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TURKEY: Pharmaceutical Sector Analysis

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Glossary of Terms

Bağ-Kur	Social security fund for the self-employed and agricultural workers
BUMKO	Department of Budget Implementation and Fiscal Control
DPT	State Planning Organization
EU	European Union
EMEA	European Medicines Agency
ES	Emekli Sandığı – see GERF
FDA	Food and Drug Administration (US)
GDP	Gross Domestic Product
GDPP	General Directory of Pharmaceuticals and Pharmacies
GERF	Government Employees Retirement Fund (=Emekli Sandığı)
GMP	Good Manufacturing Practices
IEIS	Turkish association of pharmaceutical manufacturers
IMS	Market research company serving mainly the pharmaceutical industry
INN	International Non-proprietary Name
MoF	Ministry of Finance
MoH	Ministry of Health
NHA	National Health Accounts
NHS	National Health Survey
OECD	Organization for Economic Collaboration and Development
OTC	Over the counter
SHA	System of Health Account
SPC	Supplementary Protection Certificate
SPO	State Planning Organization
SSI	Social Security Institution
SSK	Social security fund for private sector workers
SUVAK	Hope in Health Foundation
TUIK	Statistical Organization of Turkey
USD	United States Dollars
VAT	Value Added Tax
YTL	New Turkish Lira

Introduction

Pharmaceuticals are essential to achieve health outcomes, but are at the same time a major cost factor in every health system. From a patient perspective, access to pharmaceuticals is a proxy for the functioning of the health system. With increasing economic strength, patients become more demanding with regard to access to modern, sophisticated drugs and providers become more aggressive in marketing those drugs (larger markets allow for higher profits). Both factors put pressure on the financial sustainability of the system. In upwardly mobile Middle Income Countries such as Turkey, upward pressure on drug expenditure comes from a variety of factors:

- Innovation creates new essential drugs that a comprehensive insurance package has to cover on one way or the other
- Better access to primary and secondary care leads to the identification of additional, previously untreated patients
- Aging and lifestyle changes create more chronically ill people, who need continuous treatment over longer periods of time (the aging factor may not yet play a major role in a relatively young society such as Turkey)

As a rule of thumb, due to the above factors drug expenditure grows at an average rate of about twice the rate of GDP growth during the expansion phase of countries in this stage. Once per capita expenditure has reached the lower end of the expenditure range in high income countries (such as for example in Slovenia), it becomes easier to contain growth at the rate of GDP growth without impacting quality of care or limiting access.

Purpose of this paper is to reflect on the situation in the pharmaceutical sector in Turkey, identifies critical issues and discusses policy options based on current trends and the overall policy objectives of the Turkish government.

Overall Policy Objectives in the Pharmaceutical Sector in Turkey

The key objectives for health policy in Turkey have been to bring everybody into the system and to ensure equal levels of care for the entire population. This has been partially achieved. However, some of the reforms have been blocked or slowed down through legal interventions on behalf of those who may feel that their privileges could be eroded through the new Universal Health Insurance model.

Given the favorable economic development over the last years, the government has been able and willing to increase spending for health. Nevertheless, rapidly increasing expenditures in particular in the pharmaceutical sector made it necessary to introduce some control mechanisms that allow better expenditure management without limiting access to important medicines.

Given the large domestic industry, pharmaceutical policy in Turkey has always been rather industry friendly, with easy market access and comparably high price limits for generic drugs. Growth rates of 20% and more per annum were observed in the period between 2002 and 2005, making Turkey one of the “hottest” markets for pharmaceuticals worldwide. Some of this growth was due to significant volume expansion, due to the fact that SSK and Green Card patients for the first time could use private pharmacies respectively got reimbursement for

primary care prescriptions. Since then, the market growth has slowed down to moderate levels, comparable with other countries in the same income bracket.
It is not expected that policy objectives will change dramatically in the future. EU assimilation will require certain legislative adjustments; the stalled process for setting up an independent drug agency may be revitalized one day. The key question is affordability: management of effective drug prices (as reimbursed by the health insurance) and prescription volume will be a key issue in balancing the goal of providing access to state-of-the-art medicines for all with the available budget.

Institutional and Regulatory Framework

The Turkish Drug Law

Legislative basis for the pharmaceutical sector is the Act on Medicinal Products for Human Use from 1928, kept up-to-date since then through various amendments. It is not clear whether this act can provide the basis for EU accession, but this question does not seem to have priority right now.

Several by-laws define the procedures for decision making on technical and economic aspects of pharmaceuticals:

- Licensing Regulations for Pharmaceuticals - Official Gazette No 25705, 19.1.2005
- Responsibilities and working arrangements for the General Directorate of Pharmaceuticals and Pharmacies (GDPP) within the MoH are defined in the Act on the Organization and Duties of the MoH (Official Gazette, 14.12.1983) and Basic Health Care Services Act (Act No 3359, Official Gazette, 14.05.1987)
- Commissions that advise the GDPP are regulated in the Regulation on Setting the Duties of Scientific Advisory Board and Commissions for Medicinal Products for Human Use (Official Gazette No 25254, 9.10.2003)
- Reimbursement decisions are made by a commission that was originally under the Ministry of Finance, but recently has been moved to SSI. The Commission was established in 2004 with the Decree No 004/6781.

The Ministry Of Health

The responsibility for overall drug policy as well as for licensing products and providers is within the MoH.. The General Directorate of Pharmaceuticals and Pharmacies (GDPP) is responsible for registration, marketing approval/authorization, pricing of pharmaceuticals, legal classification, control of advertisement for pharmaceutical products as well as inspection of pharmaceutical manufacturers, wholesalers and retail pharmacies. In its tasks, the MoH and GDDP are assisted by a number of expert committees. Decision making is organized as a cascading process in which one committee after another provide their input respectively approval once their requirements are satisfied.

MoH regulations stipulate that product registration can only be granted to a firm registered in Turkey. Thus, any pharmaceutical product imported into Turkey should be registered in the name of the Turkish agent or a Turkish commercial entity. Prior registration by a competent authority such as US FDA or EMEA facilitates Turkish registration but is not a prerequisite

In January 2005, the new Regulation on the Registration of Medicinal Products for Human Use, in line with EU principles, was published. With the new system, the registration appraisal period is being limited to 210 days, excluding periods for addressing deficiencies in the registration file. Also, the decisions on pricing and reimbursement are not covered by the 210 day period.

Reimbursement Commission

The Reimbursement Commission consists of representatives of the Ministry of Finance, Ministry of Health, and Social Security Institution (SSI). It is responsible for issuing the positive list of reimbursable drugs and meets every two months. SSI coordinates the commission. A Medical and Economic Appraisal Commission operating under the main commission represents the technical expertise needed to assess the dossiers submitted by industry. It prepares the decisions of the main commission and makes recommendations for inclusion of new drugs into the reimbursement list. However, the main commission does not always follow the recommendations of the technical commission. As a basis for their decision the commissions review data on efficacy, safety, clinical benefit and pharmacoeconomics. However, there appears to be no clear methodology for the decision making process, neither does Turkey have an institution that can independently assess pharmacoeconomic studies provided by manufacturers for facilitating the listing of their products.

Somewhat uniquely, two representatives of the pharmaceutical industry are on the main commission (one for the R&D based and one for the domestic industry). This increases transparency of the process for a main stakeholder, but could on the other hand be seen as a conflict of interest constellation. Consumer representatives are not part of the decision making process.

In the past there were instances where the decisions to exclude some pharmaceuticals from the positive list were challenged in court by interest groups. Some of these attempts succeeded in including the pharmaceutical on the list again. However the criteria used by the courts in their decisions are not transparent either (Tatar, 2007).

The positive list is unified for all health insurance funds, although technically there are still two (identical) lists for political reasons. It is brand-based, meaning that every new generic has to apply for inclusion in the positive list. The list defines the reference prices for reimbursement. Bargaining over prices appears to take place in the commission: manufacturers sometimes offer higher rebates than the statutory 4% for drugs less than 6 years old and 11% for drugs older than 6 years, in order to get on the list. However, there seems to be no mechanism to create a preferential reimbursement status for low price alternatives to existing drugs. Negotiations on risk-sharing agreements as they are increasingly used in other countries (for example volume ceilings for new, expensive drugs) are not taking place so far.

Plans for a New Regulatory Body: The National Institution of Medicine

The establishment of a new, independent drug agency was suggested in a "Transformation in Health" document issued by theMoH in 2003. This new agency is supposed to take over all responsibilities of the GDPP. Currently, the process seems stalled for political reasons and it is not clear when these plans will be turned into reality.

The table below provides an overview of the authorities and their responsibilities in the Turkish pharmaceutical sector.

Table 1: Authorities and Their Responsibility in the Turkish Pharmaceutical Sector

Authority	**Main Function**	**Description Responsibility**
Ministry of Health	Policy making body	Overall policy and planning authority
General Directorate of Pharmaceuticals and Pharmacies (within MoH)	Regulatory body	Licensing, market authorization, pricing, legal classification and inspection
Advisory Commission for the Authorization of Medicinal Products for Human Use	Consulting body. Coordinated by the Directorate of Pharmaceuticals and Pharmacies	Evaluates registration dossiers for pharmaceuticals
Advisory Commission for Technology and Pharmacology	Consulting body. Coordinated by the Directorate of Pharmaceuticals and Pharmacies	Technical assessment of dossiers
Pricing Commission	Coordinated by the Directorate of Pharmaceuticals and Pharmacies	Determines the ex-factory price of a pharmaceutical based on the current external price referencing system.
Advisory Commission for bio-availability and bio-equivalence	Consulting body. Coordinated by the Directorate of Pharmaceuticals and Pharmacies	Review and approval of documents for bio-availability and bio-equivalence
Advisory commission on Pharmacoeconomics	Consulting body. Coordinated by the Directorate of Pharmaceuticals and Pharmacies	Evaluates pharmacoeconomic data submitted by manufacturers. Part of registration.
Reimbursement Commission	Regulatory body for reim-bursement decisions. Coordinated by SSI	Decides about inclusion of pharmaceuticals on the positive list. Determines pharmaceutical equivalent groups and reference prices for reimbursement

Modified after: Mehtap Tatar (2007b). Pharmaceutical Pricing and Reimbursement Information. European Commission, Health and Consumer Protection Directorate-General and Austrian Ministry of Health, Family and Youth. p. 28.

Intellectual Property Rights Protection

Intellectual property protection for a long time was a contentious issue between Turkey and its trade partners, mainly the US and EU with their significant R&D based industry. New licensing regulations that closely resemble European Union regulations came into force only recently, and a national patent law is in effect since January 1st, 1999, implemented for patents dating back to January 1st, 1995, meaning that until approximately 2005 copies of drugs that

are protected by patents in the US or EU were legally introduced on the Turkish market (usually it takes ten years after the issuing of the patent until a drug reaches the market). Such drugs have been a major source of profits for the domestic industry, given the fact that they can be priced as high as 80% of the originator's price without having to make significant investments into R&D.

Additional protection mechanisms such as Data Protection and Marketing Exclusivity for innovator products without patent have also been introduced in Turkey in the process of partial assimilation with EU directives. Turkey also has implemented the Bolar Provision, which allows generic drug companies to prepare their registration files and submit them for approval while the original drug is still patented. The marketing authorization for the generic can then be issued immediately as soon as the originator patent or marketing exclusivity expires.

Pricing of Pharmaceuticals in Turkey

Pharmaceutical prices in Turkey are regulated and controlled by the MoH General Directorate of Pharmaceuticals and Pharmacies. The initial price of the product is determined during the process of authorization.

Turkey uses a reference pricing system for originator products (decree on the pricing of medicinal products for human use from 30.06.2007, number 2007/12325). The price for an originator product is determined according to the lowest ex-factory price among five EU countries (France, Spain, Italy, Portugal and Greece). The reference countries may change and the number of reference countries may increase up to 10, provided that four months prior notification is given to industry.

If there is no ex-factory price available for a product in the reference countries, the price is calculated by deducting mark ups and VAT from the pharmacy retail price. In cases where the ex-factory price of a product is lower in the country of origin (for products imported into the reference countries), the price in the country of origin is taken as the reference price. If the product is available in only one of the reference countries, the ex-factory price in that country is taken as a reference. In cases where the product is not authorized in any of the reference countries, the cheapest ex-factory price in any other EU Member State is taken as a reference. If the product is not authorized in the EU at all, the country of origin is taken as a reference. For products that are available only in Turkey, the price is set by negotiations between the MoH and the company. The pharmacy retail price is determined by adding mark-ups for wholesalers and pharmacies plus VAT.

For generics, prices are determined as 80% (under discussion is a change to70%) of the price of the originator product. The final product price is determined by adding wholesale and pharmacy mark-ups and VAT. The prices of generics cannot be higher than the original's reference price and the highest price of the equivalent generic in the market. If the originator lowers the price, the generics have to lower prices as well.

The retail prices are calculated by adding a reduced rate of 8% VAT (the normal rate is 18%) as well as wholesaler and pharmacist mark-ups to the ex-factory price.

Prices for imported drugs can be adjusted to reflect currency fluctuations. Such adjustments have to be requested by manufacturers. The main factor influencing such currency related adjustments is the YTL-Euro exchange rate. At the time of the drafting of this report, a price increase appears imminent as the YTL lost value against the Euro.

Manufacturers and importers apply to the MoH when there is a need to determine or revise the price of their product. The company is obliged to document the information required for pricing and the procedure has to be completed within 90 working days following the application date. Decisions on price adjustments after the initial price determination have a 10 day deadline. If the price in a reference country is reduced by more than 3%, the company is obliged to apply to the MoH within 3 months to revise the price

The process of pricing can be schematized for originator and generic products as following:

Originator Products
Reference Price + Wholesaler and pharmacist mark-up + 8% VAT

Generic Products
80% of the Reference Price + Wholesaler and pharmacist mark-up + 8% VAT

Wholesalers and pharmacies are remunerated via regressive mark-ups with margins being regulated by Decree No 2007/26651. These regulations are binding for all pharmaceuticals.

Table 2: Wholesale and Retail Margins

of the wholesaler sales price	Wholesaler (%)	Pharmacist (%)
Up to YTL 10	9	25
YTL 10 – 50	8	24
YTL 51 – 100	7	23
YTL 101 – 200	4	16
Over YTL 200	2	12

Source: The decree on the pricing of medicinal products for human use (2007/12325)

For drugs on the positive (reimbursement) list there is a public sector statutory discount determined at the time of pricing both at manufacturer and pharmacy level. For originator products, the manufacturer discount is 4% for drugs less than 6 years on the Turkish market and 11% for those older than 6 years and for generics. These discounts are based on the pharmacy retail price. In addition, a pharmacy discount is applied on the price determined after the manufacturer discount is deducted. Pharmacy discount rates depend on the pharmacy revenue (VAT excluded).

Some manufacturers offer additional discounts to SSI to ensure that their drugs are included in the positive list. The statutory pricing regulation sets upper limits; manufacturers are free to lower their prices or give special discounts to the public sector. The price label on the package shows the official market price based on the pricing process at the MoH. It reflects the price charged for over-the-counter transactions (although pharmacists can offer cash discounts to clients as well). The discounted price for SSI shows only in the positive list and the pharmacy computer during the transaction.

Table 3: Statutory discount for reimbursed drugs at retail level

Pharmacist sales	%
Pharmacies up to 220.000 YTL	3,0
Pharmacies between 220.000 YTL - 440.000 YTL	3,5
Pharmacies between 440.000 YTL - 550.000 YTL	4,0
Pharmacies over than 550.000 YTL	4,5

Source: IEIS, 2008 (www.ieis.org.tr, accessed on March 25, 2008)

Finally, there are commercial discounts, offered by manufacturers of multisource products to boost sales volume. "In kind" discounts are given both from manufacturers to wholesalers and wholesalers to pharmacies as free goods, constituting a significant share of the profits earned in the distribution chain. Price discounts or generous payment terms can be a strong determinant of competitiveness for offers also in hospital procurement (Kanavos et. al. 2005).

Public procurement / tendering

Tendering for pharmaceuticals is carried out in public hospitals. Hospitals purchase pharmaceuticals directly from companies or wholesalers after a tendering process. The procedures and rules are set in the Public Tendering Act (Act No 4734) elaborating the steps to be followed in any public procurement. All pharmaceuticals used in hospitals should be purchased by following these rules.

Before 2008, hospitals frequently ran out of drugs needed for inpatients so that patients were required to purchase drugs from private pharmacies outside the hospitals. Since January 2008 all public hospitals are obliged to provide drugs for in-patients for free. Hospitals can be fined if they violate this rule. So far, there is no evidence available as to how effectively the policy is implemented.

Reimbursement Rules

Discussions on Social Security Reform are still going on; the original plans for full integration are delayed and two decrees on reimbursement for different layers of the population entered into force on 15 June 2007. They define two separate positive lists, one covering green card holders, civil servants, military staff and the other covering self-employed workers and

farmers, private and public sector workers and retired civil servants entered. According to SSI, the two lists are identical; the separation appears to be mainly for political reasons. Decisions on inclusion/exclusion of drugs are made by the Reimbursement Commission under SSI. In 2006, 120 OTC drugs were excluded from the list.

For reimbursement purposes, medicines are grouped into equivalent groups based on the INN (active molecule). Reimbursement is capped at 22% above the cheapest brand in the group. This method started with 77 active substances in 2005; today there are 351 groups of biologically equivalent generics (IEIS, 2008). So far, there are no groups that include several molecules with clinically similar effects (therapeutic equivalence). Such groups have been introduced in several EU countries in order to realize additional savings.

Physicians prescribe by brand name and are free to prescribe drugs priced above the reimbursement limit. If the patient accepts the choice, s/he has to pay the difference out of pocket. If the price of the prescribed drug is lower than the reimbursement limit, the actual price is reimbursed. The pharmacist can see on the screen of his computer whether the patient would have a lower cost choice and is supposed to inform the patient. Pharmacists can substitute one branded generic for another or for the originator brand - but only if the substitute has the same or a lower price.

Pharmaceuticals are fully reimbursed if a patient has a chronic disease certified by the physician. Otherwise, active members and their relatives pay a 20% copayment and retired members a 10% copayment. In-patient pharmaceuticals are fully reimbursed.

Governance Issues in the Pharmaceutical Sector

In all countries, the pharmaceutical sector is vulnerable for non-transparent dealings by special interest groups and by individuals who sometimes put their own wealth over the public interest. In general, problems can occur whereever public officials are in positions of power to make decisions that affect income generation for individuals or firms, and where rules are ambiguous with lack of transparency and public oversight. Structural weak points are the individuals or commissions that make decisions on registration, licensing, pricing, procurement and inclusion of drugs into the reimbursement lists.

The Turkish system is relatively transparent in terms of the composition of decision making bodies. A mix of people from different institutions and backgrounds increases oversight and internal controls, although true public oversight for example through inclusion of consumer representatives is lacking.

The actual criteria applied in making decisions, however, are not well understood by outsiders. This does not imply the presence of unethical practices; decisions over the last years demonstrate that for example the reimbursement commission is able to enforce decisions that are painful for certain companies. In general, legal and institutional barriers to market entry (registration and reimbursement) are not very high compared to other countries and drug companies in general appear satisfied with the possibilities to obtain licenses and reimbursement list status. This is an indicator that corruption and bribery may not be a major issue in those parts of the Turkish health system that are responsible for market access.

However, the favorable conditions for the drug business also show that the industry historically has been very influential on the political level, which is typical for countries with a large domestic industry: industrial policy objectives compete with health policy and cost containment goals, and the industry retains the lobbying power to influence this balance significantly.

We have no information about the level of integrity in the system that is responsible for market oversight. In some countries, inspectors that have to assess manufacturing practices or adherence to good practice standards in wholesale and retail operations are subject to bribery. Potential countermeasures are spotchecks with re-inspection, pairing of inspectors in mixed paris and rotation in area responsibility. What appears to be common knowledge in Turkey is that the practice of renting out pharmacist degrees for opening a pharmacy is tolerated. This may just be lax enforcement and does not imply that any bribes are paid in such cases, but it is definitely an entry point for stronger enforcement. The same is true for the widespread practice to sell prescription drugs over the counter without prescription - easy to discover if political will is there and usually addressed successfully by imposing adequate fines.

An important entry point for questionable business practices is the supply chain, with manufacturers offering bonuses (free goods or favorable payment terms) to wholesalers who pass on some of the benefit to pharmacies. The pharmacists then recommend the drugs that are promoted and get full reimbursement even if they only paid for half of the stock. Such a system benefits the supply chain, is expensive for manufacturers and puts an unnecessary financial burden on the health insurance. However, given the confidential nature of business transactions in the private sector it is difficult to address with regulatory measures. We will discuss in a later chapter how institutional buyers can use purchasing power to capture the rebates that are otherwise wasted on unrecorded profits for distributors.

A widespread form of cheating in systems with insufficient control of prescribers is the issuing of fake prescriptions that are not dispensed, but still trigger a payment from the insurance that is split between pharmacist and doctor. Turkish pharmacists have to provide a piece of the packaging with the bar code, which makes this type of prescription fraud rather difficult. It means that the pharmacist would need a customer who is willing to pay for a damaged package, which is not impossible but unlikely to happen on a large scale. A new system with unique coding of drug packages will replace the current system. Such a system may actually make it easier to “sell” a drug twice. If the buyer is a patient who pays for the drug in cash, the system would not register it, neither would the patient be aware that his package has already been charged to SSI, as the package is unaltered.

Pharmaceutical companies are highly effective in influencing prescriber behavior in various ways, from high-end and ethical education programs for doctors to blunt forms of bribery such as cash payments for achieving a certain number of prescriptions. Significant rebates for expensive drugs are sometimes given to hospitals to start treatment in patients who ask for the same drug when released to their family doctor.

Medical experts in university hospitals depend on drug makers to support their research and academic publishing through funding for clinical trials and trips to congresses. These same experts are hired by drug companies on company funded expert advisory boards and by ministries of health for advisory roles that affect drug policy. Conflicts of interest are ubiquitous and not always declared. As a result, any country in which decision making on drug policy is mainly left to medical experts tends to enjoy high acceptance of new

technologies with little consideration of cost-benefit relations and overall public health impact.

Sub-standard and Counterfeit Drugs

Counterfeit drugs are an increasing problem for all pharmaceutical markets, affluent or poor. Counterfeiters are able to produce fake versions of expensive brand name drugs in a quality that even experts cannot detect them without lab analysis. If the counterfeiters limit their activity to lifestyle drugs such as Viagra or performance enhancing drugs sold in fitness studios, the public health impact may be limited. If, however, drugs for the treatment of potentially life-threatening diseases are faked and sold into the supply chain, the potential consequence is death of innocent patients.

Turkey is a transit country between Central Asia and Europe, and as such vulnerable for imports of illegal substances. Counterfeit drugs are a lower risk diversification strategy for organized crime – the punishment for counterfeiters is usually much milder than for a heroin trafficker. Turkey is a large and affluent market for pharmaceuticals. All these conditions point at a potential high risk constellation.

Less dramatic but still a potential health risk is the sale of outdated drugs. The problem in Turkey is that pharmacies usually cannot return stocks to wholesalers as in other countries. Therefore there is a temptation to keep selling drugs that have passed the expiration date. A sting operation in 15 warehouses in İstanbul, Ankara, Adana, Batman, Hatay, Konya and Samsun found a truck full of outdated medicines used for leukemia treatment and two trucks which were full of out-of-date medicines used for cancer treatment (Source: http://www.internethaber.com/news_detail.php?id=73650, March 13, 2007). This demonstrates that constant attention to this issue is required.

The MoH is working on a unique bar code system that can identify if a product is sold twice or beyond its expiry date. However, such a system does not catch drugs that are entering the system through grey market channels and are sold for cash only.

Overall, the governance challenges in the Turkish pharmaceutical sector appear to be known and understood. The authorities are making efforts to address weaknesses step by step. In some cases, additional capacity needs to be built up, in others the solutions will come when cost pressures increase to a point at which political resistance to change can be overcome.

Market Overview

Key Figures for the Turkish Pharmaceutical Market

According to IMS, the Turkish pharmaceutical market had a value of about 11 billion YTL (about 9 billion US $) in 2007 at retail value. This includes OTC drugs.

Table 4. The Pharmaceutical Market in Turkey 2003-2007

	2003	2004	2005	2006	2007
Millions of Units (packs)	**769**	**856**	**1212**	**1292**	**1399**
Unit Growth %		**11.3**	**41.6**	**6.6**	**8.3**
Value at Retail Prices (Total Market, million USD)	**3500**	**4290**	**6644**	**6954**	**8909**
Value Growth %		**22.6**	**54.9**	**4.7**	**28.1**
Average Cost per Unit in USD	**4.55**	**5.01**	**5.48**	**5.38**	**6.37**
Total Number of Prescriptions (millions)	**449**	**486**	**648**	**716**	**737**
Average Value Per Item (USD)	**7.8**	**8.83**	**10.25**	**9.71**	**12.1**
Value Share of Top 10 Manufacturers	**37.9%**	**38.1**	**36.4**	**36.6**	**35.8**
Value Share of Top 5 Wholesalers*	**30.8%**	**30.5**	**28.5**	**28.9**	**28.5**
Per Capita Consumption in Units**	**11.6**	**12.7**	**17.7**	**18.6**	**19.8**
Per Capita Consumption in USD	**52.7**	**63.6**	**97.0**	**100.0**	**126.2**

Source: IMS
*There are 319 wholesalers as of 2007
**Population estimate based on assumed 1.5% population growth rate; 2007 value: TUIK estimate

IMS collects data from contracted wholesalers and retail pharmacies, but has less accurate data on hospital sales. It is not clear to which extent free "bonus" drugs are recorded in the IMS data collection system. Inconsistencies in data sets form difference institutions are

common. They can be based on reporting systems, differences in prices paid by different market participants, different currency values used in calculations and different definitions of the data universe that is reported.

In 2007, there are 6,713 pharmaceutical specialties on the Turkish market. 4,765 (71% of total pharmaceuticals) of these are prescription drugs (IEIS, 2007).

The share of new drugs in the market was 6% in units and 4.7% in value in 2007. The share of reimbursed drugs in the market increased at the rate of 12.2% in units and 18.6% in value, highlighting a shift to more expensive prescriptions. According to estimates of IMS Global, developing pharmaceutical markets including Turkey are expected to grow at a rate of 12-13% in 2008. The main reason is increasing access to pharmaceuticals as a result of improvement of health services in these markets (IEIS, 2008).

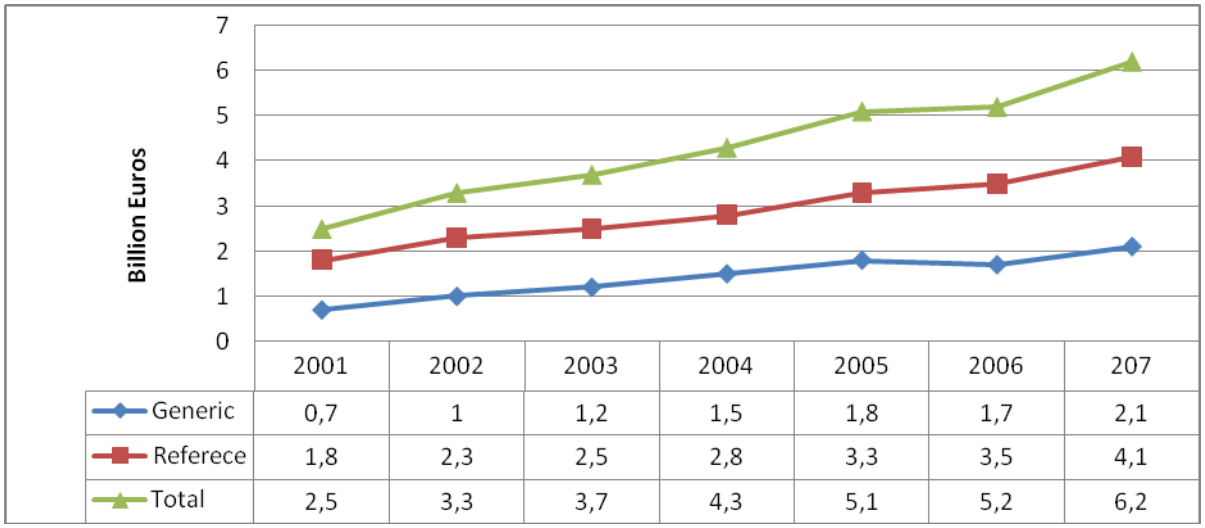
Table 5: Top 10 selling pharmaceuticals, by INN; 2005 or latest available year.

1	Fluticasone+Salmeterol	Originator Drug
2	Imatinib	Originator Drug
3	Flurbiprofen	Off patent
4	Etodolac	Off patent
5	Hydrochlorothyiazide+Valsartan	Originator Drug
6	Tiotropium Bromide	Originator Drug
7	Docetaxel	Originator Drug
8	Olanzapine	Off patent
9	Atorvastatin	Off patent
10	Amoxicillin+Clavulonic Acid	Off patent

The top ten list suggests that Turkish physicians are fast in adopting novel treatment options, (whether they are cost-effective or not), leading to significant cost pressures on the health insurance system. Some of the off-patent drugs on this list are still very expensive compared to alternatives in the same drug class that have been available as generics for a longer period of time, for example atorvastatin in comparison to simvastatin. Additional analysis should be done to identify the percentage of prescriptions for cost-effective first line treatments versus new, more expensive alternatives with similar clinical effects.

The figures below (Figure 1 and 2) show the relative shares of generic and originator (reference) drugs over the years as relatively constant, with only a slight increase of generic prescriptions in units. Turkey still appears to be a brand conscious market; doctors do not have strong incentives to prescribe generic drugs. The data appear to be not fully consistent with IMS data for the total market – for reasons explained above.

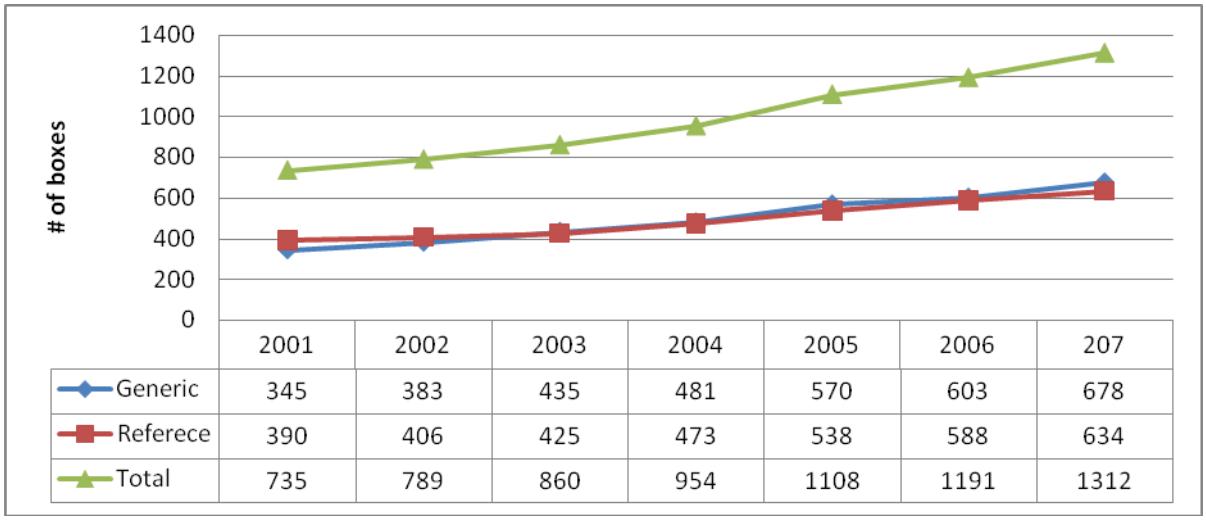
Figure 1: The Growth of Prescribed Drugs by Years (in values, Billion Euros)



	2001	2002	2003	2004	2005	2006	207
Generic	0,7	1	1,2	1,5	1,8	1,7	2,1
Referece	1,8	2,3	2,5	2,8	3,3	3,5	4,1
Total	2,5	3,3	3,7	4,3	5,1	5,2	6,2

Source: IEIS, 2008 (www.ieis.org.tr, accessed on March 25, 2008)

Figure 2: The Growth of Prescribed Drugs by Years (in packages)

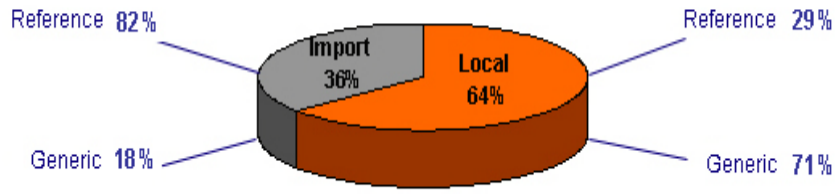


	2001	2002	2003	2004	2005	2006	207
Generic	345	383	435	481	570	603	678
Referece	390	406	425	473	538	588	634
Total	735	789	860	954	1108	1191	1312

Source: IEIS, 2008 (www.ieis.org.tr, accessed on March 25, 2008)

The majority of drugs sold in Turkey is manufactured locally. Among the imported drugs the share of originator drugs is logically higher, whereas the majority of domestically manufactured drugs are generics (Figure 3).

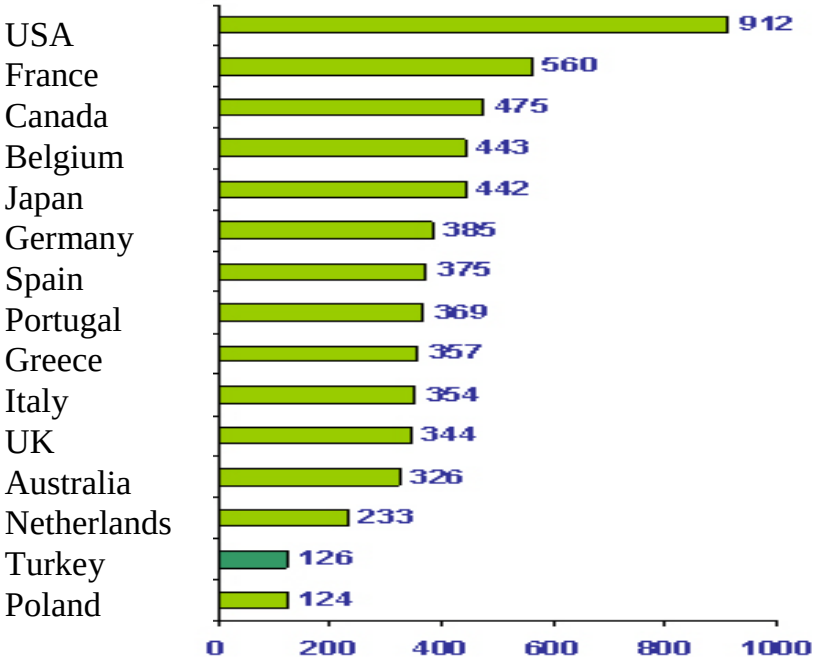
Figure 3: The Share of Imported and Locally Produced Drugs in Turkish Pharmaceutical Market, 2007 (in value)



Source: IEIS, 2008 (www.ieis.org.tr, accessed on March 25, 2008)

Compared to selected OECD countries, per capita drug expenditure in Turkey is among the lowest in 2007. However the trend in Turkey is upward, increasing from 35 US$ in 1998 to 126 US$ in 2007.

Figure 4: Per Capita Drug Expenditures of Some Selected OECD Countries (2007, US$)

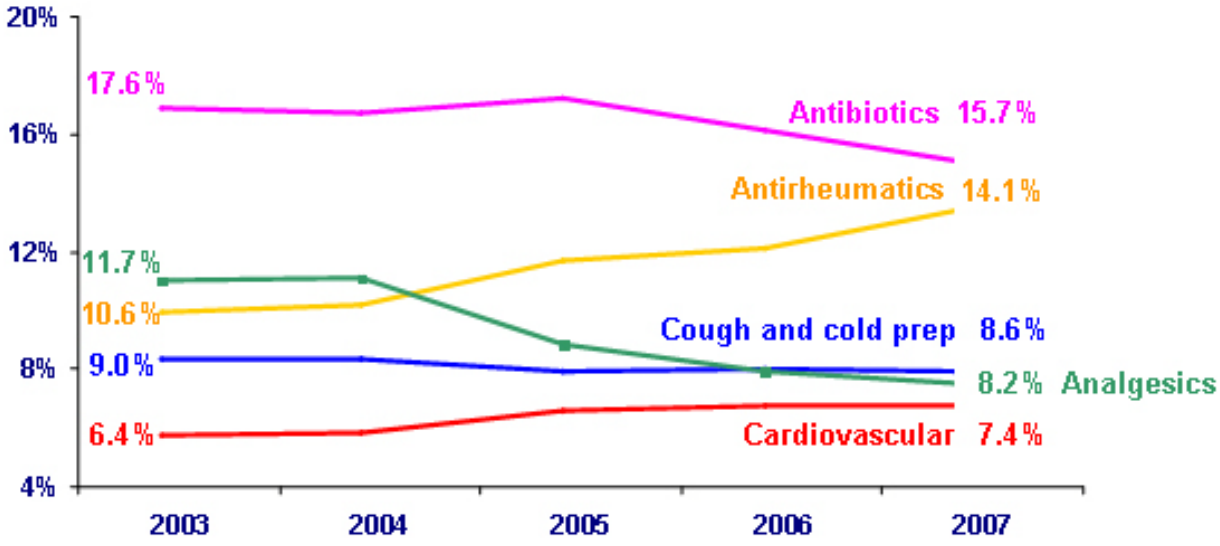


Source: IEIS, 2008 (www.ieis.org.tr, accessed on March 25, 2008)

The pharmaceutical consumption trends by therapeutic classes in Turkey suggest that inappropriate utilization is decreasing in relative terms, although excessive consumption of antibiotics is still a problem. The relative increase in antirheumatics and cardiovascular drugs has to be seen in the light of the introduction of new, expensive alternatives for these indications (for example etodolac for rheumatoid arthritis, ranking among the top 10 in 2005). Unfortunately the data do not include modern cancer treatments, which otherwise would probably show a sharp increase due to the introduction of some new, very expensive drugs with life-saving potential, which are covered by SSI and have also made it into the top of the

raking list (Imatinib, Docetaxel). The pattern is typical for a country that is adopting innovation quickly and with weak volume controls, which might create a challenge for financial sustainability over time.

Figure 5: Pharmaceutical Consumption by Therapeutic Class



Source: IEIS, 2008 (www.ieis.org.tr, accessed on March 25, 2008)

The Turkish Pharmaceutical Industry

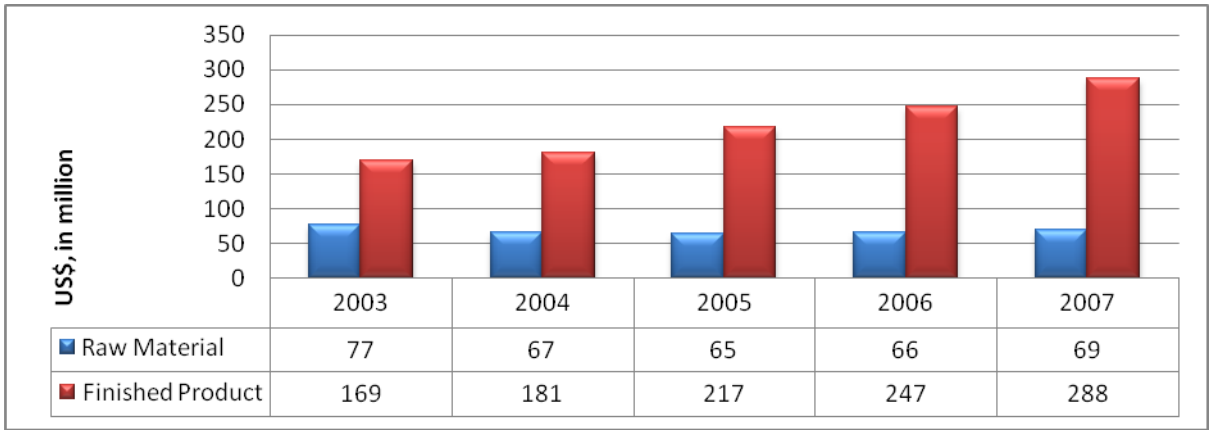
Turkey has a developed pharmaceutical industry in terms of production standards, technology and capacity. The production facilities have been inspected continuously by Ministry of Health, and accredited internationally by International Accreditation Authorities (IEIS, 2008). However, Turkey does not participate in the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S) (www.picscheme.org), which includes the so-called "stringent regulatory authorities" who mutually recognize their standards for GMP (Good Manufacturing Practice). Therefore it is not possible to confirm that all Turkish manufacturers are operating on a level equal to their counterparts in the PIC/S countries. What can be said with certainty is that manufacturers that have contracts with multinational companies are working on the same standards as these companies at least for the contracted products.

Today, there are approximately 300 pharmaceutical firms operating in Turkey, many of them just maintain a marketing organization. Among 42 manufacturing facilities in Turkey, 14 belong to multinational firms.

Approximately 25.000 people are employed in the sector in 2007, of which 50% have a university degree. (pharmacist 4, 5%, physicians 3%, chemical engineers 7, 5%, chemists 7%, biologists 9, 5%).

In 2007, pharmaceutical imports increased by 16% and reached 3.52 billion USD whereas the export increased by 14% and reached 357 million USD. The export-import ratio in 2007 was 10.1% (after 10.3% in 2006).

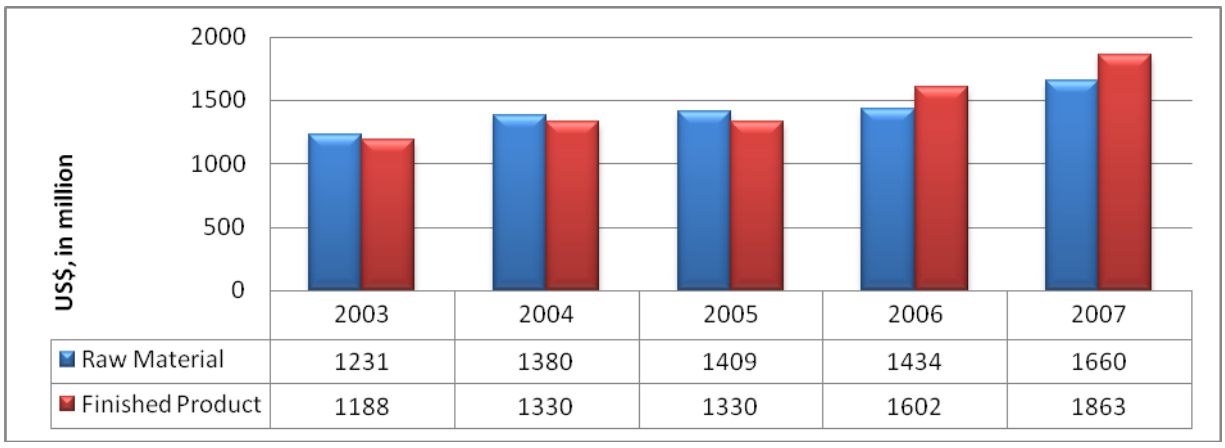
Figure 6: The Value of Exported Raw Material and Finished Pharmaceutical Products in Turkey by Years (US $ in million)



	2003	2004	2005	2006	2007
Raw Material	77	67	65	66	69
Finished Product	169	181	217	247	288

Source: IEIS, 2008 (www.ieis.org.tr, accessed on March 25, 2008)

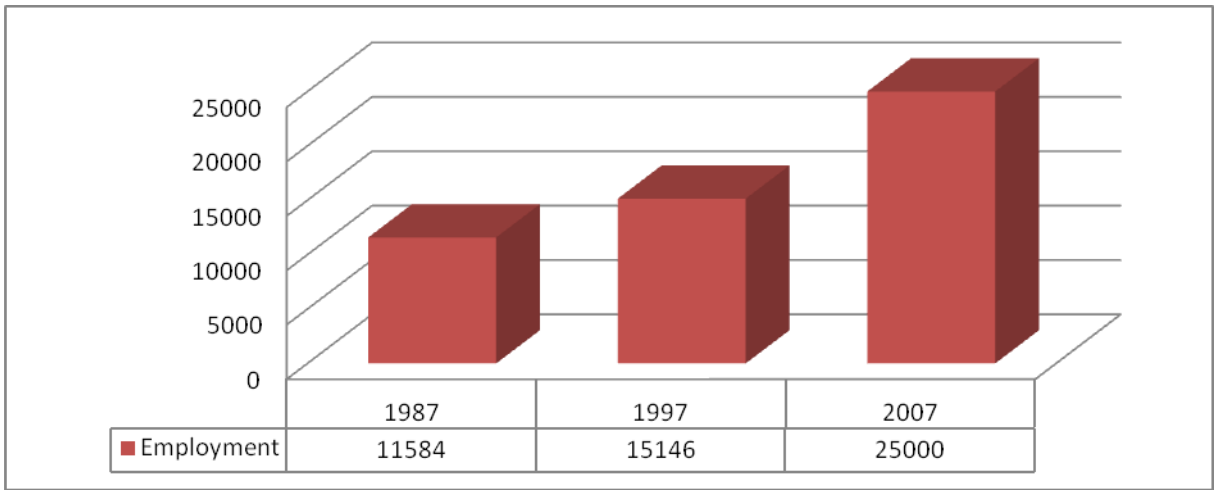
Figure 7: The Value of Imported Raw Material and Finished Pharmaceutical Products in Turkey by Years (US $ in million)



	2003	2004	2005	2006	2007
Raw Material	1231	1380	1409	1434	1660
Finished Product	1188	1330	1330	1602	1863

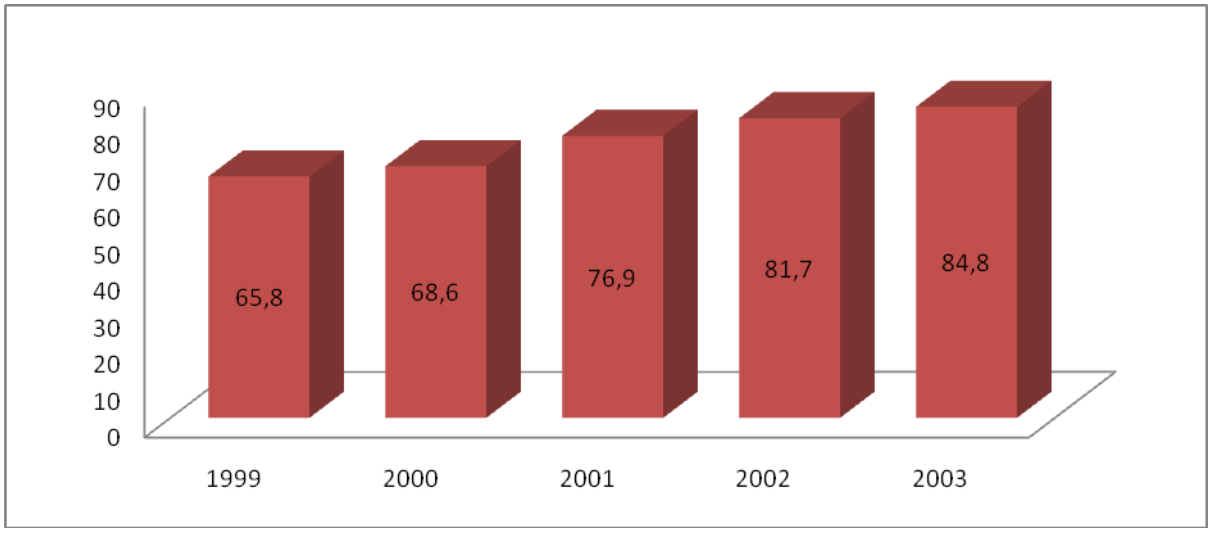
Source: IEIS, 2008 (www.ieis.org.tr, accessed on March 25, 2008)

Figure 8: Employment in the Turkish Pharmaceutical Sector in the last 20 years



Source: IEIS, 2008 (www.ieis.org.tr, accessed on March 25, 2008)

Figure 9: The Growth of Investments in Pharmaceutical Sector by Years (US$ in million)



Source: IEIS, 2008 (www.ieis.org.tr, accessed on March 25, 2008)

Turkey's industrial policy is focused on generic production. The industry needs to compete on a global level and particularly in the EU in order to maintain its growth. The investment into modern production technology as well as into technical R&D is a prerequisite for achieving this goal. Turkey looks at the success of Ireland in becoming a European hub for pharmaceutical manufacturing as a role model. Attracting foreign investment is an important part of this strategy and Turkey has had some successes in this area.

The important role of the domestic industry in terms of employment and value generation is one of the reasons why cost containment measures - that inevitably have a negative impact on industrial profitability - are not applied to the same extend as in other countries.

Two major and some smaller associations represent the pharmaceutical industry in Turkey; both of the major ones have a seat on the reimbursement commission: IEIS, founded in 1964, is the organization of the domestic pharmaceutical industry with 41 members (http://www.ieis.org.tr). AiFD represents multinational research-based companies (http://www.aifd.org.tr).

Drug Distribution and Dispensing

A wholesale cooperative owned by retail pharmacies in urban areas had about 10% wholesale market share. The concentration in the wholesale sector is likely to continue, given the cost advantages and stronger bargaining power of large integrated operations.

In 2005, there were 22600 retail pharmacies in Turkey. Pharmacy chains are not permitted (yet), but it is a well known fact that some pharmacists rent out their degree to a third party to open a pharmacy, which then is run by a technician with limited training. This phenomenon is said to be more widespread in the Eastern and Southeastern provinces of Turkey. Technicians, who are in many instances solely responsible for dispensing, have no formal training or qualifications in pharmacy. This suggests that patients may be inadequately advised, which is even more a problem if a prescription drug is dispensed without prescription – a common practice in Turkey. It also increases the risk of mix-ups with potentially fatal outcome.

Internet/mail order pharmacies are not allowed, neither is the sale of OTC drugs in drug stores or supermarkets. Hospitals have their own pharmacies for inpatient supplies. In exceptional cases (emergencies, long distances to the next retail pharmacy) they can dispense outpatient drugs as well.

Despite the perceived high density of pharmacies in urban areas, there can be access problems in rural areas that are not commercially attractive. Overall, Turkey has one pharmacist per 3000 citizens. This number includes pharmacists working in institutions and administration (Source: TUIK, http://www.tuik.gov.tr/VeriBilgi.do?tb_id=6&ust_id=1).

Table 6: Distribution of Pharmacists by Regions, 2003, (MoH, December 2005, s. p.45)

Regions	Physician	Pharmacist	% of Total Pharmacists
Marmara	30033	7398	31,3
Aegean	15529	4074	17,2
Mediterranean	10272	2915	12,3
Central Anatolia	20879	4967	21,0
Black Sea	10193	2147	9,1
East Anatolia	6385	845	3,6
Southeast Anatolia	4472	1286	5,4

A system of green and red prescriptions is used to control the sale of certain medicines, including psychotropic medicines (green prescriptions) and narcotic substances (red prescriptions). Such drugs are usually not available without a prescription.

Pharmacists are authorized to substitute (branded) generics for original products or other branded generics prescribed by the physician, as long as the substitute is pharmaceutically equivalent and cheaper than the prescribed brand. There is no "dispense as written" box on the prescription form, but patients may prefer the branded original over the generic and willing to pay the part of the price that exceeds the reimbursement ceiling out of pocket. The generic for substitution should be listed officially to be one of the equivalent drug products. Since 2001, a nationwide information system allows pharmacists to obtain information on the equivalency profile of generic drugs for substitution for all drug reimbursement schemes. This system alerts the pharmacist if a cheaper equivalent is available – the pharmacist is obliged to inform the patient about such an option (although it is hard to enforce this rule).

Pharmacies receive their income from social security funds (reimbursement for patients that come with a covered prescription) and from private out-of-pocket payments. They have to pay for drugs they buy usually within 3 months, unless the wholesaler offers more generous payment terms as an incentive. Payment from SSI is received usually only after 6 months.

In addition to their official income pharmacies receive free goods from wholesalers for which they get full reimbursement – generating significant additional profits. The offer of free goods creates a strong incentive to recommend specific brands for purely commercial reasons and runs contrary to the intended cost containing effect of the generic substitution policy.

The system that pharmacies use to process dispensing of reimbursed products is based on an online connection to a server at SSI that checks every entry and clears or rejects it. If for example a patient has received a four week prescription for an antihypertensive, the next prescription will only be cleared after a reasonable time interval. This is an effective measure to reduce system abuse. Pharmacists cut off the bar code part of the package and submit it to SSI together with the prescription as proof that the drug has been dispensed.

Payment for Pharmaceuticals in Turkey

Pharmaceuticals are a major share of public health expenditure – the current consensus figure is about 32.6% of total health expenditure. The table below shows detailed data on total health and drug expenditures of the Social Security Organizations.

Table 7: Total Health and Drug Expenditures of Social Security Organization (2000-2007) (in million US$)

Years	2000	%	2001	%	2002	%	2003	%	2004	%	2005	%	2006	%	2007	%
SSK	2.052	100	1.847	100	2.387	100	3.336	100	4.666	100	5,268	100	7,761	100	11,328	100
Treatment	999	49	919	50	991	42	1.694	51	2.462	53	2,303	44	3,834	49	6,057	53
Drug	917	45	812	44	1.248	52	1.407	42	1.889	40	2,650	50	3,680	47	4,903	43
Other	136	7	115	6	147	6	234	7	314	7	316	6	247	3	369	3
Bağ-Kur	1.170	100	1.005	100	1.458	100	2.132	100	2.615	100	2,704	100	2,667	100	2,346	100
Treatment	346	30	270	27	460	32	647	30	892	34	1,016	38	1,165	44	1,065	45
Drug	734	63	638	64	878	60	1.338	63	1.538	59	1,373	51	1,287	48	1,081	46
Other	90	8	97	10	120	8	147	7	184	7	315	12	215	8	200	9
GERF (Does not include active civil servants)	999	100	891	100	1.222	100	1.673	100	1.966	100	2,175	100	1,918	100	1,686	100
Treatment	356	36	282	32	428	35	581	35	798	41	876	40	934	49	771	46
Drug	574	57	540	61	730	60	1.016	61	1.071	55	1,198	55	884	46	824	49
Other	69	7	69	8	63	5	77	5	96	5	101	5	100	5	91	5
TOTAL HEALTH EXPENDITURE	4.223	100	3.743	100	5.066	100	7.141	100	9.245	100	10,148	100	12,346	100	15,360	100
Treatment	1.701	40	1.472	39	1.880	37	2.922	41	4.152	45	4,195	41	5,932	48	7,892	51
Drug	2.227	53	1.991	53	2.856	56	3.761	53	4.499	49	5,221	51	5,850	47	6,809	44
Other	295	7	281	8	331	7	459	6	594	6	731	7	563	5	659	4

Source: Social Security Institution, January Bulletin, 2008; www.bumko.gov.tr (for exchange rates)

Although numbers came down over the years, drugs are still responsible for about 44% of SSI expenditure. SSI is not responsible for all public health expenditure (public hospitals are subsidized from MoH); therefore the relative share of drug expenditure is higher for SSI than for the total public expenditure. The rapid increase in SSK health expenditure is due to the rules change for SSK members, who were only allowed to use SSK service providers prior to 2004. Since then, they have access to the same services as members of other organizations, which has led to a significant cost increase.

Total Health and Drug Expenditures of Main Public Social Insurance Organizations

Insurance coverage

There are no final data on insurance coverage in Turkey. Nevertheless, according to MoH the uninsured are not excluded from treatment, as on primary care level everyone is accepted. Also the Green Card system is open for everybody who is poor and there are no waiting times before services can be used. Therefore it is possible that most of the uninsured just have not signed up to the system yet because they are feeling healthy and want to avoid paying into social insurance (example informal sector workers). This is relevant from a revenue perspective but less from a cost perspective, as it is unlikely that a large part of this population would suddenly fall ill and subsequently cause an expenditure increase by joining the system.

SSK Health and Drug Expenditures

Health and drug expenditures of SSK by years are given in the table below. The numbers reflect the results of health policy changes after 2004 for SSK and its members. Before 2004 SSK had the lowest per capita and drug expenditures and their members were not allowed to use private and public hospitals other than SSK's own hospitals (as of 2005 MoH took ownership of SSK hospitals) or private pharmacies to get their drugs. Since 2004 SSK members can use all hospitals and pharmacies. These changes resulted in increasing health and drug expenditures.

Table 8: SSK expenditure (in million US $)

Years	Total Health Expenditure (THE)	Drug Expenditures (DE)	Share of DE in THE	Per Capita HE	Per Capita DE	Number of Beneficiaries
2001	1.847	812	44,0	82	36	22.549.777
2002	2.387	1.248	52,3	100	52	23.983.784
2003	3.336	1.407	42,2	132	56	25.304.588
2004	4.666	1.890	40,5	173	70	26.937.480
2005	5.725	2.650	46,3	195	90	29.345.239
2006	8.176	3.680	45,0	244	110	33.539.225
2007	11.328	4.903	43,3	348	151	32.539.501

Source: Social Security Organization, January Bulletin, 2008

Bağ-Kur is covering more than 20 percent of population (the self employers and employees in the agricultural sector). Drug expenditure for Bağ-Kur patients decreased over the last two years, probably as a result of the overall cost containment measures applied in the pricing and reimbursement system.

Table 9: Bağ-Kur expenditure (in million US $)

Years	Total Health Expenditure (THE)	Drug Expenditures (DE)	Share of DE in THE	Per Capita HE	Per Capita DE	Number of Beneficiaries
2001	1.005	638	63,5	66	42	15.261.654
2002	1.458	878	60,2	94	56	15.547.991
2003	2.132	1.338	62,7	134	84	15.881.624
2004	2.615	1.538	58,8	161	95	16.233.984
2005	2.704	1.373	50,8	169	86	15.990.253
2006	2.667	1.287	48,7	163	75	16.383.589
2007	2.346	1.081	46,1	142	66	16.473.100

Source: Social Security Organization, January Bulletin, 2008

Emekli Sandığı (Government Employees Retirement Fund – GERF) is another social security organization. The figures in the table below do not include the data for active civil servants and their dependants since this group is reimbursed directly from the budget of their institution. The share of drug expenditures for this group is slightly higher compared to the other organizations (48.9%) in 2007. In absolute terms, per capita expenditure is significantly higher which most likely is due to the age distribution (pensioners). Traditionally, public servants and pensioners are the most privileged group with the highest per capita expenditure, but absolute numbers show a downward trend since 2006.

Table 10: Emekli Sandığı expenditure (in million US $)

Years	Total Health Expenditure (THE)	Drug Expenditures (DE)	Share of DE in THE	Per Capita HE	Per Capita DE	Number of Beneficiaries*
2001	891	540	60,6	275	167	3.235.374
2002	1.222	730	59,8	362	217	3.371.299
2003	1.673	1.016	60,7	478	290	3.502.519
2004	1.966	1.071	54,5	539	294	3.649.635
2005	2.175	1.198	55,1	575	317	3.784.504
2006	1.918	884	46,1	497	229	3.857.412
2007	1.686	824	48,9	420	205	4.017.944

*: Number of beneficiaries was estimated by using dependency ratio. Active civil servants and their dependants were not included.

Source: Social Security Organization, January Bulletin, 2008

If health and drug expenditures of active civil servants and their dependants is included in GERF health expenditures (Table 11), per capita numbers decrease and come closer to the numbers for SSK members.

Table 11: Emekli Sandığı (Including Active Civil Servants and Their Dependants) expenditure (in million US $)

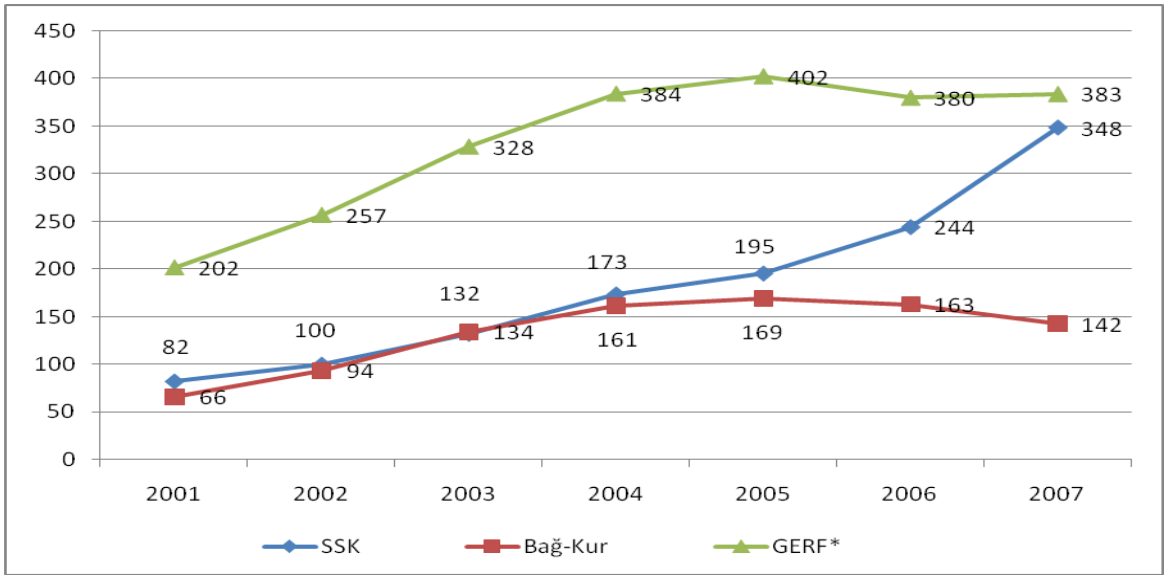
Years	Total Health Expenditure (THE)	Drug Expenditures (DE)	Share of DE in THE	Per Capita HE	Per Capita DE	Number of Beneficiaries
2001	1.728	984	57,0	202	115	8.572.259
2002	2.320	1.273	54,9	257	141	9.044.434
2003	3.036	1.667	54,9	328	180	9.248.283
2004	3.595	1.828	50,9	384	195	9.367.151
2005	3.812	1.887	49,5	402	199	9.481.295
2006	3.613	1.444	40,0	380	152	9.517.053
2007	3.759	1.567	41,7	383	160	9.801.635

Source: Social Security Organization, January Bulletin, 2008

Comparing Health and Drug Expenditures of Main Public Insurance Organizations

Figure 10 compares the per capita health expenditures of social security organizations in Turkey over the years. The figure shows that SSK has an increasing trend in per capita health expenditures. A possible explanation is that SSK patients are using services that were not available to them now to an extent that crowds out patients from GERF and Bağ-Kur (for example surgery or cancer treatments in university hospitals that have waiting lists and therefore constitute a bottleneck). If this explanation is correct than it can be expected that the trend reverses again as soon as the overhang of SSK patients has been cleared.

Figure 10: Per Capita Health Expenditures of Main Social Security Organizations in Turkey (US$)

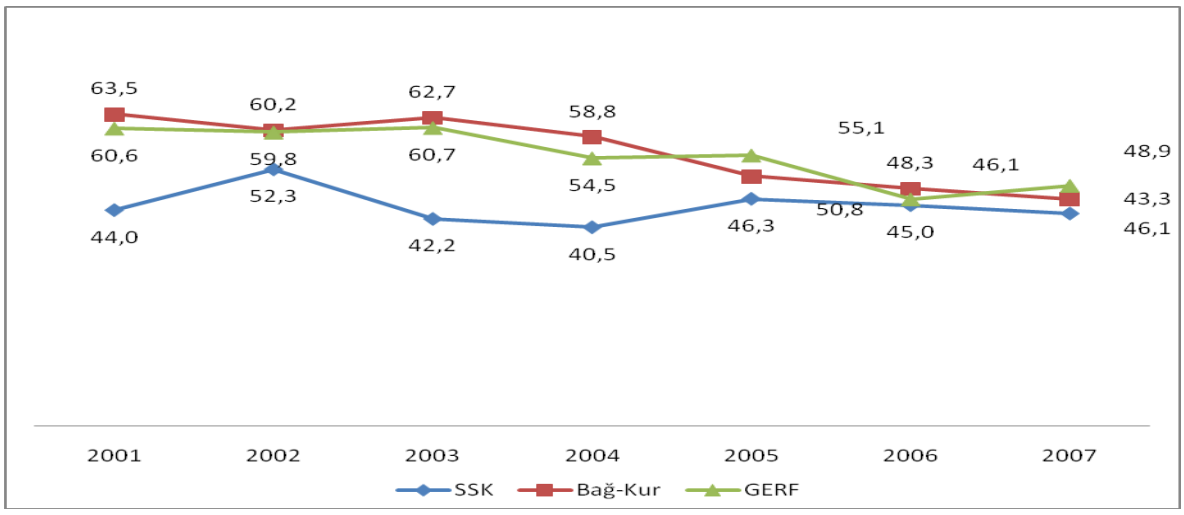


*: Including active civil servants and their dependants

Source: Social Security Organization, January Bulletin, 2008 ; Hale Akyel; BUMKO

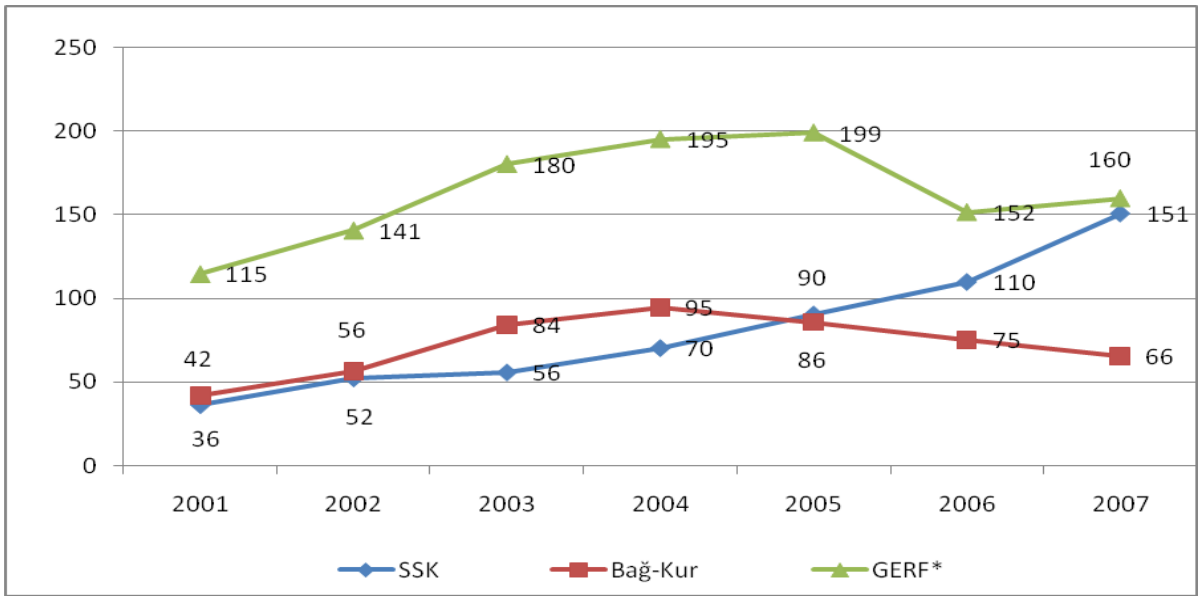
The chart below shows the trend in the share of drug expenditures in total health expenditures of main public social security organizations. Despite the higher absolute expenditure for GERF (Figure 12) the share of drug expenditure is in the same range (40-50%) for all three organizations. What needs to be considered is that hospitals are subsidized from the MoH, therefore the Social Security Organizations represent only a part of public health expenditure.

Figure 11: Share of Drug Expenditures of Main Public Social Security Organizations (%)



Source: Social Security Organization, January Bulletin, 2008

Figure 12: Per Capita Drug Expenditures of Main Public Social Security Organizations (in US$)



*: Including active civil servants and their dependants

Source: Social Security Organization, January Bulletin, 2008 ; Hale Akyel; BUMKO

Health and Drug Expenditures of Green Card Holders

Green Card is an insurance scheme covering health and drug expenditures of the poor in Turkey. Those with incomes lower than a determined level and no coverage by any other health insurance scheme are eligible to get the benefits of the Green Card scheme. There have been some fluctuations in the numbers of Green Card beneficiaries over the years, partially due to measures to curb abuse. The table below shows increasing health and drug expenditures for Green Card holders. This is a result of policy change expanding health care benefits – since 2005 outpatient services and drugs are covered in addition to in-patient services. Per capita drug expenditure for Green Card holders is now in the same range as for Bağ-Kur patients.

Table 12: Health and Drug Expenditures for Green Card Holders (in million US$)

Years	Total Health Expenditure (THE)	Drug Expenditures (DE)	Share of DE in THE	Per Capita HE	Per Capita DE	Number of Beneficiaries
2001	320,9	74,9	23,3	41	10	7.827.273
2002	364,5	7,9	2,2	39	1	9.349.725
2003	614,2	168,8	27,5	46	13	13.418.559
2004	736,1	332,8	43,6	61	26	12.586.693
2005	866,6	229,7	26,5	90	24	9.582.197
2006	2.033,5	647,1	31,8	162	52	12.550.309
2007	3.007,7	1.003,1	33,4	208	70	14.431.000

Source: Hale Akyel, 2006, p. 41; BUMKO for 2006 and 2007

Private health insurance is available in Turkey but appears to play only a marginal role. Beneficiaries are usually employees in international companies or organizations. In 2000 private health insurance companies covered 3.6% of the total health care expenditures (Ministry of Health, 2004).

Analyzing Out-Of-Pocket Health and Drug Expenditures

Statutory Copayments:
The copayment for outpatient drugs is 20% for active members (based on the HIF reimbursement rate), 10% for retirees and zero for people with chronic diseases once they have a "report" from their treating physician. People on a public payroll/pension get these copayments deducted from their pay the following month. This method was introduced as pharmacists were increasingly offering patients a discount offsetting the statutory copayment and thereby undermining the volume control effect that is the rationale for having copayments.

Additional payments have to be made in cash, covering the difference between the reimbursement level (max 22% over the lowest price in a group of equivalent drugs) and market price of a drug if the patient decides to take the more expensive brand.

Out-of-pocket purchasing of prescription drugs

The last reliable data go back to the NHA household survey in 2003: at that time, 28% of the Turkish population purchased pharmaceuticals directly from pharmacies without prescription when they felt ill. Prescriptions drugs can generally be obtained without prescription (with exceptions for controlled substances), but given the improved benefit scheme for Green Card holders and SSK patients, it will be necessary to update the household survey data. It can be assumed that out of pocket purchases of prescription drugs do not account for a large share of the market today. Patients, even those with health insurance, may decide to buy a drug for cash if they feel sick but don't want to spend time on consulting a doctor. But drugs used for such minor illnesses are usually not very expensive.

Payment for inpatient drugs and informal payments for drugs

Before 2008, hospitals frequently ran out of drugs needed for inpatients so that patients were required to purchase drugs from private pharmacies outside the hospitals. The incidence of this phenomenon was between 11% in Izmir and nearly 70% of patients in the poorer East and Southeast regions (Liu, et. al. 2005). Since January 2008 all public hospitals are obliged to provide drugs for in-patients for free. Hospitals can be fined if they violate this rule. So far, there is no evidence available as to how effectively the policy is implemented.

Table 13: Formal and Informal Payments by Insurance Status

	Insured		Green Card Holders		Uninsured	
Purpose	**Formal**	**Informal**	**Formal**	**Informal**	**Formal**	**Informal**
Donation		6,4		1,4		2,6
Physicians' medical services	25,6	79,5	10,6	15,6	22,1	9,8
Physicians' surgical services		6,8		64,0	9,9	0,1
Drugs	53,6	2,1	89,4	9,5	55,0	82,5
Laboratory/imaging services	11,2				13,0	
Nurses'/other staffs' services				5,7		0,1
Other services	9,6	5,2		3,8		4,9

Source: Tatar et. all. 'Informal Payments in the Health Sector: A Case Study From Turkey'. Health Affairs, Vol. 26, No. 4, pp. 1029-1039.

Overall, the out of pocket share of payment for prescription drugs as of today can be estimated at around 20 - 25% of the total market, which is consistent with the difference of the total market according to IMS and the total public sector payments for drugs (8909 versus 6809 million USD in 2007).

Drug benefit package under insurance – access and equity aspects

Practically all population segments have access to coverage by insurance organizations under the Social Security Institution and can get reimbursement for the same medicines in the positive lists. Remaining access barriers are physical distance from providers and cultural barriers such as lack of education or being part of a population group that suffers discrimination in their local communities. These barriers need to be addressed by measures outside the pharmaceutical sector. In general, health consciousness and care seeking behavior increases with income and education level. Even if the system provides full access for all, most of the services are typically consumed by the higher income groups.

"Catastrophic costs of illness" is an outcome typical for systems with insufficient health insurance. Patients who for example need an expensive cancer treatment cannot afford the treatment and fall into poverty while struggling to pay their bills. In Turkey, coverage as well as the reimbursement list are fairly inclusive and provide for many novel treatments with costs

up to 12,000 YTL per year (example imatinib for Chronic Myeloic Leukemia), so that poor and middle class patient are enjoying sufficient protection from the poverty inducing effects of disease. It is assumed here that a person who is currently uninsured can join the Green Card scheme or another organization appropriate for his/her status even after an illness has been diagnosed.

An open question remains the effect of the new regulation that requires hospitals to cover all costs for inpatient drugs. If properly enforced, this should address any discrimination in terms of access against the poor in inpatient settings as well.

Prescribing Practices – Rational Use of Medicines

In Turkey, around 21 million prescriptions are given by doctors per month. Average cost of prescription was 48 YTL in 2007 and 42 YTL in 2008. Average cost of prescription for Greencard holders is around 29 YTL (SSI data presented at the 2d National Health Assembly in 2008)). It is not clear whether the decrease from 2007 to 2008 is due to price changes or changes in the prescribing pattern or volume.

Physicians are allowed to prescribe up to four items per prescription, each in an amount covering a maximum of seven days. For chronic diseases, the limit is a three month supply. They have to provide indication, diploma number, specialty area and address stamp on the prescription form.

Certain new and expensive drugs can only be prescribed by specialists, for example new antirheumatic or psychiatric drugs. Narcotics and certain psychotropic drugs with abuse potential have to be prescribed on special green or red forms and are tracked from manufacturer to patient.

In 2003, a clinical practice guideline for primary care was developed by the MoH in order to define what evidence based medicine and rational use of medicines mean at this level. It sets basic rules in diagnosing, treating, monitoring and referral principles for several categories of diseases and is available in print and online. This guideline is voluntary, there is no enforcement mechanism. There is no guideline that informs physicians about the cheapest alternatives for prescribing. Information about pharmaceuticals comes almost exclusively from the industry; the government is proposing to fill this gap by publishing a bulletin to be distributed to all physicians, but this is still pending.

The system to track prescribing of physicians and link it to incentives for rational use of medicines is not yet developed. The MoH is currently in the process of setting up a physician's registry based on the unique ID number that every Turkish citizen has. On the SSI side, the Data Warehouse project will provide the computing power to process the huge amount of data generated daily in the pharmacy provision system. At the moment, physicians are uncontrolled in their prescribing and not accountable for costs they cause to the system. Physicians are not contract partners for SSI – the contract is made between the institution (hospital, health center) and SSI. Public hospitals and primary care centers have introduced a "pay for performance" model, which defines a signficant share of the physicians' salary. In the context of this scheme, it should be possible to introduce parameters of rational use of medicines as soon as the monitoring instruments are in place.

Transparency of drug prices and quality for patients; acceptance of generics

Although the Turkish market is dominated by branded generics, there is still a significant market share for older originator drugs that are priced at a level that requires patients to pay the difference to the reimbursement ceiling out of pocket. Brand loyalty in the pharmaceutical sector can be strong, and prejudice against generics is sometimes fueled by physicians and pharmacists who may have economic incentives to convince the patient to pay extra for a particular brand. From the SSI perspective, this is less relevant as the reimbursement ceiling protects SSI from overcharging. The situation is more complicated in situations in which an old, established and cost-effective treatment is given up in favor of a new, heavily marketed and much more expensive product. Both products are priced independently in Turkey and therefore the patient may only feel a minor difference through the statutory copayment. But for SSI the costs can be significantly higher without gaining any health, convenience or drug safety benefit. The classic example is the pair omeprazole/esomeprazole: while omeprazole is off patent and available at a retail price of 4.37 for a pack of 14 tablets/20 mg, the comparable pack of esomeprazole (which according to independent pharmacoeconomic analysis has exactly the same mechanism of action and no measurable benefits) costs YTL 21.51 for the same pack size and strength. Savings could also be achieved if atorvastatin and simvastatin would be treated as therapeutically equivalent – simvastatin is about 50% cheaper and is better documented in terms of its long term impact on cardiovascular events.

Table 14: Price comparison for pairs of drugs that are seen as equivalent for reimbursement purposes in other countries

Generic name	Atorvastatin	Simvastatin	Esomeprazol	Omeprazol
Pack size	**30 tbl**	**28 tbl**	**14 tbl**	**14 tbl**
Dosage	**40 mg**	**40 mg**	**20 mg**	**20mg**
Retail Price YTL	**54.53**	**21.82**	**21.51**	**4.37**

Source: Official MoH price list 2008

Conclusions and Way Forward

Turkey is committed to progress towards a modern, European framework for regulation and purchasing of pharmaceuticals. This happens in the context of an expansive health strategy with goals for increasing numbers of providers, which is likely to also increase demand for healthcare services.

Critical issues are recognized by the government, action steps have been taken to address these issues. Addressing access problems first and dealing with inefficiencies and other problems

later appears to be a politically smart choice. It creates initial support from stakeholders and makes it easier for the administration to stay in the driver's seat during further steps that will be met with more resistance from beneficiaries. However, at a certain point costs can easily get out of control. Turkey has shown that it is able to introduce initial measures for cost control without cutting access to desired innovative therapies. This will remain an ongoing challenge; it will require monitoring and targeted action to address wasteful overspending in order to be able to afford state-of-the-art treatment for an increasing number of care seekers.

Current key issues are

- A rather economically liberal approach to reimbursement, allowing **different reimbursement rates for drugs that are therapeutically equivalent** (for example different statins, proton pump inhibitors). This **encourages promotion of newer, more expensive drugs** without providing additional health benefits
- A system of capped and in some cases relatively high generic prices – due to the reimbursement cap there is **not much incentive for price competition**. The reimbursement commission is using its discretion in some limited way to encourage market entry for cheaper generics, but there is still a lot of "slack" in the prices proven by the significant **hidden discounts** that work exclusively to the **benefit of the distribution chain** instead of lowering the prices for SSI members. The same has been observed in other countries (Netherlands, Germany) and has caused the administration to switch to a model with more open price competition for generics
- **Uncontrolled prescribing** by physicians, leading to **fast uptake of new drugs** whether they have relevant benefits or not and to general over-prescribing. The multiplying effect of price and volume increases creates a **risk for financial sustainability** of the current policy

The goal for the coming years should be to create fiscal space in the SSI budget for necessary innovation and develop management tools that allow better controls of prescribing volume while improving **quality of care.**

Specific recommendations are

- Tighten the reimbursement regime by **broadening reference prices to include drugs that are therapeutically equivalent** (for example all statins, proton pump inhibitors). Physicians and industry will bring up the argument that there are always patients who only respond to one specific substance in such a group. One way to deal with this issue would be to make reimbursement for example for atorvastatin instead of simvastatin subject to pre-approval – for patients who have been treated with the cheaper alternative for a certain time. Such approvals could also be capped at a rate of 20% of all patients treated by the same physician with the same substance class.
- Develop **capacity for pharmacoeconomic assessment** of new therapies (not limited to medicines). This is a complicated field not only scientifically, but also from a political viewpoint because it has immediate consequences for individual patients and the industry. It will take several years even under optimal conditions and funding to develop a fully independent pharmacoeconomic assessment function. A weakness in Turkey is the lack of reliable baseline data on health economics, such as costs of certain diseases and available treatments. In the build-up period, the best option would probably be to develop a **combined score** based on the assessment of other, established HTA institutions such as NICE in the UK, combined with an informed judgement by national experts regarding the transferability of such assessments to the Turkish situation. Parameters to be considered are among others

    - Economic impact, level of suffering and frequency of certain diseases
    - Current treatments available and degree of satisfaction
    - Capacity to deliver new potentially complicated treatment protocols outside specialized centers
    - Possibility to limit new expensive treatments to the core indications in which they are truly beneficial
- Every selection process will create **situations in which it is difficult to reach consensus** in the responsible commission. The decision mechanism needs to be well defined and designed in a transparent way. There is a range of possibilities to allow **limited or conditional reimbursement** for products that are not clearly cost-effective, but are still seen as important for specific patient groups. For example, reimbursement can be granted conditionally for a limited time with the requirement to generate cost-effectiveness data under Turkish conditions. Or reimbursement could be limited to patients in which other options are exhausted, to be **approved individually** by experts employed by the reimbursement authority. In Germany and other countries, health insurers increasingly **pass some of the budget risk on to the manufacturers** in exchange for granting reimbursement. In some cases, payments are conditional to proven therapeutic success. In others, a volume cap is agreed and the manufacturer provides additional drug for free if the cap is exceeded
- On the commercial side, MoH and SSI should further evaluate possibilities to **capture the rebates** that are currently absorbed by the distributors – the least value adding link in the supply chain. The current situation amounts to an indirect subsidy for wholesalers and pharmacists, taken from the social insurance funds. Specific action steps that could be considered are:
    - For generics, a **waiver of statutory copayments** could be considered **for the cheapest equivalent** product in classes with many alternatives. This would create an incentive for companies to compete by lowering prices instead of giving bonus drugs to wholesalers
- The social security funds increasingly have access to data on prescriptions that could be analyzed at the individual physician level, to create **prescribing profiles**. Such profiles then can be linked to the existing "pay for performance" mechanism. An example for a parameter of rational prescribing could be the percentage of generic first line drugs used in treating hypertensive patients, or the average cost of a statin prescription in an internal medicine department. For each specialty it will be possible to define a set of criteria that are linked to evidence based and rational treatment
- Some countries have made good experiences with **"academic detailing"**: doctors whose prescribing habits raise concerns are visited by health insurance specialists who offer a consultation on treatment guidelines and alternatives. This approach is not cheap and should therefore be pilot-tested before implementing it at a larger scale
- **Electronic prescribing systems** allow a transaction based guidance for doctors – whenever they enter a drug they can see alternatives and potential cost saving options. It is also possible to provide data on the ranking of a physician compared to the peer group in terms of prescription costs, number of drugs per prescription or other parameters
- **Patient education** on rational use of drugs is inevitable to back up any measures aimed at doctors. If patients think that a doctor who only prescribes one or two drugs is a bad doctor, it will be difficult to change habits. Patient education should start at school. It should also have a general element using places such as waiting rooms and pharmacies, and a targeted element for chronic patients who can be reached by actively promoting the establishment of patient support groups and supporting educational campaigns

launched by such groups. However, it is important to limit industry influence on patient groups; otherwise the effect could be contrary to what is intended.

Potential Next Steps

1. All the measures mentioned above as options for Turkey **are already in place** in one form or another in various EU and OECD countries. A potential step towards implementation in Turkey could be to organize **visits to the authorities/health insurance** funds in countries with relevant experience or to **invite experts** from these countries to a workshop in Turkey.

2. Given the large amount of data sitting in SSI systems, it would also be possible to do some specific **research on the potential impact of suggested cost saving measures**. All parameters such as prices, reimbursement rates and prescription volume are known and it should be possible to model the impact of certain changes on drug expenditure.

3. Not much seems to be known yet about the way **hospitals** procure and utilize drugs under the new guidelines. This should also be subject for a detailed **analysis to identify potential inefficiencies and define additional rational drug use parameters** that could be built into the "pay for performance" system.

4. Under the secretariat of the reimbursement commission, SSI could hire a **small team of pharmacologists and pharmaco-economists**, who are tasked with developing a more rational format for **independent assessment of applications for reimbursement** submitted by manufacturers. The focus here would be on new molecules that come at price levels higher than current treatment options and on data that is in the public domain. The expert team would support the commission in its work by providing a second opinion on the dossier of the applicant.

The World Bank would be happy to work with MoH and SSI in implementing these suggestions and facilitating the exchange with experts in other countries and institutions.

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