efpia
European Federation of Pharmaceutical Industries and Associations

EFPIA Key priorities in Turkey

While the EU is Turkey's number one import and export partner, Turkey ranks 5th in the EU's top export markets, and 10th in the top export markets for European pharmaceuticals. In 2015, EU total exports to Turkey amounted to €79.2 billion, with pharmaceuticals making up 3.9% of these exports, representing €3.1 billion.

The pharmaceutical industry remains a key player in the Turkish economy, where over 50% of Turkey's pharmaceutical imports come from the EU. For the innovative pharmaceutical industry, Turkey represents a strategic market of importance and a gateway between Europe and the Middle East. Therefore, a strong and forward-looking trading relationship between the EU and Turkey is a key objective for the European innovative pharmaceutical industry.

The Turkish domestic pharmaceutical industry is expected to grow 10-15% until 2020, and this growth is primarily driven by continued strong domestic demand backed by expansionary economic policies, even though in financial terms, the pharmaceutical market is declining due to severe pricing pressures and significant market access hurdles for investment[2]. Nevertheless, the Turkish Government continues to use localisation policies to increase domestic production of medicines and vaccines. In 2016, generics accounted for 34.3% of the country's overall pharmaceutical market by value and 56.8% of the market in terms of volume[3].

EXPORT MARKETS

TURKEY RANKS 10TH
IN THE TOP EXPORT MARKETS
FOR EUROPEAN PHARMACEUTICALS

CONTRIBUTION TO THE TURKISH ECONOMY

50% OF PHARMACEUTICAL IMPORTS
COME FROM THE EUROPEAN UNION

The innovative pharmaceutical industry continues to be impacted by a number of longstanding, as well as more recent, market access barriers and discriminatory measures on the Turkish market, which are, furthermore, not compliant with the existing commitments under the EU-Turkey Customs Union.

[1] IHS Markit Healthcare Forecasts Q4 update, October 2016
[2] Turkish Central Bank

LOCALISATION

Delisting of imported products

The 64th Government Action Plan of the Turkish Government, included provisions threatening delisting of imported products from the reimbursement list, if localisation plans for domestic production were not submitted within a specified timeframe. As a result, in spring 2016, EFPIA member companies submitted localisation plans which covered the requested level of local production. During autumn, the Government put further pressure on companies to submit and execute localisation plans. and on 8 February, the Government announced the first wave of forced localisation and a list of 52 products to be delisted from the reimbursement list was published. The publication of the second phase of localisation, is expected for early April. An additional 300 products are expected to be in the scope of this phase, which represents a significant and worrying escalation of the localisation plan. The Turkish Medicines Agency (TITCK) has announced further three waves to follow, which is expected to impact many hundreds of products. This discriminatory measure will have serious consequences for our industry's ability to operate in Turkey. More importantly, such measures risk compromising patients' access to appropriate treatments and departs from Turkey's international obligations, notably existing commitments of the EU-Turkey Customs Union, as well as WTO rules.

INTELLECTUAL PROPERTY

Regulatory data protection (RDP)

Turkish Law currently provides an RDP term of 6 years. However, there are a number of long-standing shortcomings to this protection, as for example, the 6-year period starts running from the date of the first marketing authorisation in the EU, as opposed to the first marketing authorisation in Turkey. Given that it takes an estimated 2-3 years to register and obtain reimbursement of a new medicine in Turkey, as a result, new products will receive only 1-2 years of RDP following launch in Turkey.

Patent Law

In December 2016, the new Turkish Patent Law was adopted. The Patent Law represents a positive step forward in bringing Turkish Patent Law closer to the European Patent Convention and to the EU acquis, even though important critical elements remain, notably in relation to controversial criteria for the use of compulsory licenses.

REGULATORY ISSUES

Good Manufacturing Practice (GMP)

There are significant marketing approval delays in Turkey due to the lack of acceptance of EU inspections and efficient processes combined with a lack of resources to conduct GMP inspections in Turkey, which amount to delays in the review process for up to 18 months, which is double the average period. In this respect, industry is urging Turkish authorities to accept European inspections and allow parallel applications for marketing authorisation and GMP certification for all categories of products. Turkey has committed to join PIC/S in 2018, which is a welcome development.

PRICING AND EXCHANGE RATE

Since 2009, Turkey has imposed a fixed exchange rate for pharmaceutical pricing, and consistently failed to adjust the rate to inflation and currency fluctuations, with the effect of significantly reducing the Turkish Lira price of medicines. In January 2017, the Turkish Medicines Agency announced a new rate for pharmaceutical pricing[4], that remains around 40% under the real exchange rate.

CUSTOMS UNION

The Customs Union modernisation presents an opportunity to progress toward resolution of longstanding issues of concern in Turkey, and provides the possibility to upgrade the trade relationship and improve the operating environment for pharmaceutical companies, with the inclusion of new elements featured in recent EU FTAs. The key issues that the industry would like to see included in an upgraded agreement include:

* **Alignment of IP regulations with the EU *acquis* and existing international obligations**
* **A level-playing field in procurement**
* **Rule of law and transparency in pricing and reimbursement policies**
* **Inclusion of a comprehensive dispute settlement mechanism**

[4] 1 € = 2.3421 TRY