In the World Trade Organization
Panel Proceeding

Turkey — Certain Measures concerning the Production, Importation and Marketing of Pharmaceutical Products

(DS583)

Replies of the European Union to the Questions from the Panel

Geneva, 29 March 2021

TABLE OF CONTENTS

I. LOCALISATION REQUIREMENT 1
1.1 General factual issues 1
Question 2 1
1.3 Article III:8(a) 2
Question 4 2
Question 6 4
Question 8 9
Question 10 10
Question 11 14
Question 13 15
Question 14 17
Question 17 18
Question 18 19
Question 19: 20
Question 20. 22
Question 22: 24
Question 23 : 25

TABLE OF CASES CITED

Short Title	Full Case Title and Citation
Brazil – Aircraft (Article 21.5 – Canada II)	Panel Report, *Brazil – Export Financing Programme for Aircraft – Second Recourse by Canada to Article 21.5 of the DSU*, WT/DS46/RW2, adopted 23 August 2001, DSR 2001:X, p. 5481
Colombia – Ports of Entry	Panel Report, *Colombia – Indicative Prices and Restrictions on Ports of Entry*, WT/DS366/R and Corr.1, adopted 20 May 2009, DSR 2009:VI, p. 2535
Colombia – Textiles	Appellate Body Report, *Colombia – Measures Relating to the Importation of Textiles, Apparel and Footwear*, WT/DS461/AB/R and Add.1, adopted 22 June 2016, DSR 2016:III, p. 1131
EC – Asbestos	Panel Report, *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, WT/DS135/R and Add.1, adopted 5 April 2001, as modified by Appellate Body Report WT/DS135/AB/R, DSR 2001:VIII, p. 3305
EC – Seal Products	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, DSR 2014:I, p. 7
India – Autos	Panel Report, *India – Measures Affecting the Automotive Sector*, WT/DS146/R, WT/DS175/R, and Corr.1, adopted 5 April 2002, DSR 2002:V, p. 1827
India – Solar Cells	Appellate Body Report, *India – Certain Measures Relating to Solar Cells and Solar Modules*, WT/DS456/AB/R and Add.1, adopted 14 October 2016, DSR 2016:IV, p. 1827
India – Solar Cells	Panel Report, *India – Certain Measures Relating to Solar Cells and Solar Modules*, WT/DS456/R and Add.1, adopted 14 October 2016, as modified by Appellate Body Report WT/DS456/AB/R, DSR 2016:IV, p. 1941
US – Continued Zeroing	Appellate Body Report, *United States – Continued Existence and Application of Zeroing Methodology*, WT/DS350/AB/R, adopted 19 February 2009, DSR 2009:III, p. 1291

TABLE OF ABBREVIATIONS

Abbreviations	Full name
API	Active Pharmaceutical Ingredients
ARC	[Universal Health Insurance] Alternative Reimbursement Commission
ARS	Alternative reimbursement system
EU	European Union
GATT 1994	General Agreement on Tariffs and Trade 1994
GMP	Good Manufacturing Practices
HIN	Health Implementation Notification/Communique
SCM Agreement	Agreement on Subsidies and Countervailing Measures
SSI	Turkey's Social Security Institution
WTO	World Trade Organization

TABLE OF EXHIBITS

Exhibit No.	Title
EU-119	Excerpts from the WEB Eczane user guide
EU-120	Screenshot of the ECP platform website
EU-121	Excerpts from insurance companies' websites concerning deduction coverage
EU-122	A sample pharmacy insurance policy explaining the deduction coverage
EU-123	Entry for "Brilinta Film Coated Tablet 90 mg" in the RxMedia platform

I. LOCALISATION REQUIREMENT

1.1 General factual issues

Question 2

In their first written submissions, the parties discuss the regular rules for the reimbursement for pharmaceutical products, and indicate that there are different rules under the "alternative reimbursement system" (ARS), and that there are also certain rules for the payment for pharmaceutical products supplied from abroad.

> *(a) Regarding the regular rules and the alternative reimbursement system, the European Union states that "regardless of the pathway used, once approved, the pharmaceutical products are included in the same Reimbursement List".[1] Are the different pathways relevant to one or more issues before the Panel, or are these different pathways explained merely as part of the background factual context?*

1. The EU refers to paras. 20 – 25, 33, 69, 70, 74 of its first written submission for a general description of the two pathways and references to evidence concerning the role of the alternative reimbursement pathway in localisation.

2. The two pathways are relevant insofar as the Localisation Requirement is implemented through both of them, i.e. by using the mechanisms, legal provisions and institutional frameworks of both pathways. Thus, both pathways should be clearly identified and any Panel findings against the Localisation Requirement should cover them.

3. While distinct, the two pathways lead to the same place. The effect of the Localisation Requirement on imported products is the same whether the regular or the alternative pathway is used. Thus, regardless of the pathway, there is a single Reimbursement List (i.e. Annex 4/A). Both pathways are implemented by committees that are ultimately controlled by the SSI. The main claims and arguments on WTO-inconsistency, as well as the reasons why the measure is not protected by Article III:8(a) or justified by Article XX, are not fundamentally different for the two pathways.

4. Nevertheless, there are certain specificities of the alternative reimbursement pathway that are particularly relevant for the Localisation Requirement. In particular, the Alternative Reimbursement Regulation explicitly identifies the transition to local production (i.e. localisation) as one of the purposes of

[1] European Union's first written submission, para.24

alternative reimbursement procedures.[2] Furthermore, as the EU has explained, while it is not always clear on what legal basis, the Alternative Reimbursement Committee has at times taken the decision to approve the deactivation, reactivation or delisting of a product in the Reimbursement List.[3] Finally, as hinted by the Panel in its question 2(b) to Turkey, it is likely that the ARS was introduced close in time with the implementation of Phase 1 of the localisation process in order to facilitate the achievement of the measure's industrial policy objectives.

1.3 *Article III:8(a)*

Question 4

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 the European Union, 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)?

5. As the Panel no doubt understands, it is impossible to make legal characterisations spanning entire classes of health insurance models across WTO Members. Every model must be assessed in light of all the relevant facts. The EU is not therefore in a position to say with certainty that all models of a certain type would fall outside of Article III:8(a), much less to suggest what should be done in order to bring all such models within the scope of Article III:8(a).

6. With that *caveat*, the EU would agree that, without more, a hypothetical system in which out-patients obtain eligible and prescribed medicines through transactions

[2] Article 3(1)(i) of Regulation amending the Regulation on the Working Procedures and Principles of the Social Security Institution Healthcare Services Pricing Commission, Official Gazette No 29620, 10 February 2016 (Exhibit EU-37); Articles 1 3(a) and 6(2)(a) of the Social Security Institution Regulation on Alternative Reimbursement for Universal Health Insurance, published in the Official Gazette 29620 on 10 February 2016 (Exhibit EU-38).

[3] EU's first written submission, paras. 33, 69, 74, 138. In addition, Article 6.1(e) of the Social Security Institution Regulation on Alternative Reimbursement for Universal Health Insurance (Exhibit EU-38) provides for the authority of the ARC to decide on delisting in some circumstances.

with private pharmacies involving some type of co-payment, and in which a public body merely reimburses a part of the cost, does not fall within Article III:8(a), for all the reasons given in our previous submissions. The EU would also note that Turkey's reimbursement system has additional features further confirming that it does not fall within Article III:8(a), such as the ability of patients to choose between medicines in the same equivalent group if they cover the difference in price.

7. As to what would "bring" such systems into the scope of Article III:8(a), first of all, the ability to fit into a WTO exception is not an objective in light of which health insurance systems should be designed. There is no particular reason to fit reimbursement systems into Article III:8(a), because there is, in the normal course of events, no legitimate reason why they would infringe Article III:4. To recall, Article III:8(a) concerns public procurement, not public financing.[4]

8. Indeed, if reimbursement systems like those described in the question were, as a general matter, within the scope of Article III:8(a), there would be no coherent reason to exclude any form of governmental financial support of private purchases from that provision. To give a few examples, coupons for food purchases by consumers could be conditioned on buying domestic products; subsidies for renovating real-estate could be conditioned on using domestic materials; tax exemptions or reductions could be freely applied to domestic goods; tax credits for environmentally friendly purchases could be contingent on domestic origin of the products, etc. – all under the guise of "public procurement". This would, of course, expand Article III:8(a) beyond recognition.

9. It is difficult to say, in the abstract, how a reimbursement system could be modified to bring it in the scope of Article III:8(a). A central feature that is missing in the hypothetical system described in the question is acquisition of products by the government, without which there can be no procurement.[5] Without that, the system does not govern procurement, nor is it a process pursuant to which the government acquires products. An additional missing element is the purchasing of products by governmental agencies.[6]

[4] EU's second written submission, para. 88.

[5] EU's first written submission, section 2.4.1; EU's second written submission, section 2.4.1.

[6] EU's first written submission, section 2.4.2; EU's second written submission, section 2.4.2.

Question 6

In its second written submission, Turkey states that the "purchase" by the SSI "occurs when a patient presents a prescription for a medicine included in Annex 4/A in a retail pharmacy and the provision of that medicine to the patient is approved through the Medula system".[7] *Turkey explains that "[t]he SSI thus acquires the title to the pharmaceutical product that is included in Annex 4/A and is prescribed to a patient at the moment the pharmacy registers in the Medula system the medicine on the prescription by scanning its square-code and the Medula system approves the provision of that medicine to the patient. However, instead of taking physical possession over that product, the SSI directs the retail pharmacy to dispense immediately that medicine to the patient."*[8]

(a) Please indicate whether the European Union accepts Turkey's depiction of the process as a factual matter, and please also address whether the process as described by Turkey should properly be characterized as involving a "purchase".

10. The EU disagrees with Turkey's depiction for two sets of reasons. First, the process does not involve a purchase by the SSI, and the SSI does not acquire title over the products at any stage. Second, retail pharmacies are not mere agents of the SSI, which the SSI "directs… to dispense" medicines.

11. On the first point, it is important to distinguish "approval" in the Medula system from reimbursement by the SSI (and especially from purchase). The "approval" in the Medula system, which takes place at the time of the transaction between the pharmacy and the out-patient, is merely to confirm that the out-patient is under SSI coverage and that the medicines contained in the prescription are within the Reimbursement List. This does not, however, guarantee that the SSI will reimburse the price of that product. Indeed, even when there is a valid prescription for a reimbursable medicine, the SSI may reject reimbursement for various reasons, even though the Medula system will have "approved" the provision of the medicine to the patient.

12. This is supported by Article 5.1.4 of the HIN (SSI Health Implementation Communiqué),[9] which provides:

> The provisions registered in the MEDULA system for the services provided shall only be considered as preliminary permission and will not be sufficient on its own unless explicitly specified otherwise in the regulations. In case relevant health service rules are not electronically integrated to the system, the necessary controls shall be performed by the health service providers.

[7] Turkey's first written submission, para. 189

[8] Turkey's first written submission, paras. 206-208

[9] Exhibit TUR-10a, p. 13.

13. For example, patients requiring ongoing treatment for certain conditions, such as cancer or diabetes, are able to purchase the required medicines on the basis of a report issued by a medical doctor which is valid for a pre-determined time (e.g. 6 months), without the need for a prescription for each purchase. The Medula system will approve such a purchase. Only after that approval will the SSI actually review the compliance of a prescription or a report with the reimbursement rules. In that review, they may find that reimbursement must be refused because the prescription or report was non-compliant. In this case, the prescription or report will be sent back to the pharmacy which can correct it within five days. If it fails to do so, the pharmacy will not be reimbursed, even though the medicine will have been approved in the Medula system and provided to the out-patient.

14. Similarly, under the reimbursement rules, certain medicines are subject to reimbursement only for a maximum number of boxes during each year.[10] The first time that this number is exceeded, the patient will present the prescription to the pharmacy, it will be entered in the Medula system and "approved", so that the pharmacy will sell the drug to the patient. However, during subsequent review, the SSI will discover that the yearly maximum is exceeded and will reject reimbursement.

15. Accordingly, receiving "approval" in Medula at the time of the transaction does not necessarily mean that the product will be reimbursed by the SSI. This is a significant risk of which pharmacies are, of course, fully aware. In order to mitigate the risk of reimbursement being rejected by the SSI, pharmacies obtain professional liability insurance from private insurance companies.[11]

16. This allows us to draw two important conclusions.

17. First, "approval" in Medula is not tantamount to reimbursement. "Approval" and reimbursement are distinct. Thus, even if "reimbursement" was somehow connected to a purchase by the SSI (*quod non*), it does not occur through the Medula system. Moreover, the fact that the sale of the medicine to the patient can be approved in Medula, but ultimately not reimbursed, clearly shows the incoherence of Turkey's depiction: even in that scenario, where the SSI does not even *reimburse* the product, Turkey would seem to argue that it has "purchased" it.

[10] An example of this is the entry for "Brilinta Film Coated Tablet 90 mg" in the RxMedia platform (Exhibit EU-123), which explains that 13 boxes are to be provided in one year.

[11] These insurance products cover, to that end, so-called "SSI prescription deduction". See the excerpts from insurance companies' websites concerning deduction coverage (Exhibit EU-121) and a sample pharmacy insurance policy explaining the deduction coverage (Exhibit EU-122).

18. Second, the risk of non-reimbursement by the SSI, even where a transaction is approved in Medula, is significant. This risk is not compatible with the pharmacies acting as agents of the SSI in the provision of medicines by the SSI to the population.

19. To further understand why Turkey's depiction is incorrect, it is useful to consider more generally the situation of retail pharmacies in Turkey. As the EU has explained, these pharmacies are private entities.[12] Pharmacies can freely decide whether or not to sign the protocol with the SSI. Indeed, a significant number of retail pharmacies in Turkey are not in any relationship with the SSI. Nevertheless, these pharmacies sell the very same Annex 4/A prescription medicines to patients which are either not covered by health insurance or have private health insurance.

20. Importantly, the process by which patients covered by private health insurance obtain medicines is analogous to the SSI's process. Just like the SSI, the pharmacy and the insurance company enter into a contractual relationship; the insurance company reimburses all or part of the price; it validates and approves the medicines listed in the prescription; it makes payments directly to the pharmacy, i.e. with no prior payment of the full price by the out-patient. Moreover, Turkey's regulated prices for medicines apply in this scenario as well.

21. Specifically, on a yearly basis, the pharmacies that choose to do so sign protocols with private insurance companies. The commercial terms of the insurance company often require the pharmacy to provide a discount on the price of the medicine, just like the SSI.[13] Each private insurance company has its own system to validate and approve prescriptions, either through a web-based application such as Medula or through a call center. Like Medula, the purpose of these systems is to check whether the prescribed medicine is covered by the individual's private health insurance policy and eligible for reimbursement.[14] As soon as the patient presents it with a prescription, the pharmacy seeks approval from the insurance company. Depending on the insurance policy, the patient pays a portion

[12] EU's first written submission, paras. 12-16 and 205; EU's second written submission, sections 2.2.4.3.3 and 2.2.4.3.4, as well as paras. 106 and 116.

[13] In the case of the SSI, discounts are governed by the Protocol on the procurement of medicines from pharmacies which are members of the Turkish Pharmacists' Association (TEB) by persons covered by the Social Security Institution (Exhibit EU-52), and is reflected in the updated versions of Annex 4/A published on the SSI's website. See EU's first written submission, paras. 18 and 28.

[14] Some platforms are specific to a particular insurance company. For example, Allianz uses a system called "WEB Eczane" or "WEB Pharmacy" (excerpts from the WEB Eczane user guide, Exhibit EU-119). Other systems are used by multiple insurers. For example, the system ECP (Electronic Claim Processing) claims that it is used by 6500 pharmacies and 14 reimbursement entities (private insurance companies and retirement funds) in Turkey. For an overview, see screenshot of the ECP platform website (Exhibit EU-120).

of the total price, which is typically in the range of 20%. The rest of the price is paid directly by the insurance company to the pharmacy, meaning that the patient does not make any payment other than the co-payment provided for in his insurance policy.[15]

22. Given these similarities, it would follow from Turkey's arguments that also the private health insurance company purchases the medicines and acquires title to them, and then "directs" retail pharmacies to "dispense" those medicines to patients. Insurance companies would surely be very surprised by that description of their role. It would also follow from Turkey's analogy that retail pharmacies are not independent commercial actors but mere agents of private health insurance companies. This would be incorrect, just as it is incorrect in the case of the SSI. As the EU has explained, retail pharmacies are independent commercial actors that fully bear the commercial and financial risk, whether they are engaging in sales covered by the SSI, those covered by private health insurance, or those not covered at all.

23. In this respect, it is also helpful to consider again the relationship between retail pharmacies and wholesale pharmacies. Upon agreeing the commercial terms (which may include, for example, quantity discounts), retail pharmacies place orders for medicines with wholesale pharmacies in the desired quantities. The wholesale pharmacy delivers the medicines to the retail pharmacy and provides a standard commercial invoice. Upon delivery, it is of course the retail pharmacy that holds the title to the medicines, and does so until they are sold to an out-patient (which could in turn be covered by the SSI, a private insurer, or not at all, something that the pharmacy does not know until the moment of provision). This process works in exactly the same way regardless of whether the medicine will ultimately be reimbursed by the SSI, a private insurer, or paid out of pocket.

24. When placing orders, retail pharmacies do not know how long it will take them to sell the products. Thus, they bear the risk that the medicines' expiry date will pass before they are sold, in which case they can no longer sell them or be reimbursed for them, and have to dispose of them. Moreover, when making the order, the retail pharmacy does not know how much of the ordered quantity will be purchased by patients (i) under SSI coverage, (ii) under private insurance policy coverage or (iii) with no coverage at all. Thus, the retail pharmacies' purchases of medicines to be supplied to patients under SSI coverage are merely an indistinct

[15] Exhibit EU-119, section 1, shows that pharmacies enter into "direct payment agreements" with private insurers.

part (albeit, in most cases, a large part) of their general purchases. In all cases, it is the retail pharmacy that bears the commercial and financial risks.

25. The commercial and financial risk borne by the retail pharmacy is also demonstrated by the fact that the SSI's reimbursement term (90 days) is typically longer than the payment terms of wholesale pharmacies (in most cases, 60 days).

26. Finally, as explained above, retail pharmacies bear the risk that the SSI will not reimburse a medicine, even if it had initially "approved" it in the Medula system.

27. All this is incompatible with the notion of pharmacies acting as agents in the provision of pharmaceuticals to the population by the SSI. If this was the relationship between the SSI and retail pharmacies, the SSI would be expected to bear the brunt of the commercial and financial risk itself, for example by guaranteeing that it would purchase a certain quantity over a certain period and paying up front.

28. It should also be noted that, regardless of whether a medicine is covered by the SSI, by a private health insurer, or paid out of pocket, Turkey's regulated retail prices apply. What differs, for purposes of reimbursement to the pharmacy, is the applicable discount (and thus the pharmacists' profit). Imagine, for example, that the wholesale pharmacy charges 12 TRY, and that the retail price is set (through regulation) at 20 TRY. This is what a non-insured patient would pay out of pocket, leading to maximum profit for the pharmacy. For a privately insured patient, the health insurance company will reimburse the pharmacy, for example, 16 TRY, as a result of the discount negotiated with the pharmacy, leading to a somewhat lower profit. The SSI will tend to have a larger discount, such that the SSI might reimburse the pharmacy 14 TRY, further reducing the profit margin. Apart from this, however, the mechanics of the sale do not differ depending on whether the SSI or a private insurer are reimbursing the pharmacy.

29. Thus, Turkey's argument that price regulation demonstrates that medicines are "provided" by the SSI is also groundless because, under that logic, the same would be true for patients covered by private health insurance and those paying out of pocket.

(b) Assume a counterfactual in which the scanning of the square-code results in an immediate transfer of funds from the SSI to the pharmacy account, with an accompanying notification to the pharmacy directing it to dispense immediately thereafter the medicine to the patient. Would this bring the reimbursement within the scope of Article III:8(a)?

30. No. Quite apart from the fact that, for several reasons, this is not how the Turkish system works (because reimbursement may be subsequently refused, and

because in any event payment is delayed), even this hypothetical change would not bring the reimbursement within the scope of Article III:8(a).

31. All that would occur in that scenario is immediate reimbursement. However, this would still be mere financing and not the acquisition of title over anything, or purchase of anything. Moreover, immediate reimbursement would not mean that the pharmacy becomes an agent of the SSI in "dispensing" the medicines. The EU does not understand the Panel's hypothetical "notification" as involving anything more than agreement to reimburse. Rather, in reality and in the Panel's hypothetical, the retail pharmacy is an independent commercial actor that bears the commercial and financial risks described in the EU's response to question (a). As explained previously, the retail pharmacy holds title over the medicine it acquired from the wholesale pharmacy, and does so until the moment it is delivered to the patient.

32. Thus, even in the Panel's hypothetical, all the reasons why Article III:8(a) does not apply, as explained in the EU's previous submissions, would still be relevant.

Question 8

The parties have provided arguments on the relevance, for purposes of Article III:8(a), of certain fees and costs that out-patients pay.

(a) If Turkey were to eliminate the "prescription fee" and the "contribution fee", resulting in the out-patients paying no fees, would the challenged measure then constitute a governmental "procurement" and "purchase" for purposes of Article III:8(a)?

33. No. The existence of the prescription fee and the contribution fee is only one of many reasons why Turkey's reimbursement system does not fall within the scope of Article III:8(a). To mention some of the others:

– regardless of any co-payment, the SSI never purchases any medicines, and does not hold title over them;

– retail pharmacies are not agents of the SSI, and the SSI does not "provide" any medicines to patients, it merely reimburses a part of their price;

– retail pharmacies bear the commercial and financial risks of purchasing and holding medicines; they also bear the risk that the medicines will ultimately not be reimbursed by the SSI;

– crucially, there is a difference between purchasing something and financing a purchase by another party (in this case, an out-patient). Turkey's reimbursement system is an example of the latter, not of the former. In this respect, the amount or proportion of the financing is irrelevant;

– in many cases, patients can choose between several medicines in an equivalent group, in which case they will be required to pay the difference between the reimbursed price and the price of the acquired medicine; thus, even if there is no prescription and contribution fee, patients may very well pay a part of the price;

– the challenged measure is not the reimbursement system, but the Localisation Requirement; as explained by the EU, even if the reimbursement system did concern procurement and purchase, the Localisation Requirement surely does not.[16]

Question 10

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".[17] 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".[18]

Do the 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)?

34. Article XI:2 (a) of the GATT 1994 excludes certain measures from the scope of Article XI:1 of the GATT 1994. The European Union has not claimed that the localisation requirement is inconsistent with Article XI:1, but rather with Article III:4 of the GATT 1994 of the GATT 1994. Therefore, Article XI:2 (a) does not seem relevant in the context of this claim.

35. The European Union considers that, as confirmed by well-established practice, the various subparagraphs of Article XX of the GTT 1994 are not mutually exclusive. In other words, they may overlap, and to that extent, they may apply concurrently with regard to the same measure.

36. Without prejudice to this, each of the subparagraphs of Article XX of the GATT 1994 provides immediate context for the interpretation of the other subparagraphs. In addition, the various subparagraphs of Article XX ought to be interpreted in a coherent manner, having regard to the specific object and

[16] EU's second written submission, paras. 95-97.

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

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

purpose of that provision, as well as the overall object and purpose of the GATT 1994 and the WTO Agreement.

37. The European Union considers that measures aimed at a addressing the risk of shortage of supply of pharmaceutical products (or other products necessary for protecting human life or health) may, in principle, be justified under either subparagraph (b) or subparagraph (j) of Article XX of the GATT 1994. However, as explained in the reply to the next sub-question, this does not mean that in the present case Turkey is dispensed, under Article XX (b), from showing that there is a genuine and concrete threat of shortage of supply in respect of each pharmaceutical product.

38. Also, while Article XX (b) does not require expressly that the measure must be "temporary", that requirement is implicit in the term "necessary". Indeed, a measure taken in order to address a threatened shortage of supply would cease to be "necessary" and therefore justified under Article XX (b) from the moment that the threat has been addressed.

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"[19], 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.[20]

39. The notion of "protection" in Article XX (b) of the GATT 1994 implies the existence of a health risk[21]. Accordingly, in order to justify the localisation requirement under that provision Turkey is required, as a first step, to identify and prove the existence of the health risk that the measure is designed to address.

40. The purported objective of the measure invoked by Turkey has been aptly restated by the Panel in the introductory paragraph to this question. In essence, Turkey argues that the measure is necessary to prevent a shortage of supply of medicines resulting from Turkey's dependency on imports of medicines.

41. Turkey has specified that:

> Turkey does not argue that the pharmaceutical products covered by the localisation measure are "in short supply". Rather, Turkey has explained that the objective of the localisation measure is to ensure, in the long-term, that

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

[20] Turkey's first written submission, paras. 177-182.

[21] Panel Report, *EC – Asbestos*, para. 8.170. See also Appellate Body, *EC – Seal Products*, para. 5.197.

> all patients in Turkey have uninterrupted access to safe, effective and affordable medicines.[22]

42. This explanation implies that Turkey concedes that there is no current shortage of supply of medicines. Rather, Turkey seeks to address a threat of future shortages "in the long-term".

43. The European Union agrees that a Member is entitled to take adequate measures in order to address a threat of future shortages of supply of medicines and that such measures, where they have been shown to be "necessary", may be justified under subparagraphs (b) and/or Article (j) of Article XX the GATT 1994 if applied consistently with the *chapeau* of that provision.

44. However, the threat of shortage must be genuine. It cannot be based on mere allegation, conjecture or remote possibility. The risk invoked by Turkey in this dispute is too abstract and theoretical and cannot, by itself, justify the adoption of trade restrictive measures that are inconsistent with basic GATT rules such as Article III:4 of the GATT 1994.

45. It is of course correct that "the lack of access to medicines poses a very serious threat to human life or health"[23]. But one could say as much about many other categories of products. For instance, and to mention only some of the most obvious examples: most agricultural products, as well as the products used to grow them (fertilizers, pesticides, agricultural machinery) or to process them into food or preserve them (e.g. from chemical additives to refrigerators); energy products and the equipment used to produce them; clothing items, the raw materials from which they are made (textiles, leather) and the machinery used to manufacture them; the means used to transport and distribute all the preceding products (trucks, trains, ships), etc.

46. In all previous cases where a measure has been found provisionally justified under Article XX (b) of the GATT 1994, the invoking Member identified a concrete health risk. To the best of the EU's knowledge, in no dispute, before the present one, has a respondent sought to justify a trade restriction affecting such a broad category of products by invoking the purely hypothetical risk that imports may not be sufficient, "in the long term", to ensure an adequate supply.

47. If the type of "risk" invoked by Turkey in this case was deemed sufficient to justify a trade-restrictive measure under Article XX (b) of the GATT 1994, Turkey, and

[22] Turkey's second written submission, para. 182.

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

indeed any other Member, could remove at will large portions of international trade from the scope of application of the most basic GATT disciplines with the excuse of addressing theoretical risks of shortages "in the long term".

48. Such an outcome would be incompatible with the fundamental object and purpose of the GATT 1994 and the WTO Agreement as a whole. The GATT 1994 and the WTO Agreement seek to promote trade between the WTO Members. It would be manifestly at odds with that core object and purpose if the mere possibility of unrestricted trade (and therefore of unrestricted imports), which the GATT 1994 seeks to promote, was deemed to create, in and of itself, a threat of future shortages of supply, which could justify the adoption of trade restrictive measures pursuant to Article XX (b).

49. Indeed, as noted by the Panel in *India – Solar Cells*, "there is always some risk of a future shortage of a product"[24]. In the same case, the Appellate Body stressed its disagreement with India's assumption that all imports entail *per se* a risk of shortage as long as domestic production has not reached a certain level:

> We further disagree with India to the extent that it appears to assume, first, that all imports, in and of themselves, entail supply-related risks and, in that sense, are not "available" to meet demand; and, second, that such risks are intolerable, as long as a sufficient level of domestic manufacturing capacity of solar cells and modules has not been met, such that a situation of "short supply" exists, as long as domestic manufacturing capacity lies below this level.[25]

50. Turkey is seeking to rely in this case on the same unwarranted and unacceptable assumption as India in *Solar Cells*.

51. For the above reasons, in order to meet its burden of proof under Article XX (b) of the GATT 1994, Turkey is required to show that there is a genuine risk that the Turkish population will lack adequate access to specific medicines or, in other words, a genuine risk of shortage of supply.

52. The localisation requirement covers a very wide range of pharmaceutical products, with very different physical characteristics and therapeutic uses. The factors affecting their supply may vary considerably from one medicine to another. In view of that, Turkey must demonstrate separately the existence of a risk of

[24] Panel report, *India – Solar Cells*, para. 7.245.

[25] Appellate Body Report, *India Solar Cells*, para. 5.77.

shortage with regard to the specific pharmaceutical product and its "equivalent product(s)" (if equivalents exist).

Question 11

In its second written submission, Turkey responds to the European Union's argument that there is no reason to assume that pharmaceutical production costs will be lower in Turkey by arguing that (i) the European Union's arguments ignore the fact that the prices of medicines in Turkey are regulated and thus cannot be freely set by the pharmaceutical companies[26]; and (ii) the localisation requirement ensures that access to medicines and the sustainability of the healthcare system is not affected by foreign currency effects (i.e. the cost of imported medicines borne by the SSI increases when foreign currency gains in value or the Turkish lira depreciates.)[27] How does the European Union respond?

53. As explained by the European Union, the price of the medicines plays no role whatsoever in the design of the localisation requirement. That requirement applies regardless of the price of the imported medicines, and even if the imported medicines are less costly than the domestic ones.

54. Turkey is entitled to regulate, and does regulate in practice, the prices of all medicines, irrespective of whether they are imported or domestically produced. Therefore, the localisation requirement is unnecessary to ensure that imported medicines are not more costly to the SSI than the domestically produced ones.

55. Turkey appears to suggest that foreign manufacturers may refuse to supply their products in Turkey at the regulated price. However, Turkey does not explain why the same foreign manufacturers would be willing to incur the additional cost of setting a dedicated production facility in Turkey (and forego the economies of scale that could be achieved by using an existing foreign plant) in order to sell at that regulated price. That could make sense, from a business perspective, only if the production costs in Turkey were lower (something which Turkey has not even attempted to prove). However, if the production costs in Turkey were genuinely lower, the localisation requirement would be unnecessary to attract foreign investment to Turkey.

56. Exchange rate fluctuations are a common re-adjustment mechanism in response to trade and capital imbalances. They affect all currencies, and not only the Turkish lira. They do not, in and of themselves, justify the adoption of measures such as the localisation requirement.

[26] Turkey's second written submission, para. 242

[27] Turkey's second written submission, paras. 243-244

57. There are less trade restrictive measures to mitigate the effects of excessive exchange rate fluctuations, such as stabilization mechanisms. Turkey's pricing regulations[28] already provide for that type of mechanisms. Regulated prices are determined on the basis of reference prices in Euro in certain EU Member States. Those prices are converted into Turkish lira by using an exchange rate fixed by the responsible authorities within the first 45 of each year, according to a pre-established formula involving the use of a substantial 'adjustment coefficient'[29]. In practice, that fixed exchange rate tends to be much lower than the current market exchange rate.

58. The GATT 1994 does not allow Members to restrict trade in response to mere exchange rate fluctuations. Members are allowed to restrict trade only in the event of a genuine crisis of balance of payments, subject to the requirements and in accordance with the procedures of Article XIII of the GATT 1994. Turkey, however, has not invoked that provision.

59. Lastly, its should be noted that a significant portion of the production cost of a medicine (around 60-70%) relates to the cost of the Active Pharmaceutical Ingredients (API). The localization requirement does not require the localization of APIs. The foreign producers who localize their production in Turkey still do and will continue to purchase API from abroad in foreign currency.

Question 13

There appears to be substantial overlap and repetition between the parties' respective arguments under Article XX(b) and their respective arguments under Article XX(d). There is also a degree of overlap and repetition in the parties' respective arguments on whether the localisation requirement is "designed to" protect human life and health, and whether it is "necessary" to protect human life and health.

The parties' arguments on the "designed to" step of the analysis in Article XX(b) and (d), and in particular their arguments relating to the "design and structure" of the measure, seem to largely overlap with, and indeed incorporate, their respective arguments on the "contribution" step of the "necessity" analysis. For instance, in the context of Article XX(b), the European Union submits, in connection with the "design

[28] Decree on Pricing of Human Medicinal Products No. 2017/9901, Official Gazette 29989 of 24 February 2017 (Exhibit TUR– 18) and Communiqué on the Pricing of Medicinal Products for Human Use, Official Gazette 30195 of 29 September 2017 (Exhibit TUR – 17).

[29] *See* Artice 2.2 of Decree on Pricing of Human Medicinal Products (Exhibit TUR – 18) (" *1 (one) Euro value in Turkish Lira to be used in the pricing of human medicinal products is determined by multiplying the annual average of the adjustment coefficient determined as 70% of the euro value that is calculated based on previous year's Official Gazette declared indicative daily euro foreign exchange selling rate. The Price Assessment Commission meets within the first 45 days of each year and declares the value of 1 (one) Euro to be used in the pricing of human medicinal products within the above-mentioned procedures"*). See also Artticle 3.1 b) and 12. 4 of Communiqué on the Pricing of Medicinal Products for Human Use (Exhibit TUR – 17).

and structure" of the measure, that "the Localisation Requirement does not, and indeed cannot, contribute to the alleged objective of ensuring access to medicines with regard to any pharmaceutical product within the scope of the Localisation Requirement".[30] *Please clarify the extent to which the European Union's arguments on the "designed to" step are pertinent to the "contribution" step of the "necessity" analysis.*

60. The European Union recalls that the Appellate Body has noted that, while the "design" and "necessity" steps of the analysis to be conducted under the relevant subparagraph of Article XX of the GATT 1994 are conceptually distinct, they are connected and may overlap:

> the "design" and "necessity" steps of the analysis under Article XX(a) are conceptually distinct, yet related, aspects of the overall inquiry to be undertaken into whether a respondent has established that the measure at issue is "necessary to protect public morals". As the assessment of these two steps is not entirely disconnected, there may, in fact, be some overlap in the sense that certain evidence and considerations may be relevant to both aspects of the defence under Article XX(a). We note, in particular, that, in the context of the "design" step of the analysis, a panel is not precluded from taking into account evidence and considerations that may also be relevant to the examination of the contribution of the measure in the context of the "necessity" analysis.[31]

61. The Appellate Body has further explained that the analysis of the "design" of the measure calls for an "initial threshold examination"[32] in order to determine whether there is a relationship between an otherwise inconsistent measure and the protection of the relevant public interest covered by the invoked exception. According to the Appellate Body,

> If this initial, threshold examination reveals that the measure is incapable of protecting public morals, there is not a relationship between the measure and the protection of public morals that meets the requirements of the 'design' step.[33]

62. In paragraph 157 of its Second Written Submission, the European Union noted that the measure at issue is incapable of contributing to the objective invoked by Turkey. Therefore, in accordance with the above quoted guidance provided by the Appellate Body, the measure cannot be considered as "designed" to protect human life or health.

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[30] European Union's second written submission, para. 156.

[31] Appellate Body Report, *Colombia - Textiles*, para. 5.76.

[32] Appellate Body Report, *Colombia – Textiles*, para. 5.68.

[33] *Ibid.*

63. At the same time, the argument and evidence submitted by the European Union in order to show that the measure "is incapable of contributing" to its stated objective is also relevant in assessing the degree of the measure's "contribution" to that objective as part of the subsequent "necessity" test, should the Panel consider that the threshold examination of the "design" of the measure does not suffice to reject Turkey's attempted justification.

1.6 Article 3.1(b) of the SCM Agreement

Question 14

In its first written submission, Turkey argues that the reimbursements fall outside of the scope of the SCM Agreement because alleged subsidies to individual out-patients fall outside of scope of SCM Agreement, and that the European Union has made no showing that there is either a financial contribution to pharmacies, or an "indirect benefit" flowing through to pharmaceutical companies. In its second written submission, the European Union appears to clarify that it is only arguing that the reimbursements in question confer a direct benefit upon out-patients insofar as, and as part of its demonstration that, they confer an "indirect benefit" on enterprises. With a view to clarifying the scope of any remaining disagreement between the parties:

Is the Panel correct in its understanding that the European Union's argument under Article 3.1(b) is that the reimbursements in question confer a direct benefit upon out-patients insofar as, and as part of its demonstration that, they confer an "indirect benefit" on enterprises?

64. The European Union confirms that it does not argue that the financial contributions made to the out-patients, together with the direct benefits thereby conferred to out-patients constitute, in and of themselves, a subsidy within the scope of the ASCM.

65. Rather, the European Union argues that the financial contributions confer a direct benefit to the out-patients as part of its demonstration that, as a result, the same financial contributions also confer an indirect benefit to the Turkish producers of pharmaceutical products. It is well-established that the recipients of a financial contribution and direct beneficiaries of a subsidy may be different from the indirect beneficiaries. In such case, it is enough if the indirect benefits provided to the latter are within the scope of the SCM Agreement[34].

66. The European Union is unsure about what the question means when it states that

> the reimbursements in question confer a direct benefit upon out-patients insofar as […]they confer an 'indirect benefit' on enterprises" (*emphasis added*).

[34] See e.g. Panel Report, *Brazil – Aircraft (Article 21.5 – Canada II)*, para. 5.24 ff., where the financial contributions (the PROEX III payments) were made in support of export credits extended to the purchaser, and not to the producer, of Brazilian regional aircraft.

67. The existence of a direct benefit to the out-patients is not conditional upon the existence of an indirect benefit to enterprises. A different matter is whether such a direct benefit to the out-patients is legally relevant, in and of itself, for the purposes of the ASCM in the absence of any indirect benefit to enterprises.

Question 17

Turkey contends that "[a]ccording to the European Union, what makes the alleged subsidy contingent upon the use of domestic over imported products in the present case is the 'localisation requirement'. The localisation requirement (localisation measure) is addressed only to producers of pharmaceutical products and not to patients. It therefore does not impose any condition or requirement for the patients to use domestic over imported pharmaceutical products."[35]

Please respond to Turkey's contention. In particular, please comment on whether the localisation requirement, in and of itself, requires the use of any domestic over imported pharmaceutical products by out-patients as a condition for the grant of the alleged subsidy. If yes, please clarify whether that condition establishes contingency in fact, or contingency in law, for purposes of Article 3.1(b).

Please explain whether or not a condition requiring the use of domestic over imported pharmaceutical products by out-patients can be discerned from the terms of the localisation requirement itself, or inferred from the measure's design, structure, and modalities of operation. Please explain whether the localisation requirement implicitly or, by necessary implication, sets out such a condition.

68. The localisation requirement, in and of itself, requires the use of domestic over imported pharmaceutical products by out-patients as a condition for granting the subsidy. The existence of that condition can be inferred from the explicit terms of the measure at issue and, therefore, establishes "contingency in law".

69. The financial contributions which have been identified by the European Union, and hence the direct and indirect benefits conferred thereby, are conditional, as a matter of law, upon the out-patients who are beneficiaries of Turkey's Social Security system requesting, and being supplied by the pharmacies, a pharmaceutical product included in the Reimbursement List.

70. If an out-patient requests, and is supplied by the pharmacy, a pharmaceutical product not included in the Reimbursement List, the financial contributions identified by the European Union will not take place as a matter of law: the out-patient will not be supplied that pharmaceutical product unless it pays the full price; and the SSI will make no payment for that product to the pharmacy under the Reimbursement Scheme.

71. In turn, the inclusion of pharmaceutical products in the Reimbursement List is conditional, again as a matter of law, upon the product in question being produced

35 Turkey's first written submission, para. 405.

in Turkey. Like imported pharmaceutical products (i.e. imported products for which pharmaceutical companies have not made commitments to localise production in Turkey or whose commitments have been rejected), with the same or similar properties as domestically produced products, are legally excluded from the Reimbursement List.

Question 18

In its panel request, the European Union claimed that "certain elements, terms and conditions of general application" of the localisation requirement had not been published promptly.

(a) Is the Panel correct in its understanding that the European Union's claim under Article X:1 is directed at the non-publication of certain "terms and conditions" of the localisation requirement, as opposed to the localisation requirement "as a single measure", and as opposed to certain legal instruments or documents?

72. The European Union's claim is directed both at the non-publication of certain "terms and conditions" of the Localisation Requirement and, also, at the legal instruments and documents containing some key elements of the Localisation Requirement that were not in compliance with Article X:1.

73. First, as explained in the first written submission, the substantive and procedural elements of the Localisation Requirement have, for the most part, not been adequately published.[36]

74. For example, Turkey did not publish in any form the authorities' criteria for accepting or refusing commitments.

75. Second, the terms and conditions that Turkey did actually publish, were published in a manner inconsistent with Article X:1.

76. While the Turkish authorities published the various announcements on localisation, those announcements did not elaborate on the details of the localisation policy of pharmaceuticals and even those announcements were not published in an adequate way.[37]

77. A number of key elements of the Localisation Requirement were only included in various presentations by Turkish officials, the Roadmap for the Process of localization, the HSPC Decision and in private communications between the SSI

[36] European Union's first written submission, para. 252.
[37] Ibid., para. 253.

and/or TMMDA with the companies concerned, none of which have been adequately and promptly published.[38]

(b) If this is correct, please enumerate the "terms and conditions" of general application that should have been published, but which were not.

78. As explained,[39] the terms and conditions that Turkey should have published in manner compliant with Article X:1 are the following :

(a) the process and various steps that must be taken as part of localisation;

(b) the phases of localisation;

(c) the product categories to which those phases relate;

(d) various steps and deadlines for the submission of commitments, the information that should be included in the commitments or justifications on why commitments could not be made,

(e) the authorities' criteria for accepting or refusing commitments;

(f) the criteria, phases and deadlines for delisting or deactivate their products (as the case may be);

(g) instructions on the various steps to be followed (including follow up, possible updates or alternative commitments, variation applications);

(h) instructions for submitting progress reports.

Question 19:

To the European Union: According to the European Union, "[w]here the production of a pharmaceutical product has been localised in Turkey in accordance with the localisation requirement, applied in conjunction with the Turkish rules for approving the importation and marketing of pharmaceutical products, the importation of that pharmaceutical product is no longer permitted." In its panel request and first written submission, the European Union refers to this second measure at issue as "the import ban".

(a) Is the measure being challenged (i) the Turkish rules for approving the importation and marketing of pharmaceutical products per se, or (ii) the localisation requirement as "applied in conjunction" with those rules?

(b) If the localisation requirement did not exist, and/or were withdrawn or otherwise brought into conformity with Turkey's obligations under the GATT 1994, would the rules for the importation and marketing of pharmaceutical products still be inconsistent with Article XI:1?

79. The European Union recalls that the challenged measure is the Localisation Requirement as "applied in conjunction" with the rules for approving the importation and marketing of pharmaceutical products.

80. The panel request and the European Union's submissions confirm the above:

[38] Ibid., paras. 254-256.

[39] European Union's second written submission, paras. 130-134.

i. Section 3.1 of the panel request sets out that: even in certain cases where imported products are not excluded from the reimbursement scheme by virtue of the localisation requirement, Turkey gives priority to the review of applications for inclusion of domestic pharmaceutical products in the list of products covered by the reimbursement scheme, as well as with respect to any pricing and licensing policies and processes, over the review of the applications of like imported products.

ii. The first written submission: By this measure, when the production of a pharmaceutical product has been localised in Turkey in accordance with the Localisation Requirement, applied in conjunction with the Turkish rules for approving the importation and marketing of pharmaceutical products, that pharmaceutical product can no longer be imported in Turkey."[40] or "Therefore, to the extent that a pharmaceutical product has been localised in Turkey in accordance with the Localisation Requirement, it can no longer be imported.[41]

iii. The second written submission: As explained in the first written submission, the Import Ban measure prohibits the importation of those pharmaceutical products whose production has been localised in Turkey in accordance with the Localisation Requirement.[42]

81. Regarding the question under b), the European Union points out that it did not challenge the rules for the importation and marketing of pharmaceutical products on their own (*per se*), in the absence of the Localisation Requirement.

82. However, for the sake of argument, it can be noted that Article 20(2) of the Regulation on the Marketing Authorisation of Medicinal Products for Human Use provides that a second import authorization is not granted to "*for any product with the same formulation and pharmaceutical form, already authorized by the Ministry, to the same real person or legal entity, even if the product has a different commercial name*" regardless of whether the product is localised or not. Therefore, it appears *prima facie* that the rules for the importation and marketing of pharmaceutical products enact an import ban, at odds with Article XI:1, once the products are manufactured domestically.

Question 20.

To the European Union: In its second written submission, Turkey asserts that "while Article 20 of the Marketing Authorization Regulation prevents the same real person or legal entity from getting a second marketing authorization for a product with the same

[40] European Union's first written submission, para. 300.

[41] European Union's first written submission, para. 304.

[42] European Union's second written submission, para. 284.

qualitative and quantitative composition and the same pharmaceutical form, nothing prevents the applicant requesting a marketing authorization "from referring to different production sites in its application for marketing authorization" and "[i]n fact, the application form must indicate 'the sites involved in the different stages of the manufacture' of the medicines for which a marketing authorization is requested". Thus, Turkey concludes, "there may be more than one production site indicated". How does the European Union respond?

83. The European Union submits that even if marketing authorizations were to indicate the manufacturing site or sites, this is not relevant for assessing the existence of the Import Ban.

84. Specifically, Article 20(2) of the Marketing Authorization Regulation provides that:

> A second local or import marketing authorisation shall not be granted for any product with the same formulation and pharmaceutical form, already authorized by the Ministry, to the same real person or legal entity.

85. It follows that a marketing authorization can either be: i. an authorization for production in Turkey, which has to be obtained for producing medicine in Turkey; or ii. an authorization for import into Turkey, which has to be obtained for importing medicine into Turkey. Under each type of marketing authorizations, more than one production facilities can be listed, i.e., a producer can list different production facilities in its local production marketing authorization application, all of which are located in Turkey. Similarly, a producer outside of Turkey can list different production facilities in its import marketing authorization application, all of which are located outside Turkey. This means that the same marketing authorization cannot register both a local and a foreign manufacturing site because they require different marketing authorizations. Otherwise, Article 20(2) would become inapplicable because pharmaceutical companies could easily register new manufacturing sites on their existing marketing authorisation.

86. For completeness, as explained, sister companies cannot obtain a second (import) marketing authorization for the localised product.[43]

87. In this respect, Article 8 o) of the Regulation on Marketing Authorisation requires demonstrating that a sole company is authorized to import, register and sell a pharmaceutical product, except for co-marketing:

> In the case of an imported product, a document showing that the importing real person or legal entity is the sole representative authorized for importing, registering and selling the subject product in Turkey, and in the case of comarketing, a document issued by the licensor showing that a real person or legal entity other than the sole authorized representative in Turkey is also

[43] European Union's second written submission, paras. 275-276.

> granted co-marketing authorization, along with a Turkish translation thereof, and the written consents issued by the real persons or legal entities with regard to the co-marketing arrangement between such real persons or legal entities to undertake such co-marketing activity.[44]

Article 8 ö) contains similar provisions for companies manufacturing on license.

88. It follows from the above provisions, read together with the abovementioned Article 20 of the Marketing Authorization Regulation, that the very same product may not have both a local production marketing authorization and an import marketing authorization at the same time, regardless of applications made by sister companies.

89. In any event, even if a sister company were able to obtain an import marketing authorization (*quod non*), the Import Ban in such a form would still be inconsistent with Article XI:1 of the GATT 1994 as it has a limiting effect on importation.

90. First, the pharmaceutical company whose product was localised could not import that product for which a local marketing authorisation was granted (product with the same formulation and pharmaceutical form, already authorized by the Ministry, to the same real person or legal entity).[45]

91. Second, this hypothetical layout of the Import Ban would constitute in any event an additional burden on importation on for pharmaceutical companies. Pharmaceutical companies manufacturing domestically would be required to set up a sister company and to apply for a separate (import) marketing authorization. Moreover, the sister company would be required to apply for all the other administrative authorizations (the GMP certificate, inspection certificate for importation, sales permission, registration of the product in the Pharmaceutical Tracking System; request the approval of prices by the Ministry of Health, Price Evaluation Commission). These additional requirements would be costly, generate considerable delays, and would thus limit the competitive opportunities available to imported products and have limiting effects on the importation of products. In this respect, panels established that nullification or impairment arises from prohibited quantitative restrictions, not only due to effects on trade volumes, but

[44] Annex EU-89.

[45] European Union's second written submission, para. 272.

also because importers investment plans would be affected negatively and transaction costs would increase.[46]

92. Finally, the alleged possibility to obtain a second marketing authorization for different indications (i.e. for different diseases) of a localised product is contradicted by the functioning of the Localisation Requirement. The latter applies to pharmaceutical products irrespective of their indications. It is noteworthy that the Reimbursement List does not distinguish between the indications of each pharmaceutical product listed.[47] If no commitments are given, if the commitments are refused or if they are not fulfilled, the respective pharmaceutical products are deactivated from the Reimbursement List for all their indications. Leaving aside the different composition or form of a product, as explained, a marketing authorization may cover several indications.[48] The marketing authorization provided by Turkey as an example does not specify the indications covered by the respective product either.[49] Turkey has failed to adduce sufficient evidence to prove this claim.

93. In any event, even if the abovementioned possibility were to exist (*quod non*), the Import Ban would still apply with respect to the localised product insofar the localised indication.

Question 22:

Turkey argues that the import ban measure is an "internal measure" that falls outside the scope of Article XI. Addressing this argument in the terms of Article XI:1, please explain how the import ban measure does or does not amount to a "restriction" "on importation" of localised pharmaceutical products.

94. The WTO jurisprudence established that "any form of limitation imposed on, or in relation to importation constitutes a restriction on importation within the meaning of Article XI:1."[50]

95. The European Union reiterates[51] that the Import Ban prohibits the importation of those pharmaceutical products whose production has been localised in Turkey in accordance with the Localisation Requirement. The lack of an import marketing

[46] Panel Report, *Colombia –Ports of Entry*, para. 7.236.

[47] Exhibit EU-102

[48] European Union's second written submission, para. 278.

[49] Exhibit TUR-132.

[50] Panel Report, *India – Autos*, para. 7.265.

[51] European Union's second written submission, para. 284.

authorisation for a particular pharmaceutical products leads to the impossibility to import that product because an import marketing authorisation is a prerequisite for the inspection certificate required for the customs procedure. An inspection certificate is required for importing a number of pharmaceutical products into Turkey. The importer is required to submit the inspection certificate when making a customs declaration at customs offices.

96. The fact that the Import Ban entails the impossibility to obtain an *import* marketing authorization is revealing that this measure is a prohibition on importation.

97. It follows that the Import Ban constitutes a prohibition in importation of localised pharmaceutical products. The fact that marketing authorization rules also regulates domestic products cannot render Article XI:1 of the GATT 1994 inapplicable. Even accepting Turkey's argument that a sister company could import the localised pharmaceutical products, as explained above, this would still be a restriction on importation under Article XI:1.

Question 23 :

In its second written submission, Turkey notes that the European Union does not dispute Turkey's description of the prioritization measure as "an ongoing conduct or practice of general application", but still fails to provide any evidence that Turkey "effectively gives" priority to domestic pharmaceutical products over imported products. How does the European Union respond?

(a) Specifically, is the European Union challenging the prioritisation measure as "ongoing conduct" and/or a "practice"? If not, what is it challenging?

(b) What is the relevance of discretion in decision-making in establishing the existence of the prioritisation measure insofar as the European Union is challenging "ongoing conduct" and/or a "practice"?

98. The European Union recalls[52] that it challenged the Prioritization Measure as a measure of general and prospective application and not as one or more specific instances of the application of such a measure or an ongoing conduct.[53]

[52] Response of the European Union to Turkey's request for a preliminary ruling, para. 71.

[53] In *US – Continued Zeroing*, the Appellate Body concluded that the USDOC's "continued use" of "zeroing" to calculate the margins of dumping in 18 different anti-dumping proceedings could be challenged as a "measure" it described as "ongoing conduct", Appellate Body Report, *US–Continued Zeroing*, paras. 180-181.

99. The European Union's submissions show that it challenged as such the various legal instruments supporting the Prioritization measure:

    i. the Prioritization Measure is imposed through a number of legal instruments, namely the SSI Regulation on Drug Reimbursement setting out the priority given to the review of applications for listing for reimbursement and the Priority Assessment Guideline setting out the priority given to the review of applications for GMP and market authorisation;[54]

    ii. it is clear from the terms, design, structure, and expected operation of the Prioritization Measure that it is a *de iure* discriminatory measure, and that, by its very nature, it accords less favourable treatment to imports;[55]

    iii. it is not required to show that Turkey effectively gives priority to domestic pharmaceutical products over imported ones.[56]

100. The European Union does not try to prove the actual conduct of the Turkish authorities when treating applications relating to domestically manufactured products for reimbursement, pricing policies, and licensing procedures.

101. According to Turkey, the European Union appears to describe the Prioritization Measure as a conduct or a practice, i.e. the fact that Turkey gives priority to the review of applications for inclusion of domestic pharmaceutical products over the review of the applications of like imported products.[57] In this respect, it is alleged that the European Union is required to prove that Turkey effectively gives priority to domestic pharmaceutical products over imported products.[58]

102. Turkey's arguments are irrelevant because, as explained, the European Union did not challenge the Prioritization Measure as an ongoing conduct. The mere description of the Prioritization Measure as a measure giving priority to the review of applications relating to domestic pharmaceutical products[59] does not classify this measure as "ongoing conduct" for which the European Union would be required to show an effective application by Turkish authorities. This description simply reflect that the various action plans, programmes and legal instruments

[54] European Union's first written submission, para. 371.

[55] European Union's first written submission, para. 379.

[56] European Union's second written submission, para. 308.

[57] Turkey's first written submission, paras. 664-677.

[58] Turkey's second written submission, paras. 303-304.

[59] European Union's first written submission, para. 322.

underpinning the Prioritization Measure seek to grant priority to the review of applications regarding domestic pharmaceutical products inclusion in the reimbursement scheme, and to the review of GMP and marketing authorisation applications.

103. Since the European Union did not challenge that Import Ban as "ongoing conduct" and/or a "practice", it does not need to reply to the question under b).

104. In any event, the European Union explained[60] that Turkish legislation does not grant discretion to the relevant authorities but :

    i. mandates listing pharmaceutical products manufactured in Turkey on the agenda of the Medical and Economic Assessment Committee and of the Drug Reimbursement Committee as prioritized topics for review to be include in the Reimbursement List and that these Committees hold extraordinary meetings for that purpose;

    ii. the Priority Assessment Guideline enables giving priority, *inter alia*, to applications regarding pharmaceutical products manufactured in Turkey.

105. No such possibility exist for imported products that are like local products. It must be recalled that demonstrating "less favourable treatment" does not require proof of actual effects of the Import Ban. In any event, Turkey's actions plans and programmes confirm that it grants priority to domestically produced pharmaceutical products for reimbursement, pricing policies and licensing procedures.[61]

[60] European Union's second written submission, paras. 301-308. European Union's first written submission, paras. 376-381.

[61] European Union's second written submission, para. 304.