

Turkish Pharmaceutical Market



Turkey is a key emerging market for pharmaceutical companies despite its many challenges

Ranked as the 16th largest pharmaceutical market in the world and the seventh biggest in Europe in 2011 in terms of sales, Turkey's domestic market offers many opportunities. According to data from the Association of Research-Based Pharmaceutical Companies, the Turkish pharmaceutical market was worth an estimated TRY15.4bn (\$8.1bn) in 2013, and showed a positive growth rate of 6.4% in 2013 compared to a 4.8% decline in 2012. The Health Transformation Program introduced in 2003 has led to universal healthcare coverage in Turkey, with almost 98% of the population covered by public health insurance. Meanwhile, key drivers for the Turkish pharmaceutical industry are its growing economy, aging population, and increasing life expectancy, as well as its increase in per capita physician visits, offering substantial market potential for pharmaceutical products.

Furthermore, due to its geographical location, Turkey serves as an important hub for global pharmaceutical companies seeking to expand their operations into the Middle East and Eastern Europe. More recently, Turkey has become a regional center of operations for many multinational pharmaceutical companies such as Sanofi, Novartis, Merck Serono, Novo Nordisk, and GlaxoSmithKline.

However, there are many challenges that pharmaceutical companies have to overcome in the country, including the complex regulatory and pricing process and the mandatory discounts imposed on pharmaceutical products in order to gain inclusion on Turkey's drug reimbursement list.

Drug approval delays plague the Turkish market

According to regulations, the maximum duration of the new drug licensing process in Turkey is 210 days; however, in reality it has been reported that it takes an average of 772 days for drug approval. This delay is largely due to the mandatory requirement imposed by the Turkish authorities for overseas manufacturers exporting pharmaceutical products to Turkey to obtain Good Manufacturing Practice (GMP) certification issued by the Turkish Ministry of Health. This requirement acts as an entry barrier for companies planning to launch new products in Turkey, as well as denying access to the most innovative medicines. For example, Novo Nordisk was not able to launch any new products in Turkey between 2006 and 2012.

It is expected that the GMP certification delays can be resolved once the US Food and Drug Administration and European Medicines Agency start accepting Turkish GMP certificates, for which Turkey should obtain membership of the Pharmaceutical Inspection Convention and Pharmaceutical

Inspection Cooperation Scheme. However, in the meantime, approval delays will continue to present a significant downside of the Turkish market, not least because the six years of market exclusivity given to innovative pharmaceuticals start from the moment that the product is first licensed within the EU Customs Union area. As a result, approval delays reduce the actual data exclusivity period in Turkey to as little as two years.

Reference pricing, statutory discounts, and the Turkish lira/euro exchange rate are key pain points for the industry

Turkey introduced a price-setting procedure using an external reference system based on 5–10 reference countries (all from the EU) in 2004. Prices are most often benchmarked to five nations that have some of the lowest prices for drugs in Europe. As a result, price cuts introduced over the past few years as part of austerity measures across Europe have had a negative impact on drug prices in Turkey.

Another sore point for the pharmaceutical industry is the fixed Turkish lira/euro exchange rate that is followed for price benchmarking. This exchange rate was fixed in 2009 and has not been updated since, leading to an additional price reduction of 15% as the Turkish lira has depreciated in recent years against the euro. This pricing mechanism, compounded by the mandatory discounts enforced on drugs for inclusion in the reimbursement list, has made drug prices in Turkey 50–60% lower than the mean European prices.

Statutory discounts, which have been repeatedly applied to pharmaceutical products included on the reimbursement lists since 2009, increased from 23% in 2009 to 41% by the end of 2011. With an estimated 89% of the drugs sold in Turkey being sold through the reimbursement system, pharmaceutical companies have very little choice but to comply with this mandate.

The impact on the profitability of pharmaceutical companies has been significant, with some companies even experiencing a decline in their sales in Turkey. These statutory price discounts are also believed to have led to shortages of many drugs, including high-demand oncology drugs. In order to address the drug shortages, the government plans to open up the drug import market by removing the monopoly held by the Turkish Union of Pharmacists. In addition, to overcome the situation of drugs not being imported into Turkey due to low reimbursement prices, the Ministry of Health has started working on a new pricing decree, which it aims to implement in 2014.

The pharma industry hopes that Turkey will no longer use reference pricing from EU countries that are facing economic problems, and that it will also update the exchange rate used to calculate reimbursement prices. Although the Ministry of Health is keen, the Social Security Institute is opposed to the new system and is in the process of discussions with the ministry on this issue. While the Ministry of Health has already started to allow flexible pricing (with prices set at current exchange rates) for some blood products that are in short supply due to low pricing, it remains to be seen if this new pricing system is going to be applied for all imported products.