Turkey's Pharmaceutical Industry and Key Developments

In Turkey, the active population, retirees and their dependants are covered by health insurance provided by the Social Security Institution ('SSI'). Employers must pay monthly contributions for their employees, who automatically become covered. Those who are self-employed may also benefit from this insurance coverage by voluntarily paying monthly contributions. Health insurance provided by the SSI covers practically every physical examination, test and treatment (both outpatient and inpatient) carried out at public healthcare institutions and university hospitals. Any treatment or surgery which is not directly linked to an individual's actual health is not covered, such as cosmetic surgery, for example. The SSI also covers emergency services undertaken at private health institutions.

Much of the public is covered by SSI health insurance, while only a small proportion benefits from private insurance by paying monthly contributions.

As of January 2012, under general health insurance, every citizen in Turkey is now covered by SSI health insurance. The aim is that all citizens who were not covered by SSI health insurance packages now benefit from public health insurance.

For a pharmaceutical product to be reimbursed, it will be registered in the 'reimbursement list' of the SSI. The price is subject to obligatory discounts to be registered in the reimbursement list. As the SSI is the biggest buyer of pharmaceutical products, for pharmaceutical companies, sales of pharmaceuticals start with entering the reimbursement list.

All products sold to the SSI by foreign or domestic producers must be listed on a reimbursement list.

Key Developments

On April 2, 2019, the European Union ('EU') requested a consultation before the World Trade Organisation ('WTO') regarding measures adopted by Turkey in relation to the production, importation and marketing of pharmaceutical products, which it claimed would be non-compliant with international agreements.

Background to the Request

The increase in the number of imported products and the lack of domestic manufacturing pushed the government to identify a new solution to enliven the local economy and enable a 'know-how' transfer.

Following the announcement of the Structural Transformation Programme Action Plan for Healthcare Industries by the Prime Minister, Ahmet Davutoğlu on November 7, 2014, Turkey started adopting measures to localise the production of a substantial amount of pharmaceutical products sold in Turkey. On December 10, 2015, the 64th government announced the 2016 Action Plan (64th Government Action Plan), and according to action item No. 46:

- It will be ensured that the medicines for which application is made to be manufactured in Turkey are prioritised in licensing registered by the Ministry of Health ('MoH') upon being considered together with reimbursement policies of the Social Security Institution ('SSI').
- The SSI will make the relevant arrangements in the legislation and accelerate the evaluation process for the inclusion of healthcare products manufactured domestically into the reimbursement list.
- Imported products to be delisted from the reimbursement list will be identified, provided that relevant guarantees are issued for the provision of treatment.

The plan implied that imported products having a locally manufactured equivalence will be delisted from the reimbursement list.

Following the 64th Government Action Plan, a Health Industries Steering Committee (SEYK) was formed by the Prime Ministry. One of the major topics in the SEYK agenda was set for 'transition from import to local manufacturing'. Accordingly, in line with the 64th Government Action Plan, a localisation process started for imported pharmaceuticals.

On March 4, 2016, the MoH and the SSI published an announcement regarding the localisation process. In this announcement, it was stated that in accordance with Action Item No. 46 of the 64th Government Action Plan, sales figures for imported products having more than one generic available in the market would be examined. In order to prevent any supply shortage in the market, a timetable was created as a result of the negotiations with the related associations, trade unions and companies for the localisation of the products having more than 50% local manufacturing market share. Within this context, companies were asked to provide an undertaking with respect to local manufacturing of the imported pharmaceuticals (which do fall within the determined category) or provide suitable reasons if they are not able to provide an undertaking for local manufacturing by March 22, 2016. The announcement also provided information about the foundation of the 'Transition from Import to Local Manufacturing Commission' ('Transition Commission').

Although the announcement dated March 04, 2016 stated that the aim of the process was not to delist the imported products but to 'incentivise' local manufacturing, if companies did not agree to manufacture the relevant products locally, they would be delisted.

Following the announcement, the MoH held several meetings with company representatives, outlining the process and timeline. Each company individually negotiated with the MoH about their plans (if any) with respect to local manufacturing of their imported products which fall within the category set by the government.

Since the SSI's announcements on February 8, 2017, it has removed from the reimbursement list two groups of

products which have two or three local alternative generics.

EU's Legal Grounds

In the consultation request circulated to WTO members on April 10, 2019, the EU claimed that the various measures implemented by Turkey via legal and administrative tools are inconsistent with Turkey's obligations covered under the provisions of the General Agreement on Tariffs and Trade 1994 ('GATT 1994'), Trade Related Investment Measures ('TRIMs Agreement'), Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS Agreement') and Agreement on Subsidies and Countervailing Measures ('ASCM'), in particular:

- Article III:4 of the GATT 1994, because, by excluding imported pharmaceutical products for which localisation commitments have not been given, have not been accepted or have not been fulfilled from the reimbursement scheme, the localisation requirement accords to imported pharmaceutical products being treated less favourably than similar products of national origin covered by that scheme in respect of laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use.
- Article III:4 of the GATT 1994, because, by according priority to the review of applications for inclusion in the reimbursement scheme, as well as with respect to any other pricing and licensing policies and processes of pharmaceutical products of national origin, the prioritisation measure is more favourable than to similar imported products.
- Article X:1 of the GATT 1994, because Turkey failed to publish all general application matters relating to the localisation and technology transfer requirements, and the prioritisation measure promptly, and in such a manner as to enable governments and traders to become acquainted with them.
- Article X:2 of the GATT 1994, because, through these measures, Turkey applies a new or more burdensome requirement, restriction or prohibition on imports which is enforced before being officially published.
- Article X:3(a) of the GATT 1994, because Turkey failed to administer its laws, regulations, decisions and rulings in relation to the localisation requirement, the technology and transfer requirements and the prioritisation measure in a uniform, impartial and reasonable manner.
- Article XI:1 of the GATT 1994, because, once a foreign producer locally produces a particular pharmaceutical product pursuant to the localisation requirement, applied in conjunction with the Turkish rules for approving the importation and marketing of pharmaceutical products, that product can no longer be imported, and, therefore, Turkey institutes and maintains a prohibition or restriction, other than duties, taxes or other charges on the importation of products of other contracting parties.
- Article 2.1 of the TRIMs agreement, because the localisation requirement is an investment measure inconsistent with Article III:4 of the GATT 1994.
- Article 3.1 of the TRIPS agreement, because the technology transfer requirement does not apply to domestic producers of pharmaceutical products; it, therefore, treats the producers of other Member States less favourably than the domestic producers in respect of their protection of intellectual property.
- Article 27.1 of the TRIPS agreement, because the technology transfer requirement may cover patent rights and does not apply to domestic producers and patents are not available and patent rights are not enjoyable without discrimination as to whether products are imported or locally produced.
- Article 28.2 of the TRIPs agreement, because the technology transfer requirement may cover patent rights and because it restricts or infringes the right of patent owners to assign, or transfer by succession the patent and to conclude licensing contracts.
- Articles 39.1 and 39.2 of the TRIPS agreement, because the technology transfer requirement may require foreign producers to transfer undisclosed information protected by those provisions to a Turkish producer.
- Article 3.1 b) of the ASCM, because the reimbursement scheme operated by the Turkish social security system involves the granting of a subsidy within the meaning of Article 1.1 of the ASCM. The localisation requirement makes that subsidy contingent upon the use of domestic goods over imported goods, thereby violating Article 3.1 b) of the ASCM. A statement of available evidence about the existence and nature of that subsidy is annexed to this request.

Consequently, the EU stated that competitive opportunities in the Turkish market on imported pharmaceutical products are significantly impaired, compared to domestically produced products.

Consultation Procedure and Next Steps

The Dispute Settlement Understanding, on which the EU made this consultation application, will be applied to disputes brought pursuant to the consultation and dispute settlement provisions of the agreements listed in Appendix 1 of the Dispute Settlement Understanding which covers the agreements on which the EU grounded its allegations.

The dispute settlement system of the WTO established under the Dispute Settlement Understanding is a key element to provide security and predictability to the multilateral trading system. The members of the WTO recognise that the dispute settlement system is intended to preserve the rights and obligations of members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law. With

Article 2 of the Dispute Settlement Understanding, the Dispute Settlement Body ("DSB") has been established to administer these rules and procedures and, except as otherwise provided in a covered agreement, the consultation and dispute settlement provisions of the covered agreements. Accordingly, the DSB has the authority to establish panels, adopt panel and appellate body reports, maintain surveillance of the implementation of rulings and recommendations, and authorise the suspension of concessions and other obligations under covered agreements.

Further to the Dispute Settlement Understanding, before bringing a case, a member must exercise their judgment as to whether action under these procedures would be fruitful. The aim of the dispute settlement mechanism is to secure a positive solution to a dispute. A solution mutually acceptable to the parties to a dispute and consistent with the covered agreements is clearly preferable. In the absence of a mutually agreed solution, the first objective of the dispute settlement mechanism is usually to secure the withdrawal of the measures concerned if these are found to be inconsistent with the provisions of any of the covered agreements. Provision of any compensation should only be looked at if the immediate withdrawal of the measure is impracticable, and be used temporarily pending the withdrawal of the measure which is inconsistent with a covered agreement. The last resort which the Dispute Settlement Understanding provides to the member invoking the dispute settlement procedures is the possibility of suspending the application of concessions or other obligations under the covered agreements on a discriminatory basis vis-à-vis the other applicant member, subject to authorisation by the DSB of such measures.

Pursuant to the provisions of the Dispute Settlement Understanding, the EU, therefore, made a consultation request on 2 April 2019. Additionally, on 24 April 2019, the United States ('US') requested to join in these consultations, pursuant to Article 4.11 of the Dispute Settlement Understanding. The US stated that they have a substantial trade interest in these consultations, as they are one of the world leaders in the development, production, licensing, and marketing of pharmaceuticals and in 2018, the US exported $219 million of pharmaceutical products to Turkey. The US is also of the opinion that measures adopted by Turkey in relation to the production, importation, and marketing of pharmaceutical products, including localisation and technology transfer requirements, an import ban on localised products, and a prioritisation measure, are inconsistent with Turkey's obligations under covered agreements.

Under the provisions of the Dispute Settlement Understanding, the complainant is required to reply to the request within 10 days following the date of receipt and enter into consultations in good faith within no more than 30 days following the date of receipt. Turkey positively replied and entered into the consultation period and the various parties met in Geneva on 9 and 10 May 2019.

If the dispute is not settled within 60 days from the date of receipt, the EU may request that a panel be established. The EU may request such a panel if the parties collectively believe that the consultations failed in settling the dispute. The parties may agree also on more time than the 60-day period. It will be interesting to see if the various parties will extend the consultation period once they publish the result of the meeting in Geneva.

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