



## 2016 Top Markets Report **Pharmaceuticals** Country Case Study

### Turkey

Turkey's pharmaceutical and healthcare market developed rapidly during the 2000s, driven by a modernizing economy, expanded universal health insurance, and a large and growing population. Over the last five years, however, government price cuts have severely undermined sales and profitability growth for both domestic and multinational companies. Moreover, the investment climate continues to suffer from regulatory approval delays, a lack of transparency and a weak IPR framework. Still, rising pharmaceutical demand due to positive, long-term demographic and economic trends holds promise for U.S. companies.

Overall  
Rank

**37**

Turkey is the 29<sup>th</sup> largest pharmaceutical market in the world and the second largest in Central/Eastern Europe.<sup>1</sup> Sales are forecast to grow from \$7.6 billion in 2015 to \$9.8 billion by 2020, representing an annual growth rate of 5.2 percent. In 2015, Turkey spent \$39 billion on healthcare, or around 5.5 percent of GDP, which is average for a developing country. Healthcare spending is projected to reach \$50.9 billion by 2020, driven by a growing population, urban migration, rising affluence and the increasing prevalence of chronic conditions, such as diabetes, heart disease, cancer and dementia. Although public spending will continue to dominate the market, growing demand for higher quality care and market liberalization is spurring private healthcare spending, which is expected to rise from \$9 billion in 2015 to \$11.9 billion by 2020.

Although pharmaceuticals sales have risen steadily by volume over the last decade, they have dropped precipitously by value from \$11 billion in 2010 to \$7.6 billion in 2015. This is attributed to currency weakness and several rounds of government price cuts on drugs in response to budgetary shortfalls. In the near-term, continued cost-containment measures, as well as the

#### Figure 1: Turkey Snapshot

**Population:** 79 million  
**Population over 65:** 5.9 million (7.5%)  
**Total healthcare expenditure:** \$39.4 billion (5.5% of GDP)  
**Government healthcare expenditure:** \$30.4 billion (77% of total)  
**Private healthcare expenditure:** \$9 billion (23% of total)  
**Total pharmaceutical sales:** \$7.6 billion (1.1% of GDP; 19.4% of total healthcare exp.)  
**Per capita pharmaceutical sales:** \$97  
**Generic sales:** \$2.8 billion (37% of total sales)  
**Patented sales:** \$4.1 billion (53% of total sales)  
**OTC sales:** \$.8 billion (11% of total sales)  
**U.S. pharmaceutical exports:** \$108 million

complex regulatory environment and lengthy approval process, will hamper market growth.

In the long-term, Turkey provides considerable commercial opportunities for U.S. companies. The large population size and low per-capita pharmaceutical spending suggest enormous growth potential, particularly as universal insurance coverage deepens

and private healthcare spending expands. Turkey's slow march towards regulatory harmonization with the European Union and continued sector modernization will make it increasingly attractive to innovative drug companies.

Sales of generics, which account for 37 percent of the total market, are projected to grow from \$2.8 billion in 2015 to \$4 billion by 2020, representing an impressive annual growth rate of 7.5 percent. Although subject to low prices and intense competition, the sector benefits from government policies favoring generic usage. Meanwhile, patented drug sales, which account for 53 percent of the total market, are projected to grow from \$4.1 billion in 2015 to \$4.8 billion by 2020, representing an annual growth rate of 3.4 percent. Despite increasing demand for innovative medicines, the sector faces headwinds due to patent expirations and challenging regulatory and pricing conditions. Still, the continued involvement of multinational firms in the market is a positive indicator of the segment's potential.

#### U.S. exports

The United States exported \$108 million of pharmaceuticals to Turkey in 2015, representing 3 percent of the import market. Over the last five years, U.S. pharmaceutical exports have declined at an annual rate of .6 percent. U.S. companies face numerous market access barriers in Turkey, including an unworkable government product inspections system, regulatory delays, a preference for the local generics industry and a poor intellectual property framework. Most significantly, the difficult pricing and reimbursement regime is causing companies to withdraw from the market. Nevertheless, Turkey's expanding population offers export growth potential if U.S. drug manufacturers are able to accept prices that are far below the European average and are able to turn a profit on the low margins available.

#### Competitive environment

Turkey's domestic pharmaceutical industry is highly fragmented and intensely competitive. The sector consists of over 300 local companies, most of which produce generics, and employs around 23,000 people. Around 70 firms manufacture pharmaceutical end-products in Turkey, mostly around Istanbul. Currently, the top 25 companies hold around 80 percent of the market share, but further consolidation is likely due to

pricing pressure and lowered profit margins. R&D activities mostly concentrate on modifying existing molecules and adjusting dosages.

Turkey has the potential to be a pharmaceutical manufacturing hub. The workforce is young, with a large number of skilled science and engineering graduates, while wages remain comparatively low.<sup>2</sup> Its geographic position provides strategic access to markets in Central/Eastern Europe, North Africa and the Middle East. Yet, foreign direct investment has recently slowed, and Turkey remains heavily reliant on imports for both innovative medicines and APIs.

To address this trade imbalance, the Turkish government is keen to promote domestic production and R&D and has identified several areas, such as biologics manufacturing, where it is willing to provide subsidies and investment incentives.<sup>3</sup> Unfortunately, government price cuts in the domestic market have undermined these goals by severely weakening the viability of the domestic industry and discouraging international investment. The decline in domestic profitability has also resulted in product withdrawals, dire shortages of life-saving medicines and a rise in unmet medical needs.<sup>4</sup>

#### Healthcare, pricing and reimbursement

The Turkish government introduced universal healthcare to all citizens in 2004 and is the country's largest healthcare provider. The Ministry of Health (MOH) oversees national health policy and services, although the system is managed on a provincial level. While out-of-pocket spending on healthcare is considered low for a developing country, the system also suffers from overcrowding and poor facilities.<sup>5</sup> Since 2012, citizens who make less than around \$150 a month are provided free access to healthcare services while those earning more pay a graduated social security premium. In its current form, the financing structure and budgetary outlays for healthcare are not sustainable in the long-term. In response to growing deficits, the government has resorted to ad hoc cost containment measures, including pharmaceutical spending caps and a rigid pricing policy.

Pharmaceutical pricing is regulated by the General Directorate of Pharmaceuticals and Pharmacies, which is part of the MOH, and the Pharmaceuticals and Medical Devices Agency. Turkey uses a reference price system by taking the lowest price available amongst

France, Italy, Portugal, Greece and Spain. It then applies a 12 percent discount on the reference price and, on top of that, adds a further public discount of 28 percent for generics and 41 percent for innovative drugs.<sup>6</sup>

For many years, the reference price was also then converted from Euros to Turkish Liras at a rate fixed in April 2009. As the Lira lost value in the following years, it resulted in a *de facto* price discount of more than 50 percent and billions of dollars in lost revenue for companies exporting to Turkey. Fortunately, legislation enacted in July 2015 has abolished the fixed exchange rate, and reference prices are now converted at 70 percent of the previous year's average Euro/Lira exchange rate.<sup>7</sup> Although the new system still does not reflect the true exchange rate, it at least gives companies the ability to raise prices following years of suppression.

Reimbursement decisions are the responsibility of the Reimbursement Commission, led by the Social Security Institution (SGK). The reimbursement system is based on a positive list whereby medicines are categorized according to active substance. Drugs are reimbursed up to 10 percent above the cheapest medicine within the category, with consumers paying the difference if they opt for a more expensive drug.<sup>8</sup> By shifting the financial burden onto the patient, the system encourages usage of cheaper generics. It is, however, leading to a race to the bottom in pricing and a proliferation of low-cost, substandard medicines. It is also contributing to shortages and supply issues, as drugs become increasingly unprofitable.

### **Challenges and Barriers for U.S. Exports**

#### Pricing and reimbursement

As described above, since 2009, Turkey has imposed a number of price cuts on generic and innovative drugs hindering market viability and access. Transparency remains an issue, as reimbursement criteria are not clearly defined and decisions lack sufficient explanations.<sup>9</sup> It is also time consuming. Reimbursement decisions take over a year to be finalized, and delays are not uncommon as the Reimbursement Commission meets only four times a year.

#### Good Manufacturing Practices (GMP) inspection requirements

In response to the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) requiring inspections of Turkish manufacturing sites, in 2010, Turkey began requiring U.S. and EU companies to have their pharmaceutical manufacturing plants inspected by Turkish authorities before being issued GMP certificates and receiving marketing approval for their products. According to U.S. industry, the MOH has not demonstrated the capacity to conduct these inspections in a timely manner, leading to excessive backlogs in processing GMP certificate applications and delayed market entry. Such issues hinder economic and scientific cooperation and put foreign firms at a disadvantage.

The Turkish government recently implemented “parallel submissions,” which would allow companies to apply simultaneously for GMP certification and marketing authorization but only for pharmaceutical applications deemed highly innovative. While a positive step, due to limited resources, products without this designation are inevitably subject to even longer delays.

#### Regulatory delays

The marketing approval process for pharmaceuticals can take more than 500 days, well beyond the 210 day limit as stipulated in Turkish law.<sup>10</sup> Combined with the GMP inspection backlog and long reimbursement decision process, a drug may take around three to five years to reach the market after regulatory submission. Yet Turkey provides no form of patent term restoration or mechanism to reconcile these delays.

#### Regulatory data protection (RDP)

Although Turkish laws provide for six years of RDP, in practice this protection is greatly limited.<sup>11</sup> This is because RDP is tied to the patent term so that data exclusivity ends when the patent expires, even if this is earlier than six years. The RDP term also begins on the date of marketing approval in Europe, which is inevitably many years earlier than in Turkey given its regulatory approval problems. Moreover, Turkey does not recognize RDP for combination products or biologics.

### Patent enforcement

Patent protection for pharmaceuticals is a relatively new concept in Turkey, which first started granting it in 1999.<sup>12</sup> Turkey lacks an effective patent linkage system for resolving patent disputes, and courts lack technical expertise to hear patent cases. As a result, most administrative decisions do not receive appropriate judicial review and cases are ruled against the patent holder.

### Localization

The government's aggressive support for domestic pharmaceutical production has led to increasing localization concerns. Examples include preferential reimbursement arrangements for domestically produced products, the delisting of imported products from the reimbursement list, inspection requirements

favoring domestic firms and more efficient regulatory approval pathways for locally manufactured products.

### Transparency

Transparency remains problematic throughout Turkey's regulatory system. For example, in February 2016, Turkey released a draft patent law with wide-ranging implications, including further restrictive patentability requirements for second usage and vague and concerning language on compulsory licensing to satisfy domestic demand. Nonetheless, the government provided a mere nine days for public comment on the measure.

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<sup>1</sup> Figure 1: Turkey Snapshot:

Pharmaceutical sales, Pharmaceutical sales per capita: Association of Research Based Pharmaceutical Companies (AiFD), BMI

OTC medicine sales, Generic drug sales, Patented drug sales: IMS Health, IEIS, BMI

Health spending, Govt. health spend, Private health spend: World Health Organization (WHO), BMI

Population, Population over 65: World Bank/UN/BMI

See also: BMI, *Turkey Pharmaceuticals & Healthcare Report*, January 2016 (referenced throughout)

<sup>2</sup> Investment Support and Promotion Agency of Turkey and Deloitte, *The Pharmaceutical Industry in Turkey*, March 2014. [http://www.invest.gov.tr/enUS/infocenter/publications/Documents/PHARMACEUTICAL\\_INDUSTRY.pdf](http://www.invest.gov.tr/enUS/infocenter/publications/Documents/PHARMACEUTICAL_INDUSTRY.pdf)

<sup>3</sup> Association of Research-Based Pharmaceutical Companies (AiFD), *Turkey's Pharmaceutical Sector Vision 2023 Report*, [http://www.aifd.org.tr/PDF/2023\\_Rapor/2023\\_strat\\_en.pdf](http://www.aifd.org.tr/PDF/2023_Rapor/2023_strat_en.pdf)

Daily Sabah, *Turkey aims to become pharmaceutical production and R&D hub*, August 2015,

<http://www.dailysabah.com/nation/2015/08/10/turkey-aims-to-become-pharmaceutical-production-and-rd-hub>

<sup>4</sup> Pharmaceutical Manufacturers Association of Turkey (IEIS), Turkish Pharmaceutical Exporters, Global Business Reports, *Turkey Pharmaceuticals 2015*, June 2015,

<http://www.ieis.org.tr/ieis/assets/media/untitled%20folder/Turkey%20Pharmaceuticals%202015%20-%20Book%204.pdf>

<sup>5</sup> World Bank Group, *Going Universal*, September 2015, [http://www-wds.worldbank.org/external/default/WDSContentServer/WDSP/IB/2015/09/10/090224b0830cc779/1\\_0/Rendered/PDF/GoingUniversal0s0from0the0bottom0up.pdf](http://www-wds.worldbank.org/external/default/WDSContentServer/WDSP/IB/2015/09/10/090224b0830cc779/1_0/Rendered/PDF/GoingUniversal0s0from0the0bottom0up.pdf)

<sup>6</sup> European Pharmaceutical Review, Ozge Atilgan Karakulak and Zeynep Koray, *Turkey: A rising star in the pharmaceutical industry*, Volume 20, Issue 1 2015

<sup>7</sup> Schonherr, Pierfrancesca Maran, *Turkey: Pricing Issues in the Turkish Pharmaceutical Sector*,

<http://roadmap2016.schoenherr.eu/pricing-issues-in-the-turkish-pharmaceutical-sector/>

<sup>8</sup> These new reimbursement policies apply to specific categories of medicine, but that set of categories could be expanded at any time by the SGK. BMI

<sup>9</sup> Pharmaceutical/Medtech Market Assessment And PRMA In CEE, CIS, Asia, *Turkey. Pharmaceutical Market Access Barriers 2014*, <http://cispharma.blogspot.com/2015/04/turkey-pharmaceutical-market-access.html>

<sup>10</sup> Association of Research-Based Pharmaceutical Companies (AiFD), *Frequently Asked Questions*, <http://www.aifd.org.tr/en/Sektorel-Bilgiler/SSS.aspx#defaultplace>

<sup>11</sup> First published by Mondaq, Gökçe İzgi, LL.M. and Merve Evrim, *Data Exclusivity for Pharmaceutical Drugs in Turkey*, August 2015, <http://www.morogluarseven.com/news/data-exclusivity-pharmaceutical-drugs-turkey>

<sup>12</sup> Fikri Mülkiyet Platformu, Adv. Dr. Cahit Suluk, *Pharmaceutical Patents in Turkey*, August 2015, <http://fikrimulkiyetplatformu.org/pharmaceutical-patents-in-turkey/>