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An Analysis of Public Pharmaceutical Policy, Pricing and Spending in Turkey

Türkiye'de Kamu İlaç Politikaları, İlaç Fiyatlaması ve İlaç Harcamasının Analizi

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Kadir GÜRSOY*

ABSTRACT

Turkey has undergone significant changes on its pharmaceutical policy with Health Transformation Program launched in 2003. For instance, Turkey moved from cost-based pricing system to external reference pricing system, reimbursement commission was first established, and positive list was introduced. Then Universal Health Insurance nearly covering whole population was put into practice. From 2003 to 2009, public pharmaceutical spending grew drastically, rising more than 7% annually on average in real terms. As a consequence, Turkish government announced a 3-year global budget on late 2009 along with new copayments for hospital outpatient visits and for prescriptions to reduce excessive utilization and additional rebates to lower drug prices. Those policies were quite successful in curbing overall expenditure, dropping by 28% in real terms in three-year time, as well as roughly 14 billion TL saving. In addition, spending in 2009 hiked to 1.7% of gross domestic product and then dropped to 1% in 2012 and stayed close to 1% in 2013 and 2014. However, Turkey faces new challenges to stabilize spending and increase credibility, transparency, and consistency of its reimbursement decisions. Designing clear methodology on reimbursement decision, revising positive list, developing alternative reimbursement methods such as risk sharing agreements, introducing jumbo pricing, lauching new generic pricing policy and tendering, and incentives for rational drug use will help reach those targets.

Anahtar Sözcükler: Pharmaceutical policies, pricing of drugs, pharmaceutical spending, Turkey, drug reimbursement

ÖZ

Türkiye, 2003 yılında uygulanmaya konulan Sağlıkta Dönüşüm Programı ile birlikte ilaç politikalarında büyük bir değişime gitmiştir. Örneğin, maliyet bazlı fiyatlama sisteminden dış referans fiyatlamaya geçilmiş, geri ödeme komisyonu kurulmuş, tekil bir pozitif liste oluşturulmuştur. Ayrıca, neredeyse tüm nüfusu kapsayan Genel Sağlık Sigortası hayata geçirilmiştir. 2003-2009 yılları arasında, kamu ilaç harcamaları reel olarak yıllık ortalama %7'den fazla büyümüştür. Buna istinaden, bürokratlar 2009 yılı sonuna doğru 3 yıllık ilaç global bütçe anlaşmasını, sağlık hizmetlerinden aşırı yararlanmayı dizginleyen katılım payı uygulaması ve ilaç fiyatlarını aşağı çeken kamu iskontoları ile birlikte duyurmuştur. Uygulanan bu politikalar kamu ilaç harcamalarını azaltma konusu ciddi başarı sağlamış ve harcama 3 yıllık süreçte reel olarak %28 düşmüş, yaklaşık 14 milyar TL tasarruf sağlanmıştır. Ayrıca, 2009 yılında kamu sağlık harcamalarının gayrisafi yurtiçi hasıla içindeki payı %1,7'den 2012 yılında %1 seviyelerine gerilemiş ve 2013-14 yıllarında %1 seviyesinde sabitlenmiştir. Ama, Türkiye ilaç harcamasını istikrarlı bir seviyede tutmak ve geri ödeme kararlarının kredibilite, şeffaflık ve tutatlılığını artttırmak için yeni düzenlemeleri yapmak zorundadır. Geri ödeme kararları için daha şeffaf bir yaklaşımın tasarlanması, pozitif listenin yeniden gözden geçirilmesi, risk paylaşımı anlaşmaları gibi yeni geri ödeme yöntemlerinin belirlenmesi, jumbo fiyatlama sisteminin uygulanması, yeni bir jenerik fiyatlama politikasının benimsenmesi, jenerik ürünler için ihaleler açılması, ve rasyonel ilaç kullanımının teşvik edilmesi bu hedeflere ulaşmada katkı sağlayacaktır.

Keywords: İlaç politikaları, ilaçların fiyatlaması, ilaç harcamaları, Türkiye, ilaç geri ödemesi

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INTRODUCTION

Pharmaceuticals play a crucial role to achieve desired health outcomes, but at the same time they are a major cost driver for every healthcare system. Together with aging populations, extended life spans, and innovative and high-technology drugs; pharmaceutical spending has been on rise and many countries have been adopting cost containment strategies to curb spending (Carone et al., 2012; Adamski et al., 2010; Moreno-Torres et al., 2010; Kwong et al., 2014; Ognyanova et al., 2011). Turkey has a fast growing pharmaceutical industry with easy market access having a size of US$12.5 billion in 2012, sixth biggest in Europe and sixteenth largest in the world (Investment Support and Promotion Agency of Turkey, 2014). For the last decade, Turkish healthcare system has been witnessing a significant transformation under the Health Transformation Program (HTP) aiming to increase the efficiency of the healthcare system and enhance access to healthcare facilities (Ministry of Health (MOH), 2003; World Health Organization, 2012; Rockefeller Foundation, 2010). Today, the system nearly covers all the population (98%) through Universal Health Insurance (UHI) implemented in 2008 (Social Security Institution (SSI), 2015) and the SSI is the single public payer of pharmaceuticals in Turkey, financing nearly 74% of total drug spending in 2013 (TurkStat, 2014).

With wider and easy access to pharmaceuticals Turkish public pharmaceutical spending raised drastically, 58% real growth over 7 years from 2002 to 2009, and government introduced 3-year global budget (2010-2012) in late 2009 allowing better expenditure management and price controls without limiting access to vital medicines. The strategy was quite successful in terms of bending the cost curve, public drug spending reduced by 9.9% and 27.7% in 2012 relative to 2009 in nominal and real terms respectively, yet nominal spending rose by 10% annually from 2012 till 2014.

Turkey needs to implement solid regulations such as launching jumbo pricing model based on therapeutic equivalence, implementing alternative reimbursement methods relying on risk sharing arrangements, further improving cost-effectiveness analysis during reimbursement process, and developing a new generic drug policy in order to stabilize spending and maintain sustainability, strengthen credibility, transparency, and consistency of its reimbursement decisions, as well as provide earlier access

to vital and innovative medicines. This study aims at analyzing how public pharmaceutical spending evolved with adopted policies, measuring the policy impacts, and then sets forth new policy options that can help maintain future financial stability and provide earlier access to new technologies.

This study first summarizes the recent public policy changes undergone in the last decade in the pharmaceutical industry in Turkey, then underlines pricing process of the pharmaceuticals, shows the methods for the analyses and provides the results, and finally discusses the main recommendations to further enhance the system and stabilize spending.

I- BACKGROUND ON TURKISH PHARMACEUTICAL POLICY AND LATEST REFORMS

Turkish healthcare system has experienced a significant alteration with HTP since 2003 (World Bank, 2009). HTP was designed to improve the main health outcomes lagged behind comparable countries, advance efficiency of the healthcare system, enhance equal access for all citizens, and achieve universal coverage with financial sustainability (MOH, 2003; Rockefeller Foundation, 2010). Parallel to HTP, in 2004, notification on the pricing of Medicinal products for human use was published. With this notification, Turkey moved from cost-based pricing system to external reference pricing system and reimbursement commission responsible for issuing the positive list of drugs was firstly established. In addition, value added tax (VAT) on pharmaceuticals reduced to 8% from 18%, and then pharmaceutical industry and government started to contract on public rebates.

In 2005, positive lists for three social security organizations[1] were

1 Prior to 2006, three separated health insurance schemes operated with widely differing benefits, regulations and contribution levels. Social Insurance Institution (SSK), founded in 1964, covered the largest segment of the population (blue and white-collar workers in the public and private sectors and their dependents). The Social Insurance Agency of Merchants, Artisans and Self-Employed (Bag-Kur) was estab¬lished in 1971 and since 1987 has offered health benefits covering the self-employed. Government Employees Retirement Fund (Emekli Sandigi), established in 1949, covered retired civil servants and their families. Moreover, active civil servants' health expenditures were financed through allocations from the government budget to institu¬tions through general revenues. Finally, Green Card program, introduced by the government in 1992 as a social assistance mechanism to cover poor people earning less than one-third of the minimum wage, was financed from the MOH budget via general revenues.

introduced and then they were integrated under a unique list together with the introduction of equivalent groups[2], drugs were grouped into equivalent groups based on the active molecule and reimbursement was capped at 30% above the cheapest brand in each group. Furthermore, till 2005 SSK was running its own pharmacies, they were closed and its beneficiaries obtained the right to access private pharmacies. Green Card holders were given access to pharmaceuticals for the first time. In 2006, all social security organizations were unified under one umbrella, namely SSI. The cap in equivalent groups was reduced to 22%.

In 2007, Health Implementation Practice was introduced by SSI to harmonize and equalize the benefits offered and set rules for reimbursement, invoicing, and copayments. Then a new copayment regime was introduced. Based on this regime, pharmaceuticals are fully reimbursed if a patient has a chronic disease certified by a physician. Otherwise, contributors and their dependents pay a 20% coinsurance and beneficiaries a 10% coinsurance. Inpatient pharmaceuticals are fully reimbursed (SSI, 2014). Besides, notification on pricing of Medicinal products for human use was revised; generic drugs were priced at 80% of their originator drugs, and wholesalers and pharmacies were remunerated via regressive mark-ups with margins being regulated by the government.

In 2008, pharmacy discounts were announced and applied progressively based on pharmacy sales. Besides, Medical and Economic Appraisal Commission operating under Reimbursement Commission was established to represent the technical expertise needed assessing the dossiers submitted by the pharmaceutical industry and prepare recommendations for inclusion of new drugs into the reimbursement list. The recent guideline for reimbursement applications has made pharmacoeconomic analysis compulsory and the implicit criterion at present is the budget impact of inclusion/exclusion of a procedure/technology from the positive list. At the end of 2009, due to huge increase in public pharmaceutical spending, global budget was implemented for the upcoming three years, government and pharmaceutical industry signed a contract indicating a global budget of 14.6, 15.6 and 16.7 billion

2 Equivalent product means products whose active substance(s), pharmaceutical forms and unit amounts of raw material are the same.

TL for the years 2010, 2011, and 2012 respectively. It was also announced if the budget was exceeded, additional cost containment measures to be taken. Moreover, external reference pricing of generics was reduced to 66% of their originator drug reference price and cap in equivalent drugs were further lowered to 15%. In addition, as a demand-side measure, copayments were increased for hospital outpatient visits (5 TL for public and university hospitals, 12 TL for private hospitals) (SSI, 2014).

In 2010, civil servants were also brought under UHI. At the end of 2010, as 2010 global budget was exceeded, rebates were further increased and reference pricing for generic drugs dropped to 60% of the originator drug price. In 2011, equivalent drug band was lowered to 10% and SSI started to track prescribing behavior of physicians and sent all physicians summary notices on their performance. In 2012, a new copayment practice for prescribed drugs was introduced, 3 TL up to three packs and additional 1 TL for each additional pack in each prescription (SSI, 2014). Finally according to the protocol signed between SSI and Turkish Pharmacists' Association, pharmacy discounts were updated in 2013 and pharmacies having a yearly sales less than 700 thousands TL, and remaining would receive service charge of 0.75, 0.25 TL per each prescription written respectively.

In September 2014, a law was put into practice allowing SSI to negotiate with pharmaceutical companies and accomplish risk-sharing agreements and SSI has set rules on how this practice will work in 2015. As of October 2014, for selected 15 equivalent groups, equivalent band was equalized to base price.

II- PRICING PROCESS OF PHARMACEUTICALS IN THE POSITIVE LIST

In February 2004 a new pharmaceutical pricing system, namely the external reference pricing system, was launched. Formerly, the system relied on a cost-based pricing method. Under the decree on the pricing of medicinal products for human use, the reference price of an originator product is determined according to the lowest ex-factory price among 5 European Union member countries, namely France, Spain, Italy, Portugal, and Greece (MOH, 2012). Under this decree, government has the right to change reference countries and increase the number of countries up to 10. For originator products,

reference price is 100% of the price in the lowest ex-factory price. For generics, prices are determined as 60% of the price of the originator product. The prices of generics cannot be higher than the originators' reference prices 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. "20 year old products" is a unique category present only in Turkish market defined in pricing decree as products whose any form are marketed before 1987 in any country (MOH, 2012). The price of 20 year old drugs is determined as 80% of the reference price if they have references (If the drug's ex-factory price is lower than 6.79 then their reference price is 100%). Otherwise, their price depends on the cost data during the production process.

Turkey also applies molecule-based equivalent grouping. There are roughly 1,500 equivalent groups. For each equivalent group, the base price is calculated and up to 10% over the base price is reimbursed by SSI and the remaining is financed out-of-pocket (SSI, 2014). However, a drug having the lowest price can only be accepted as a base-priced drug if it takes at least 1% sales volume of that group over the last 5 months. Patients are free to choose which drug they want to purchase, either the most expensive one or the base-priced one. With this implementation, on average Turkey saves 4% yearly. It is important to note that equivalent band practice sometimes creates stickiness of the drug prices and do not further encourage price erosion.

Once the ex-factory price of the drug is determined, the price is converted into TL by using the fixated euro value (1.9595); this price constitutes the selling price to the wholesalers. However, some of the blood products are valued based on the current euro-TL exchange rate. The fixated euro value is updated based on the fluctuations in the euro-TL exchange rate. Even though 1 euro is currently exchanged for around 2.95 TL in the market as of June 3, 2015 and pricing decree envisages an update in case of a change in the foreign exchange rate, government avoids using this current rate to hold TL prices of drugs lower. The euro value was increased to 2 as of July 1, 2015. The pharmacy retail price is determined by adding wholesale and pharmacy mark-ups and 8% VAT. Wholesalers and pharmacies are remunerated via regressive mark-ups with margins being regulated by the decree on pricing of medicinal products. The

regulation is binding for all pharmaceuticals and government holds the power to update the rates.

For drugs in the positive list, there is a public sector statutory rebate determined depending on the wholesaler's price and product group. For example, all products having wholesale price lower than 3.56 is exempted from that rebate. For originator products, rebate is 20% (41%) if the wholesale price is between 3.55 and 6.78 (more than 6.78 TL). Table 1 shows all rebates for different product groups. All these rebates are based on the pharmacy retail price. In addition, a pharmacy discount is applied on the price determined after the rebate is deducted if the payment is reimbursed by SSI. Pharmacy discount rates depend on the pharmacy revenue. 0%, 1%, 2.5%, and 3% pharmacy discounts are applied for the pharmacies having a yearly sales less than 700 thousands TL, between 700 thousands TL and 900 thousands TL, from 900 thousands TL to 1,500 thousands TL, and above 1,500 thousands TL respectively.

Table 1. *Statutory Rebates for Reimbursed Drugs at Retail Level (SSI, 2014)*

Product Group	**Regarding the sale price to wholesalers (in TL)**			
	Up to 3.56	3.56 to 6.78	6.79 to 10.21	Above 10.22
Originators without Generics	0.0%	20.0%	41.0%	41.0%
Generics and Originators with Generics	0.0%	20.0%	28.0%	28.0%
20 year-old products				
Referenced	0.0%	20.0%	28.0%	28.0%
Without Reference	0.0%	20.0%	41.0%	41.0%
Blood , Enteral nutrition products, and medical formula	0.0%	11.0%	11.0%	11.0%

Some manufacturers also offer additional discounts to SSI to ensure that their drugs are added to the positive list and earn a competitive advantage over comparator drugs. The statutory pricing regulation sets upper limits, yet manufacturers are free to lower their prices or give special discounts to the public sector.

To give a concrete example for the pricing process, let's assume that drug X is a generic drug and its originator brand is priced for 38.65 Euros in Spain, the lowest reference price in 5 EU countries. Then reference price of the drug is 60% of the originator, which is 23.19 Euros. Then we convert euro prices to TL with fixated exchange rate (1.9595) and selling price to

the wholesaler is 45.44 TL. We add wholesale and pharmacy mark-ups and VAT and we get 66.38 TL. Then we apply public rebates of 28% since drug X is a generic drug whose wholesaler price is above 10.22, we get 47.79 TL. We also deduct 10% coinsurance and 3% pharmacy discount. After all those calculations, the final price that SSI pays to the pharmacy is 36.80 TL if it is not in any equivalent groups.

To make it clear how the equivalent band works, assuming that the equivalent group A consists of 7 drugs, each having different after public rebate prices. Then unit price for one capsule of each drug is determined and lowest unit price is calculated. Provided that unit prices are 10 TL, 9 TL, 10.5 TL, 11 TL, 10.9 TL, 15 TL, and 12 TL and the lowest unit priced-drug cannot fulfill the 1% sales volume condition. Hence, the base-price is 10 TL and the maximum amount SSI will pay is 11, which is 10% above the base-price. If the patient purchases the drug having base-price of 10.9, SSI will fully cover the cost and no out-of-packet payment for the patient. However, if he/she buys 12 (15) TL priced-drug, then SSI only covers 11 TL, 1 (4) TL is paid out-of-pocket.

III- METHODS

According to SSI health spending data, public drug spending from 2002 to 2014 were collected. Consumer price index (CPI) and gross domestic product (GDP) growth rates for each year were obtained, calculated and then real growth rate was compared with GDP growth for each year. Furthermore, each year's spending was converted into 2002 year's spending, defined as base year, by eliminating CPI and then GDP growth rate and real spending numbers were figured out. Claims data from SSI for all ambulatory care drugs reimbursed were collected monthly in the period of January 2009 to December 2014, and then saving impact of cost-containment measures, namely increase in public rebates and copayments for outpatient visits and prescriptions, were worked out. Assuming that fixated euro exchange rate was updated, possible new public pharmaceutical spending was analyzed and exchange rate sensitivity to drug spending was evaluated. Besides, all reimbursed drugs were grouped as generics and originators, and each share on overall spending was computed.

Based on SSI claims data, number of written prescriptions and average cost per prescription from 2007 to 2014 were also computed. In addition, the distribution of prescriptions among different healthcare providers was assessed and spending per each prescription among providers was found. Deficiencies of current generic pricing policy was pointed out by giving an example and as an alternative option to molecule-based equivalence, saving impact of introducing therapeutic equivalence for one ATC-3 group was studied.

IV- RESULTS

Nearly 74% of the all pharmaceutical spending is reimbursed through SSI, and the remaining is covered by out-of-pocket payments or private insurance (TurkStat, 2014). As seen Figure 1, publicly-funded pharmaceutical market reached 17.5 billion TL and 1.4 billion packs by sales volume in 2014. After the introduction of HTP till 2009, real spending growth nearly raised parallel to GDP growth, more than threefold increase in nominal spending. However, pharmaceutical spending rose drastically by 16.3% in real terms in 2009 even the Turkish economy shrank by 4.8%, signaling a great strain on the public budget. From that point, with the implementation of global budget and other demand side measures explained in the previous section, spending in real terms reduced by 10.2%, 6.4%, and 14% in 2010, 2011, and 2012 respectively. All those cost reduction practices saved nearly 14 billion TL in three years. However, it should be noted that if the fixated euro exchange rate were updated based on the current rate, 10% increase in fixated euro exchange rate would boost public pharmaceutical spending by 8.4% on average. In other words, 10% increase in the fixated rate approximately raises overall public spending 1.5 billion TL. After 2012, there has been an upward trend in spending, average of 2% annual real growth. Furthermore, spending in 2009 hiked to 1.7% of GDP compared to 1.5% in 2002 and then dropped to 1% in 2012 and stayed close to 1% in 2013 and 2014 (Figure 2).

Figure 3 shows how spending evolved in real terms assuming that year 2002 has a base of 100. From 2002 to 2009 public pharmaceutical spending rose by 58% in real terms, 7% annually; thanks to easy access to pharmaceuticals with the introduction of universal health insurance and

Figure 1. *Public Pharmaceutical Spending, Real Growth and GDP Growth*

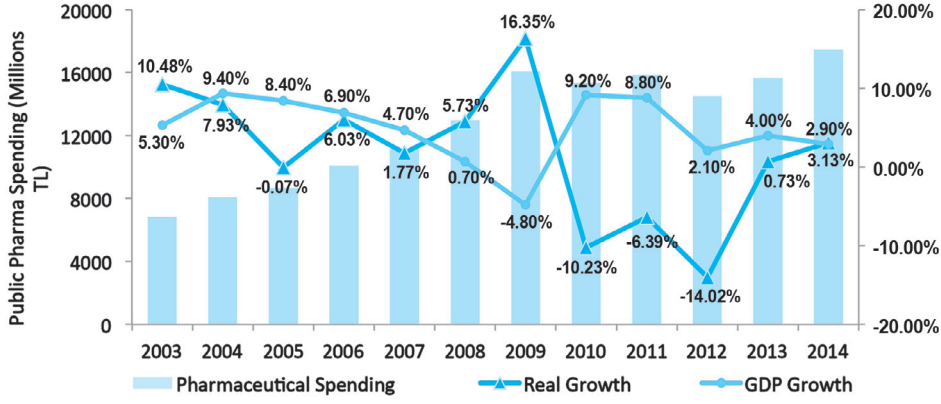
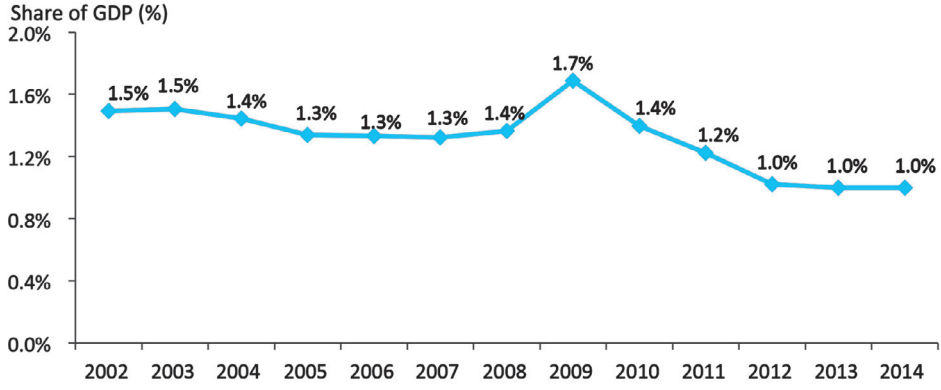
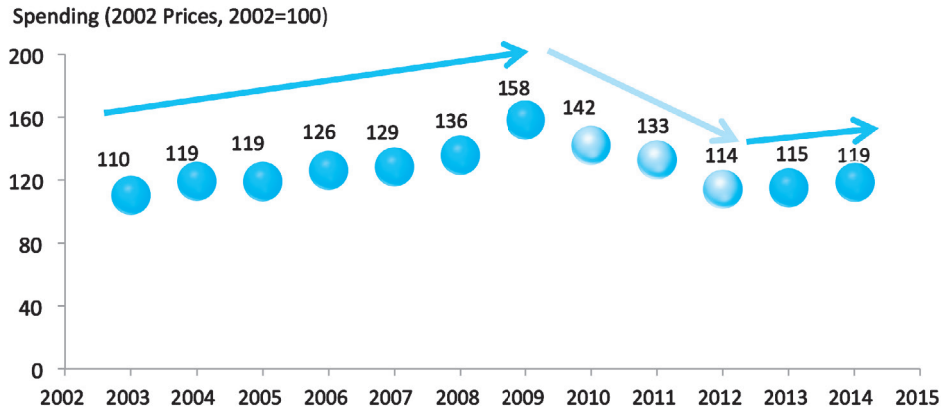


Figure 2. *Public Pharmaceutical Spending as a Percent of GDP, 2002-2014*



no strict cost-containment measures. Then the spending in 2012 in real terms approximately dropped to 2003 level and over four-year time, 2009 to 2013, spending shrank roughly by 28% in real terms while overall GDP growth at the same period is higher than 26%. This also clearly shows that the cost-containment regulations worked well to mitigate costs. Yet, it is noteworthy that starting from 2013 spending rises in real terms with new innovative drugs entering the reimbursement list.

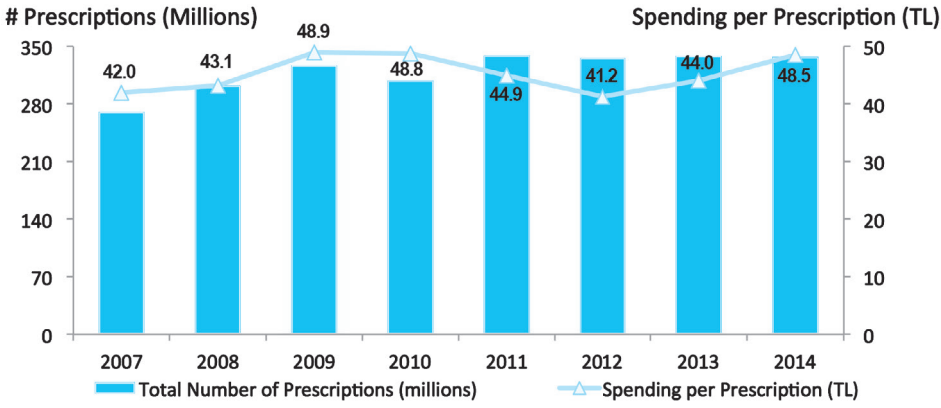
Figure 3. *Public Pharmaceutical Spending as a Percent of GDP, 2002-2014*



Pharmaceutical spending has two determinants: utilization and costs. When looking at utilization figures (Figure 4), number of prescription written went down in 2010 and then stayed at 2009 level after an average annual increase of 10% in 2008 and 2009. The increase in 2008 and 2009 stemmed from introduction of UHI with an extensive benefit package and easy access to pharmaceuticals, while the reduction was mostly due to copayments introduced for outpatient visits and prescriptions. On the cost side, spending per prescription from 2007 to 2009 rose nearly by 15%, and then it started to decrease thereafter with price cuts in drugs till 2013. However, in 2010 even average reduction in final drug prices were more than 15% as a result of an increase in public rebates and generic reference pricing cut, spending per prescription only went down by 1%, indicating a considerable shift from lower priced-drugs to more expensive one, particularly from smaller packs to larger packs in 2010. In 2011, there was almost 8% drop in spending per prescription compared to 2010 due to additional rebates introduced in late 2010. As a result, in the cost side increasing public rebates together with fixed euro exchange rate resulted in lowered drug prices till 2013. Since 2013, even number of prescription stayed still, spending per prescription rose by 8.4% annually with new high-cost drugs penetrating to the Turkish market.

When it comes to the average discounted price, what is paid by SSI,

Figure 4. *Prescription and Spending Per Prescription (Publicly Funded)*



Note: Spending and # prescriptions figures do not contain medicines prescribed to foreign citizens residing in Turkey and medicines dispensed through Association of Turkish Pharmacists.

while the generics price dropped to 7.61 TL in 2013 from 10.27 TL in 2009 (26% reduction), originators only shrank by 18% mostly due to cost-containment measures adopted since late 2009 such as increase in public rebates and reduction in the reference pricing of generics and their originators from 66% to 60%. The main reason behind higher average price reduction in generics compared the originators stemmed from the fact that they were much more affected by those measures. When we ignore the drugs entering the reimbursement list in 2010 and onwards, average generic (originators) price in 2013 decreased to 6.6 TL (14.3 TL). New generics (originators) penetrating the market in 2010 and onwards had nearly 69% (36%) higher average prices than the old ones entering the reimbursement list before 2010. When we look at the newly reimbursed drugs after 2012, the results are different. On one hand new originators had 2.41 times higher prices; on the other hand new generics were only 48% expensive. This clearly shows that average prices for new drugs are on the rise in the recent years.

Turkey has a strong branded generics market with domestic production. In 2014 generics represented nearly 50% of sales volume of all ambulatory

care drugs and 30% of value, reducing 2.7 percentage points in volume and 2.4 points in value compared to 2009. Compared to European Union (EU) averages, generic share in Turkey regarding sales volume is close to EU figure (50%). However, generics share in total sales value is fairly higher than EU average (18%) (Sheppard, 2010), arguing whether there is still room for further price reduction on generics.

The price reduction with first generic entry changes depending on the regressive wholesale and pharmacy margins, public rebates, and whether the originator is a 20 year old or not. As explained in the previous section the higher the wholesale price, the more the rebates and rebates differ according to product group. A 20 year old originator drug price did not change when its generic entered the market, then no price reduction occurred. If not, the price erosion ranged between 19% and 28%. As an example, an originator drug with the lowest reference price of €165 was paid for 252 TL by SSI. Provided its first generic entered the market, SSI would only pay for 180 TL, a reduction of 28%. Here, it means that generics erode prices at most 28% given no additional rebates offered, signaling a need for new policies to gain higher benefit from generics.

In Turkey, there are more than 1500 equivalent groups, generating roughly 60% of all sales value in 2014. We can call those groups as unprotected market, since it is free to penetrate the market as soon as drugs are admitted to the reimbursement list. With molecule-based equivalent grouping and capping SSI payment no more than 10% above the base price Turkey saves 4% yearly on average. On the other hand, drugs in the groups generally tend to lower their prices close to the cap and do not compete against prices, instead mostly focusing on marketing. In other words, equivalent band practice sometimes creates stickiness of the drug prices and do not further encourage price erosion. For instance, for some high sales value groups, weighted average discounted prices are so close to 10% cap. It is estimated that lowering the band to base price for all equivalent groups end up shrinking public spending by nearly 3%, approximately 500 million TL savings yearly. SSI released a pilot implementation for 15 selected equivalent groups and reduced the band to base price starting from 1 October, 2014.

Another interesting analysis is about the distribution of prescriptions

among healthcare providers. In 2012, nearly half of the prescriptions (48%) were written by general practitioners (GPs) consisting primary care physicians and family practitioners, stating that absence of referral system encouraged people routenely by-pass primary healthcare to seek services at higher levels. It is believed the share of written prescription by GPs in total written prescriptions will rise with the introduction of referral chain. 35% of all prescriptions were given by secondary and tertiary public hospitals. The share of university hospitals where mostly tertiary care was provided is around 3%, private hospitals took nearly 15% share. There is no marked change in the structure of distribution of prescriptions in 2013 and 2014.

When it comes spending per prescription among providers, it embodies interesting results. Averages spending per prescription in family practice, public and private hospitals were nearly the same, meaning either GPs were prescribing higher-cost medicines or public and private hospitals were operating like family medicines, mostly indicating the importance of gate keep system. Without implementing gate keeping system, patients can easily access to public and private hospitals where more serious health problems are diagnosed. In universities, spending per prescription was 4 times higher than other hospitals since they treat complicated diseases.

V- DISCUSSION: NEW CHALLENGES AND POLICY OPTIONS

Both demand and supply side measures introduced since 2009 seem to perform well in terms of reducing pharmaceutical spending together with the fixated euro exchange rate. However, increasing public rebates and fixated euro exchange rate put great pressure on manufacturers and some manufacturers requested government to reduce rebates or increase their wholesaler prices for many drugs, otherwise they would leave the Turkish market (AIFD, 2013). Their main arguments are that their discounted prices in Turkey are referenced in other 32 countries, prices cannot cover their costs and they are reluctant to bring their new innovative products to the Turkish market. As a result, for 323 originator drugs the rebates were lowered by 7.5 to 9 percentage points, 154 drugs' prices rose by 15%, and 39 drugs received price increases due to exchange rate parity update by Price Appraisal Committee between 2011 and 2013. Increasing rebates seems not to be an appropriate method to ensure long-term sustainability

and provide access to vital medicines (AIFD, 2013). As a solution, Turkey needs to launch new policies to better stabilize the growth in pharmaceutical spending and speed up the earlier access to innovative drugs.

As a first step, reimbursement commission needs to further develop capacity for pharmacoeconomic assessment of new therapies, design clearer methodology for the decision making process relying on cost-effectiveness analysis, and consider value for money (Worldbank, 2008; OECD, 2008). This will avoid questions on the reimbursement commission's decisions, increase credibility of the commission, and ensure transparency. In 2013, total spending for newly reimbursed drugs after 2012 aggregated 3% of overall drug spending, indicating the importance of reimbursement decision.

Secondly, SSI may introduce internal reference pricing system based on therapeutic equivalence as it was adapted in Germany and Holland (Worldbank, 2008; Galizzi et al, 2011; Danzon and Ketcham, 2004). This will allow further lowering drug prices and create room for innovative drugs to get reimbursed, as well as better allocation of limited budget. As an example, merging existing 8 equivalent groups into one therapeutic group and accepting the price cap as the average of three lowest discounted prices would reduce prices further by 42% on average, totaling 200 million TL saving annually. Alternatively, Turkey can announce tenders[3] for drugs having the same active molecule or therapeutic equivalence, further reducing prices as in Holland, Germany, Belgium, and Hungary (Ferrario and Kanavos, 2013; Kanavos et al, 2009).

Thirdly, Turkey can implement a new generic pricing policy since Turkey seems not to maximize its full potential with respect to generic medicines. Today, the generic drugs only reduce the ex-factory price of the originator drug by 0% and 40% depending on whether originator drug is 20 year old or original respectively and this reduction occurs when first generic enters the market. According to a study conducted in the US, first generic price was slightly lower than the originator, but second generic dropped the average price by 50%, and when larger number of generics penetrated the market, prices fell by 80% (IMS, 2005). As an option, in the case of each additional

3 Tendering is a mechanism whereby purchaser buys drugs based on a competitive bidding process (Leopold et al, 2008)

generic entry after the first generic, reference price can be reduced by 10 percentage points till the price reaches 30% (50% for 20 year old drugs) of reference price. Under this scenario, prices could further erode by 21% for selected 12 equivalent groups having high level of sales value.

Fourthly, equivalent band for some groups encourages competition and reduce prices to a certain level, but after that point prices do not lower further. In this regard, to reduce prices further, SSI could only pay the base price and the remaining would be covered out-of-pocket. Moreover, in order to boost competition and further take down the prices, drug's price that is certain percent higher than the base price can be removed from the list or SSI can ask for them to reduce the price otherwise they will be out of reimbursement list.

Fifthly, Turkey may implement new reimbursement strategies based on risk sharing agreements[4] to get rid of uncertainty of sales, encourage earlier access to innovative drugs, as well as analyze efficiency of the drugs in real-life experience, assessing whether the new drug generates additional benefit in real-life data. As risk sharing agreements, Turkey can adopt price-volume, conditional treatment continuation, pay-back, no cure no pay agreements with pharmaceutical companies (Carone et al., 2012; Adamski et al., 2010; Ferrario and Kanavos, 2013; Cook et al, 2008; Barros, 2011). Moreover, Turkey can avoid announcing public rebates for certain drugs having confidential agreements, letting higher prices be referenced by other countries.

Finally, since the physicians are the most important actor inducing the demand for pharmaceuticals, incentives for rational use of medicines to physicians need to be developed together with tracking prescribing behavior of physicians (Worldbank, 2008; Hogerzeil, 1995; Laing et al, 2001). Today, SSI does not pay the physicians, but instead pays healthcare providers in return of their services. However, allocating a budget for physicians who stimulate low-cost drugs will help mitigate pharmaceutical spending.

4 In the literature, risk sharing agreements are named as managed entry agreements.

CONCLUSION

Over the last decade Turkey has achieved compelling improvements in its pharmaceutical system. Turkey moved from a system of multiple insurance schemes covering only majority of the population to a sin¬gle-payer system providing the whole popula¬tion with access to a wide range of health services and ensuring unity, equity, and efficiency in the delivery of these services. Easy access to health services without strict cost-control mechanisms ended up skyrocketing public pharmaceutical spending, 58% increase from 2002 to 2009 in real terms. Then, government implemented demand and supply side cost-containment measures to curb pharmaceutical spending and pharmaceutical spending dropped by 2.5% and 27.2% between 2009 and 2013 in nominal and real terms respectively. Starting from 2013, there has been an upward trend in spending. Turkey faces new challenges to enhance its system, provide earlier access to innovative drugs, and stabilize pharmaceutical spending because both increasing public rebates is not sustainable in the lung-run and it exerts great burden on pharmaceutical companies. To hit those targets, further developing capacity for pharmacoeconomic assessment relying on health economics principles and methodologies, revising positive list and introducing jumbo pricing model based on therapeutic equivalence, lauching new generic pricing policy, implementing risk sharing agreements with pharmaceutical companies, and giving incentives for rational drug use may be policy options for Turkey.

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