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

(DS583)

RESPONSES OF THE UNITED STATES OF AMERICA TO QUESTIONS FROM THE PANEL TO THIRD PARTIES

March 29, 2021

TABLE OF REPORTS

Brazil – Retreaded Tyres (AB)	Appellate Body Report, *Brazil – Measures Affecting Imports of Retreaded Tyres*, WT/DS332/AB/R, adopted 17 December 2007
EC – Approval and Marketing of Biotech Products	Panel Reports, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/R / WT/DS292/R / WT/DS293/R / Add.1 to Add.9 and Corr.1, adopted 21 November 2006
EC – Seal Products (AB)	Appellate Body Reports, *European Communities – Measures Prohibiting the Importation and Marketing of Seal Products*, WT/DS400/AB/R / WT/DS401/AB/R, adopted 18 June 2014
Korea – Various Measures on Beef (AB)	Appellate Body Report, *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, WT/DS161/AB/R, WT/DS169/AB/R, adopted 10 January 2001
Russia – Traffic in Transit	Panel Report, *Russian Federation – Measures Concerning Traffic in Transit*, WT/DS512/R and Add.1, adopted 26 April 2019
US – Gambling (AB)	Appellate Body Report, *United States – Measures Affecting the Cross-Border Supply of Gambling and Betting Services*, WT/DS285/AB/R, adopted 20 April 2005
US – Gasoline (AB)	Appellate Body Report, *United States – Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R, adopted 20 May 1996

QUESTIONS FROM THE PANEL

Question 1. The Panel understands that policies for the reimbursement of medicines vary to some extent across different countries. The Panel also understands that its terms of reference are confined to the specific Turkish measures at issue. Having said this, the Panel observes that Turkey's Universal Health Insurance Scheme, as described by the parties, appears fundamentally similar to many others in providing for out-patients to obtain their prescribed pharmaceuticals from private pharmacies, for the cost of many prescribed pharmaceuticals to be covered by a public payer (in the form of a social health insurance, national health service, or other public body), with eligibility established by a reimbursement list established by the public payer. It is also common for the out-patients to make some form of co-payment, and to have the reimbursement rate (100% or otherwise) vary according to the medicines prescribed, the population group, any difference with respect to a reference price, etc.

(a) For Canada and any other third parties that consider Turkey's challenged measure to fall outside of the scope of Article III:8(a), would it be correct to say that, in principle, all such systems for covering the cost of out-patients' prescribed pharmaceuticals fall outside of the scope of Article III:8(a)? How would a pharmaceutical reimbursement system involving a public payer and private pharmacies have to be (re)structured in order to be brought within the scope of Article III:8(a)?

(b) For any third parties that consider Turkey's challenged measure to fall within the scope of Article III:8(a), would it be correct to say that, in principle, all such systems for covering the cost of out-patients' prescribed pharmaceuticals fall within the scope of Article III:8(a)? How would a pharmaceutical reimbursement system involving a public payer and private pharmacies have to be (re)structured in order to be brought outside of the scope of Article III:8(a)?

1. The United States responds to Questions 1(a)–(b) together. 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."

2. 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.

3. 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."

4. 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."

5. 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.

6. 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.

7. 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.

8. 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.

9. 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.

Question 2. According to Turkey, the localisation requirement is justified under the general exceptions in Article XX(b) and/or XX(d) because the localisation requirement is necessary "to ensure an uninterrupted access to safe, effective and affordable medicines for all patients in Turkey". More specifically, "it is necessary to guarantee that pharmaceutical products are physically available in the country" because there are "risks of overreliance on imported pharmaceutical products".[1] The local production of pharmaceutical products "prevents the risk of a shortage of supply" which could arise "if pharmaceutical companies decide to supply other countries where they can receive a higher price for their products, instead of Turkey".[2]

(a) Do the third parties agree that, in respect of the subset of measures relating to the protection of human (and animal/plant) life or health, measures to address risks of shortages of the type that do not necessarily meet the detailed provisions and limitations of Article XI:2(a) or Article XX(j), e.g. because there is not a "shortage" and they are not being applied temporarily, may nonetheless be justified under Article XX(b)?

(b) Please comment/elaborate on Turkey's argument that it is undisputed that "the lack of access to medicines poses a very serious threat to human life or health"[3], and that it is not required to further demonstrate the existence of a risk of shortage of supply, and even less so the existence of such a risk separately for each category of pharmaceutical products subject to the localisation requirement.[4]

10. The United States responds to Questions 2(a)–(b) together. As noted above in response to the Panel's Questions 1(a)–(b), the DSB set standard terms of reference for the Panel in this dispute. The Panel need not address application of provisions that are not part of the terms of reference for this dispute or raised by a party to resolve a claim within the terms of reference. Further, the responses of the United States are without regard for whether the facts of the dispute demonstrate that there is or is not a "risk of shortage" and without regard for whether the facts further demonstrate that the measures are or are not being applied "temporarily."

11. 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

[1] Turkey's first written submission, para. 486.

[2] Turkey's first written submission, para. 127.

[3] Turkey's second written submission, para. 179.

[4] Turkey's first written submission, paras. 177–182.

of the Article XX subparagraphs; and, (2) applied consistently with the requirements of the chapeau.[5]

12. 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.[6] 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."[7]

13. The text of Article XX(b) does not make justification of a measure contingent on meeting other obligations of the covered agreements, including Article XI:2(a) and Article XX(j). 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. By the terms of Article XX, Article XI:2(a) cannot be construed to limit the applicability of the general exceptions in Article XX.

14. Further, the fact that one provision or defense could be invoked with regard to the same factual circumstances by a Member does not mean that another defense is no longer available. Nothing in the texts of Article XI:2(a) and Article XX suggest the mutually exclusive applicability of these provisions. In fact, respondents frequently invoke multiple subparagraphs of Article XX, as Turkey did in this dispute by invoking Article XX(b) and (d).

15. Indeed, it would be redundant to have an independent exception whose test relies on meeting another, independent exception. Moreover, the test for an exception under Article XX(b) is not rendered inapplicable if the measure at issue fails to meet the test for another exception under Article XX.

16. For any argument under Article XX, the responding Member bears the initial burden of establishing that the measure at issue meets the applicable test for an exception under Article XX.[8] Nothing in the language of Article XX(b) suggests that a responding Member can avoid meeting its burden due to the nature of the asserted objective or necessity to achieve that objective, no matter the seriousness of the asserted concern.

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[5] *EC – Seal Products (AB)*, para. 5.297; *US – Gasoline (AB)*, pp. 22–23; *US – Gambling (AB)*, para. 282; *Korea – Various Measures on Beef (AB)*, para. 157.

[6] *Brazil – Retreaded Tyres (AB)*, paras. 144–145; *see also EC – Seal Products (AB)*, para. 5.169 (finding that, to make out a defense under Article XX(a), the responding Member had to show: (1) "that it has adopted or enforced a measure 'to protect public morals;'" and, (2) that the measure is "'necessary' to protect such public morals").

[7] *Korea – Various Measures on Beef (AB)*, para. 157.

[8] *E.g.*, *Brazil – Retreaded Tyres (AB)*, paras. 144–145.

17. As for the validity of an asserted objective, the United States observes that it is for the respondent—not the complainant—to identify the legitimate objectives that motivate a given measure. 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.

Question 3. Does "use" in Article 3.1(b) of the SCM Agreement cover the use of pharmaceutical products by individual out-patients?

18. The parties have provided briefing to the Panel as to whether all the elements for demonstrating that a prohibited subsidy exists under Article 3.1(b) of the SCM Agreement are met. The United States confines its response to the hypothetical as posed by the Panel in Question 3 without regard as to whether such other elements have been established.

19. Article 3.1(b) disciplines subsidies that are conditioned on the "use of domestic over imported goods." As explained below, 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.

20. 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."[9]

21. 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.

22. 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."

[9] *The New Shorter Oxford English Dictionary*, 4th edn, L. Brown (ed.) (Clarendon Press, 1993), at 3531–32.