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

(DS583)

THIRD PARTY EXECUTIVE SUMMARY
OF THE UNITED STATES OF AMERICA

June 4, 2021

EXECUTIVE SUMMARY OF THE U.S. THIRD PARTY ORAL STATEMENT

1. To establish that a measure is justified under Article XX, the responding Member asserting the defense must show that the measure at issue is: (1) provisionally justified under one of the Article XX subparagraphs; and, (2) applied consistently with the requirements of the chapeau.

2. Turkey asserts, among other things, that its localization requirement for reimbursements for pharmaceuticals is justified under the general exceptions in Article XX(b) and (d). In regards to its defense under Article XX(b), Turkey states that the localization measure is "designed to ensure an uninterrupted access to safe, effective and affordable medicines for all patients in Turkey which falls within the range of policies to protect human life and health." Turkey further states that "[t]he fact that the localisation measure is concerned with ensuring adequate access to medicines and thus pursues an objective of protecting human life and health is confirmed by the design and structure of that measure as well as by the authorities responsible for its implementation." In the alternative, Turkey states that the localization measure is justified under Article XX(d) "because the measure is necessary to secure compliance with the laws and regulations requiring Turkey to ensure accessible, effective and financially sustainable healthcare."

3. In response, the European Union contends that Turkey's localization requirement is not justified under Article XX(b) because it "is not designed to achieve the public health objective alleged ex post facto by Turkey in its first written submission, but rather to pursue Turkey's economic development and industry policy goals, and is very trade restrictive." The European Union goes on to assert that the requirement is not necessary because "Turkey has not shown that the Localisation Requirement makes a contribution to that objective and, in any event, there are adequate alternatives that are less trade-restrictive or, indeed, not trade-restrictive at all." Similarly, the European Union contends that Turkey's localization requirement is not justified under Article XX(d), including because Turkey has failed to identify laws and regulations that require Turkey "to ensure the financial sustainability of Turkey's healthcare system with the requisite degree of specificity and normativity."

4. The text of Article XX establishes that for a measure to qualify under an Article XX general exception, the measure at issue: (1) must satisfy one of the Article XX subparagraphs; and (2) be applied consistently with the requirements of the chapeau.

5. Therefore, to establish that measures are preliminarily justified under Article XX(b), Turkey must establish, consistent with the text of that provision: (1) that the measure's objective is "to protect human, animal or plant life or health"; and (2) that the measure is "necessary" to the achievement of its objective. For Article XX(d), Turkey must establish two elements set out in its text: (1) that the measure is designed to "secure compliance" with laws or regulations that are not themselves inconsistent with some provision of the GATT 1994; and (2) that the measures are "necessary to secure compliance."

6. The text of Article XX(b) does not make justification of a measure contingent on meeting other obligations of the covered agreements, including other exceptions listed in Article XX.

The text of Article XX(d) similarly does not rely on meeting other obligations. The chapeau to Article XX makes clear that "nothing in this Agreement shall be construed to prevent the adoption of or enforcement by any contracting party of measures" that meet one of the exceptions in Article XX.

7. Respondents frequently invoke multiple subparagraphs of Article XX, as Turkey did in this dispute by invoking Article XX(b) and (d). The fact that one provision or exception could be invoked with regard to the same factual circumstances by a Member does not mean that another exception is no longer available.

8. In relation to a challenged measure, it is for the responding Member to invoke Article XX and establish that the measure at issue satisfies an exception under Article XX. Nothing in the language of Article XX(b) and (d) suggests that a responding Member can raise Article XX but avoid meeting its burden of argument due to the nature of the asserted objective or necessity to achieve that objective, no matter the seriousness of the asserted concern.

9. In its third party submission, Canada asserts that in assessing the structure and operation of Turkey's localization requirement "to assess the relationship between the measure at issue and the policy objective" for the analysis under Article XX(b), the Panel "should take into account the Members' characterization of the objective, but it is not bound by this, and may form its own characterization of the objective based on all the evidence put forward."

10. The United States observes that it is for the responding Member to identify the objective that motivates a given measure. By invoking an Article XX general exception, the responding Member is indicating that, despite the apparent inconsistency of a measure with another WTO commitment, there is a basis in Article XX to justify the measure. If the Member did not identify the general exception at issue, it would simply not have asserted that there is any Article XX basis to justify the inconsistent measure.

11. If a complainant wishes to challenge the genuineness of a respondent's professed objective, it can do so by demonstrating that the measure fails to contribute toward the alleged objective, and that less trade restrictive options are available to meet the objective in question. It is not for the respondent, or the Panel, to recharacterize or determine for itself the objective of the measure at issue.

12. On Canada's approach, there would not be a reason to conceive of Article XX as an "affirmative defense," which is not a GATT term, to be asserted by the responding Member. This is because if a panel "may form its own characterization of the objective based on all the evidence put forward," then this characterization by a panel is part of the panel's "objective assessment" under DSU Article 11. And if the panel should make an "objective assessment" of the objective of the measure, so too should the complaining party as part of bringing forward its affirmative case.

13. Further, if a panel "may form its own characterization of the objective based on all the evidence put forward," then a responding Member arguably would not need to assert *any* general exception under Article XX. That is, even with silence by a responding Member, a panel could

examine the measure to determine whether it has the objective of one of the subparagraphs of Article XX. If the panel were to so conclude, the panel would need to ensure that the relevant subparagraph could not be established "based on all the evidence put forward." If the panel failed to make that assessment, the panel would not have ensured that (in the terms of Article XX) nothing in the Agreement had been construed to prevent the application of a measure satisfying Article XX.

14. The United States does not consider this to be a correct result under Article XX. Rather, Article XX becomes relevant if there is an apparent inconsistency of a measure with another WTO commitment. The responding Member is free to invoke an Article XX general exception to indicate its belief that there is a basis in Article XX to justify the measure. But if the Member chooses not to identify any general exception, it also chooses not to assert an Article XX basis for the otherwise inconsistent measure.

EXECUTIVE SUMMARY OF THE U.S. RESPONSES TO PANEL QUESTIONS TO THIRD PARTIES

15. Response to Questions 1(a)–(b): The Panel's questions refer to the scope of Article III:8(a). The Panel need not reach the issues raised in these questions. As noted in the chapeau of Question 1, the terms of reference for this dispute are "confined to the specific Turkish measures at issue."

16. Under Article 7.1 of the DSU, the standard terms of reference – which were used in this dispute – call on the Panel "[t]o examine . . . the matter referred to the DSB" by the claimant, and "to make such findings as will assist the DSB in making the recommendations or in giving the rulings provided for in the covered agreements." As this text establishes, the Panel has two functions: (1) to "examine" the matter – that is, to "[i]nvestigate the nature, condition or qualities of (something) by close inspection or tests"; and (2) to "make such findings as will assist the DSB in making the recommendations or in giving the rulings provided for" in the covered agreement.

17. Article 11 of the DSU confirms this dual function of panels, and similarly provides that the function of panels is to "make an objective assessment of the matter" before it, and "make such other findings as will assist the DSB in making the recommendations or in giving the rulings provided for in the covered agreements."

18. As Article 19.1 of the DSU provides, these "recommendations" are issued "[w]here a panel or the Appellate Body concludes that a measure is inconsistent with a covered agreement" and are recommendations "that the Member concerned bring the measure into conformity with the agreement." Article 19.2 of the DSU clarifies that "in their findings and recommendations, the panel and Appellate Body cannot add to or diminish the rights and obligations provided in the covered agreement."

19. The European Union identified certain measures of Turkey in its panel request, identifying for each measure the covered agreement or agreements for which the measures are inconsistent. The Panel was established with the standard terms of reference as specified by Article 7.1 of the DSU. Subsequently, Turkey filed a request for preliminary findings by the

Panel regarding the panel request of the European Union, and the Panel received submissions from the parties and third parties concerning Turkey's request. The Panel made findings regarding Turkey's "preliminary ruling" request on July 10, 2020, concluding that the measures of concern to Turkey fell within the terms of reference.

20. The terms of reference for this dispute do not address the reimbursement of medicines in other Members. The Panel need not address the application of Article III:8(a) to such reimbursements. The Panel's role in this dispute, as directed by the above cited articles of the DSU, is to make recommendations where it concludes that a measure identified by the European Union in its panel request is inconsistent with a cited covered agreement so that Turkey, the "Member concerned" in this dispute, may bring the measure in question into conformity. The Panel should avoid providing views on other Members' measures regarding reimbursement of pharmaceuticals or statements beyond the application of its interpretation of relevant WTO provisions to Turkey's specific reimbursement scheme.

21. Furthermore, the framing of the Panel's question, through its reference to other Members' reimbursement schemes, overlooks one of the central arguments in this dispute – whether the localization requirements of Turkey's measures are inconsistent with Turkey's obligations under the covered agreements.

22. Finally, it is not the role of the Panel to make recommendations as to how a concerned Member, having been found to maintain a WTO-inconsistent measure, should change its measure so as to be consistent with its WTO obligations. Assuming for the purpose of argument that any of the identified measures in this dispute are found to be inconsistent with an obligation under the covered agreements, Turkey would determine how to bring its measures into compliance with the obligation at issue.

23. Directing Turkey, or any Member, as to how to structure or restructure pharmaceutical reimbursements to come within the scope of Article III:8(a) is not an issue before the Panel; moreover, such an exercise overlooks the potential conflicts with other obligations in the covered agreements by focusing on one obligation to the exclusion of the rest of the obligations of the WTO Agreements. Although a measure may fall within the scope of Article III:8(a) such that the other provisions of Article III do not apply, the measure could nevertheless be inconsistent with another obligation or obligations under the covered agreements.

24. Response to Question 3: Article 3.1(b) of the SCM Agreement disciplines subsidies that are conditioned on the "use of domestic over imported goods." The conditionality must be triggered by the act of "using" goods, either in the sense of employment to some end by an end user or as an input into, or instrumentality of production (e.g., equipment) for, downstream production.

25. The Oxford English Dictionary defines the ordinary meaning of "use" as "the act of putting something to work, or employing or applying a thing, for any (esp. a beneficial or productive) purpose."

26. Thus, the term "use" in Article 3.1(b) refers to the employment of a domestic good as an input or instrumentality in a productive process, or enjoyment of a good for its intended purpose by an end user. Therefore, the relevant good must be one that is "used," either as a finished good by an end-user or as an input in downstream production.

27. In contrast, Article 3.1(b) does not speak to subsidies conditional for their granting on domestic manufacturing. The ordinary meaning of the language in Article 3.1(b) does not discipline subsidies by virtue of the fact that they are provided for production activities in the territory of the grantor. Article 3.1(b), by its terms, is directed to subsidies contingent on "the use of domestic over imported goods." That is, the conditionality for the subsidy must relate to "use."