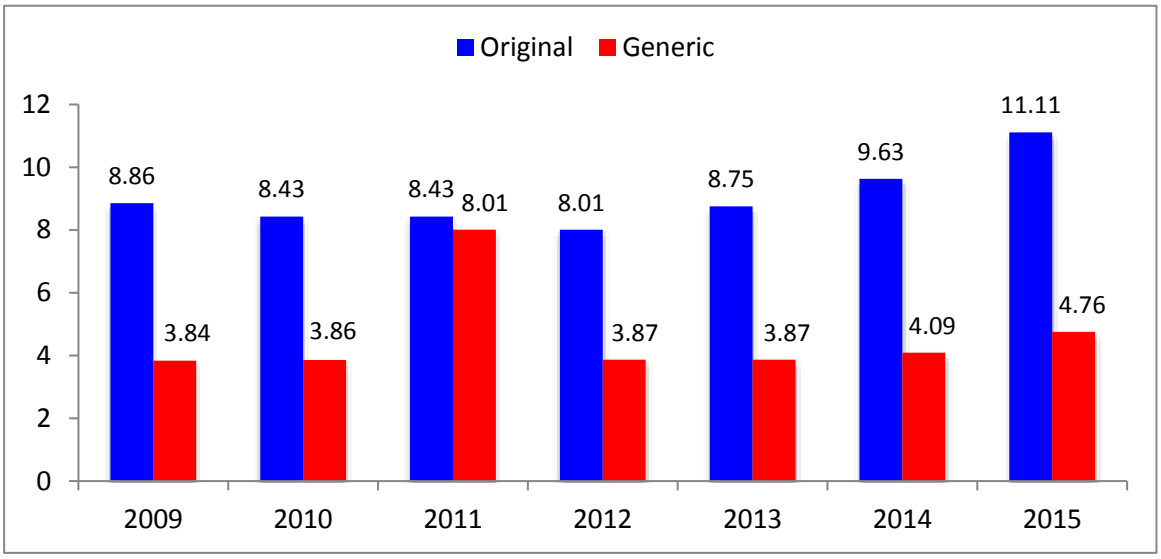
Pharmaceutical Manufacturers Association of Turkey, 2016

Table 4: Breakdown of Medical Products Market

	2009		2015	
	Value (Billion TRY)	Share (%)	Value (Billion TRY)	Share
Medical Products market	13.20	100	16.86	100
Drugs	12.71	96.3	15.87	94.1
Prescription Drugs	12.60	95.5	15.82	93.8
Reimbursed	12.35	93.6	14.67	87.0
Non-reimbursed	0.25	1.9	1.15	6.8
Non-prescription Drugs	0.10	0.8	0.04	0.3
Reimbursed	0.10	0.8	0.02	0.1
Non-reimbursed	0.00	0.0	0.03	0.2
Non-Pharmaceutical Drugs	0.49	3.7	0.99	5.9
Reimbursed	0.04	0.3	0.00	0.0
Non-reimbursed	0.46	3.5	0.99	5.9

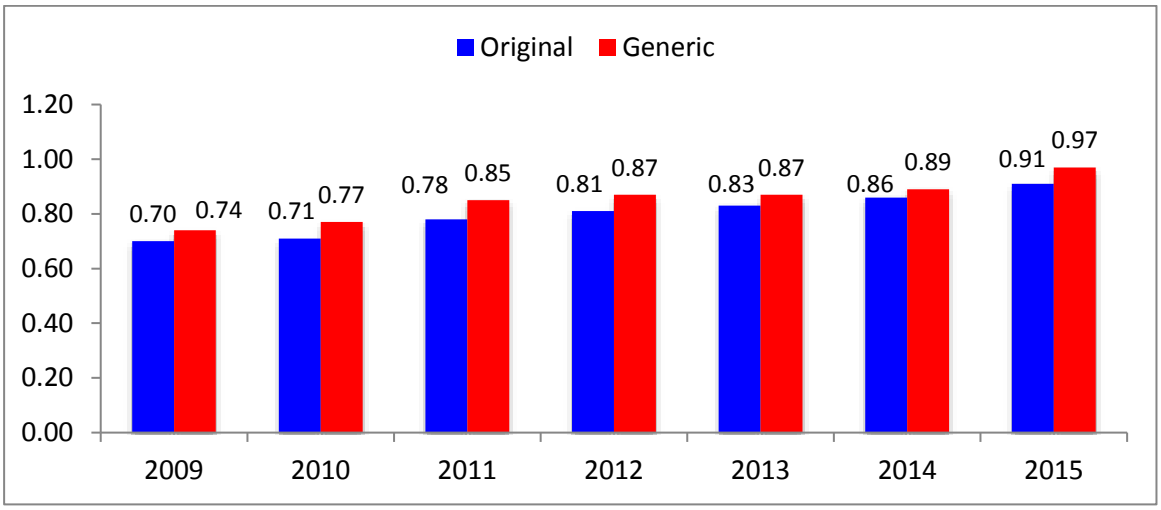
Pharmaceutical Manufacturers Association of Turkey, 2016

Figure 6: Distribution Between Original and Generics in Terms of Value (Billion TRY)



Pharmaceutical Manufacturers Association of Turkey, 2016

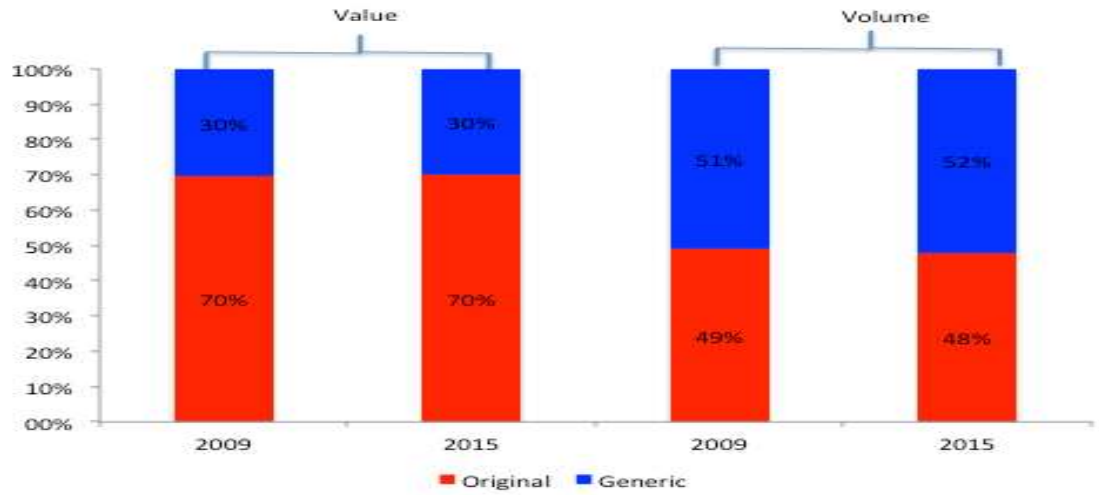
Figure 7: Distribution Between Original and Generics in Terms of Units (Billion Boxes)



Pharmaceutical Manufacturers Association of Turkey, 2016

The market shares of generics and originals have not changed significantly between 2009 and 2015. Originals had a 48% of market share in terms of volume but 70% in terms of value (Figure 8). The distribution of originals and generics by type of origin is shown in Table 5.

Figure 8: Market Shares of Originals versus Generics in Terms of Value and Volume



Pharmaceutical Manufacturers Association of Turkey, 2016

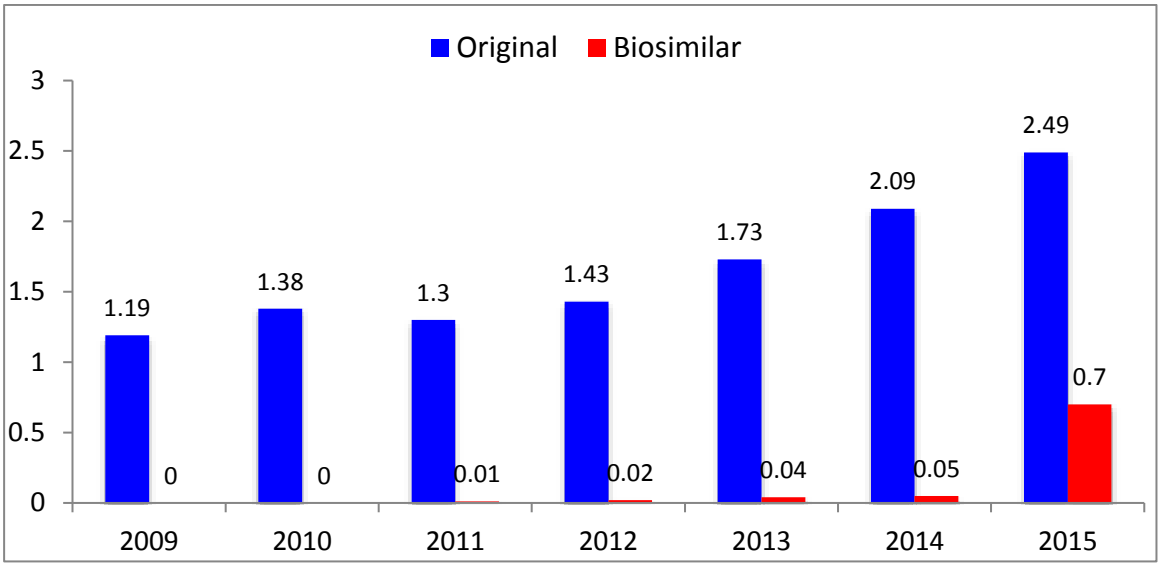
Table 5: Distribution of Originals and Generics by Type of Origin

	Original				Generic			
	2009		2015		2009		2015	
	Import	Local	Import	Local	Import	Local	Import	Local
Box	37%	63%	49%	51%	6%	94%	3%	97%
(million)	258	439	445	462	46	692	27	939
TRY	75%	25%	79%	21%	12%	88%	5%	95%
(million)	6.644	2.220	8.797	2.309	472	3.371	232	4.530

Pharmaceutical Manufacturers Association of Turkey, 2016

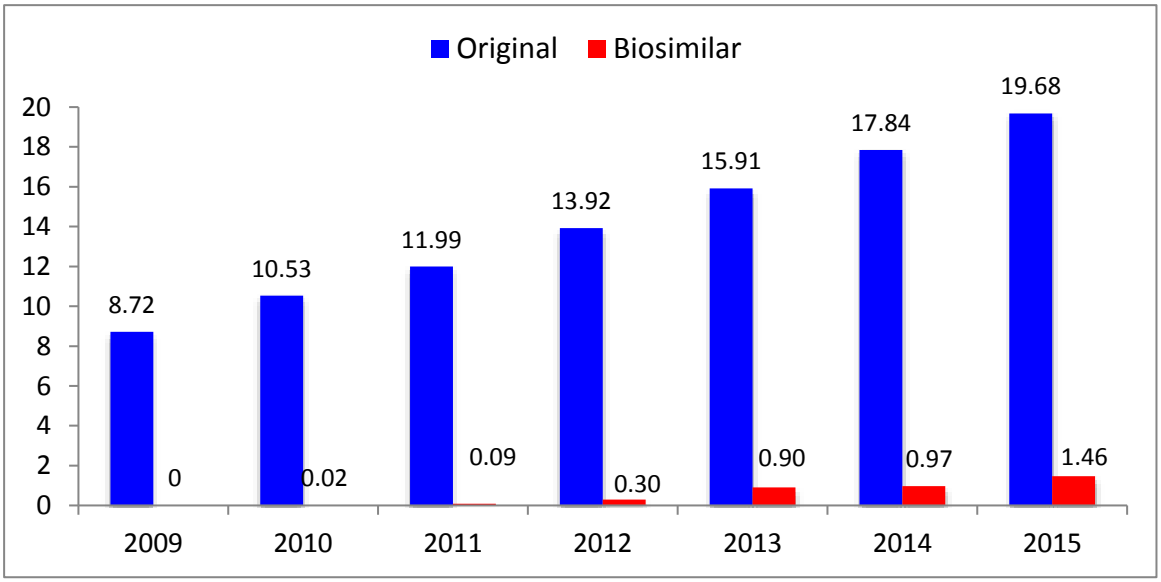
In 2015, there were 183 reference biotechnological and 38 bio-similar medicines available the Turkish pharmaceutical market.13 of the biotechnological drugs (34%) were produced in Turkey. Biosimilars containing abciximab, enoxaparin sodium, epoetin alpha, erythropoietin alpha, filgrastim, infliximab and somatropin were licensed in 2015 and enoxaparin sodium, epoetin alpha and infliximab were produced in Turkey. Figures 9 and 10 show the development of biotechnological and biosimilar drugs in Turkey.

Figure 9: Development of Biotechnological Drugs in Terms of Value in Turkey (Billion TRY)



Pharmaceutical Manufacturers Association of Turkey, 2016

Figure 10: Development of Biotechnological Drugs in Terms of Volume in Turkey (Million Boxes)



Pharmaceutical Manufacturers Association of Turkey, 2016

The Turkish pharmaceutical industry is comprised of both research based and generic manufacturers. There were 118 foreign firms and 337 local firms in the market in 2015. 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 of Turkey (İlaç Endüstrisi İşverenler Sendikası,IEIS). The distribution channel of pharmaceuticals starts from manufacturers to wholesalers and to pharmacies. 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 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. 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. Until 2012 there were no restrictions on pharmacists in choosing the location but with the Act No 6308, population based restrictions started to be applied in order to control the number and distribution of pharmacies. Accordingly, the number of pharmacies in a district is determined by the criteria of 1 per 3,500 people. There are around 24.000 pharmacies scattered all around the country.

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

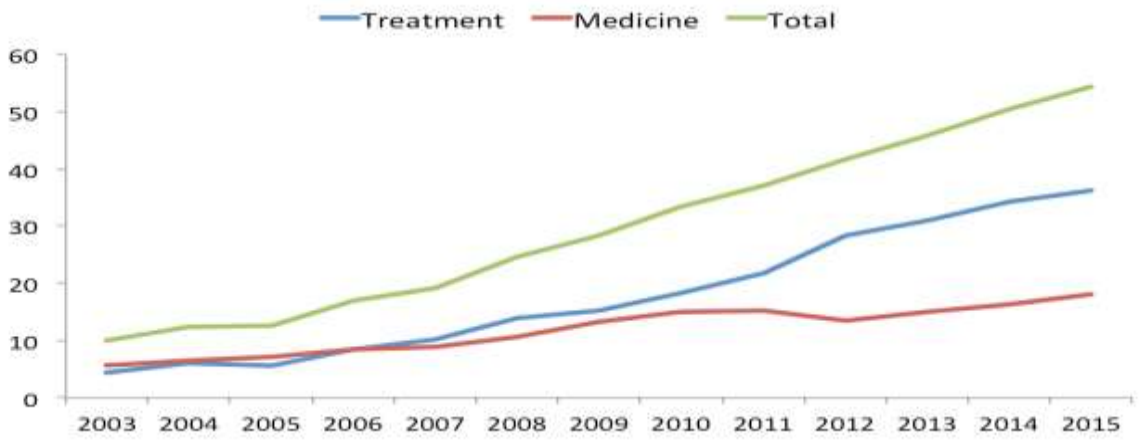
The size of pharmaceutical expenditures has been extensively debated especially at the beginning of the reform initiatives and the discussions have been the driving force behind cost containment measures introduced over the years. The impact of these policies can clearly be seen from the breakdown of the SSI expenditures (Table 6 and Figure 11).

Table 6: Health Expenditures of the SSI (million TRY), 2003-2015

	Treatment		Medicines		Total
Years	TRY	%	TRY	%	TL
2003	4,363	43.7	5,615	56.3	9,978
2004	5,906	48.0	6,399	52.0	12,305
2005	5,626	44.6	7,001	55.4	12,627
2006	8,490	50.3	8,372	49.7	16,862
2007	10,268	53.7	8,858	46.3	19,126
2008	13,953	56.6	10,717	43.4	24,670
2009	15,129	53.5	13,161	46.5	28,290
2010	18,377	55.0	15,047	45.0	33,424
2011	21,855	58.9	15,246	41.1	37,101
2012	28,275	67.9	13,384	32.1	41,659
2013	31,072	67.6	14,883	32.4	45,955
2014	34,175	67.6	16,354	32.4	50,529
2015	36,318	66.7	18,104	33.3	54,422

Sosyal Güvenlik Kurumu, 2015

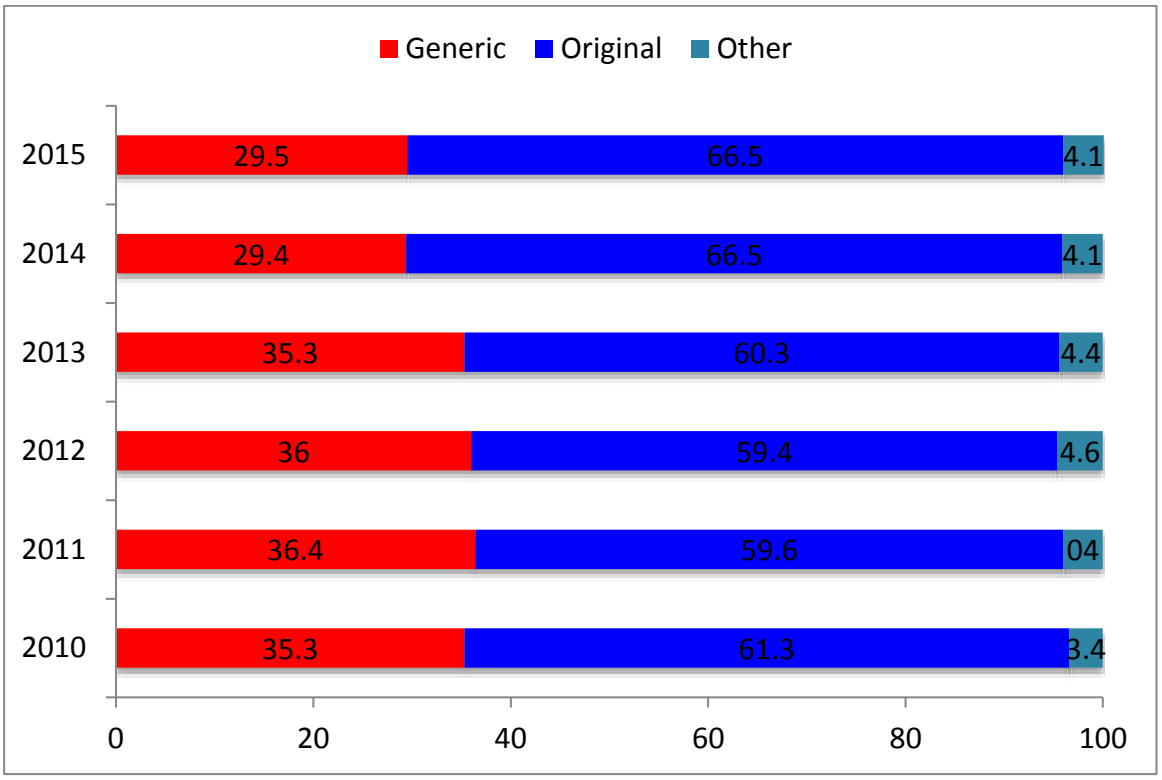
Figure 11:Total Treatment and Pharmaceutical Expenditures of the SSI (million TL) (2002-2015)



Sosyal Güvenlik Kurumu, 2015

The government started determining a global budget for pharmaceuticals in 2010 and increased the pressure on the pharmaceutical sector. 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. The share of generics in the total pharmaceutical expenditures has decreased over the years (Figure 12).

Figure 12: Distribution of Pharmaceutical Expenditures by Type (%)



Market access of high cost medicines has been on the agendas of policy makers in Turkey as elsewhere. The highly regulated market with high rate of statutory discounts have refrained manufacturers of these medicines from entering the market. The preferred route for these drugs has been through the named patient programme (NPP) where the regulations are more flexible and prices are high. However, in 2016 the government introduced an alternative payment mechanism mainly to improve the reimbursement of these products. The details of this program are explained below. However, there are concerns that this highly regulated market and low prices may jeopardize improvements in health indicators and may raise inefficient use of resources in the health care system (Lichtenberg, Tatar, Çalışkan, 2014; Lichtenberg, Tatar, Çalışkan, 2017).

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

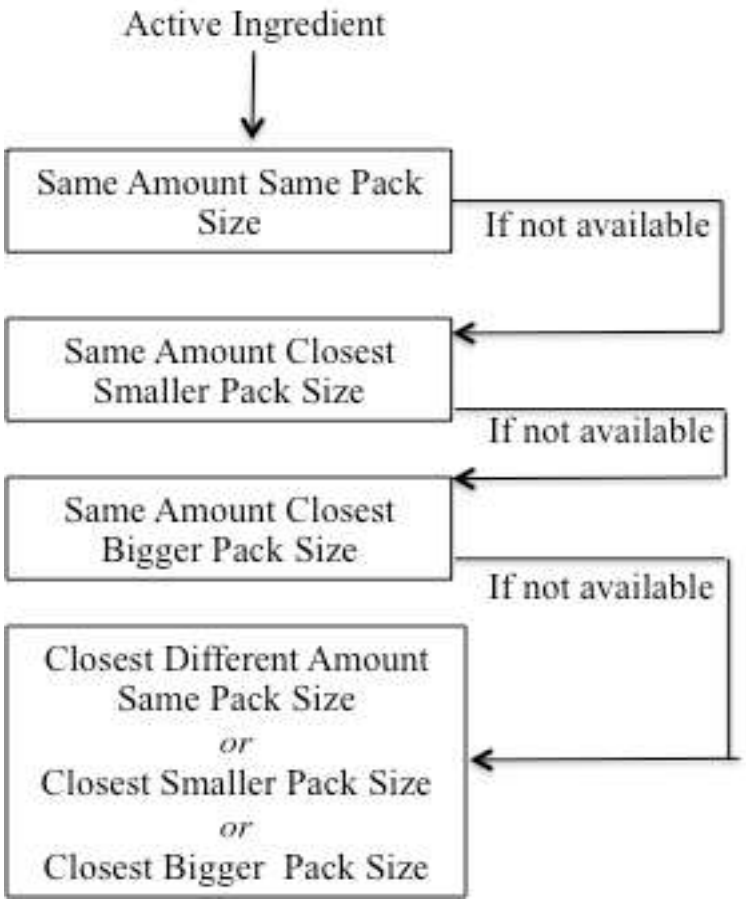
The main actor in pricing of medicines is the Turkish Medicines and Medical Devices Agency. The rules of pricing are determined by the Council of Ministers Decision dated 15.06.2015 (decision no 2015/7752) and the Communiqué on Pricing of Human Medicinal Products (Official Gazette, 2015) and the decree published based on this Communiqué. There is a statutory pricing policy in Turkey based on external reference pricing with some negotiation opportunities for specific cases. These are explained in detail below.

There is a Pricing Assessment Commission comprised of members from Ministry of Finance, Ministry of Development, Treasury and SSI. The commission works under the coordination of Ministry of Health. The responsibilities of the Commission are determined by the Ministry of Health Directive for Price Assessment Commission. The Commission meets in the first five days of January, April, June and October. If needed, the Commission can be called for meeting at any time upon the invitation of one of the members of the Commission. The Commission decides on all pricing issues and especially on the rates explained below that are left to the assessment of the Commission. Each year, the Commission determines the fixed Euro exchange rate for the upcoming year in the first five days of January. The fixed Euro value for each year is calculated by multiplying the previous years average Euro value declared by the Turkish Central Bank by an adjustment coefficient of 70%.

The prices are determined at ex-factory level and then wholesale, pharmacy mark-ups and Value Added Tax are added to calculate the retail price. The VAT for medicines is 8% (18% for other products). The external reference pricing was introduced in 2004 as an outcome of the initiatives to contain pharmaceutical expenditures. The reference price is the cheapest price in France, Spain, Portugal, Greece and Italy. The pricing rules are summarized below:

1. The following route is followed in order when determining a reference for a product
    a. Same active ingredient same pharmaceutical form
        i. Same amount of active ingredient and same package size
        ii. If not available, same amount of active ingredient with the closest smaller package size
        iii. If not available same amount of active ingredient with the closest bigger package size
        iv. If not available, the closest different amount of active ingredient with the same package size, if not available the closest smaller package size and if this is not also available the closest bigger package size.
    b. If the same active ingredient with the same pharmaceutical form is not available in Turkey or reference countries, pharmaceutically similar products (defined as a product with same active ingredient with same or different amounts and different pharmaceutical forms) can be priced by the rules outlined in a(i) above.

Figure 13: Route for Determining a Reference Product

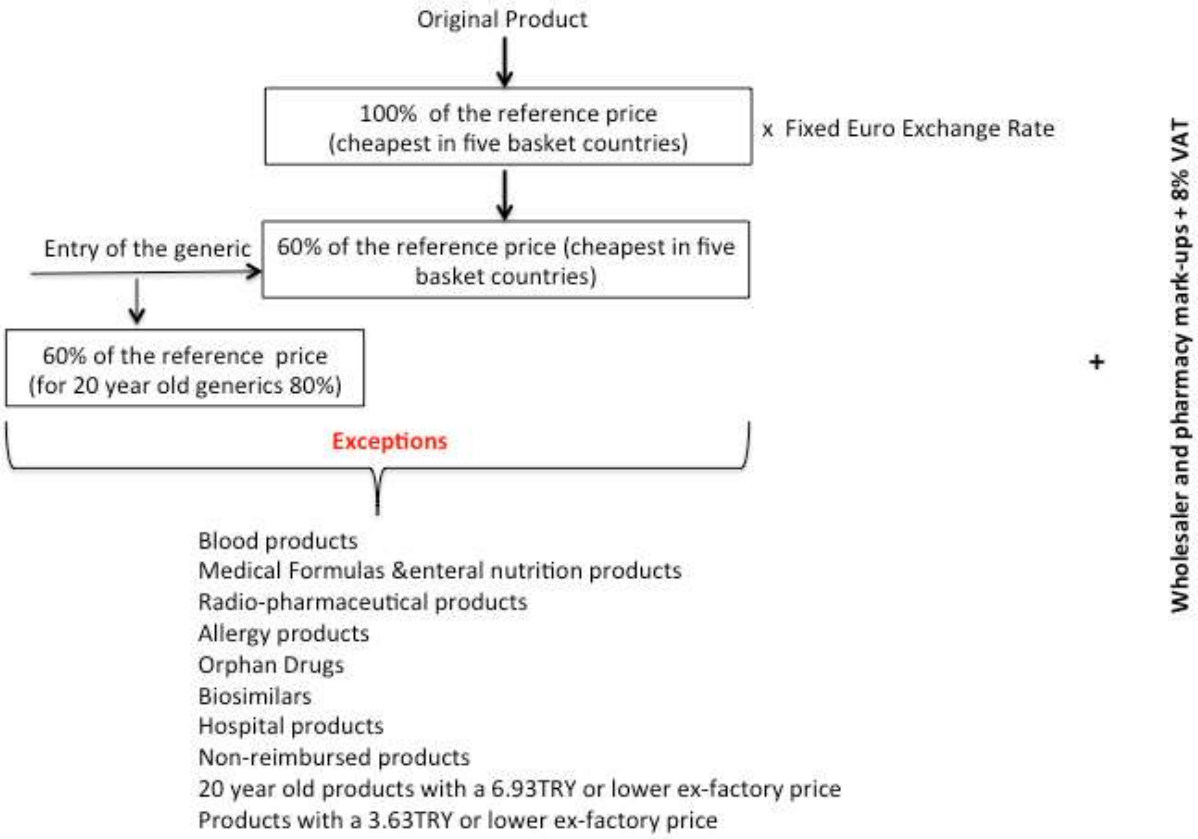


2. The price of the reference product is 100% of the reference price until the introduction of the first generic to the market. After the entry of the generic, the price of the reference product is decreased to 60% of the reference price.
3. The price of the generic can be up to 60% of the reference price. The price of the 20 years old generics (defined as an active ingredient that is launched first before 1.8.1987 in any pharmaceutical form) can be up to 80% of the reference price.
4. When pricing for the first time, 100% of reference price is taken for products with 3.63 TRY (0.92€) ex-factory price and for 20 year old products with 6.93 (TRY) (1.8€) or more ex-factory price.
5. 20 year old products with a 6.93TRY (1.8€) or lower ex-factory price and others with a 3.63TRY (0.92€) or lower ex-factory price are exempt from reference follow-up. These products are named as ‘products without a reference follow-up’. Reference products manufactured in Turkey under this category can take up to 100% of the reference price. Generics manufactured in Turkey under this category are priced by the reference product in Turkey. Imported generics are priced up to 100% of the reference price in Turkey or 100% of the cheapest product in reference countries if the reference product is not available in Turkey.

6. Blood products are priced up to 100% of the price of the reference product. Upon the demand of the applicant an additional 10% can be added. The commission can decide to use current Euro exchange rate for these products in order to secure availability. In this case, the current exchange rate published by the Turkish Central Bank at the last working day of the week is taken and this rate is renewed every two weeks. Cost Card can be used for products, manufactured in Turkey. The price demanded based on the Cost Card cannot be more than 25% of the reference price. If the demanded price is more than 25% then the Commission assesses the demand.
7. Medical formulas and enteral nutrition products can take up to 100% of the cheapest reference price. Cost Card can be used for products, manufactured in Turkey. The price demanded based on the Cost Card cannot be more than 15% of the reference price. If the demanded price is more than 15% then the Commission assesses the demand.
8. Radiopharmaceutical products are priced up to 100%of the reference price. Cost Card can be used for products, manufactured in Turkey. The price demanded based on the Cost Card cannot be more than 15% of the reference price. If the demanded price is more than 15% then the Commission assesses the demand.
9. Allergy products are priced up to 100%of the reference price. Cost Card can be used for products, manufactured in Turkey. The price demanded based on the Cost Card cannot be more than 15% of the reference price. If the demanded price is more than 15% then the Commission assesses the demand.
10. Orphan drugs can be priced up to 100% of the reference price. Upon the demand of the applicant an additional 5% can be added. Cost Card can be used for products, manufactured in Turkey. The price demanded based on the Cost Card cannot be more than 20% of the reference price. If the demanded price is more than 20% then the Commission assesses the demand.
11. Biosimilar products are priced 100% of the reference price. If it is not available in Turkey, then 100% of the original product. Cost Card can be used for products, manufactured in Turkey. The price demanded based on the Cost Card cannot be more than 15% of the reference price. If the demanded price is more than 15% then the Commission assesses the demand.
12. The following rules are applied for hospital-only products:
    a. 100% of the reference price is taken
    b. For imported products, the ex-factory price in reference countries and the countries where the product is imported, if this is not available the hospital price in these countries, if this is not available the cheapest ex-factory price in EU countries and if this is not available, the ex-factory price in any country provided that the product is available in the country is used.
    c. For products produced in Turkey, the price of the highest equivalent product in the market or cost card can be used. The price demanded based on the Cost Card cannot be more than 15% of the reference price. If the demanded price is more than 15% then the Commission assesses the demand.
13. The non-reimbursed medicines can take the 100% of the ex-factory price in reference countries. If the medicine is not available in these countries, the ex-factory price in any

country in the world. For products produced in Turkey, the price can be determined with the request of the applicant. These products are exempt from reference follow-up. If these products are listed in the reimbursement list, all rules for reimbursed medicines explained above are applied.

Figure 14: General Rules of Pricing



The final retail price of a product is calculated by adding wholesaler and pharmacy mark-ups and VAT (8%). Wholesaler and pharmacy mark-ups are displayed in the table below.

Table 7: Wholesaler and Pharmacy Mark-Ups

For the Portion of Ex-Factory Price Up to	Wholesaler Mark-Up	Pharmacist Mark-Up
10 TRY (2.54€) (including 10 TRY)	9	25
10-50 TRY (2.45€-12.72€) (including 50TRY	8	25
50-100 TRY (12.72€-25.45€) (including 100 TRY)	7	25
100-200 TRY (25.45€-50.89€) (including 200 TRY)	4	16
Over 200 TRY (50.89€)	2	12

There is an early access program (Named Patient Program- NPP) for medicines that does not have marketing authorization or that are not in the market. These medicines are imported from abroad and both the Turkish Medicines and Medical Devices Agency and the SSI are involved in the process. There is a guideline published by the TITCK for this program and the reimbursement rules are determined by the Health Implementation Guide of the SSI. The first importation of the medicine starts with the demand of a physician for a specific patient. The physician should fill in the forms published by the TITCK and clinically and scientifically prove that the patient needs that medicine that is not available. The forms and the prescription of the physician are submitted to the TITCK's relevant departments. These documents are then submitted to the Advisory Committee in the TITCK and after the approval of the prescription by this Committee the medicine is listed in the Imported medicines list. This procedure usually takes one week but may extend if a second view is needed. Once the medicine's use is approved by the TITCK, the submission is sent to the SSI and is assessed by the Pricing Commission. After approval by the SSI the medicine is listed in the Overseas Drug List by its active ingredient name (Attachment 4/C). The SSI reimburses the medicine after the inclusion of the medicine to the list. Since the beginning of these procedures, the medicines have been imported by the Turkish Pharmacists Association from the overseas wholesalers. However, the SSI has decided that from April 2017 the importation of these medicines will be followed by the SSI and will be distributed to the patients through The Turkish Post Office. The prices of these medicines are determined with the current exchange rate.

The SSI is the only body responsible for reimbursement of all health care services including medicines. The reimbursement principles for medicines are regulated by the Decree on Reimbursement of Medicines (Official Gazette, 2016a). Access to reimbursement is granted only after getting a retail price form the MoH. The rules of reimbursement are published in the Health Implementation Guide and its attachments. 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 commissions deciding on the reimbursement status of the medicines: The Medical and Economic

Evaluation Commission (MEEC) and the Medicines Reimbursement Commission (MRC). The former undertakes the assessment and the latter undertakes the appraisal functions.

The MRC is formed by three representatives from the SSI, two representatives from the MoH and the Ministry of Finance and one representative from the Ministry of Development and Treasury. The Director General of the General Health Insurance department at the SSI is the head of the commission. The Commission meets twice in a year but the head of the commission can ask for extraordinary meetings during the year. The tasks and responsibilities of the commission are listed in the Decree as follows:

- Deciding on the medicines to be reimbursed by the SSI and reimbursement rules.
- Reviewing and deciding on the views and reports prepared and submitted by the MEEC.
- Deciding on the problems of obtaining life-threatening disease medicines and other medicines with public health relevance.
- Deciding on the exemptions from co-payments.
- Deciding on de-listing of medicines or re-arrangement of reimbursement rules based on their budget impact, market share, clinical and technical data and economic and fiscal assessments.
- Reviewing the applications of originals without generics and generics without originals with lower reference prices determined by the MoH and deciding on new public discounts for these medicines.
- Determining the equivalent drug groups that the internal reference pricing system will be based on.
- Arranging extra meetings other than the published calendar to decide on reimbursement of medicines manufactured in Turkey.
- Arranging extra meetings other than the published calendar to decide on reimbursement of medicines that are imported from abroad with the NPP program with applications for ordinary reimbursement status.

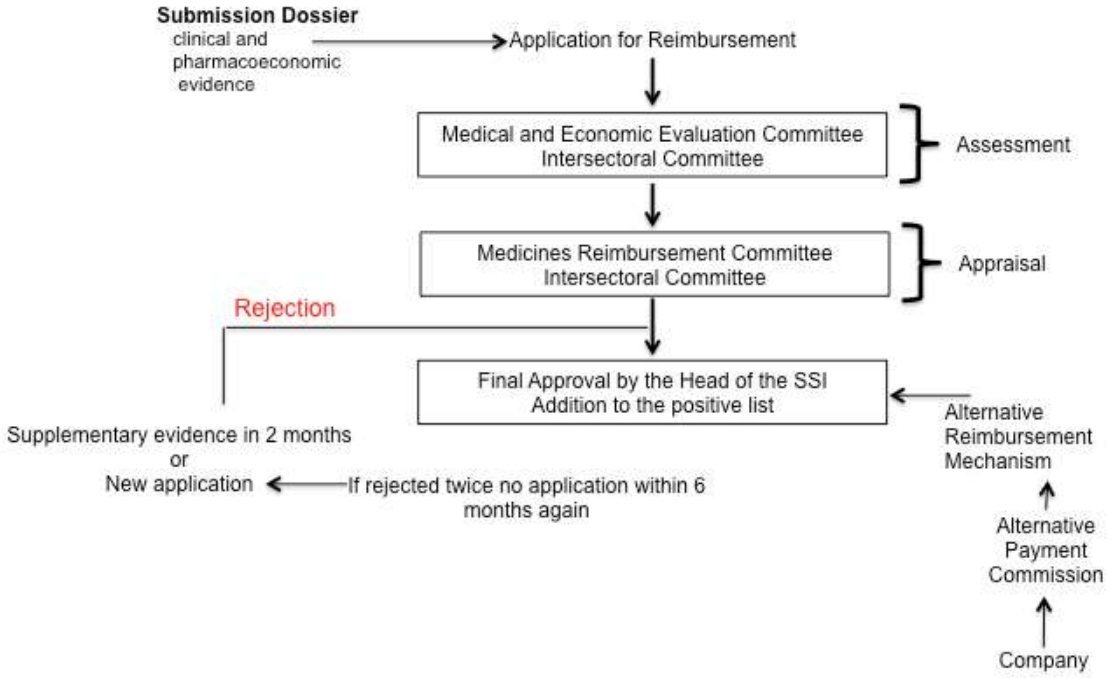
The MEEC is formed by six members from the SSI, two members from the MoH, one member from the Ministry of Development, of the Ministry of Finance and Treasury, two members from academia (at least one should be a physician) and three observant members from the Pharmaceutical Manufacturers Association of Turkey, the Pharmaceutical Industry Association of Turkey and the Association of Research Based Pharmaceutical Companies. The observant members do not have the right to vote. The Head of the Department of Pharmaceuticals and Pharmacies of the SSI is the natural head of the commission. The tasks and responsibilities of the commission are listed in the Decree as follows:

- Assessing the literature and data in the submission dossier.
- Reviewing the clinical, technical, economic and financial data submitted to be included in the positive list and submitting the opinion of the commission to the MRC.

- Reviewing the reports on market share, budget impact, clinical and technical data and economic and financial evaluation of medicines reimbursed by the SSI and submitting the opinion of the commission to the MRC.
- Assessing the application of companies, the MoH or other relevant organizations to be de-listed from the positive list and submitting the opinion of the commission to the MRC.
- Forming an opinion on equivalent groups to be used in internal reference pricing.
- Reviewing the applications of originals without generics and generics without originals with lower reference prices determined by the MoH and submitting the opinion of the commission to the MRC.
- Assessing the exemptions from co-payments and submitting the opinion of the commission to the MRC.
- Assessing the prescription and reimbursement rules for a medicine and submitting the opinion of the commission to the MRC.
- Assessing and deciding on the applications of medicines with equal or lower pack size and with a unit price within the limits of drug equivalent groups and assuring the announcement of this decision on the wen site of the Institution with the approval of the head of the MRC. Same assessment is also made for manufactured medicines as well.

The reimbursement process is presented in Figure 15 below.

Figure 15: Reimbursement Process for Medicines



If the first application of the company is rejected by the SSI, the company can provide additional information related directly with the reasons for rejection and apply again within two months with only these supplementary documents. If the company does not apply within two months with the supplementary documents than it has to prepare the dossier again and apply by following the application calendar announced by the SSI. If the application is rejected for the second time then the company cannot apply again within 6 months. However, if there is a new scientific evidence or a change in the indication, these timelines are not followed.

The company follows the guidelines issued by the SSI for reimbursement applications. The application dossier is comprised of three main sections. In the first section, general information and documents from the company are requested including the sales permission, prospectus, pricing information, FDA and EMEA documents if available, market approval and reimbursement status in other OECD countries, information about the status of the medicine in reference countries, epidemiology of the disease that the drug is indicated for. In the second section the clinical and pharmacological profile of the product is presented. This section covers information on the therapeutic class, treatment route, results of clinical studies, safety data, information on alternative therapies and epidemiology of the disease. The third section involves pharmacoeconomic evidence. This information is not required for generics with an original in the positive list, for orphan drugs and co-marketed drugs with drug on the list. The analysis is made from payer perspective. The comparator should be the most frequently used alternative or the alternative that is used in the literature for comparison. The SSI accepts only cost minimization and cost effectiveness analysis. Cost utility analysis can be submitted as supplementary information. This section also covers the budget impact analysis for innovative medicines and for first entry molecules. Budget impact analysis is made for three upcoming years.

The reimbursement price of medicines is different from the retail price. There are statutory discounts determined by the SSI and published in the HIG. Discounts are based on the ex-factory price of the medicine. Table 8 below presents the statutory discount rates published in 2016.

Table 8: Statutory Discount Rates of the SSI, 2016

3.1.1 Ex-factory price	**SSI Discount Rate (%)**
General rule	
Medicines with ex-factory price ≤ 4.23 TRY (1.07€)	No discount
Medicines with ex-factory price ≥4.24 TRY (1.08€)	10% or 11% basic discount
Medicines with 20 years label	
Ex-factory price between 4.24 TRY (1.07€) – 8.09 TRY (2.05€)	0%
Ex-factory price between 8.10 TRY (2.06 €) -12.19TRY (3.10€)	10%
Medicines with 12.20 TRY (3.10 €) or more reference ex-factory price	28% (basic 11%+17%)
Medicines with 12.20 TRY (3.10 €) 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 4.24 TRY (1.07 €) – 8.09TRY (2.05€)	10%
Ex-factory price 8.10 TRY (2.06 €)-12.19 TRY (3.10 €) TRY	31% (basic 11%+20)
Ex-Factory price 12.20 TRY (3.10 €) and more	41% (11%basic +30%)
Originals with generics and generics	
Ex-factory price between 4.24 TRY (1.07 €) – 8.09 TRY (2.05 €)	10%
Ex-factory price between 8.10 TRY (2.06 €) – 12.19 TRY (3.10 €)	18% (basic 11% + 7%)
Ex-factory price 12.20 TRY (3.10 €) or more	28% (basic 11% + 17%)
All blood products, medical food, radiopharmaceutical products and enteral nutrition products with ex-factory price 4.24 TRY (1.08 €) and more	11%

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 internal reference price is calculated in comparison to the pharmaceutical with the lowest price in equivalent groups. Accordingly, the SSI pays the cheapest price plus 10 %. The reference pharmaceutical 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. They don't have to justify their preferences. If this is the case then the pharmaceutical is either replaced by a reimbursable one by the pharmacist or the patient pays the difference. This replacement is made with the consent and demand of the patient, it is not mandatory. This is the only measure applied to increase the use of generics in the market.

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. These rates are determines annually with a protocol signed with the SSI and the Turkish Association of Pharmacists. Table 9 shows the current rates.

Table 9: Pharmacy Discount Rates in Reimbursement, 2016

Pharmacy turnvover	Pharmacy discount (%)
Pharmacies with annual revenue 0-700,000 TRY (0-178,122€)	0
Pharmacies with annual revenue between 700,001-900,000 TRY (178,122€-229,013€)	1
Pharmacies with annual revenue between 900,001-1,500,000 TRY (229,014€-381,689€)	2,5
Pharmacies with annual revenue more than 1,500,001 TRY (281,690€)	3

Pharmaceuticals are fully reimbursed if a patient has a chronic disease certified by a medical report and for some diseases listed by the SSI for exemption from co-payments. There is no discrimination in terms of population groups. 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.

There are no claw-backs in Turkey. Risk sharing schemes have been long discussed and an alternative payment mechanism was introduced in 2016 with the Decree on General Health Insurance Alternative Reimbursement (Official Gazette, 2016b). Alternative reimbursement model was defined as reimbursement models created to waive normal reimbursement rules for health care services and products based on medical and economic benefits of the product and to motivate local production of imported goods. An Alternative Reimbursement Commission was established comprised of the head of the SSI, Director General of the General Health Insurance Department and one member from the Ministry of Finance, Ministry of Development and Treasury. The Commission meets upon the invitation of the head of the SSI or the Director General of the General Health Insurance Department. The tasks and responsibilities of the Commission are listed below:

- To decide on the new reimbursement model for the health care services based on its financial and medical benefit and to prepare draft contracts.
- To determine the prices of the health services to be reimbursed.
- To determine the reimbursement model and prices of health care services that will motivate the exportation of these services and to decide whether to continue reimbursing alternative treatment methods under the same category.

- To decide on different discount levels published in the Health Implementation Guideline and to decide on hiding principles of these different levels of discounts.
- To determine the health care services, including imported drugs, that will be given reimbursement guarantee and their prices. In addition to this decide on de-listing alternative therapies in the same group.
- Updating, cancelling before the last date or renewing the contracts between the SSI and the firm.
- To decide on the co-payment and exemption rules of the reimbursement model.

Since its introduction, a number of pharmaceutical firms have applied to the SSI for reimbursement through this route. First example of alternative reimbursement was made for Hepatitis C drugs. The SSI has given a reimbursement guarantee for a certain number of patients for a specified timeline. In the model some old Hepatitis C drugs were also de-listed from the reimbursement list. The extra discounts given by the companies are hidden in this model.

The SSI has also introduced a global budget mechanism for medicines in 2010 in order to control pharmaceutical expenditures. The global budget is determined for a three-year period. The amount was 14.6 million TRY (3.7 million €) for 2010, 15.5 million TRY (3.9 million €) for 2011, 16.6 million TRY (4,2 million €) for 2012, 15.7 million TRY (3.99 million €) for 2013, 17.1 TRY (4.28 million €) for 2014, 18 million TRY (4.58 million €) for 2015. If there is an over spending for the relevant year, extra measures such as discounts, prescription restrictions, restraints on reimbursement rules are taken for the following year.

As explained above in describing the reimbursement rules and principles, pharmaco-economic 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 organization structure of the MoH. The department has published some HTA reports since its establishment but as the reimbursement decision is under the responsibility of the SSI these reports did not have any impact on the decisions of the SSI.

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.

As outlined in the previous sections, payment rules by public reimbursement agencies are determined by the Health Implementation Guideline issued by the SSI. The HIG covers rules of payments for all health goods and services ranging from outpatient to in-patient care and pharmaceuticals to medical devices. The HIG is binding for both the public and the private sectors. 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, anesthetics, medicines (except blood products), blood components (erythrosine suspensions, full blood, thrombocytes, plasma etc), disposable goods, anesthetic fees, laboratory, pathology and radiology tests and food 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. 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 route does 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 (the cheapest price in France, Greece, Italy, Portugal and Spain). Prices of hospital-only medicines are determined the same way in Turkey but the price of the product is determined as 100% of the reference price.

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. 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 (12,723 €). 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 53.261 TRY (13,553 €) 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 by 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, based on the requests of physicians, 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 bet, 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 outpatient 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 outpatient medicine list. In other words, both lists are used in hospitals. These lists are published as attachments to the HIG.

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 final hospital bill includes all expenditures including pharmaceutical expenditures. 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. In this case, the price of the medicine is paid to the pharmacy by the SSI but the amount is subtracted from the bill of the hospital.

5 Interface management and developments

Interface management or integrated care is not organized in Turkey yet.

Turkey has undergone a global health care reform process since 2003 and the pharmaceutical sector has been subject to substantial changes in terms of licensing, pricing and reimbursement. All of these policies have been explained in detail in relevant sections. The last of these changes has been the introduction of alternative payment mechanisms by the SSI. 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. There is no sign of making a radical shift from current health care policies in general and pharmaceutical policies in particular. Incremental changes will be in place in the future instead of a radical shift from the current system.

6 Pharmaceutical data fact sheet: Turkey

		2015	2014	2013	Source	Notes
Demography						
Population	total	79,814,871	78,741,053	77,695,904	TUIK	Data as of 31 December
	0-14 years	18,886,220	18,862,430	18,849,814	TUIK	
	15-64 years	53,359,594	52,640,512	51,926,356	TUIK	
	> 64 years	6,495,239	6,192,962	5,891,694	TUIK	
Life expectancy	at birth	78	77	76,9	MoH	
	at age 65	17,8	17,9	18	TUIK	
Economic data in TRY						
Gross domestic product (1000s)		2,237,529,940	2,044,455,876	1,809,713,087	TUIK	Please indicate in which currency the data are provided. Please provide, wherever possible, absolute figures; if not possible, you can provide the estimated share of public/private funding. Preferred sources: EUROSTAT, OECD, WHO or respectively for expenditure data EUROSTAT-OECD-WHO Joint SHA collection when available, or national sources
Health expenditure (millions)	total	104,568	94,750	84,390	TUIK	
	public	82,121	73,382	66,228	TUIK	
	private	22,446	21,368	14,156	TUIK	
Health expenditure in the outpatient sector	total	Not applicable	Not applicable	Not applicable	Not applicable	
	public	Not applicable	Not applicable	Not applicable	Not applicable	
	private	Not applicable	Not applicable	Not applicable	Not applicable	
Health expenditure in the in-patient sector	total	Not applicable	Not applicable	Not applicable	Not applicable	
	public	Not applicable	Not applicable	Not applicable	Not applicable	
	private	Not applicable	Not applicable	Not applicable	Not applicable	
Prescriptions						
No. of prescriptions	in volume	Not available	Not available	Not available	Not available	Prescription in volume = number of items prescribed.
Prescriptions	in value	Not available	Not available	Not available	Not available	Prescription in value = public expenditure of prescribed medicines.

Pharmaceutical consumption						
Total (billion)	In packs	1,94	1,82	1,77		DDD = defined daily doses
	In DDD	Not available	Not available	Not available		
Out-patient sector	In packs	Not available	Not available	Not available		
	In DDD	Not available	Not available	Not available		
In-patient sector	In packs	Not available	Not available	Not available		
	In DDD	Not available	Not available	Not available		
Generic shares						
Shares in % of total market (in-patient/ out-patient)	In volume	51.6	51.0	51.1		Volume: Expressed in number of prescriptions Value: Expressed in expenditure
	In value	30.0	29.9	30.7		
Shares in % of total out-patient market	In volume	Not available	Not available	Not available	Not available	
	In value	Not available	Not available	Not available	Not available	
Shares in % of out-patient reimbursement market	In volume	Not available	Not available	Not available	Not available	
	In value	Not available	Not available	Not available	Not available	
Shares in % of out-patient off-patent market	In volume	Not available	Not available	Not available	Not available	
	In value	Not available	Not available	Not available	Not available	
Shares in % of the in-patient market	In volume	Not available	Not available	Not available	Not available	
	In value	Not available	Not available	Not available	Not available	
Retailers of medicines						
No. of community pharmacies	private	Not available	Not available	Not available	Not available	Data as of 1 January Hospital pharmacies dispensing to out-patients are not included in this figure
	public	Not available	Not available	Not available	Not available	Data as of 1 January Private pharmacies are pharmacies owned by private persons or entities; public pharmacies are in public ownership.

No. of hospital pharmacies for out-patients		Not available	Not available	Not available	Not available	Data as of 1 January
No. of dispensing doctors		Not available	Not available	Not available	Not available	Data as of 1 January
No. of other POM disp.,		Not available	Not available	Not available	Not available	Data as of 1 January
Total no. of POM dispensaries		Not available	Not available	Not available	Not available	Data as of 1 January
Pharmaceutical expenditure TRY						
Pharmaceutical expenditure (million TRY)	Total	Not available	Not available	Not available	Not available	Data as of 31 December Note: Preferred sources: EUROSTAT-OECD-WHO Joint SHA collection when available, or national sources
	Public	16,951	17,629	17,234	MoH	
	Private	Not available	Not available	Not available	Not available	
Pharmaceutical expenditure in the out-patient sector	Total	Not available	Not available	Not available	Not available	
	Public	Not available	Not available	Not available	Not available	
	Private	Not available	Not available	Not available	Not available	
Pharmaceutical Expenditure in the in-patient sector	Total	Not available	Not available	Not available	Not available	
	Public	Not available	Not available	Not available	Not available	
	Private	Not available	Not available	Not available	Not available	

TUIK: Turkish Statistics Instiute

7 References

Kanzık, I.; Hıncal, A. (No date), Access of Patients to Innovative Drugs. Comparison of the Registration Processes of Drugs Containing New Molecular Entities in Turkey with those in the USA and EU Countries, IDE Scientific and Sectoral Report Series 1.

Lichtenberg, F. et al, (no date), The Effects of Pharmaceutical Innovation on Longevity, Hospitalization and Health Expenditures in Turkey 1999-2010, Polar Health Economics and Policy, Ankara. http://www.polarsaglik.com/uploads/polar/pdf/Longevity_report-ENG.pdf

Lichtenberg, F.; Tatar, M.; Çalışkan, Z. (2014), 'The effect of pharmaceutical innovation on longevity, hospitalization and medical expenditure in Turkey, 1999-2010', Health Policy, 117(3), 361-73.

Lichtenberg, F.; Tatar, M.; Çalışkan, Z. (2017), 'The Impact of Innovation on Health Outcomes and Utilization in Turkey: a Re-Examination', Health Policy and Technology, DOI: http://dx.doi.org/10.1016/j.hlpt.2017.01.003

Official Gazette, (2015), The Communiqué on Pricing of Human Medicinal Products, 11.12.2015, No 29559.

Official Gazette, (2016a), Decree on Reimbursement of Medicines, 10 February 2016, No 29620.

Official Gazette, (2016b), Decree on General Health Insurance Alternative Reimbursement, 10 February 2016, No 29620.

Pharmaceutical Manufacturers Association of Turkey, (2016), Turkish Pharmaceutical Market 2015, Ankara. www.ieis.org.tr.

Sağlık Bakanlığı (2016), Sağlık İstatistikleri Yıllığı, Ankara

Sosyal Güvenlik Kurumu, (2015) Aylık İstatistik Bülteni, http://www.sgk.gov.tr/wps/portal/sgk/tr/kurumsal/istatistik/aylik_istatistik_bilgileri (accessed, 17.01.2017

Türkiye İstatistik Kurumu, (2015), Sağlık Harcamaları Haber Bülteni,

Türkiye İstatistik Kurumu, (2016), Adrese Dayalı Nüfus Kayıt Sistemi Sonuçları, 2015, Haber Bülteni No 21507.