scienceINDUSTRIES
SWITZERLAND

Mixed Economic Committee Switzerland - Turkey
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Issues raised by scienceindustries

scienceindustries is representing 250 companies of the chemical, pharmaceutical and biotechnological industry of Switzerland.

The member companies of scienceindustries were responsible for more than 45% of overall exports of Switzerland in 2018.

A. Importance of Turkey as trade partner

Turkey is an important trade partner on a global level. It is ranked 17th in exports and 22nd in imports.

The major product groups exported by our member companies in 2018 were pharmaceutical products, vitamines, diagnostics (42.9%), fragrances and aromas (4.9%), varnishes and paints/inks (1.6%) and organic chemicals (1.2%). They contributed 92.8% to all exports from our industry to Turkey.

The Swiss chemical, pharmaceutical and biotechnological industry contributed 54.5% to the total exports to Turkey in the year 2018.

B. A Free Trade Agreement to deepen and intensify the relationship

Due to the high importance of Turkey as trade partner, we welcomed the finalization of the negotiations on the modernization of the existing free trade agreement EFTA-Turkey

C. Issues for the chemical and pharmaceutical industry

Customs

Cerificate of manufacturer: scienceindustries seeked clarification on the need to deliver a certificate of manufacturer for products exported under the FTA EFTA-Turkey. We would like to thank the Turkish Ministry of Trade very much for the immediate clarification. This was highly appreciated by the member companies of scienceindustries.

Non-preferential origin declaration issued by a Chamber of Commerce: Turkey is demanding the proof of origin from the Chamber of Commerce of the country of departure of the goods. This may be difficult if the seller in Switzerland ships his goods to a warehouse in the EU, such as the Netherlands, from which the delivery of the goods to Turkey is performed. Thus, the certificates of origin of all deliveries are issued by a Swiss Chamber of Commerce. Turkey does not accept this and requires a certificate of origin from a Chamber of Commerce of the country of departure despite the fact, that the seller and biller are located in Switzerland. This leads to increased administrative burden and costs for the seller. Additionally, in most cases it is not possible to get a Certificate of Origin from a Chamber of Commerce in the non-Swiss country of departure. **We therefore would highly appreciate if Turkey would accept for such deliveries the Certificate of Origin issued by a Swiss Chamber of Commerce.**

Pharma

The pharmaceutical industry is keen to collaborate with the Turkish Government and find ways to ensure sustainable and affordable access to medicines, continued investment in research and development and manufacturing. The pharmaceutical industry would like to be a partner in delivering the Turkish Government's vision of healthcare for the country.

Exchange Rate (FX)/Pricing: Turkey began using International Reference Pricing (IRP) to set prices for all registered pharmaceuticals in 2004. Prices are set to the lowest level found in five reference countries ("basket"), i.e. France, Spain, Italy, Portugal and Greece, plus the country of origin. Prices are in Euro currency and the lowest price in reference countries is converted into Turkish Lira. Initially, the Euro/TL exchange rates were routinely adjusted to meet fluctuations in the foreign exchange markets, as required by Turkish laws. However, since 2011, Turkey has consistently failed to adjust prices of pharmaceuticals, resulting in artificially lower prices. This is problematic because of the disruption it can cause in the supply chain, leading to potential access issues, as well as from a predictability and rule of law perspective.

Cross Exchange Rate: Reference price of a drug in Turkey must be in EUR currency due to the Price Legislation. If it is non-EUR currency, it must be converted to EUR at the first step of pricing process. Even though the fixed EUR rate started to be updated each year since 2015, the same regulation was not applied to the currencies other than EUR. For all other currencies, the exchange rates were kept fixed at the rates on February 13th, 2009. This regulation causes reference price to be exposed to another price erosion for countries with appreciated currency over the years such as Switzerland (CHF) and United States (USD). Besides that, the consequences of this regulation are not same for every non-EUR currency. Some non-EUR currencies are taking advantage from this regulation change since they have been depreciating against EUR for almost 10 years as opposed to CHF and USD. This leads to unfair competition for Swiss and US based companies in addition to excessive price erosions.

Mandatory institutional 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 the introduction of alternative reimbursement pathways, more and more products have discounts of more than 41%.

IP – Regulatory Data Protection (RDP): In 2005, the Turkish Government established a 6-year period of protection for regulatory data for products registered in Turkey. This was a positive step towards establishing effective protection of the clinical and related data generated by innovative pharmaceutical companies in the development and marketing authorization of new medicines. The pharmaceutical industry is however concerned by the different limitations restricting the scope and effectiveness of Regulatory Data Protection in Turkey, from a legal, economic and public health perspective. These limitations undermine company incentives to introduce innovative products into the Turkish market. The 6-year RDP period in Turkey starts running with the date of the first marketing authorisation (MA) in any country of the Customs Union, as opposed to the date of the first MA in Turkey. Given the extended regulatory approval times and delays stemming from the GMP certification approval period, it can take one to three years to obtain an MA for a new medicine in Turkey. As a result, approval in Turkey occurs long after approval in the EU, which means that new products will receive, in practice, no more than two to three years of RDP in Turkey. In addition, the Ministry of Health currently accepts and processes generic applications during an originator product's RDP term. This is automatically granted on the day of RDP-expiry. Finally, the scope of RDP in Turkey is unduly limited as it does not include combination products, nor biological medicines. **It is important for Turkey to ensure the 6-year RDP period should only start running with the date of marketing authorization in Turkey.**

Weak Patent Enforcement: We were informed that IP Court judges may need sufficient and relevant training in order to gain the capacity to effectively resolve disputes. When referring and deferring cases to expert panels, appropriate procedural safeguards need to be established. The existence of an effective mechanism for resolving patent disputes before marketing of follow-on products are essential.

The new compulsory license (CL) provisions of the Industrial Property Law are concerning because they can now be granted in the case where a third party claims that market demands are not being met (rather than just non-use).

Localization policies: The pharmaceutical industry is concerned about the forced localisation measures, both in terms of policy and economic impacts in Turkey. This issue has been already addressed in the last Joint Economic Commission in 2018. For further details please see the appendix.

Long Regulatory & Good Manufacturing Practice (GMP) Approval Timelines: The GMP certificates issued by non-Turkish authorities such as the European Medicines Agency are not recognised and the Ministry of Health is required to conduct an inspection of the manufacturing site in the country the manufacturing is being done. This creates significant delays in the marketing authorization process in Turkey. Recently, there have been a number of improvements – such as the "Prioritization Guideline" – to the system, including the possibility of parallel submission of the regulatory dossier while GMP inspections are ongoing for products classified as particularly innovative. While the industry welcomes this recent development, concerns remain whether this will further prolong the approval timelines of products that have not been prioritized. **A mutual GMP recognition between Swissmedic and TITCK would improve pharmaceutical trade volume between Turkey and Switzerland.**

Parallel trade: Parallel trade can cause serious quality issues and misusage of products because of the possible failures in cold chain and unprescribed/non-recommended treatment.
Parallel trade can also cause malfunctioning in the supply chain due to deviations in preplanned forecast for the Turkish market and potentially leading to shortages.

IVD (in-vitro diagnostics)

A hospital incurs costs from acquisition of Medical Devices & IVD's from public tenders and main financing methodology is the reimbursement from Social Securities Institute. Tender prices (acquisition cost) have been increasing due to inflation and FX depreciation, but reimbursement prices have been kept flat for the last 10 years. This leads to deterioration in hospital financing and worsening payment terms & bad debts. In May 2018, Ministry of Finance have bailed out outstanding debts of University Hospitals, by injecting funds directly to

companies at a further discount. Even though the immediate crisis was handled, there were no structural reforms to ensure that similar issue will not be encountered again.

We believe that while amending & increasing reimbursement prices are a way to overcome the problem, a more in depth structural reform would enable better access to innovative solutions and realize value of diagnostic information in the long run.

In order to ensure health policy decisions regarding IVD's are taken and necessary follow up mechanisms work within the health authority, we believe the decision makers should realize value of IVD. It is Roche's upmost strategy to increase IVD awareness among these key stakeholders, to make sure structural reforms that reflect the added value of access to innovative diagnostics are discussed and prioritized.

The trend towards local manufacturing is also observed in IVD, where some of the global players are partnering with local companies to take advantage of price exemptions.

Appendix: Detailed Information on issues

Forced Localisation

Following the implementation of provisions in Article 46 of the 64th Government Action Plan (released on 10 December 2015), the Turkish government began forced localisation measures in the pharmaceutical industry. This means that unless localised, imported products with at least two locally manufactured generics would be delisted by the Social Security Institution (SSI), which covers more than 90% of the Turkish market. On 8 February 2018, the SSI executed the first wave of delistings. The second wave of delistings was announced in May 2017 and implemented on 31 July 2018. While no further waves have taken place since then, the second wave remains 'open', with products from the third wave moving to the second wave as their locally manufactured generics entered the market and – subject to market dynamics – imported products remain at risk of being delisted. The pharmaceutical industry is concerned about these measures, both in terms of policy and economic impacts in Turkey. The EU Commission has brought this issue to the WTO in April 2019. In September 2019, the WTO formally established a Panel on the EU-Turkey dispute settlement on pharmaceuticals.

Exchange Rate (FX)/Pricing

Between 2009 and 2015, the Euro/TL exchange rate was kept at 1.96, which did not reflect the actual exchange rate. For example, in 2013 the applied exchange rate for pharmaceuticals (the 'pharma exchange rate'), was 33% lower than the actual exchange rate. A new Pharmaceutical Pricing Decree was published on in July 2015 that annulled the former decree and established that the Euro-to-TL exchange rate for pharmaceuticals would be 70% of the average exchange rate during the previous year. In February 2018, The Turkish government limited the 2018 pharma exchange adjustment rate by 15% (should be 23% based on realization) which sets the pharma exchange rate to 2.69 TL instead of 2.87 TL, citing budgetary constraints and a high budget deficit compared to 2017. Later, there was an additional 2.5% increase through adjusting mandatory reimbursement discounts. In February 2019, the annual update of the exchange rate saw an increase of around 26.4% vs 2018. Specific changes in the process of exchange rate update:

- On the positive side, there has been no cap imposed by the government on the increase of the exchange rate used in the calculation (in 2018 there was a 15% cap);
- On the negative side, there was a lower adjustment multiplier used for the final exchange rate calculation (from 70% used in 2017 and 2018 to 60% used in 2018)

Cross Exchange Rate

Even though the EUR rate started to be updated each year since 2015, the same regulation was not applied to the currencies other than EUR. For all other currencies, the exchange rates kept fixed at the rates on February 13th, 2009. As EUR is considered as the standard foreign currency in the price list, all prices are converted to EUR at all times. The EUR prices for each products have been calculated with regards to their proportion to TRY. For instance to find the EUR price for CHF, the CHF price was first converted into TRY with the CHF/TRY rate in 2009 and the calculated TRY price was converted in the EUR price again with the EUR/TRY rate in 2009.

E.g. Conversion of 100 CHF to EUR price:

CHF Price	Exchange Rates on Feb 13, 2009	EUR Price Calculation	EUR Price
100 CHF	CHF / TRY = 1,4157 EUR / TRY = 2,1181	EUR= 100 x 1,4157/2,1181	66,84 EUR

From 2009 to 2019, as CHF value increased more than EUR compared to TRY, the implication of this regulation is price erosion. The current price loss due to this regulation is 37.15%. The calculation method can be found below.

For Switzerland referenced products in the MoH Price List:

The lowest possible ex-factory price of 5 reference countries, Portugal, Spain, France, Italy and Greece, cannot be taken as reference price due to the current cross exchange rate regulation.

Besides, the price erosion is not a problem for some non-Euro currencies. Even, these currencies are taking advantage of the current situation since they have been depreciating against Euro for almost 10 years. The payer is overpaying for the products whose reference prices are in these currencies. So, this regulation causes overvaluation and public loss.

To be able to sustain access for the innovative products which meet unmet medical needs and to provide an environment of fair competition, non-Euro currencies should be updated corresponding to rates declared by TCMB at the time when FDK announces annual pharma Euro currency rate.

Parallel trade

The pricing policies mentioned cause drug prices in Turkey to be one of the lowest in the pharmaceutical industry. The impacts are not solemnly on Turkey, neighboring countries are also negatively affected. Parallel trade issue arises and this negatively affects sales of companies as well as trading of products with unregulated price tags in those countries.