TURKEY – CERTAIN MEASURES CONCERNING THE PRODUCTION,
IMPORTATION AND MARKETING OF PHARMACEUTICAL PRODUCTS

Status Report by Türkiye

The following communication, dated 25 April 2023, from the delegation of Türkiye to the Chairperson of the Dispute Settlement Body, is circulated at the request of that delegation.

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**STATUS REPORT REGARDING IMPLEMENTATION OF THE
RECOMMENDATIONS AND RULINGS BY TÜRKİYE**

Türkiye submits this status report under Article 21.6 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU) to inform the Dispute Settlement Body (DSB) of its progress in the implementation of the arbitration award in DS583.

On 25 July 2022, the Arbitrators issued their award (WT/DS583/ARB25 and WT/DS583/ARB25/Add.1) in the dispute Türkiye – Certain Measures concerning the Production, Importation and Marketing of Pharmaceutical Products (DS583). On the same day, in accordance with Article 25.3 of the DSU, the Award was notified to the DSB, the Council for Trade in Goods, the Committee on Subsidies and Countervailing Measures and the Committee on Trade-Related Investment Measures. Pursuant to paragraph 15 of the Agreed Procedures for Arbitration (WT/DS583/10), the Award was not adopted by the DSB.

Consequently on 18 August 2022, Türkiye informed the DSB in writing (WT/DS583/15) that, pursuant to Article 21.3 of the DSU, it intended to implement the recommendations and rulings of the Arbitrators and the Panel in this dispute in a manner that respects its WTO obligations, but that it needed a reasonable period of time to do so. Türkiye reiterated this statement at the DSB meeting of 29 August 2022.

On 10 January 2023, Türkiye and the European Union informed the DSB (WT/DS583/17) that they had agreed, pursuant to Article 21.3(b) and Article 25.4 of the DSU that the reasonable period of time for Türkiye to implement the recommendations of the Award of the Arbitrators would expire on 25 April 2023.

Türkiye hereby informs the DSB that it has taken appropriate steps to implement the recommendations and rulings in this dispute.

First, the Social Security Institution published the new Drug Reimbursement Regulation in the Official Gazette dated 25 August 2022 which came into force on that same day and has replaced the previously applicable regulation. The new regulation fully respects Türkiye's WTO obligations.

Second, the Health Industries Steering Committee which is the policy-making body for the localization measure, met in December 2022 and recommended the Social Security Institution to initiate the application process for relevant pharmaceutical companies regarding the re-activation of their products in the reimbursement system. Consequently, the Health Services Pricing Committee adopted this recommendation at its meeting in January 2023.

In accordance with these decisions and for transparency purposes, the Turkish Medicines and Medical Devices Agency issued an announcement on 18 April 2023 stating that "Transition from Import to Manufactured Products Project" has been terminated. Social Security Institution is now expected to initiate the process for reactivation of the relevant pharmaceutical products in the reimbursement list.

Third, the Social Security Institution has prepared the new draft Alternative Drug Reimbursement Regulation taking into account the recommendations issued in this dispute and shared it with the relevant stakeholders. Once the consultations are completed, the new Alternative Drug Reimbursement Regulation, which fully respects Türkiye's WTO obligations, will be published in the Official Gazette.

Finally, the relevant authorities are also currently preparing amendments to the Guideline for Working Principles and Procedures of Human Medicinal Products Priority Assessment Commission.

Türkiye considers that the above-described actions bring it into compliance with the arbitration award.

Türkiye stands ready to respond to the questions the European Union may have in relation to the implementation in this dispute.

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