

## **EU Requests Consultation before The WTO on Turkey's Localisation Policy**

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 are claimed to be non-compliant with international agreements.

### **Background**

Following the announcement of the Structural Transformation Programme Action Plan for Healthcare Industries by the Prime Minister Ahmet Davutoğlu on November 7, 2014, Turkey commenced adopting measures to localise the production of a substantial amount of pharmaceutical products sold in Turkey. On December 10, 2015, the 64<sup>th</sup> Government announced the 2016 Action plan (64<sup>th</sup> Government Action Plan), which included an item saying that measures would be taken to prioritise domestically produced medical supplies and medical devices. The plan states that: *“Import products to be removed from the reimbursement list will be identified provided that the provision of medical treatment is duly guaranteed.”* implying that of imported products with a locally produced equivalence will be delisted from the reimbursement list.

The policy requires foreign producers to commit to localise their production of certain pharmaceutical products in Turkey. If not, those products concerned are excluded from any reimbursement, which affects the vast majority of sales in Turkey by the Social Security Institution (“SSI”). The duration of the localisation requirement is not set and its scope is periodically adapted, modified, updated or extended. The localisation process for each producer who accepts localisation is managed specifically and non-transparently.

It is understood that the SSI has removed from the reimbursement list two groups of products, which have two or three local alternative generics.

### **EU’s Legal Grounds**

The EU claims that the various measures implemented by Turkey via legal and administrative tools do not comply with Turkey’s obligations covered under the provisions of 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 and Article 2.1 of the TRIMs Agreement - the exclusion of the imported product which has not committed to be localised is a priority in the processes of market authorisation, pricing and reimbursement in favour of local products, this creates unequal treatment between imported and localised products.
- Article X of the GATT 1994 - because Turkey did not publish the general application measures for localisation in such a manner to enable those concerned to become acquainted with them, enforced some measures before they were officially published and did not administer the legislation in line with the localisation requirement.
- Article XI of the GATT 1994 - objects once production is localised, the product can no longer be imported; therefore, Turkey imposes a restriction on the import rather than taxes, duties or charges.
- Articles 3.1, 27.1, 28.2, 39.1 and 39.2 of the TRIPS Agreement - because the non-execution of the technology transfer requirement to the domestic producers leads to unequal treatment between domestic and other producers. It also restricts or infringes the right of the patent owners to assign or transfer the patent and to conclude licensing contracts for the patents and requires the foreign producers to transfer undisclosed information to a Turkish producer.
- Article 3.1 of the ASCM – objects since the reimbursement is deemed as a granting of a subsidy in terms of the ASCM.

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

### **Consultation Procedure and Next Steps**

Under the provisions of the Dispute Settlement Understanding, the complainant is required to reply to the request within 10 days following of the date of receipt, and enter into consultations in good faith within no more than 30 days after the date of receipt.

It is known that Turkey has positively replied and entered into the consultation period. The parties met in Geneva on the 9-10 May.

If the consultations fail to settle the dispute within 60 days from the date of receipt, the EU may request that a panel be established. The EU may request a panel during the 60 day period if the parties jointly consider that consultations have failed to settle the dispute. The parties may allow themselves more time than the minimum of 60 days. We will wait to see if parties will extend the consultation period once they publish the result of the meeting in Geneva.