In the World Trade Organization

Panel Proceedings

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

(DS583)

Second Written Submission

by the European Union

Geneva, 30 October 2020

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Argentina – Import Measures	Panel Reports, *Argentina – Measures Affecting the Importation of Goods*, WT/DS438/R and Add.1 / WT/DS444/R and Add.1 / WT/DS445/R and Add.1, adopted 26 January 2015, as modified (WT/DS438/R) and upheld (WT/DS444/R / WT/DS445/R) by Appellate Body Reports WT/DS438/AB/R / WT/DS444/AB/R / WT/DS445/AB/R, DSR 2015:II, p. 783
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US – Upland Cotton	Article 22.6 DSU Arbitration Decision, WT/DS267/ARB/1 31 August 2009

TABLE OF ABBREVIATIONS

Abbreviation	Full Name
AIFD	Association of Research-Based Pharmaceutical Companies
EU	European Union
FIT Programme	Feed-In Tariff Program
FWS	First Written Submission
GATT 1994	General Agreement on Tariffs and Trade 1994
GMP	Good Manufacturing Practices
HISC	Healthcare Industries Steering Committee
HMPPAC	Human Medicinal Products Priority Assessment
HSPC	Healthcare Services Pricing Commission
IEIS	Union of Employers in Pharmaceuticals Industry
IRH	Implementing Regulation for Healthcare
SCM Agreement	Agreement on Subsidies and Countervailing Measures
SGK	Social Security Institution
SSI	Turkey's Social Security Institution
SUT	Sağlık Uygulama Tebliği (TR)
TEB	Turkish Pharmacists' Association
TMMDA	Turkish Medicines and Medical Devices Agency
TRIMs Agreement	Agreement on Trade-Related Investment Measures
WHO	World Health Organization
WTO	World Trade Organization

TABLE OF EXHIBITS

Exhibit No.	Title
EU-103	Turkish language version of Exhibit EU-76 (TMMDA and SSI communication to Bayer Türk Kimya San rejecting proposed commitments, Annex V to Defense by the SSI in court proceedings raised by the Association of Research-Based Pharmaceutical Companies (AIFD) before the Turkish State Council, Case 2017/1308, 29 June 2017)
EU-104	Article on the SSI's website entitled "27 İlacı Daha Geri Ödeme Listesine Aldık" ("We have included 27 medicines in the Reimbursement List")
EU-105	Daily Sabah, article entitled "Turkey reimburses about 8,500 drugs, including rare medicines", 15 June 2020
EU-106	Dictionary entry for "temin"
EU-107	Dictionary entry for "bedel"
EU-108	Dictionary entry for "görüşme"
EU-109	SSI's Activity Report 2018 (in Turkish, with excerpts in English)
EU-110	SSI's Activity Report for 2019 (in Turkish, with excerpts in English)
EU-111	TMMDA Administrative Operation Report 2019 (in Turkish, with excerpts in English)
EU-112	TMMDA Administrative Operation Report for 2018 (in Turkish)
EU-113	Comparison of sales levels for de-activated pharmaceutical products, 2018 to 2019
EU-114	WHO, Pharmaceutical Production and Related Technology Transfer (2011)
EU-115	WHO, 69th World Health Assembly, 28 May 2016, WHA 69. 25, Addressing the global shortage of medicines and vaccines
EU-116	WHO, Local Production for Access to Medical Products: Developing a Framework to Improve Public Health (2011)
EU-117	Report on the Turkish healthcare market, September 2020
EU-118	Comparison between applications for priority granted for imported and domestic products

1. INTRODUCTION

1. In this submission, the EU will respond to the arguments in Turkey's first written submission. On all points, Turkey's arguments must be rejected. The EU has demonstrated that all of the measures at issue exist and are inconsistent with the cited provisions of the covered agreements, and Turkey has failed to rebut those claims. On many points, in fact, Turkey essentially confirms the EU's argument.

2. The EU addresses, in turn, the Localisation Requirement (section 2), the Import Ban on localised products (section 3), and the Prioritisation Measure (section 4).

2. THE LOCALISATION REQUIREMENT

2.1. INTRODUCTION

3. In its attempts at avoiding scrutiny of the Localisation Requirement under the GATT 1994, Turkey's strategy is, essentially, twofold.

4. First, Turkey seeks to cast doubt on the EU's demonstration of the existence and precise content of that measure. This attempt must fail, because Turkey itself has no choice but to agree that the measure exists, and to confirm the EU's description of most of its essential features.

5. Second, Turkey tries to present the facts in such a way as to create the impression that its reimbursement system for out-patient pharmaceuticals somehow constitutes the direct provision of pharmaceutical products by the government, in order to bolster its argument under Article III:8(a) of the GATT 1994. To this end, Turkey misrepresents the facts and stretches the law. This attempt, too, cannot succeed.

2.2. FACTUAL BACKGROUND

6. In the following sections, the EU will first address Turkey's objections regarding the EU's exhibits and the EU's translations. Then, it will respond to Turkey's claim that the existence and precise content has not been demonstrated.

7. Following this, the EU responds to a number of factual points in which Turkey's first written submission misrepresents the facts or otherwise falls short of a correct presentation.

2.2.1. Turkey's comments on the European Union's exhibits

8. In its first written submission, Turkey claims that it is essential for it to receive a Turkish language version of certain exhibits provided by the European Union.[1]

9. There is no requirement to submit bilingual exhibits. Nor has Turkey made any specific allegation against the accuracy or probative value of the exhibits that are not accompanied by a Turkish language version. Furthermore, the vast majority of the EU's more than one hundred exhibits confirm that every reasonable effort has been made to submit a Turkish version wherever possible.

10. Regarding the specific exhibits Turkey refers to, the EU responds as follows.

11. Exhibit EU-35 is an English translation of the HSPC Decision regarding the Localization Process of October 2016. This decision is, of course, well known to Turkish authorities. It was frequently attached to various communications addressed by them to interested parties and other official documents.[2] A Turkish language version of it was also submitted by the EU in Exhibit EU-46, where it appears as an annex to a 2017 TMMDA and SSI communication.

12. Exhibit EU-76 is a TMMDA and SSI communication to Bayer Türk Kimya San rejecting proposed commitments, filed as Annex V to the SSI's defense in domestic court proceedings before the Turkish State Council. This document is also in Turkey's possession. Nevertheless, to be as helpful as possible, the EU hereby submits a Turkish language version of the document.[3]

13. With respect to the remaining exhibits Turkey raises (EU-66, EU-70, EU-74, EU-75, EU-80 and EU-83), the EU has not submitted a Turkish language version because it was not authorised to do so. In several instances, what the EU received from the companies concerned for purposes of submission to the panel was a redacted translation only. In two instances, what the companies provided was a synopsis (EU-80, EU-83). As the EU explained, the reason for these redactions was the companies' concern that they might be exposed to retaliation or other adverse consequences, as their identity

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1 Turkey's first written submission, para. 16.

2 EU's first written submission, paras. 141, 148 and footnotes 137 and 138.

3 Turkish language version of Exhibit EU-76 (Exhibit EU-103).

could be deduced from the original or integral documents.[4] The EU has taken every possible step to assure itself of the correctness and authenticity of each of these documents.

14. In any event, the purpose of submitting such documents into evidence is not to identify the details, such as the name of the company or the product concerned, or the time and place of a meeting with Turkish authorities, but to exemplify certain types of actions taken by Turkish authorities. In that respect, Turkey does not dispute that its authorities have included additional products into the second phase of localisation and organised meetings with the companies concerned for that purpose[5] (as confirmed by Exhibit TUR-59; organised meetings concerning the localisation of products in the scope of the third phase of localisation;[6] de-activated products from the Reimbursement List where no localisation commitments were given;[7] cancelled the de-activation of products when commitments were given;[8] accepted localisation commitments (as confirmed by exhibit TUR-55);[9] and confirmed that certain products are outside the scope of localisation (as does exhibit TUR-54).[10]

2.2.2. Turkey's comments on translation

15. Throughout its submission, Turkey takes issue with the translation of certain Turkish terms. Turkey argues that, in some of its exhibits, the EU has provided "an erroneous or misleading translation with a view to skew the Panel's opinion".[11] This is incorrect. The EU has invested significant time and resources, working with professional translation services, in order to ensure that its translation of Turkish documents is rigorous and true to the original. While mistakes are always possible, nothing in the EU's translations supports Turkey's allegation that the EU was attempting to mislead the Panel. Instead, it is Turkey that is attempting to "skew the Panel's opinion" by providing tendentious, stretched or plainly incorrect translations that are

4 EU's first written submission, para. 101, footnotes 179 and 184.

5 Exhibit EU-66.

6 Exhibit EU-70.

7 Exhibit EU-74.

8 Exhibit EU-75.

9 Exhibit EU-80.

10 Exhibit EU-83.

11 Turkey's first written submission, para. 17.

a poor fit with the original, but may seem to lend some support to Turkey's arguments.

16. One example is Turkey's objection to the term "reimbursement list" in the title of Annex 4/A (*Bedeli Ödenecek İlaçlar listesi*); Turkey instead prefers "list of medicines to be paid for".[12] Turkey's translation is literal and artificial. The purpose of a translation is to convey the same meaning as the original, and not to just convert text literally word for word, which is in any event impossible given that there is no neat one-on-one correspondence between words in different languages.

17. First, there are many possible renditions of *bedel* in English, including "price", "return", "consideration", "compensation" and "remuneration".[13] Second, throughout its submissions and exhibits, Turkey itself translates the word *ödeme* as either "reimbursement" or "payment", as it suits Turkey.[14] Third, Turkey itself refers interchangeably to this list as "the list of medicines *paid for* by the SSI" and "the list of medicines *to be paid for* by the SSI".[15] Fourth, in its own first written submission, Turkey refers to the Annex 4/A list as the "reimbursement list". Thus, at para. 696 Turkey states:

> "Figures show that, for each application period, the time between application and inclusion in the *reimbursement list* for domestically manufactured products does not meaningfully differ from the time between application and inclusion for imported products…"[16]

18. Similarly, at para. 350 Turkey refers to its "reimbursement scheme":

> "The *reimbursement scheme* considered in its totality is aimed at ensuring the availability and affordability of pharmaceutical products for out-patients in Turkey."

19. Another accurate rendering could be, for example, "*List of Reimbursable Medicines*". Even if one translated as literally as possible ("the list of medicines *the price of which is to be paid*"), we would simply come full circle, back to the concept of reimbursement of pharmaceutical products by the SSI.

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12 Turkey's first written submission, para. 66 and Exhibit TUR-27, compared to Exhibits EU-51 and EU-102.

13 Dictionary entry for "bedel" (Exhibit EU-107).

14 In Exhibit TUR-11, in Article 1(1)(g), the word "ödeme" appears to have been translated as "payment" even though Turkey itself elsewhere (including the heading of that provision) translates it as "reimbursement".

15 Turkey's first written submission, paras. 55 and 623.

16 See also Exhibit TUR-64.

20. Turkey's proposal also disregards the context of the translated terms, and numerous explicit references to the list as the "Reimbursement List" by Turkish authorities. The Turkish authority that decides to place products on the list in question or remove them from it is called (as Turkey accepts[17]) the Drug *Reimbursement* Commission. In deciding on these matters, Turkish authorities apply an instrument entitled "the Social Security Institution's Drug *Reimbursement* Regulation".[18]

21. Also, the title "Reimbursement list" is commonly used for the list in question by Turkish authorities and others in Turkey. For example, the Minister of Family, Labour and Social Services Ms. Selçuk referred to the annexes of the IRH (SUT) as "reimbursement lists" in an article on the SSI's website entitled "27 İlacı Daha Geri Ödeme Listesine Aldık" ("We have included 27 medicines in the Reimbursement List").[19] Moreover, the EU has already submitted evidence of Turkish authorities referring to the Annex 4/A list as the "Reimbursement list" (*Geri Ödeme listesi*).[20] Turkey itself has submitted evidence that uses the same language.[21] Indeed, in an exhibit expressly prepared to correct alleged EU translation errors, which claims to be "prepared by a certified translator", containing the "Localisation process road map", the term "reimbursement list" is used.[22] Finally, a leading Turkish daily newspaper, on its English language website, refers to the "list of drugs eligible for reimbursement", and explains that Turkey "reimburses" those drugs.[23]

22. Turkey also claims that the word *temin* should not be translated as "procurement" but as "provision". Thus, instead of "Protocol on the Procurement of Medicines from Pharmacies which are Members of the Turkish Pharmacists' Association by Persons Covered by the SSI" (Exhibit EU-52), Turkey proposes "Protocol on the Provision of Medicines to the

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17 Turkey's first written submission, para. 76.

18 Exhibit EU-8.

19 Exhibit EU-104.

20 Presentation entitled "Pharmaceutical Localisation Project Work Conducted by the Ministry of Health", given by representatives of the TMMDA, December 2017 (Exhibit EU-23), Turkish language version of slide 14, right-hand box; Presentation entitled "Local Production", delivered at the Symposium on Rational Approach to Current Issues concerning Medicines, Ankara, 7-9 October 2016 (Exhibit EU-40), Turkish language version of slide 9 ("Gecis planinin olusturulmasi"), lower left-hand box.

21 Exhibit TUR-99 Press article, Shortage of Supply in This Medicine, Sağlık Aktüel, 23 August 2012 refers to the "'reimbursement' list".

22 Exhibit TUR-60, p. 1.

23 Daily Sabah, article entitled "Turkey reimburses about 8,500 drugs, including rare medicines", 15 June 2020, Exhibit EU-105.

Persons Covered by the Social Security Institution by the Pharmacies which are Members of the Turkish Pharmacists' Association" (Exhibit TUR-20). This is a transparent attempt to make the words mean whatever serves Turkey's argument (i.e. Turkish authorities are simply "providing" medicines to patients without any reimbursement). By contrast, the EU's proposed translation of the word "temin" ("procurement") does not particularly serve the EU's argument, but is neutral. In fact, the word *temin* has a number of possible renderings in English, including "procurement". [24]

23. Exhibit TUR-11 (a competing translation of the Social Security Institution Regulation on Drug Reimbursement, 10 February 2016, Exhibit EU-8) contains a number of errors, some of which may be telling. Thus, in Article 1(1)(d), the words "imalat" and "ithalat" (meaning, respectively, "manufacturing" and "import") appears to be wrongly translated as "import or export". In Articles 5(1)(g) and 9(c), Turkey's translation conveniently omits the word "locally" where the EU's translation reflects the clear content of the provision: "locally manufactured" products receive priority treatment when assessing applications for inclusion in the Reimbursement List.

24. With respect to what the EU has described as "de-activation" of products on the Reimbursement List, Turkey uses the term "passivise" or "passivate".[25] While there does not seem to be a substantive disagreement here, in the EU's view, the term "de-activate" better conveys the meaning of "pasiflenmek" in this context.

25. Turkey also claims that the term "*görüşme*" should be translated as "meeting" or "discussion, not as "negotiation".[26] In fact, the term *görüşme* has a wide range of possible renderings, including interview, meeting, talk, discussion, debate, dialogue, conference, deliberation, bargaining, negotiation, conversation, hearing etc.[27] In any event, it is not clear to the EU to what extent this is relevant or how it helps Turkey. It may very well be the case that, in practice, little or no actual "negotiation" occurs in meetings between Turkish authorities and the companies threatened by localisation, but that it is rather a "meeting" in which companies are informed of the measures that will be imposed on them, of the timeline for

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[24] Dictionary entry for "temin" (Exhibit EU-106).

[25] Exhibit TUR-58, cover page.

[26] Compare Exhibits EU-45 and TUR-60.

[27] Dictionary entry for *görüşme* (Exhibit EU-108).

compliance and the consequences of non-compliance. But this would not seem to be particularly helpful to Turkey's position.

2.2.3. The European Union has clearly demonstrated, and Turkey confirms, the "existence and precise content" of the Localisation Requirement

26. Turkey argues that the EU has "failed to establish the existence and precise content" of the Localisation Requirement. In essence, Turkey complains that the measure consists of different elements or components, but that the EU allegedly failed to explain in sufficient detail how those elements operate together, which means, according to Turkey, that the "existence and precise content" of the measure are not shown.[28]

27. Turkey errs. The EU has explained in great detail, based on extensive evidence, what the components of the measure are and how they interrelate. It is unclear from Turkey's submission what sort of explanation Turkey would like, or what it considers to be lacking.

28. There is no requirement for a complainant to separately list or qualify each of the "components" of a measure, or explain how each of them relates to all of the others. Turkey reads the Appellate Body report in *Argentina – Import Measures* as supporting such a requirement. However, the Appellate Body simply stated that "the constituent elements that must be substantiated with evidence and arguments in order to prove the existence of a measure challenged will be informed by how such measure is described or characterized by the complainant", and added, by way of illustration, that "for instance, a complainant challenging a single measure composed of several different instruments will normally need to provide evidence of how the different components operate together as part of a single measure and how a single measure exists as distinct from its components".[29]

29. The live issue, for the Appellate Body, was whether or not several "components" are sufficiently related, or operate together, such that they can be described as a single measure as opposed to several *different* measures. The Appellate Body did not set out a requirement to provide, in exhaustive detail, a legal and factual characterisation of each element of a measure and how it relates to all of the others. The issue of explaining how

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[28] Turkey's first written submission, section VI.A.

[29] Appellate Body Report, *Argentina – Import Measures*, para. 5.108.

different components of a measure operate together does not present itself in this case, because (as the EU will explain below) it is undisputed that the Localisation Requirement exists as a measure in its own right, and that the various elements cited by the EU form part of it or of its implementation.

30. Much less does the requirement proposed by Turkey apply to the evidence provided in support of the EU's claims. For example, the October 2016 presentation Turkey complains of is *evidence* that demonstrates the existence and precise content of the measure. [30] A number of elements or characteristics of the measure (such as its timing or the phases of localisation) have not been otherwise published in a legal instrument or a general nature. The presentation therefore demonstrates a number of actions that are planned or taken as part of the Localisation Requirement and in order to implement the Localisation Requirement, as publicly explained by a representative of the Turkish authorities in charge of implementing that measure. With respect to Article X of the GATT 1994 in particular, the fact that those actions exist without having been properly published is clearly relevant.

31. While the EU and Turkey obviously disagree on a number of factual aspects as well as on the legal characterisation of the measure, the existence and precise content of the Localisation Requirement are in fact undisputed. Turkey clearly accepts that this measure exists. In fact, it doubles down by explaining how solidly it is based in Turkish law.

32. Thus, Turkey states:

> "…the so-called localisation measure, which constitutes the core of the European Union's challenge, is an *essential part* of the procurement process of pharmaceutical products purchased and provided by the SSI to patients in Turkey in the discharge of its public function, namely the provision of healthcare services to the Turkish population."[31]
>
> "…the purchase of only domestically produced medicines in certain groups of medicines, falling under different phases of localisation, by the SSI *has been decided by the Turkish government*. While implementing this policy, a transition period has been accorded to the pharmaceutical companies that have been willing to bring the production of their

[30] Turkey's first written submission, para. 120.

[31] Turkey's first written submission, para. 6.

pharmaceutical products falling under those phases to Turkey."[32] (emphasis added)

33. Furthermore, Turkey agrees with the main factual elements of the Localisation Requirement and Turkey's reimbursement system for out-patient pharmaceuticals, as described by the EU. Thus, for example, it agrees that:

- products may be de-activated or "passivized"[33], including as "a result of the localisation measure";[34]
- pharmacies invoice the SSI for the price of the medicines they supplied to patients as well as other fees;[35]
- on top of the reimbursed price, patients must pay a "contribution fee" and a "prescription fee" to pharmacies in order to receive the medicines;[36]
- medicines are provided to in-patients directly, through a system that differs from the one at issue in this dispute;[37]
- the Localisation Requirement "derives from" several high-level instruments adopted by the Turkish Government, corresponding to those cited by the EU;[38]
- the Localisation Requirement "entails production activities in Turkey"[39];
- the TMMDA selects which imported products will be subject to localisation[40];
- the measure is implemented in five phases without a set timeline, two of which have already been implemented, as described by the EU[41];
- various Turkish authorities including the TMMDA, the HISC, the Localisation Assessment Commission and the SSI are "involved in the implementation of the localisation measure";[42]

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32 Turkey's first written submission, para. 136.

33 Turkey's first written submission, para. 79.

34 Turkey's first written submission, para. 82.

35 Turkey's first written submission, para. 108.

36 Turkey's first written submission, para. 110.

37 Turkey's first written submission, para. 111-114.

38 Turkey's first written submission, para. 128-135.

39 Turkey's first written submission, para. 137.

40 Turkey's first written submission, para. 138.

41 Turkey's first written submission, para. 139-140.

42 Turkey's first written submission, para. 142.

- all reimbursable medicines (i.e. all pharmaceutical products with a valid marketing authorization and sales permit included in Annex 4/A) are "subject to localisation", i.e. initially considered within the scope of localisation";[43]
- the TMMDA identifies the companies whose products are subject to localisation, informs them of possible de-activation, invites them to submit commitments (i.e. "a declaration whether or not a pharmaceutical company will relocate within a specified period of time the production of the relevant pharmaceutical products to Turkey";)[44]
- if those commitments are accepted, variation applications must be submitted;[45]
- companies must submit progress reports, and may request additional time, or the localisation of an alternative product;[46]
- if there is no localisation commitment, a period of one year is accorded to the company to "reconsider its position"; if it does not, or if its commitment has not been accepted or fulfilled, the products will be "passivized" or de-activated;[47]
- the status of a product as activated or de-activated may be updated;[48]
- the different phases have been implemented according to a timeline, which by and large corresponds to the evidence set out by the EU (while Turkey disagrees that all phases should be considered as ongoing, pointing out that Phases 3 and 4 have so far not been implemented, it does accept that there is no set timeline, that products have been shifted from Phases 3, 4 or 5 to Phases 1 or 2, and presumably also that Phases 3 and onwards have not been cancelled, such that they continue to exist as parts of the measure).[49]

34. With all this in mind, it is unclear to the EU how there can still be any dispute as to the existence and content of the measure at issue. None of the specific factual objections raised by Turkey would mean that the measure,

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43 Turkey's first written submission, para. 138.

44 Turkey's first written submission, para. 148-149.

45 Turkey's first written submission, para. 150.

46 Turkey's first written submission, para. 151.

47 Turkey's first written submission, para. 152-153.

48 Turkey's first written submission, para. 154.

49 Turkey's first written submission, para. 155-163

as challenged, does not exist. Rather, there is a difference in the emphasis given to particular facts, the meaning of certain facts, and above all in the legal characterisation of the measure. The EU addresses those issues in the following section.

2.2.4. Turkey misrepresents a number of facts concerning the Localisation Requirement and the reimbursement system for out-patient pharmaceuticals

2.2.4.1 Whether pharmaceutical products are "regular goods" and whether their sales are "commercial transactions" are not pertinent questions

35. Turkey emphasises time and again that the products at issue are not "regular goods", that patients are not consumers, and that the sales of medicines to patients by pharmacies are not ordinary commercial transactions, but are heavily regulated, in particular to ensure safety.[50]

36. This is a classic straw man argument. The EU has not disputed that pharmaceutical products are, and should be, heavily regulated, including in terms of price. Nor has the EU claimed that prescription medicines are like any other product. Clearly, in Turkey and elsewhere, these products are strictly regulated and can only be legally obtained on the basis of a prescription from a medical doctor. Clearly, the distribution and marketing of those products is strictly framed by the health insurance scheme in force. Disputing any of these points would be dishonest, since they hold true in the EU and all of its Member States.

37. More importantly, disputing them would have been pointless, as nothing in the EU's argument depends on them.

38. Article III:8(a) of the GATT 1994 sets a dividing line between situations to which the national treatment rule applies and those to which it does not. However, the dividing line is not what Turkey would like it to be. The national treatment rule is not limited to "purely commercial" transactions, to unregulated sectors, or to sectors other than health. Instead, Article III:8(a) carves out certain very carefully defined measures from the national treatment rule: "laws, regulations or requirements governing the procurement by governmental agencies of products purchased for governmental purposes and not with a view to commercial resale or with a view to use in the production of goods for commercial sale". To avail itself of

[50] See, for example, Turkey's first written submission, para. 20.

Article III:8(a), Turkey must demonstrate that its measure ticks all of the boxes of that provision. Failing that (and, as the EU has explained and will further explain below, Turkey has failed), Turkey can attempt to justify the measure on the basis of Article XX. Neither for the purposes of Article III:8(a), nor for the purposes of Article XX, would it be even remotely enough to show that the measure is a "public health" measure, or that the product at issue is "heavily regulated", or "not ordinary".

39. Thus, while it is true that "WTO Members should be free to organize their social security and healthcare system"[51], this does not mean that they are "free" to breach their WTO obligations in the process.

2.2.4.2 The Localisation Requirement plainly has a restrictive impact on the access of pharmaceutical products to the Turkish market

40. Turkey claims that "any measure taken with respect to the functioning of the social security system, including its scope, have no impact on the access of pharmaceutical products to the Turkish market".[52] This is an extraordinary statement. Perhaps Turkey has a peculiar definition of what "market access" means. To the EU, it is clear that reimbursing the price of product A while not reimbursing the price of like product B has a *disastrous* impact on the market access of product B. Even if product B can still be legally sold, the impact on the "conditions of competition" of such a measure between those two like products is clear. Turkey's argument is tantamount to saying that a discriminatory sales tax at a rate of 100% has no impact on market access since the product can still be freely sold.

41. While the trade impact of this measure is not difficult to predict, the EU has examined the data. And indeed, the picture is clear. A comparison of 2018 and 2019 sales levels for a range of imported products that were de-activated in the Reimbursement List in the course of 2018 shows, in most instances, a massive drop in sales.[53] This data is drawn from the IQVIA database which Turkey submitted with the intention of showing that "pharmaceutical products which did not comply with the localisation

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51 Turkey's first written submission, para. 26.

52 Turkey's first written submission, para. 20.

53 Comparison of sales levels for de-activated pharmaceutical products, 2018 to 2019 (Exhibit EU-113). This table was prepared on the basis of the data on de-activation contained in Annex 4/A to the Health Implementation Notification/Communiqué (SUT - Sağlık Uygulama Tebliği) as updated on 5 May 2020 (Exhibit EU-102) and the data on sales levels submitted by Turkey in the Table with sales data 2018-2019 (IQVIA database) (Exhibit TUR-103).

measure continue to be sold on the Turkish market".[54] While *some* sales may very well still take place, the data undeniably shows a significant adverse impact on imports. On average, imports of de-activated products in the list submitted by Turkey (TUR-103) decreased by 61% from 2018 to 2019. For 53% of products in that list, imports dropped by more than 95% percent from 2018 to 2019. For 31% of the products in that list, imports even fell to zero in 2019.

2.2.4.3 Turkey misrepresents the reimbursement system for out-patient pharmaceuticals as a system of direct provision by the government

42. Turkey describes the reimbursement system for pharmaceuticals in Turkey as a system of direct provision, in total disregard of the facts. In a nutshell, Turkey describes the system as follows:

> The Turkish healthcare system includes the provision of pharmaceutical products. These pharmaceutical products are purchased by the SSI and provided to patients either directly by hospitals, in case of inpatient treatment, or through retail pharmacies acting on behalf of the SSI, in case of out-patient treatment. In both scenarios, the costs of pharmaceutical products necessary for a patient's treatment are covered by the State.[55]

43. Turkey bases those assertions on misrepresentations of the facts.

44. For instance, Turkey attempts to contrast reimbursement with what it calls "direct payments" by the SSI to pharmacies.[56] It is uncontested that the SSI partly reimburses the price of medicines sold to out-patients by retail pharmacies, based on periodical invoices issued by the pharmacies.[57] What Turkey describes as "direct payments" are, in fact, *reimbursements* to pharmacies. There is no relevant difference between those two terms. Either way, patients acquire the medicines from pharmacies, and the SSI finances (pays for, or reimburses) a part of the cost. The fact that invoicing is done on a periodical basis, and not separately for each transaction, is of no

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54 Turkey's first written submission, para. 494.

55 Turkey's first written submission, para. 64.

56 Turkey's first written submission, para. 65

57 EU'S first written submission, paras. 15-18.

relevance. Indeed, as Turkey explains, wholesalers invoice retail pharmacies in a similar fashion.[58]

45. It is also significant that even Turkey's description or translation of various documents, in particular Annex 4/A of the IRH/SUT, seeking to replace "reimbursement" with "payment", uses the future tense, as in the products that "will be paid for", or are "to be paid for".[59] Similarly, Annex 4/C is described as "drugs that *shall* be paid in case of supply from abroad."[60] Referring to payment in the future implies that a transaction takes place, and certain costs are then subsequently paid for by the SSI, i.e. reimbursed.[61]

46. Turkey tries to avoid using the word "reimbursement", even when it leads to nonsensical results. For example, it describes the IRH as dealing with the "provision and payment" for pharmaceutical products, which is done under two sets of rules: first, "standard" rules for "payment"; second, "alternative reimbursement" rules.[62] This, of course, begs the question of what the second set of rules is an alternative to. If it is an "alternative" reimbursement system, that to which it is an "alternative" must logically also be some kind of "reimbursement" system.

47. Furthermore, Turkey states incorrectly that the SSI, or more specifically the Pharmaceutical Unit of its General Directorate, performs the task of providing pharmaceutical products to the population.[63] This is simply incorrect. All Turkey can cite to in support is a very general constitutional provision requiring the State to regulate in pursuit of health and to set up health institutions. Nowhere in the legal provisions governing the SSI, or that unit, is the "provision of pharmaceutical products to the population" listed as a task or responsibility.

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58 Turkey's first written submission, para. 103.

59 See section on translation above.

60 Exxhibit TUR-10, Article 4.3.3.

61 Turkey itself explains that the retail pharmacies "submit at the end of each month a consolidated invoice to the SSI for the amount of the medicines included in Annex 4/A that they have dispensed to patients during that month. The invoices cover the price of the medicines, pharmacies' mark-up, VAT and a service fee. The amount of the service fee is determined in the Protocol and is paid to the retail pharmacies in return for the service they perform on behalf of the SSI (i.e. to dispense pharmaceutical products to patients). The invoices submitted by the retail pharmacies are paid by the SSI through the retail pharmacies' bank accounts within 60 days", Turkey's first written submission, para. 108.

62 Turkey's first written submission, paras. 62-63.

63 Turkey's first written submission, para. 217.

2.2.4.3.1 *Turkey misquotes sources concerning the alleged "provision" of pharmaceuticals to patients by the SSI, and the alleged "purchasing" by the SSI*

48. As already discussed in the section dealing with Turkey's translation objections, Turkey peppers its submission with misquoted or misleading words or concepts that suit its version of the facts. For example, Turkey claims that it follows from Article 62 of Law 5510[64] that "the SSI is the single public authority *purchaser* of healthcare services in the healthcare sector for *both out-patients and inpatients*."[65] This is incorrect. The provision simply states that is an obligation for the SSI to *finance* (not "purchase") health-care services under the health insurance system, and there is no specific reference to out-patients either.

49. Next, Turkey states that the HSPC "decides the prices of the healthcare services *provided by the SSI*, through healthcare service providers."[66] This is another attempt to portray the SSI as a direct provider of medicines, which would suit Turkey's Article III:8(a) argument. However, the cited provision says nothing of the sort. Instead, it empowers the HSPC to "identify the amounts to be *paid*" by the SSI, and to work on "healthcare services to be *funded*" by the SSI.[67]

50. Similarly misleading is the citation of Article 10(2) of the SSI's Regulation on Universal Health Insurance Procedure. According to Turkey, Article 10(2) "states that pharmaceutical products deemed necessary for out-patient treatment shall be provided by retail pharmacies contracted with the SSI."[68] In fact, the provision, as submitted into evidence by Turkey, states that "medicines financed by the Institution… are obtained from pharmacies contracted with the Institution". Thus, the truth of the matter is simpler and in line with the EU's description: out-patients obtain (i.e. acquire) medicines from pharmacies, and the SSI (partly) provides financing.

2.2.4.3.2 *Out-patients pay a part of the price, or cost, of pharmaceutical products*

51. An important aspect of Turkey's portrayal of the reimbursement system as the direct provision of pharmaceuticals to patients is that, according to

64 Exhibits EU-1 and TUR-2.

65 Turkey's first written submission, para. 32.

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

67 Exhibit EU-36, Article 6.

68 Turkey's first written submission, para. 100, citing Exhibit TUR-24.

Turkey, the SSI pays the entire price, or cost, of covered pharmaceutical products. However, the record clearly shows that this is incorrect. Turkey itself indirectly shows it to be incorrect. Thus (regardless of whether the fee is translated as a "contribution" or "co-payment") it is undisputed that out-patients, when acquiring pharmaceutical products from pharmacies, pay contribution fees that are calculated, in most cases as a 10% or 20% percentage of the total price. This is on top of a fixed "prescription fee" calculated per pack of medicines obtained. Thus, the IRH/SUT provides that "persons receiving pensions and allowances from the Institution and their dependents shall pay 10% and other persons 20% in *contributions for medicines reimbursed* by the Institution." (emphasis added)[69] This provision is further proof of the fact that the SSI in fact reimburses to pharmacies only a *part* of the total price, or cost, of medicines, whereas the rest of the price is paid for by consumers.

52. Even more tellingly, as Turkey explains:

> "For pharmaceutical products with an equivalent group, the maximum price paid by the SSI is the lowest price in the equivalent group increased by 10%. If a patient prefers a more expensive pharmaceutical product (from the same equivalent group), he or she must pay the difference between the price of that product and the price paid by the SSI."[70]

53. In this paragraph, Turkey confirms that, at least in some cases, the patients themselves pay a part of the price of the product, beyond the so-called contribution and prescription fee. This demonstrates that the price of a pharmaceutical product is conceptually distinct from the "price paid by the SSI". In other words, the SSI reimburses a certain fixed amount which may or may not correspond to the actual retail price of the product. Thus, what occurs between a patient and a pharmacy, in all cases, is a retail transaction, in which the patient acquires the medicine for a certain price, which is partly reimbursed by the SSI to the pharmacy and partly covered by the patient. Thus, it is incorrect that "patients do not pay for [pharmaceutical products included in the Annex 4/A and prescribed by medical doctors] as their costs are covered by the SSI".[71] Rather, patients cover a part of the price, and the other part is reimbursed by the SSI. This

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69 Excerpts from the Health Implementation Notification/Communiqué (SUT - Sağlık Uygulama Tebliği) or "the Reimbursement List", updated as of 5 May 2020 (Exhibit EU-102), Articles 1.8 and 1.8.2.

70 Turkey's first written submission, para. 87.

71 Turkey's first written submission, para. 110.

type of reimbursement system is incompatible with Turkey's description of a system of "direct provision" of medicines by the government.

2.2.4.3.3 *Retail pharmacies do not act "on behalf" of the SSI, and the SSI does not act "on behalf" of patients in relation to retail pharmacies*

54. Turkey argues that it somehow follows from Article 73 of Law 5510 that the SSI contracts with pharmacies "on behalf" of patients.[72] Alternatively (or additionally?), Turkey argues that it is pharmacies that act on behalf of the SSI. Nothing in Article 73 supports either assertion. The provision simply states that the SSI will conclude contracts for the provision of healthcare services with healthcare service providers (leading to the partial reimbursement of the costs of those providers), and that persons with health insurance coverage can alternatively purchase services from non-contracted providers and be reimbursed themselves.

55. It is simply incorrect that, for out-patients, pharmaceutical products are purchased by the SSI and provided to patients by the SSI through "retail pharmacies acting on behalf of the SSI". The SSI never purchases any pharmaceutical products. The persons doing the purchasing are, first, wholesalers (from manufacturers), then retail pharmacies (from wholesalers), and ultimately patients (from retail pharmacies). The SSI never provides those products to patients either. Instead, patients acquire the products from pharmacies, and the SSI (partly) finances this through reimbursement. Pharmacies do not act "on behalf" of the SSI; there is simply no evidence supporting such a statement. While it is true that the Turkish State, through the SSI, covers (some, not all) of the costs of those products, this in itself does not show what Turkey is trying to show with its portrayal of the reimbursement system: that Article III:8(a) of the GATT 1994 applies.

56. The diagram inserted at para. 84 of Turkey's first written submission, presumably meant to illustrate that pharmacies are mere agents for the SSI, is misleading and incomplete. First, it attempts to depict retail pharmacies as in a subordinate position by placing them below the SSI, by drawing an arbitrary line separating them and from wholesalers and producers, and placing them into a single group with the SSI, for no apparent reason. Second, the diagram omits important elements of the

[72] Cover page of Exhibit TUR-2.

reimbursement system, such as the pharmacies' profit margin, the contribution and participation fees paid by patients, as well as the possible additional payments by patients for more expensive products within the same equivalent group.

57. Turkey's description of the role of retail pharmacies is equally misleading or legally irrelevant. For example, it is irrelevant that, under Turkish law, pharmacies are described as "healthcare service providers".[73] This does not mean that they act on behalf of the State, as agents or conduits "through" which the SSI somehow "provides" medicines to patients. As Turkey acknowledges, retail pharmacies are "private entities", unaffiliated with the government.[74] The fact that their activities are regulated, or that they are required to act in line with general objectives such as product safety, does not make them governmental actors or agents of the SSI.

58. Turkey argues that retail pharmacies receive a service fee, in addition to the retail mark-up. This fee is, according to Turkey, "paid to the retail pharmacies in return for the service they perform on behalf of the SSI (i.e. to dispense pharmaceutical products to patients".[75] If this was indeed a system of direct provision with pharmacies acting as agents of the State (and not a system in which there are retail transactions between pharmacies and patients, and in which pharmacies are partly reimbursed by the State), this would then be all that the pharmacies receive. In other words, if all that the pharmacies are doing is "dispensing" governmental goods to patients, then all that they should be receiving is a fee for dispensing those goods, i.e. the service fee. The retail mark-up would then make no sense whatsoever.

59. Furthermore, it is undisputed that retail pharmacies freely decide to place orders for desired quantities of pharmaceutical products with wholesalers, freely conclude sales contracts with them acting in their own name, and ultimately acquire the products at issue from them. The SSI is not involved in this transaction, or more generally in the relationship between retail pharmacies and wholesalers. Thus, retail pharmacies pay the full price and take ownership of the products supplied, until they sell those products to patients, in retail. The pharmacy retains ownership and control of their

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73 Turkey's first written submission, para. 104.

74 Turkey's first written submission, para. 104.

75 Turkey's first written submission, para. 91.

stock, once purchased from wholesalers, until they are sold to patients. Accordingly, for example, any overstocking that results in loss of medicines due to the passage of their shelf life is entirely at the cost and commercial risk of the pharmacy. The management of that stock of medicines is an important part of each pharmacist's own profit and loss. The SSI does not reimburse retail pharmacies for products that go unsold.

2.2.4.3.4 *The transactions between retail pharmacies and out-patients are retail transactions*

60. The EU sees further support for its position in Turkey's explanation that "all products except "hospital products" and "serums" must be accorded a retail price."[76] This shows that there are, indeed, *retail* transactions between pharmacies and end-users (out-patients), in contrast with the regulation of in-patient pharmaceuticals ("hospital products") where this is not the case.

61. Furthermore, as Turkey states, pharmacies receive, as part of reimbursement, a mark-up. There are separate mark-ups for wholesale and retail pharmacies. Each of these mark-ups is added, together with VAT, to form what Turkey itself describes as the "retail price" of those products.[77] If indeed the system was one of direct provision in which pharmacies act merely as agents of the SSI, there would be no sense in describing the pharmacies as "retail pharmacies", the transactions between them and out-patients as "retail transactions", or their mark-up as a "retail mark-up". One would not expect a governmental agency (or a private actor to which such a role was delegated) charged with the provision of governmental goods to the public to be engaging in "retail" or charging a "mark-up".

2.2.4.3.5 *The sharp distinction between the reimbursement system and the direct provision of pharmaceuticals by public hospitals is highly significant*

62. The EU has highlighted the difference between the reimbursement system for out-patient pharmaceuticals and the system of direct provision to in-patients, in particular by hospitals. This difference is crucial, as it illustrates the reasons why the former measure is not covered by Article III:8(a) of the GATT 1994, while the latter may be. It also shows that the EU is not challenging genuine public procurement measures.

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[76] Turkey's first written submission, para. 59.

[77] Turkey's first written submission, para. 40.

63. In its submission, Turkey helpfully clarifies further differences between the two systems, which illustrate very well why it is appropriate to draw a sharp distinction between them.

64. First, as the in-patient system entails direct provision rather than reimbursement, patients receive their medicines directly from the hospitals and there are no contribution fees,[78] contrary to the reimbursement system.

65. Second, the SSI Regulation on Universal Health Insurance Procedure clearly explains that in-patient medicines are "*provided* by the healthcare service providers where the treatment is carried out", whereas out-patient medicines are "*obtained from pharmacies*" and merely "financed" by the SSI.[79]

66. Third, Turkey stresses that "it is mandatory for the healthcare providers contracted with the SSI to supply the medicines to be used in inpatient treatment".[80] This seems to imply that there is a legal obligation to supply such products to inpatients, whereas no such obligation exists for out-patients. The absence of such an obligation also follows from Article 5.3.1 of 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[81], which only requires pharmacies to supply prescribed medicines if they are "available at the pharmacy". If this is correct, then this would lend further support to the EU's explanation that pharmaceutical products are owned and held by pharmacies, and are then supplied to patients by those pharmacies through a retail transaction.

67. Fourth, Turkey points out that the out-patient and in-patient systems are "governed by different legal instruments", and that the costs of in-patient pharmaceuticals are paid through a "centralized system", unlike the reimbursement system.[82]

2.2.4.4 Turkey has not shown that products de-activated due to the application of the Localisation Requirement cannot be subsequently de-listed

78 Turkey's first written submission, para. 111.

79 Turkey's first written submission, para. 112, Articles 10(1) and (2), Exhibit TUR-24.

80 Turkey's first written submission, para. 112.

81 Exhibit EU-52.

82 Turkey's first written submission, para. 113.

68. Turkey states that, unlike in all other circumstances in which products are de-activated or "passivized" in the Reimbursement List, "pharmaceutical products which are "passivized" as a result of the localisation measure are not excluded from Annex 4/A after 10 months from the moment of their passivation but instead retain the "passivized" status. Thus, contrary to what is suggested by the European Union such products are never "excluded" from the Annex 4/A list."[83]

69. This may or may not be the case in practice. However, Turkey points to no evidence showing that its assertion is true as a matter of Turkish law. Instead, the legal rules Turkey itself cites simply provide for the subsequent delisting of deactivated products in certain circumstances. Those rules do not exclude products deactivated on the basis of the Localisation Requirement (indeed, in some circumstances the de-listing of such products appears to be particularly likely).[84] Thus, whether or not this is followed in practice, Turkish law appears to provide for delisting of at least some products deactivated under the Localisation Requirement, which exacerbates the potential negative impact of that measure.

2.2.4.5 The Localisation Requirement has been implemented and communicated in a way that is not even remotely "transparent" or "inclusive"

70. Turkey claims that the Localisation Requirement "has been implemented in an inclusive and transparent manner and communicated to the public through a number of publications and public announcements."[85]

71. Turkey attempts to back this assertion up with a detailed description of the process through which the Localisation Requirement has been implemented so far. Yet, that description amply shows the opposite of Turkey's argument.

72. Turkey's description shows that only the most general features of the measure, such as its stated rationale, have been communicated to the public *ex ante*.[86] The public announcements Turkey cites say nothing about

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83 Turkey's first written submission, para. 82.

84 Notably, Article 12.5(ç) of the SSI Regulation on Drug Reimbursement (Exhibit EU-8) provides as follows: "Products which had no sales in the ending year will be deactivated by the Secretariat… Products in respect to which a request for reactivation is not made by the end of the 10th month from the deactivation date will be delisted upon approval by the Drug Reimbursement Committee Chair." The absence of sales may be a direct consequence of de-activation due to the Localisation Requirement, which would then eventually lead to de-activation.

85 Turkey's first written submission, para. 164.

86 Turkey's first written submission, paras. 165, 166.

the phases of localisation, the criteria for the selection of products covered by localisation, the nature and content of "commitments" sought, and other crucial elements of the measure. Moreover, almost without exception, those communications are retrospective. They announce what has been done, instead of informing interested parties on what will be done in the future, by whom, and according to which criteria.

73. For example, the Announcement concerning the localisation process of 4 March 2016[87] simply states that an assessment of certain products has been performed, that a schedule was decided and an authority set up. Therefore, the announcement continues, within the following month "localisation… will commence" (without specifying what that means precisely), companies must submit "commitments for products" or, failing that, "justifications". None of these crucial concepts are explained. Similarly, the various announcements of updates to Annex 4/A simply announce *ex post facto* which products have been de-activated or removed from the list already.

74. Turkey proceeds to make the highly dubious claim that meetings with pharmaceutical industry associations, in which those associations were "informed" of developments related to the Localisation Requirement, and even e-mails in which the companies concerned were informed of the inclusion of their products in the scope of localisation or invited for meetings to discuss their commitments, are proof of inclusiveness and transparency.[88]

75. Perhaps Turkey believes it should be applauded because it does not simply de-activate imported products from the Reimbursement List without any prior notice. The EU disagrees. Transparency is not just a matter of informing interested parties that their products are about to be shut out of the market, or inviting them to secret meetings in which they are to present their commitments or propose alternative measures. Transparency and inclusiveness would entail, at a minimum, explaining the basic elements of the measure (how the Localisation Requirement works, which products it covers, what criteria it is based on, what sort of commitments or alternative measures are expected from interested parties etc.) to the *public*, including traders and the governments of other WTO Members, in an accessible manner that complies with the usual requirements of legal form, and precedes the application of the measure. Turkey has failed to do so, as its

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87 Exhibit EU-48.

88 Turkey's first written submission, paras. 169-171.

own arguments show. Indeed, Turkey has to date not even published a list of products that have been localised.

2.2.4.6 Omitted sections of documents only partly submitted by Turkey confirm the EU's understanding of the Localisation Requirement

76. In a number of instances, Turkey cites only portions of certain documents which appear to support its position, while omitting others. The omitted sections lend support to the EU's understanding of the Localisation Requirement.

77. For example, in the SSI's Activity Report for 2018, the following statements appear, showing that Turkey prioritizes domestically produced medicines, including through the reimbursement system, and that it aims to include especially "export-oriented" products in reimbursement:[89]

> "In reimbursement and pricing policies and in licensing procedures, the requisite arrangements and applications are to be put in place for priority assessment of medicines and medical devices produced in Turkey… Studies are to be carried out to put licensed products produced for export on the reimbursement lists..." (p. 29)

78. In the SSI Activity Report for 2019 (dated March 2020), the following statement appears, showing the continuing implementation of the Localisation Requirement:[90]

> "In line with the goal of increasing domestic production under the localisation process, the 10th Development Plan and the 64th Government Action Plan, the products that can be localised have been identified by the Turkish Medicines and Medical Devices Agency and studies on those products have begun. Since there are so many national and international actors having an impact on the studies conducted as part of the process, it has not been possible to achieve that goal." (p. 103)

79. In the TMMDA Administrative Operation Report for 2019, published in February 2020, Turkey's Exhibit TUR-78 omits the following relevant statements:[91]

- Demonstrating the effect of the application of the Localisation Requirement, and the clear import substitution objective

[89] The EU submits a Turkish version of this document in Exhibit EU-109, together with an English translation of relevant sections.

[90] SSI Activity Report for 2019 (Exhibit EU-110).

[91] TMMDA Administrative Operation Report 2019 (Exhibit EU-111), in Turkish. The EU submits a Turkish version of this document together with a translation of the relevant sections.

> "TARGET 3.2: To extend localisation efforts to include more products and more trademarked and commercialised local and national healthcare technologies
>
> PERFORMANCE TARGET: To replace imports with domestic production and support the production of innovative medical products
>
> PERFORMANCE INDICATOR: Proportion of produced medicines on the reimbursement list" (page 186)

- Showing that the Localisation Requirement has an explicitly economic objective (supporting the economy and domestic production), and explaining that the measure achieved its objective of increasing domestic production at the expense of imports:

> "OBJECTIVE 3: To prioritise assessment of applications for medicines that contribute to public health and the national economy, and to support domestic production
>
> TARGET 3.2: To extend localisation efforts to include more products and more trademarked and commercialised local and national healthcare technologies
>
> PERFORMANCE TARGET: To replace imports with domestic production and support the production of innovative medical products
>
> Proportion of produced medicines on the reimbursement list
>
> EXPLANATION
>
> This indicator involves monitoring the production status of reimbursable products as part of pharmaceutical localisation efforts. This objective has been achieved through an increase in local production.
>
> MEASUREMENT METHOD: Number of domestic products on the Medicines Reimbursement List in Annex 4A as a proportion of the total number of medicines on that list
>
> ANALYSIS: Target exceeded" (page 200-201)

- Showing that the objective of the Localisation Requirement was to activate production capacity and to increase the level of technology in Turkey, and providing figures for the value of localised products:

> "In 2019, in line with our Vision and the requirements of our mission, we stepped up localisation efforts for pharmaceuticals, medical devices and vaccines. The aim of the pharmaceutical localisation project is to tap unused capacity and take steps to promote the advanced technology that Turkey needs through export-oriented growth. Universities, industry and public authorities are working together to this end. The pharmaceutical localisation project should lead to domestic production of some TRY 6.1 billion worth of pharmaceuticals and has included a total of 623 medicines, worth around TRY 3.1 billion, to date. In terms of value, before the localisation project, 42% of pharmaceuticals on the Turkish market were produced domestically, whereas today the figure is 48%." (page 208)

80. In the TMMDA Administrative Operation Report for 2018, Turkey's Exhibit TUR-79 omits the following relevant statements:[92]

- Showing the existence of the prioritisation measure:

> "In reimbursement and pricing policies and the licensing process, necessary practices and regulations would be put in place with a view to priority assessment of pharmaceuticals and medical devices produced in Turkey." (page 116)

- Stating that an objective of the Localisation Requirement is to attract "investment projects" and to improve public finances:

> "In this context, investment projects of many national and international companies submitted to our Agency in the field of pharmaceuticals can be evaluated and effective projects can be implemented in terms of public finance. Localization and Indigenization efforts will gain momentum with the realization of these projects"(pages 167-168)

2.3. THE LOCALISATION REQUIREMENT IS INCONSISTENT WITH ARTICLE III:4 OF THE GATT 1994

81. Apart from its arguments on Article III:8(a) of the GATT 1994, Turkey does not dispute that the Localisation Requirement is inconsistent with Article III:4 of the GATT 1994. Thus, there is no disagreement on the main elements of that provision: the domestic and imported products at issue are like, the Localisation Requirement is a law, regulation or requirement affecting the internal sale, offering for sale, purchase, transportation, distribution, or use of products, and it accords less favourable treatment to imported like products.

82. The European Union will therefore not comment on these issues further, but will refer to the factual sections of its submissions, and to section 2.3 of its FWS. Article III:8(a) will be addressed in the section below.

2.4. TURKEY HAS FAILED TO SHOW THAT ARTICLE III:8(A) OF THE GATT 1994 APPLIES TO THE LOCALISATION REQUIREMENT

83. Article III:8(a) of the GATT 1994 provides:

> The provisions of this Article shall not apply to laws, regulations or requirements governing the procurement by governmental agencies of products purchased for governmental purposes and not with a view to

[92] TMMDA Administrative Operation Report 2018 (Exhibit EU-112), in Turkish. The EU submits a Turkish version of this document, while providing the translation of the relevant sections in the body of this submission.

commercial resale or with a view to use in the production of goods for commercial sale.

84. The EU refers to the general discussion of this provision in paras. 177-180 of its FWS. The EU will address Turkey's assertions on the various elements of Article III:8(a) in the order in which they are made.

2.4.1. Turkey has failed to show that either the reimbursement scheme for out-patient pharmaceuticals, or the Localisation Requirement, are "laws, regulations, or requirements governing procurement"

85. To recall, the EU has argued that this condition for the application of Article III:8(a) is not fulfilled because no procurement is involved, which means that Turkey's measures (neither the reimbursement scheme for out-patient pharmaceuticals, nor the Localisation Requirement itself) do not constitute a process pursuant to which Turkey acquires products, and do not "govern" procurement.[93]

86. Turkey argues that there can be "procurement" even when there is no acquisition of products, as in this case, because there is nevertheless a "process of obtaining products."[94] This is incorrect. As the EU has already explained, the jurisprudence defines "procurement" as "'*[t]he action of obtaining something*; *acquisition'*, or 'the action or process of obtaining equipment and supplies'."[95] The Appellate Body explained that the term "procurement" refers to "the process pursuant to which a government acquires products."[96] In other words, the Appellate Body has tied the concept of "procurement" to the concept of "acquisition" or "obtainment" of products.[97] If a government never actually acquires products (whether by way of purchase or otherwise), there can simply be no procurement. Instead of loosening it, as Turkey suggests, the requirement of a "process" pursuant

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93 EU's first written submission, section 2.4.1.

94 Turkey's first written submission, para. 188.

95 Appellate Body Report, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 5.59 (emphasis added).

96 Appellate Body Report, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 5.59.

97 Moreover, in *India – Solar Cells*, neither the panel nor the Appellate Body accepted India's argument that the concept of "procurement" goes beyond "direct acquisition". Appellate Body Report, *India – Solar Cells*, para. 5.36; Panel Report, *India – Solar Cells*, paras. 7.130 – 7.133. EU's first written submission, paras. 186-187.

to which products are acquired (meaning that the simple act or practice of acquiring a product is not enough) makes the legal test *stricter*.

87. Next, Turkey argues that the SSI acquires the medicines because it pays for their cost,[98] and is therefore the "ultimate buyer" of those products, the pharmacies being just an "agent for the SSI" and the "distribution network of the SSI".[99] The system is set up in this way, Turkey argues, "so as not to physically stock the products in the premises of the SSI, for logistical reasons".[100]

88. First, this view cannot be accepted for systemic reasons. Under Turkey's reading, whenever a government would finance or pay for something, even partly, this would constitute public procurement and would therefore fall outside the scope of Article III of the GATT 1994. This is plainly wrong, as it would expand the scope of Article III:8(a) far beyond what was intended by the drafters. Article III:8(a) is a government procurement exception, not a government financing exception. Financing is not in itself the equivalent of an acquisition, and therefore a process for the governmental financing of something is not in itself a procurement process.

89. Turkey is also wrong on the facts.

90. First, the act of payment does not on its own constitute an "acquisition", much less a "purchase" of anything, generally or even in Turkish law. Turkey quotes the sources in a misleading manner to suggest that they support such an assertion, whereas in fact they support the EU's argument.[101]

91. Article 63 of Law 5510 in no way suggests that the SSI "acquires" any medicines. To the contrary, it lists "the healthcare services to be *financed* by" the SSI, including "treatments".[102] Article 73 of that same law likewise does not state that the SSI purchases anything, but rather that it enters into contracts with healthcare service providers and that it pays the cost of medicines, both of which are consistent with the notion of a reimbursement system.[103]

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98 Turkey's first written submission, para. 189

99 Turkey's first written submission, parsa. 192 and 200.

100 Turkey's first written submission, para. 203.

101 Turkey's first written submission, para. 189 and fn 204.

102 Annex EU-1.

103 Exhibit EU-1.

92. The fact that Turkey's Public Procurement Law exempts the SSI from tendering procedures which apply to government procurement also tends to suggest that no procurement is involved, and certainly that no "process pursuant to which the government acquires products" is involved. Indeed, Article 3(h) of that Law further supports the EU's argument by explaining that the persons "purchasing… drugs… with prescription during out-patient treatment" are "persons whose treatments are undertaken", i.e. patients.[104]

93. The Protocol concluded between pharmacists and the SSI similarly does not support Turkey's position. As already discussed, to the extent the Protocol discusses "procurement", it concerns procurement by patients, i.e. the persons acquiring or obtaining the medicines from pharmacies. Turkey cites a number of provisions of the Protocol, but none of them do anything to support the proposition that the SSI acquires, purchases, obtains or procures medicines. It is simply irrelevant that the TPA represents all pharmacists, that retail pharmacies are designated as "primary healthcare service providers", that prescriptions must contain certain information, that invoices are issued on a monthly basis, that pharmacies are subject to penalties, that medical doctors are a regulated profession, etc.[105] Rules stating that pharmacies shall "supply" or "dispense" products to patients likewise do not support the proposition that the *SSI* procures, acquires, obtains or is supplied with anything.[106] Likewise, Turkey cites a clause of a model contract between pharmacies and the SSI referring to the "procurement" of medicines, but this concerns "procurement" by *patients*.[107]

94. Turkey also misreads or misrepresents certain elements of the Protocol. The fact that patients obtain pharmaceutical products on the basis of prescriptions does not mean that they do not purchase those products, and it certainly does not mean that the SSI purchases, acquires, obtains or

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104 Exhibit TUR-65, Article 3(h). The EU has requested a new translation of this provision, which supports the same conclusion by referring to "procurement by persons of prescription medicines and medical items for outpatient treatment", i.e. "procurement" of prescription medicines by out-patients. The translation is as follows:

"(h) procurement of services by contracting authorities covered by this Law for diagnosis and treatment to be provided to persons entitled pursuant to their special legislation, procurement by persons of prescription medicines and medical items for outpatient treatment of persons whose treatment is undertaken by their institutions and mutual procurement of goods and services for diagnosis and treatment among contracting authorities providing healthcare services and covered by this Law."

105 Turkey's first written submission, paras. 196-202.

106 Article 3.1 of the Protocol, Turkey's first written submission, para. 196.

107 EU-52, p. 25; compare with Turkey's first written submission, para.199. In in the EU's translation, the clause refers to the "receipt" of medicines by patients, as opposed to "procurement" by patients. In either version, it does not refer to procurement by the SSI.

procures them.[108] Incidentally, it also does not mean that the patients cannot choose their medicines. By Turkey's own admission, at least in some circumstances patients are free to choose between different products within the same equivalent group, and may be required to pay a price difference if the one they choose is more expensive. Nor does the fact that pharmacies are prohibited from double-charging patients for a product that is reimbursed by the SSI[109] mean that the SSI purchases, acquires, obtains or procures those products. It simply means that pharmacies may not engage in fraud. If the wording of that provision shows anything, it is that the term "provision" ("provided it to a patient…") is also used in Turkish law to describe a *sales* transaction between a pharmacy and a patient. Therefore, that word does not imply that the pharmacy is a simple agent or conduit of the SSI, or that the system is one of direct provision.

95. Finally, Turkey argues that there is an "articulated connection" between procurement by the SSI and the Localisation Requirement because of the following:

> "Pharmaceutical products that are not included in Annex 4-A or whose status is indicated as "passive", for instance *because they do not comply with the localisation measure, are not procured* by the SSI."[110]

96. This statement shows that, quite apart from the fact that the SSI does not procure, purchase, obtain or acquire anything under the reimbursement scheme for out-patient pharmaceuticals, the Localisation Requirement itself (which is, as Turkey points out, the measure challenged by the EU) is not a law, regulation or requirement that governs procurement. This is because the Localisation Requirement goes beyond a simple preference for domestic products. "Not complying" with the localisation measure means failing to submit or respect localisation commitments (typically, a plan to produce a particular product in Turkey, or subcontract to a Turkish manufacturer, within a certain timeframe and possibly including all sorts of other requirements) that are deemed acceptable by Turkish authorities. As the EU has explained, there is little guidance on what would make such commitments acceptable, and the authorities have significant discretion. In other words, Turkish authorities may very well conclude that a

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108 Turkey's first written submission, para. 202.

109 Turkey's first written submission, para. 202.

110 Turkey's first written submission, para. 204.

pharmaceutical company is "not complying" with the Localisation Requirement for reasons that go far beyond a particular product being of Turkish origin or imported.

97. Thus, even if the *reimbursement system* concerned procurement (*quod non*), through the Localisation Requirement, which is the specific measure at issue, Turkey actively seeks to obtain localisation commitments from foreign producers, rather than to simply apply an 'origin rule' for the "procured products". If the Localisation Requirement was genuinely a measure that governed *procurement*, Turkey would not be seeking to induce the localisation of foreign producers in Turkey, but merely limit itself to apply an origin rule. Thus, the Localisation Requirement is not a necessary and usual component of a procurement system, but rather an industrial policy and economic development measure that seeks, inter alia, to attract investments in Turkey.[111]

2.4.2. Turkey has failed to show that the Localisation Requirement entails the purchase of products by governmental agencies

98. The EU does not dispute that the SSI is a "governmental agency".[112] However, in the context of the reimbursement system and the Localisation Requirement, the SSI engages in neither procurement nor the purchase of any products.

99. The EU has explained that the "purchase" requirement is additional to the "procurement" requirement, and argued that, with respect to out-patients, no Turkish governmental agency ever acquires pharmaceutical products, whether through purchase or otherwise.[113]

100. In response, Turkey considers that the EU's reading of "purchase" as "acquisition of property" is "too narrow". Turkey suggests an alternative definition of "purchase" as "the action or an act of obtaining something in exchange of payment".[114] As a general matter, that definition is not incorrect. After all, it comes from the same source as the definition proposed by the EU. However, dictionaries often give several slightly

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111 TMMDA Administrative Operation Report 2018 (Exhibit EU-112), pages 167-168.

112 Turkey's first written submission, paras. 212-217.

113 EU's first written submission, section 2.4.2.

114 Turkey's first written submission, para. 207.

different meanings to a word. Interpreting the ordinary meaning of a legal term is therefore not a question of picking the most convenient option from a dictionary, but taking into account the legal provision at issue and the jurisprudence surrounding it. The definition provided by the EU is a better fit in light of the jurisprudence, as already the EU's FWS explains.[115] The term "procurement", as interpreted by the Appellate Body, already contains the concept of "obtaining" products. Since the "purchase" requirement is additional, it must mean something more. And indeed, "purchase" refers to a specific contractual arrangement, which differs from other arrangements like a lease, rental or hire in which products are obtained or acquired, but without the element of acquiring property over them.

101. In any event, the SSI does not even "obtain" any products, as the EU has already explained at length. The relevant products are first obtained, acquired, and purchased by retail pharmacies from wholesalers, and then by out-patients from retail pharmacies. The SSI merely provides financing through reimbursement. Providing financing is different from obtaining, acquiring or purchasing products.

102. Turkey's argument to the contrary would render any distinction between the concepts of "payment", "procurement", "purchase" and "acquisition" moot. In particular, it would make the discussion of the distinct concepts of "procurement" and "purchase" in WTO jurisprudence utterly pointless.[116] In essence, for Turkey, paying for something is the same as being the ultimate buyer, purchaser and procurer of a product.

103. Turkey finds support for its interpretation in the statement of the panel in *Canada – FIT* that ""purchase" does not require obtaining physical possession over the goods that are purchased."[117] This does not help Turkey at all. As Turkey acknowledges, the reason why there could be no physical possession of the good in that case was because the good was *electricity*. The reason why people do not take "physical possession of electricity" is, of course, that they might get electrocuted. More seriously, the reason why the panel in that case found that there was a purchase despite a lack of physical possession is that there was a "transfer of an entitlement to electricity".[118]

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115 Turkey's first written submission, paras. 198 – 203.

116 See the case law cited in section 2.4 of the EU's first written submission.

117 Turkey's first written submission, para. 208.

118 Turkey's first written submission, para. 208. Panel Report, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 7.229.

This fits precisely with the EU's argument that a purchase requires the acquisition of *property* over a good. In the case at hand, the SSI never acquires property, nor any other kind of "entitlement" to the products in question. Thus, there is quite simply no purchase by the SSI.

104. Turkey also argues that, to qualify for Article III:8(a), a governmental agency must engage in procurement, but that there is no requirement for a governmental agency to purchase products.[119] This is incorrect. As the Appellate Body explained in *India – Solar Cells*:

> The measures within the scope of Article III:8(a) are "laws, regulations or requirements governing … procurement", and *the entity purchasing products needs to be a "governmental agency"*. (emphasis added) [120]

105. This incorrect reading of Article III:8(a) introduces an alternative argument by Turkey that, even if "paying" for the products and therefore being the "ultimate buyer" does not in itself constitute a purchase, the SSI could be said to engage in purchasing because retail pharmacies, allegedly acting "on behalf of" the SSI, purchase medicines from wholesalers.

106. The EU has already explained that retail pharmacies cannot be regarded as agents of the SSI, even when one looks at their relationship with patients purchasing prescription medicines. Much less can it be said that retail pharmacies act "on behalf of the SSI" when they "obtain the pharmaceutical products included in Annex 4/A from the wholesalers" and "hold their inventory".[121] There is no support whatsoever for these assertions. As already explained, retail pharmacies are private entities, they freely order and purchase their medicines from wholesalers (also private entities) through a private sales contract, hold and manage their inventory on their own (including holding property rights over it), and bear the risks associated with their stock, with no SSI involvement. Thus, Turkey's attempt to portray the retail pharmacies' purchase of medicines from wholesalers as a "purchase" by the SSI fails.

107. Finally, the EU has already addressed Turkey's assertion that patients do not purchase pharmaceutical products. There is no doubt that patients obtain those products (including property over them) as part of a transaction. The cost of obtaining those products is partly covered by the SSI when it

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119 Turkey's first written submission, para. 209.

120 Appellate Body Report, *India – Solar Cells*, para. 5.18.

121 Turkey's first written submission, para. 209.

reimburses the pharmacies, and partly by the patients themselves, through (at least): (a) the "contribution fee", calculated in most cases as 10% or 20% of the price of the specific pharmaceutical products; (b) the "prescription fee", calculated as a fixed amount per pack received by the patient; (c) any difference in price that may exist because the patient purchased a more expensive product from the same equivalent group. This shows that there is clearly a "purchase" by patients. Turkey's argument that the "contribution fee" is a contribution to the social security system[122] is irrelevant because it concerns, at best, the ultimate use to which the money is put. The relevant point of view, however, is not that of the entity that receives that money downstream, but that of the purchaser (the patient) when engaging in the relevant transaction. For the patient, the fee is a part of the price that must be paid to obtain the pharmaceutical product. Indeed, the fee is even calculated as a percentage of the price of the specific pharmaceutical product being purchased. Following Turkey's logic,[123] when a consumer buys a bottle of wine or a pack of cigarettes, the excise duty would not be considered a part of the price because it is a tax, to be ultimately used by the government in the exercise of its functions. This would be clearly incorrect.

108. Of course, in any event, even if it was shown that patients, for whatever reason, do not "purchase" pharmaceutical products, it would still not follow that the SSI does. Therefore, even if Turkey was right (*quod non*), this would not solve the Article III:8(a) issue.

2.4.3. Turkey has failed to show that the Localisation Requirement involves the procurement of products purchased for "governmental purposes"

109. The EU has argued that, even if it could be said that the Turkish government engages in procurement and purchases pharmaceutical products, this would not be for "governmental purposes", because the products are not purchased for the use of government, to be consumed by government, or to be provided by government to recipients in the discharge of public functions.

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122 Turkey's first written submission, para. 210.

123 Turkey's first written submission, para. 236: "The contribution fee and the prescription fee paid by patients in retail pharmacies are not the resale price of the pharmaceutical product, as the European Union seems to suggest, but form part of the patients' contribution to the social security system and aim at preventing abuse."

110. Turkey disagrees and explains, at length, the reasons why healthcare is an important governmental objective.[124] Turkey is preaching to the choir. The EU already agreed that this is true.[125]

111. However, as the EU will explain in the section dealing with Article XX of the GATT 1994, while reimbursing medicines is obviously linked to the protection of human health, the Localisation Requirement is not.

112. Moreover, the relevant question under this part of the Article III:8(a) test is not simply whether the measure is linked to a governmental objective. A mere governmental objective is not enough. It must also be shown that products are "purchased for the use of government, consumed by government, or provided by government to recipients in the discharge of its public functions". [126]

113. Turkey does not claim that the products are "purchased for the use of government" or "consumed by government". Instead, it claims that they are "provided by government" (the SSI) to patients through retail pharmacies.[127] This argument must be rejected from the same reasons explained above, with respect to the requirements of "procurement" and "purchase". For the reasons given already, retail pharmacies cannot be regarded as agents of the SSI. Moreover, however one characterises the different payments involved, it is clear that no Turkish governmental agency *provides* the pharmaceutical products to anyone – pharmacies do.

2.4.4. Turkey has failed to show that the Localisation Requirement involves the procurement of products not with a view to commercial resale

114. Turkey takes issue with the EU's arguments on "commercial resale", claiming that the EU misrepresents its reimbursement system as a set of purely commercial transactions.[128]

115. Turkey fails to engage with the EU's actual argument, which is far more nuanced. The EU has stated that, if it was held that the government

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124 Turkey's first written submission, paras. 218-229.

125 Turkey's first written submission, para. 211.

126 Panel Report, *India – Solar Cells*, para. 7.156, summarizing the findings of the Appellate Body in *Canada – Renewable Energy / Feed-In Tariff Program*, paras. 5.66 – 5.68 and 5.74.

127 Turkey's first written submission, para. 231.

128 Turkey's first written submission, paras. 232-240.

purchases pharmaceutical products when *reimbursing* their cost to the pharmacies, then it would logically follow that the government is purchasing those products with a view to their *commercial resale* by pharmacies. The EU has explained that the panel should never reach this point of the analysis, and that this conclusion would only follow if it was (incorrectly) accepted that the Localisation Requirement entails the procurement and purchase of products by governmental agencies.[129]

116. While not providing a direct response to that argument, Turkey does make a number of startling remarks, which must be corrected. It argues that:

- patients cannot choose the products,[130] even though Turkey itself describes a (likely, common) scenario in which patients can choose between different products in an equivalent group[131];
- all elements of the exchange between the retail pharmacy and the patient are "decided by the Turkish government",[132] even though (obviously) patients are free to decide whether, when or where to purchase a product, even though particular pharmacies may not even have the product on stock, and even though patients may sometimes decide which specific product to purchase, as explained above;
- pharmacies are not "profit-seeking", and they do not provide the products "for profit",[133] even though pharmacies are private entities with a commercial interest (including, for example, making sure that they manage their own inventories in an efficient manner), and even though they receive a mark-up as well as a service fee.

2.5. THE LOCALISATION REQUIREMENT IS INCONSISTENT WITH ARTICLE X:1 OF THE GATT 1994

117. Turkey submits that, first, the European Union keeps changing the scope of its claim under Article X:1 between the "Localisation Requirement" as a whole and certain "elements" of the "Localisation Requirement". Second, it alleges that the European Union fails to show that the single localisation measure falls within the scope of Article X:1 of the GATT 1994 and that that

129 EU's first written submission, section 2.4.4.

130 Turkey's first written submission, para. 236.

131 Turkey's first written submission, para. 87.

132 Turkey's first written submission, para. 236.

133 Turkey's first written submission, para. 237.

measure has not been published promptly in such a manner as to enable governments and traders to become acquainted with it. Third, to the extent that what the European Union challenges is the lack of adequate and prompt publication of some specific instruments or documents, the European Union fails to show that those instruments or documents fall within the scope of Article X:1 of the GATT 1994 and that they have not been published promptly and adequately as required by Article X:1.

118. As regards Turkey's first argument, there is no inconsistency in the European Union's approach. While the European Union referred to the Localisation Requirement as a whole it did that to show that all the instruments underpinning this measure falls within the concept of "laws, regulations, judicial decisions and administrative rulings",[134] pertain to "requirements on imports, or affecting the sale of imports" and were "made effective" by Turkey. Then it showed that some of these legal instruments were not published promptly in such a manner as to enable governments and traders to become acquainted with them.

119. As to Turkey's second argument, it has to be pointed out that Turkey did not challenge the qualification of the Localisation Requirement as "law, regulation and requirements" under Article III:4. Turkey attempts to sow confusion by claiming that the European Union does not specify if and on which basis it concludes that the localisation measure as a single measure is a "law", a "regulation", a "judicial decision" or an "administrative ruling".

120. The European Union explained that the Localisation Requirement is imposed through a number of legal instruments resulting from governmental action, and setting out rules with which compliance is necessary to obtain an advantage from a government.[135] Therefore, these various legal instruments fall under the category of either "law", "regulation" or "administrative rulings". At the same time, given the fact that the Localisation Requirement is to a significant extent "embodied" through "specific laws or decrees" or "formal legal instruments", it should, as a whole, be described as a "law or regulation".[136]

121. As to the alleged failure to substantiate why the Localisation Requirement as a single and cohesive measure has been "made effective", the European

134 European Union's first written submission, section 2.5.1.

135 European Union's first written submission, para. 231.

136 European Union's first written submission, para. 159.

Union explained[137] that a number of the legal instruments ("various announcements", "bilateral communications" with pharmaceutical companies, deactivation of imported products, etc.) forming part of the Localisation Requirement show the implementation of this measure as an overarching measure.

122. Further, Turkey repeats[138] its mantra that the European Union failed to explain how the localisation measure, as a single and cohesive measure, has allegedly not been published promptly and adequately since it acknowledges that the documents laying down the "general objectives and features" of that measure have been so published as well as other documents and announcements relating to the localisation measure.

123. Turkey errs. The publication of the broad outlines of the Localisation Requirement does not mean that all the legal instrument included in this measure have been published in accordance with Article X:1. Its substantive content has, for the most part, been put in place in an entirely non-transparent manner, through a series of announcements, presentations and communications, none of which have been adequately and promptly published.

124. At the beginning of its third argument, Turkey makes the procedural claim[139] that a number of instruments in section 2.5.4 of the European Union's first written submission (the presentations and individual communications, the Roadmap for the process of localization and the HSPC Decision[140]) were not identified by the European Union in the Panel Request and should fall outside the Panel's terms of reference. In this respect, it is sufficient to recall that the Panel held in its preliminary ruling that it is sufficient to provide in the panel request an illustrative list of relevant legal instruments that put in place, evidence, implement, and administer the challenged measures.[141] Thus, it is not required to list exhaustively in the panel request all the instruments that are covered by the Article X:1 claim.

125. Next, Turkey asserts that it should have been first demonstrated that each and every of those "specific legal instruments" which have allegedly not

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137 European Union's first written submission, section 2.5.3.

138 Turkey's first written submission, paras. 284-289.

139 Turkey's first written submission, paras. 292-294.

140 Turkey's first written submission, paras. 317, 325.

141 Preliminary ruling, para. 3.14.

been published promptly and/or adequately fall within the scope of Article X:1 of the GATT 1994. Turkey considers that various presentations by Turkish officials[142], the "Roadmap for the Localisation Process" and the HSPC Decision regarding the Localisation Process do not quality as "laws, regulations or administrative rulings of general application". Moreover, the European Union allegedly failed to show that each and every of those instruments "pertain to" certain matters listed in Article X:1 or were "made effective".

126. The abovementioned instruments fall within the concept of "law", "regulation" or "administrative ruling" as they have a degree of authoritativeness setting out detailed steps and rules for the implementation of the Localisation Requirement; they are of "general application" since they are generally directed to imports of the covered pharmaceutical products in Turkey; pertain to "affecting their sale, distribution, transportation, insurance, warehousing inspection, exhibition, processing, mixing or other use" since the Localisation Requirement affects the sale of imported products by conferring an advantage on locally produced pharmaceutical products by encouraging their sale, purchase and use, to the detriment of like imported products; and, as already shown,[143] these instruments setting out the detailed steps of the Localisation Requirement were "made effective" by the implementation of this measure.

127. Finally, Turkey takes issue in detail with its failure to comply with Article X:1 with respect to the localisation announcements, the various presentations and private communications, the Roadmap for the process of localization and the HSPC Decision.

128. First, as regards the localisation announcements, Turkey argues that the panel in *EC – IT Products* did not conclude that a website is *per se* an inappropriate medium for publication in the sense of Article X:1 of the GATT 1994 and the draft measure annexed to the minutes of a meeting was determinative for finding an inconsistency with Article X:1. Turkey considers that it complied with Article X:1 by publishing the final version of the localisation announcements on the TMMDA and SSI websites, which were easily accessible to traders and governments.

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142 Turkey considers (para. 296) these to be mere working documents.

143 European Union's first written submission, paras. 244-245.

129. The panel in *EC–IT Products* concluded that the purpose of the publication requirement is so that governments and traders know what conditions would apply to their goods when imported into another Member's territory.[144] In a similar vein, the panel in *Thailand–Cigarettes (Philippines)*[145] found that a publication simply listing components of a measure did not satisfy the publication obligation in Article X:1 of the GATT 1994, because this list "would not enable importers to become acquainted with the detailed rules" applicable to them.[146]

130. The announcements published on TMMDA's website lack details and various steps that must be taken as part of localisation and, thus, do not supply traders and governments with adequate knowledge of the Localisation Requirement measure:

i. the "Announcement on the Localisation Process" of 4 March 2016 refers in brief manner to "Volumes of sales of products with import licences and more than one generic have been examined…First, to avoid any supply shortage on the market, a schedule was created in consultation with the relevant associations, trade unions and companies for the localisation of products with a production share of 50% or more."[147];

ii. the Announcement on the localization process of 5 April 2016 provides only cryptic information: "As mentioned in the announcement published on 04.03.2016 on our Agency's official website, equivalent groups' company commitments regarding the localization process are currently under review by the Council. The review will completed shortly and information will be supplied subsequently."[148]

iii. The announcement of 8 February 2017 is also very brief: "Requests for updating of the list attached to the announcement dated 8 February 2017

144 Panel Report, *EC–IT Prod*ucts, para. 7.108.

145 Panel Report, *Thailand–Cigarettes (Philippines)*, para. 7.789.

146 In a different context, the Appellate Body in *Mexico-Rice* found that simply posting an announcement of the initiation of the investigation on the investigating authority's website along with the requested information and relevant deadlines was not sufficient to satisfy the obligation to notify all known and unknown exporters. See Appellate Body Report, *Mexico–Anti-Dumping Measures on Rice*, paras. 245-253. Also, the obligation in Annex B(1) to the SPS Agreement to publish all sanitary and phytosanitary regulations which have been adopted are published promptly in such a manner as to enable interested Members to become acquainted with the refers not just to the mere act of placing an announcement on a website, but doing so in a way that would make the measure generally known to importers with sufficient content to enable them to become acquainted with it. See Panel Report, *Korea — Radionuclides*, para. 7.464.

147 Exhibit EU-56.

148 Exhibit EU-48.

can be made to the Medicines and Medical Devices Agency within the two months following 8 February 2017, which is the publication date."

iv. the Announcements on localisation of 8 February 2017[149], 25 April 2017[150], 19 January 2018[151] and 16 May 2018 include a list of products "related to the regulation for the List of Drugs to be Reimbursed (ANNEX-4/A) within the scope of the 10th Development Plan and 64th Government Action Plan"; "to be removed from the Medicines Reimbursement List"; and "Lists of medicines to passivate in Reimbursed Medicine List" without further explanations.

131. According to Turkey, the presentations and private communications also fall outside the scope of Article X:1 as they are not "laws, regulations or administrative rulings" and are not "of general application" or "made effective".

132. As already explained,[152] a number of key elements of the Localisation Requirement were only included in various presentations by Turkish officials, and in private communications between the SSI and/or TMMDA with the companies concerned. The presentations set out, notably, the process and various steps that must be taken as part of localisation, the phases of localisation, and the product categories to which those phases relate. Companies are informed in individual communications that their products are to be included in the localisation process, invited to make commitments, notified of the authorities' decision to accept the commitments, refuse them, delist or deactivate their products (as the case may be), and instructed on the various steps to be followed (including follow up, possible updates or alternative commitments, variation applications etc.). Therefore, the presentations and the individual communications are therefore "law", "regulation" or "administrative ruling" and, like described above for the various announcements were "made effective". While the individual communications were addressed to specific companies, they are nevertheless "of general application" as they convey rules affecting an

149 Exhibit EU-59.

150 Exhibit EU-61.

151 Exhibit EU-62.

152 European Union's first written submission, paras. 254-255.

unidentified number of economic operators not limited to those specific companies.[153]

133. Third, Turkey considers that it was not established that the Roadmap for the process of localization and the HSPC Decision are "law", "regulation" or "administrative ruling" and have "general application". Besides, the Roadmap for the process of localization merely contains information for Turkish officials but do not constitute official instructions or guidelines while the HSPC Decision has been communicated to all interested parties by the relevant authorities.

134. The Roadmap for the process of localization[154] sets out in more detail the various steps and deadlines for localisation including the submission of commitments or justifications on why commitments could not be made, the information that should be included in company commitments, explained that it should contain a time schedule not surpassing 18 months, companies making commitments are also required to submit progress reports at the end of each "term", or on a quarterly basis under the sanction of removal from the Reimbursement List.[155]

135. The above shows that the Roadmap for the process of localization has a degree of authoritativeness setting clear rules for the localisation process and is issued by TMMDA. Moreover, this document is not "mere information for Turkish officials" since it was addressed to companies concerned by the localisation process. Therefore, the Roadmap for the process of localization may be properly characterized as a 'law, regulation, administration ruling or judicial decision' as those terms are used in Article X:1. Moreover, it affects an unidentified number of companies concerned by the Localisation Requirement and, thus, has "general application". The implementation of the Localisation Requirement shows that the Roadmap has been "made effective".[156]

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153 For example, the HSPC Decision regarding the Localisation Process is frequently attached to various communications to companies covered by the localisation process. TMMDA has also sent communications to companies requesting them to submit localisation commitments, and providing instructions on the process. Other communications inform companies to submit a variation application and a progress report. Se the European Union's first written submission, paras. 108, 136, 144, 147.

154 Exhibit EU-45.

155 European Union's first written submission, paras. 113-116.

156 For example, the communication of 10 October 2017 makes effective the Roadmap by instructing companies on the process of submitting progress reports to TMMDA.

136. The HSPC Decision sets out the process and criteria for implementing the Localisation Requirement, including commitments and delisting/deactivation and the SSI. The SSI has explained that this decision serves as the valid legal basis for the application of the Localisation Requirement.[157] Therefore, like the Roadmap, this decision has a degree of authoritativeness and was issued by the HSPC, a commission established under SSI's leadership, so that it may be properly characterized as a 'law, regulation, administration ruling or judicial decision'. It also has general application as it applies to an unidentified number of companies and was "made effective" as shown by the implementation of the Localisation Requirement, including by attaching this decision to individual communications between companies and TMMDA and various announcements.

137. Finally, the Panel in *EC–IT Products* concluded that measures are to be published "in such a manner as to enable governments and traders to become acquainted with them" and they must be generally available through an appropriate medium rather than simply making them publicly available.[158]

138. The Panel in *Chile – Price Band System* analysed the meaning of the phrase "to publish" in light of the requirement to "publish" safeguard investigation reports under Article 3.1 of the Agreement on Safeguards. This analysis may be of some relevance in the present dispute, especially given that Article 3.1 of the Agreement on Safeguards[159] expressly refers to Article X of the GATT 1994:

> "[W]e note that the Minutes of the relevant [Chilean Distortion Commission] sessions have not been 'published' through any official medium. Rather, they were transmitted to the interested parties and placed at the disposal of 'whoever wishes to consult them at the library of the Central Bank of Chile'… In order to determine whether it is sufficient under Article 3.1 of the Agreement on Safeguards to make the investigating authorities' report 'available to the public' in such a manner, we first refer to the dictionary meaning of 'to publish'. The term can mean 'to make generally known', 'to make generally accessible', or 'to make generally available through [a] medium'… As regards the minutes of the relevant [Chilean Distortion Commission] sessions, we therefore find that they have not been generally made available through an

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157 European Union's first written submission, para. 108 and Exhibit EU-46.

158 Panel Report, *EC–IT Prod*ucts, para. 7.1084.

159 Article 3.1 of the Agreement on Safeguards states in relevant part: "A Member may apply a safeguard measure only following an investigation by the competent authorities of that Member pursuant to procedures previously established and made public in consonance with Article X of GATT 1994. (...) The competent authorities shall publish a report setting forth their findings and reasoned conclusions reached on all pertinent issues of fact and law."

appropriate medium so as to constitute a 'published' report within the meaning of Article 3.1 of the Agreement on Safeguards."[160]

139. The fact that the HSPC Decision was attached to individual communications addressed to companies is not an appropriate medium to be make this decision generally known or accessible to governments and traders to become acquainted with it. This decision was made accessible only to companies making products included in the first two phases of the localisation measure but not "generally made available" to governments and traders.

2.6. THE LOCALISATION REQUIREMENT IS NOT JUSTIFIED UNDER ARTICLE XX(B) OF THE GATT 1994

140. Turkey has submitted, in the alternative, that, should the Panel find that the Localisation Requirement does not fall within the scope of Article III:8(a) of the GATT 1994 and is inconsistent with Article III:4 of the GATT 1994 and Article 2.1 of the TRIMs Agreement "any such inconsistency is justified under Article XX(b) of the GATT 1994".[161]

141. More precisely, Turkey contends that "by requiring that certain pharmaceutical products be produced domestically in order to be included in Annex 4/A, the localisation measure seeks to ensure that those products are available to patients in Turkey"[162] and that "a policy that seeks to ensure access to medicines aims at 'protecting human life and health' within the meaning of Article XX(b) of the GATT 1994."[163]

142. The European Union does, of course, agree that the alleged objective to ensure adequate access to medicines falls within the scope of Article XX(b) of the GATT 1994 and is "extremely vital and important".[164]

143. Nevertheless, for the reasons explained below, the European Union submits that the Localisation Requirement is not justified under Article XX(b) of the GATT 1994. The Localisation Requirement 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

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160 Panel Report, *Chile – Price Band System*, para. 7.127.

161 Turkey's first written submission, para. 414.

162 Turkey's first written submission, para. 443.

163 Turkey's first written submission, para. 442.

164 Turkey's first written submission, para. 470.

industry policy goals, and is very trade restrictive. Furthermore, the Localisation Requirement is not necessary to achieve its alleged public health objective: 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. In addition, the Localisation Requirements is not applied in accordance with the *chapeau* of Article XX of the GATT 1994.

2.6.1. The Localisation Requirement is not designed to achieve the public health objective alleged by Turkey

144. The Localisation Requirement is not designed to achieve the public health objective alleged by Turkey. Rather, as already shown by the European Union in its first written submission , the Localisation Requirement has been designed to promote the economic development and industrial policy objectives pursued by Turkey in the pharmaceutical sector.

145. Those objectives are also reflected, for example, in the following passages of the Strategic Plan of TMMDA for 2018-2022 published by the Ministry of Health on 11 October 2018:

> Depending on Turkey's current location and the history it is responsible for, it is assumed by all authorities that it will be one of the ten largest economies in the world in 2023. As the target of 2023, it is aimed to have 25.000-30.000 USD per capita national income. One of the important actors of this process will be the pharmaceutical industry.
>
> […]
>
> Turkey Pharmaceutical Market, with its USD $9.1 billion pharmaceutical market, ranks in Europe 6th, in the World 16th in 2011. In 2012, Turkey's pharmaceutical market has a total of USD $8.6 billion with producer prices. […] In 2015, imports were amounted USD $4,621 billion and exports were amounted USD $939 million, and the ratio of exports to imports was 20.3%.
>
> Increasing demand for medicines and medical devices due to increasing and aging population in our country, increase in average life expectancy, improved healthcare and access to medicine, increased welfare level and awareness create pressure on social security expenditures and current account deficit. With the resulting foreign trade deficit and objectives within the framework of Turkey's industrial vision, Turkey Pharmaceutical Sector Strategy Paper (2014-2017) has been prepared by the Science, Industry and Technology Ministry in order to support the government's public health and development goals and to ensure that our country's pharmaceutical industry is sustainable and effective. In long term, it is expected that Turkey will be a global pharmaceutical R&D and production center and reach a competitive position in the field of pharmaceuticals

and medical devices. With this program, it is aimed to move to a production structure that can produce high value-added products, offer products and services to global markets, and meet a greater portion of the domestic pharmaceutical and medical device need. In this context, it is envisaged to increase the efficiency in the global value chains by increasing the domestic production capacity in the medium term, developing the R&D and enterprise ecosystem, developing new molecules in the long term, producing higher value-added medicines and medical devices.[165]

146. The same economic development and industrial policy objectives figure prominently in the Structural Transformation Program for Healthcare Industries Action Plan of 7 November 2014:

> 1. Aim and Scope of the Program
>
> The fact that demand for medicines and medical devices has intensified due to factors like rising and aging population, increased average life expectancy, improved access to health services and medicine, increased welfare level and awareness in our country, leads to a pressure on social security spending and current deficit.
>
> In the long haul, it is vital that Turkey becomes a global hub for R&D and production in medicines and that it reaches a competitive position in medicines and medical devices sector. The aim of this program is to switch to a production structure that is able to produce high added-value products; to place products and services to the global markets; and is capable of meeting a larger portion of domestic need for medicines and medical devices.
>
> In this framework, what is envisaged is to boost domestic production capacity in the medium-run; to develop ecosystems for R&D and entrepreneurship and to augment effectiveness in the global value-chain by way of adopting a structure that is capable of devising new molecules and producing medicines and medical devices of higher added-value in the long run.
>
> 2. Target of the program
>
> […]
>
> Meeting, value-wise, 60% of the domestic need for medicines through domestic production.[166]

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165 Strategic Plan of TMMDA for 2018-2022 published by the Ministry of Health on 11 October 2018, section 2.8.A.2 (Exhibit TUR–38)**.**

166 The Structural Transformation Program for Healthcare Industries Action Plan, 7 November 2014, coordinated by the Ministry of Health and Ministry of Development (Exhibit EU–14) (underlining added). The objective of meeting 60% in value of domestic need for medicines through domestic production is also mentioned in the "Project on the Localization of Medicines, Transition from Importation to Manufacturing", presentation by Dr Hakki Gursoz, President of the TMMDA,6 March 2017 (Exhibit EU-34), at slide 2, and in the Presentation entitled "Pharmaceutical Localisation Project Work Conducted by the Ministry of Health", given by representatives of the TMMDA December 2017 (Exhibit EU-23), at slide

147. Similarly, the "65th Government Program" of 24 May 2016 states that:

> "We will increase our capacity in medical technology, the pharmaceutical and cosmetics industry and health tourism. Our goal is to make our country a regional leader in the field of healthcare with local and national production. "[167]

148. The above quoted passages evidence a preoccupation with the large size of Turkey's trade deficit in the pharmaceutical sector, together with a desire to promote the domestic production of higher value-added pharmaceutical products with a view to becoming competitive in global markets, thereby contributing to the development of Turkey's economy. These are legitimate economic development and industrial policy industrial objectives. But Turkey can and ought to pursue them in a manner consistent with its obligations under the WTO Agreement.

149. The structure and design of the Localisation Requirement is fully consistent with the economic development and industrial policy objectives of Turkey reflected in the above quoted passages.

150. In contrast, the structure and design of the Localisation Requirement cannot be reconciled with the public policy alleged by Turkey in this dispute. If Turkey's objective were to ensure access to medicines, it would facilitate imports of pharmaceutical products, rather than restrict those imports. As discussed below, promoting local production is just one of the possible tools for ensuring access to medicines. Moreover, there are many alternative tools available for promoting local production without restricting imports of pharmaceutical products.

151. Far from being necessary to ensure access to medicines, the Localisation Requirement could undermine that objective by causing a shortage of supply of medicines. The Localisation Requirement is based on the expectation that restricting imports of pharmaceutical products will induce foreign producers to localise production in Turkey. However, if that inducement fails, the Localisation Requirement will lead to a shortage of pharmaceutical products. Thus, the Localisation Requirement is a very risky bet to pursue the public health objective alleged by Turkey.

2, after recalling that the growth in demand for medicines and medical devices puts pressure on the social security expenditure and deficit.

167 65th Government Programme (Exhibit EU–16).

152. Turkey's submission acknowledges that the Localisation Requirement entails the "risk of a sudden shortage of supply". Nevertheless, Turkey explains that this risk is addressed by "dividing" the Localisation Requirement into five phases. Turkey further explains that:

> As of today, Turkey has implemented only Phase 1 and Phase 2. Phase 1 covers pharmaceutical products for which local production has at least 50% market share and there are at least 3 locally produced generics (produced by 3 different companies). Phase 2 covers pharmaceutical products for which local production has at least 10% market share and there are at least 2 locally produced generics (produced by 2 different companies) [168]

153. Turkey stresses that "[i]n order to avoid any supply shortages in the market, at the first stage, a schedule was formed on the basis of negotiations with relevant associations, trade unions and companies for the localisation of products" [169] and that "[t]he capacity of the production sites in our country has been assessed simultaneously, and it has been observed that the production sites have the sufficient capacity"[170].

154. Turkey's explanations involve a recognition that the Turkish authorities assessed, before the implementation of Phase 1 and Phase 2, that there was no significant risk of shortage of supply of the pharmaceutical products covered by those phases. Yet, in the absence of such risk of shortage of supply, the Localisation Requirement cannot possibly be considered "necessary" in order to ensure access to the pharmaceutical products covered by those two phases.

155. At the same time, Turkey's explanations have the implication that the Turkish authorities consider that the Localisation Requirement cannot be applied with regard to other products where local production is not sufficient yet (the products covered by Phases 3 to 5) because restricting imports of those products could, by Turkey's own admission, entail the "risk of a sudden shortage of supply".[171]

156. It follows that, by Turkey's own admission, the Localisation Requirement does not, and indeed cannot, contribute to the alleged objective of ensuring

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168 Ibid.

169 Turkey's first written submission, para. 453.

170 Turkey's first written submission, para. 453.

171 Turkey's first written submission, para. 453.

access to medicines with regard to any pharmaceutical product within the scope of the Localisation Requirement.

157. The inconsistencies between Turkey's alleged public health objective and the structure and design of the Localisation Requirement show that the Localisation Requirement is not designed to achieve the public health objective invoked by Turkey. Turkey cannot explain away those manifest inconsistencies simply by citing vague and rhetorical political statements included in documents of the Turkish government where an unsubstantiated link is asserted between access to medicines and the Localisation Requirement[172].

2.6.2. The Localisation Requirement is not necessary to achieve the public health objective alleged by Turkey

158. Should the Panel conclude that the Localisation Requirement is designed to achieve the objective alleged by Turkey, the European Union submits that Turkey has not met its burden of proving that the Localisation Requirement is necessary to achieve that objective.

2.6.2.1 Turkey has not met its burden of proving that there is a risk of shortage of supply of the products covered by the Localisation Requirement

159. The notion of "protection" in Article XX(b) of the GATT 1994 implies the existence of a health risk[173]. 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.

160. According to Turkey, the Localisation Requirement is designed to address the health risks that could result from a shortage of supply of the pharmaceutical products covered by that measure, which would deprive the Turkish citizens from adequate access to medicines, thereby endangering their health.

161. Therefore, in order to prove that the Localisation Requirement is justified under Article XX(b), Turkey is required to prove that there is a risk of shortage of supply of the pharmaceutical products within the scope of the Localisation Requirement.

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172 *See* Turkey's submission, paras. 455 ff.

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

162. In *India - Solar Cells*, the Appellate Body provided detailed guidance with regard to the factors to be taken into account for the purpose of establishing that a product is in short supply:

> [A] panel should examine the extent to which a particular product is 'available' for purchase in a particular geographical area or market, and whether this is sufficient to meet demand in the relevant area or market. This analysis may, in appropriate cases, take into account not only the level of domestic production of a particular product and the nature of the product that is alleged to be 'in general or local short supply', but also such factors as the relevant product and geographic market, potential price fluctuations in the relevant market, the purchasing power of foreign and domestic consumers, and the role that foreign and domestic producers play in a particular market, including the extent to which domestic producers sell their production abroad. Due regard should be given to the total quantity of imports that may be 'available' to meet demand in a particular geographical area or market. It may thus be relevant to consider the extent to which international supply of a product is stable and accessible, including by examining factors such as the distance between a particular geographical area or market and production sites, as well as the reliability of local or transnational supply chains. Whether and which factors are relevant will necessarily depend on the particularities of each case. Just as there may be factors that have a bearing on 'availability' of imports in a particular case, it is also possible that, despite the existence of manufacturing capacity, domestic products are not 'available' in all parts of a particular country, or are not 'available' in sufficient quantities to meet demand. In all cases, the responding party has the burden of demonstrating that the quantity of 'available' supply from both domestic and international sources in the relevant geographical market is insufficient to meet demand.[174]

163. While the Appellate Body Report in *India – Solar Cells* was concerned with the existence of a shortage of supply within the context of Article XX(j) of the GATT 1994, the guidance provided in the above quoted passage is equally pertinent for assessing the existence of a risk of shortage of supply in the present case.

164. In accordance with that guidance, Turkey has the burden of demonstrating that there is a risk that "the quantity of available supply from both domestic and international sources in the relevant geographical market may be

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174 Appellate Body Report, *India – Solar Cells*, para. 5.71.

insufficient to meet demand"[175], having regard to all relevant factors affecting supply and demand, including those identified in the above quoted passage.

165. The Localisation Requirement covers a very wide range of pharmaceutical products, with very different physical characteristics and therapeutical uses. In view of that, Turkey must demonstrate separately the existence of a risk of shortage with regard to, at least, each category of "equivalent products".

166. Turkey has failed to meet that burden of proof. Indeed, Turkey has provided no relevant evidence of the existence of a risk of shortage of supply. Quite to the contrary, Turkey has stressed that there is no risk of shortage of supply as regards the products covered by the First and Second phases[176], which remain the only phases of the Localisation Requirement implemented by Turkey.

167. In practice, disruptions of supply of pharmaceutical products appear to be occasional and of short duration. Turkey has been able to identify just five instances of alleged disruption of supply since 2012[177]. In three instances, Turkey's allegations are based on press articles of limited probative value. In the other two instances, Turkey relies on official correspondence between Turkish authorities, which nevertheless provides scant information as regards the causes and extent of the disruption.

168. In the case of Tamoxifen, a breast cancer medicine, the cause of the alleged disruption is not identified in the press article supplied by Turkey.[178] According to another press article included in the same exhibit, Mr. Hakkı Gürsöz, the President of the Turkish Medicines and Medical Devices Agency, denied the existence of a "supply problem for cancer medicines". He explained that:

> "There may be occasional disruptions in accessing medicines due to ceasing of production activity, problems in the supply of raw materials or problems due to safety. Sometimes the reason may be the high cost of production or the price of the medicines. In that case, we first make the diagnosis and then decide what to do."

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175 Appellate Body Report, *India – Solar Cells*, para. 5.71

176 Turkey's first written submission, para. 453.

177 Turkey's first written submission, para. 488.

178 Haci Biskin, "Shortage of Supply in Medicine to Cure Breast Cancer", *Gazete Duvar*, 22 September 2017, Exhibit TUR-98.

> He emphasized that the claims that cancer problems are experienced are frequently brought up and they are faced with purposeful perception management. "There is no supply problem for cancer medicines that we have identified at the moment. Last year, the short-term problem experienced in breast cancer patients' medications was caused by the firm, which has the highest market share of the drug, wants to close the production line abroad. We also produced this product locally. There is no procurement problem that reaches us about other cancer medicines. After this problem has been solved, the normal supply flow has continued. "[179]

169. In the case of Purinethol, the cause of the alleged disruption is, again, unclear. The press article provided by Turkey mentions that the product was available in Turkey, but the SSI did not include it in the reimbursement list.[180]

170. In the case of Salofalk, the press article cited by Turkey alludes to price negotiations with the importer, which had already been successfully concluded, but had delayed the distribution of the product. Nevertheless, the press article also raises the question whether "the problem is the official procedure[181].

171. In the case of Oxytocin, there is no indication that the disruption was caused by a shortage of imports. Rather the official correspondence relied upon by Turkey mentions that "the use of the two medicines have reportedly been increased, due to Turkey's efforts to reduce the caesarean operations. Therefore, it is reported that the quantities produced are not enough." [182]

172. Finally, in the case of Carnitine, there is no indication of the cause of the disruption of supply[183].

173. The anecdotal evidence concerning the alleged five instances of disruption of supply discussed above is hardly probative of a genuine risk of shortage of supply affecting each and every pharmaceutical product actually or

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179 "Local solution for imported medicine used in intestinal diseases", *Anadolu*, 16 January 2017, Exhibit TUR-98.

180 "Shortage of Supply in This Medicine", *Sağlık Aktüel*, 23 August 2012, Exhibit TUR-99.

181 "Shortage of Supply in This Medicine", Sağlık Aktüel, 23 August 2012, Exhibit TUR-99.

182 Letter from Antalya Provincial Health Directorate to the Ministry of Health on 7 March 2016 and the relevant correspondence with hospitals, Exhibit TUR-101.

183 Letter from the Ministry of Family and Social Policies, Directorate General of Services for Persons with Disabilities and the Elderly, to the Ministry of Health on 25 March 2016, Exhibit TUR-102.

potentially covered by the Localisation Requirement, which could render necessary the adoption of that measure. Rather, it suggests that disruptions of supply are infrequent, limited in time and, more often than not, attributable to factors other than a disruption of imports, including the Turkish administration's own inefficiencies.

2.6.2.2 Turkey has not met its burden of proving that local production of the products concerned contributes to achieve the alleged objective

174. Turkey has not met its burden of proving that the Localisation Requirement makes a contribution to the alleged public health objective.

175. Turkey limits itself to invoke a series of selective quotations (often taken out of context) from documents of various international organizations in support of the abstract proposition that local production of pharmaceutical policy contributes to improving access to medicines[184].

176. It is generally agreed, however, that local production of pharmaceutical products is not a panacea for improving access to medicines. In specific contexts, and subject to certain conditions, local production may be a useful tool, alongside other policy tools, for improving access to medicines. In other contexts, however, local production may fail to contribute to improving access to medicines. Indeed, depending on the circumstances, efforts to promote local production may well be counterproductive, by increasing unnecessarily the costs of medicines or lowering their quality.

177. The WHO has noted in this regard that:

> There is no clear consensus on if, how or under what conditions local production and technology transfer may improve access to drugs and vaccines in low- and middle-income countries[185].

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184 Turkey's first written submission, paras. 472-483.

185 WHO, Pharmaceutical Production and Related Technology Transfer (2011), p. 14 (Exhibit – 114). *See* also WHO, Local Production for Access to Medical Products: Developing a Framework to Improve Public Health (2011), pp. 7-8 ("Even as local production is being actively pursued in a number of developing countries, however, a causal link between local production and improved access to high-quality medical products remains implicit in most cases. The evidence that is published to date can neither support nor refute these assumptions. Even within India, a large producer of medical products, the link between Indian domestic production and access of the Indian population to these products is not well established"); and p. 20 (there is "no direct evidence from literature review" that local production contributes to "reliability of supply" and only "little direct evidence in low- and middle-income countries" that it contributes to "improved quality standards", whereas there is evidence that "some locally produced medicines are more expensive than foreign-made counterparts (e.g. Brazil, Jordan, Turkey, Malaysia, United Republic of Tanzania, Viet Nam)").

> […]
>
> Whether and how local production improves access to medicines is likely to depend on the specificities of each context and may vary over time and by product. Local production can lead to improved access (defined as improved quality assurance, affordability, appropriateness of products or security of supply) – but it does not necessarily do so. Furthermore, some of these objectives may be more feasible to achieve than others in a given context, or there may be trade-offs between them[186].

178. Turkey has not demonstrated how, in the specific context of the Turkish market for each of the categories of "equivalent products" covered by the Localisation Requirement, local production would contribute to improve access to those products by the Turkish citizens, as compared to the situation preceding the introduction of that measure.

179. In the absence of that demonstration, Tukey has not met its burden of proving that the Localisation Requirement makes a contribution to the public health objective invoked by Turkey.

180. Turkey concedes implicitly that there is no evidence of such contribution, but seeks to justify the lack of evidence by arguing that "at this stage it is difficult to isolate the contribution"[187]. It is recalled, however, that the implementation of Phases 1 and 2 started in 2016 and 2017, respectively. If the Localisation Requirement were capable of making a contribution to the stated objective, some effects should be noticeable by now. Turkey is aware that its attempted justification lacks credibility and goes on to assert that "the implementation of the localisation measure so far has helped to resolve problems related to the availability of certain pharmaceutical products on the Turkish market"[188]. Tellingly, however, Turkey provides no supporting evidence whatsoever for this assertion.

2.6.2.3 The Localisation Requirement is very trade-restrictive

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186 WHO, Pharmaceutical Production and Related Technology Transfer (2011), p. 13, Exhibit – 114.

187 Turkey's first written submission, paras. 472-483.

188 Turkey's first written submission, para. 491.

181. Contrary to Turkey's disingenuous assertions[189], the Localisation Requirement is extremely trade-restrictive because, in practice, it has the effect of excluding imports from a very large part of the Turkish market.

182. While imported products caught by the Localisation Requirement can still be legally imported and sold, they are excluded from reimbursement. This creates a strong disincentive on their sales in Turkey.

183. The SSI reimburses most of the cost of the products included in the Reimbursement List[190]. Consumers are, therefore, most unlikely to choose a non-reimbursed product over a like reimbursed product. As a result, in practice, imported products excluded from reimbursement are unable to compete with the reimbursed like domestic products.

184. Moreover, the Reimbursement Scheme covers approximately 90% of all sales of pharmaceutical products in Turkey[191]. Hence, imported products excluded from reimbursement are in practice effectively excluded from a very large part of the market.

2.6.2.4 There are adequate less or non-trade-restrictive alternatives to the Localisation Requirement in order to achieve the objective alleged by Turkey

185. The shortage of medicines can occur for many different reasons. These include unexpected fluctuations in demand (e.g. in the case of a sudden outbreak of an infectious disease or of natural disasters or accidents), lack of timely communication about supply and demand information, manufacturing problems and quality compliance issues, inadequate pricing mechanisms or procurement procedures, complexity and diversity of regulatory requirements, etc. Often shortages of supply are the result of a combination of those causes.

186. Given their multifaceted causes, there is no single response to the shortages of medicines. As mentioned above, local production of pharmaceutical products is not a panacea for improving access to medicines. In specific contexts, and subject to certain conditions, local production may be a useful tool for improving access to medicines. But there are other tools available. Such other tools include the creation of contingency reserves of medicines

189 Turkey's first written submission, paras. 493-494.

190 Turkey's first written submission, para. 110.

191 Pharmaceutical Industry Employers Union (IEIS), Turkey Pharmaceutical Industry 2015 report (Exhibit EU-9), Table 1, page 5.

at risk of shortage, and in particular of those previously identified as essential, the diversification of sources of supply, the simplification of supply chains, the facilitation of imports, the improvement of pricing mechanisms and procurement procedures, the harmonization and simplification of regulatory requirements and increased international cooperation.

187. The World Health Organization has recommended "to develop strategies that may be used to forecast, avert or reduce shortages/stockouts"[192]. Those strategies include:

> a) to implement effective notification systems that allow remedial measures to avoid medicines and vaccines shortages;
>
> b) to ensure that best practices for medicines and vaccines procurement, distribution and contract management processes are in place to mitigate the risk of shortages;
>
> c) to develop and/or strengthen systems that are capable of monitoring medicine and vaccine supply, demand, availability and of alerting procurement departments to possible medicine and vaccine availability problems;
>
> d) to strengthen institutional capacity to ensure sound financial management of procurement systems, to prevent funding shortfalls for medicines;
>
> e) to prioritize, in the case of shortages, the health needs of the most affected groups and to ensure these groups have timely access to medicines;
>
> *f)* to advance, gradually, regional and international cooperation in support of national notification systems including, but not limited to, sharing of best practices, training for human capacity building through regional and subregional structures where necessary[193].

188. In particular, the importance of monitoring medicine supply, demand, and availability and of alerting responsible departments to possible shortages cannot be overemphasised. This can be done through Turkey's Drug Tracking System[194]. Turkey can issue special import permits for those

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192 WHO, 69th World Health Assembly, 28 May 2016, WHA 69. 25, Addressing the global shortage of medicines and vaccines, Exhibit - 115.

193 Ibid, Exhibit - 115.

194 Turkey's first written submission, para. 197.

products as soon as a potential risk of scarcity is identified[195]. Imports are a much more time efficient tool than the Localisation Requirement (which can take up to 18 months[196]) in improving access to medicines. Such a tool is also much more targeted in addressing topical supply issues.

189. Furthermore, in those cases where local production can be an effective tool, it can be more effectively supported by resorting to alternative measures which, unlike the Localisation Requirement, do not restrict trade in a manner inconsistent with the WTO Agreement.

190. The World Health Organization has developed a comprehensive "Policy Framework for Government support for local production and access", which lists the following types of measures[197]:

1) *Direct support to reduce the cost of manufacture:*

- Grants, subsidies, soft loans, provision of land;
- Tax and duty exemptions for imported inputs for local production of essential medical products.

2) *Indirect support of local production for improving access:*

- Invest in strengthening regulation of national medical products;
- Develop national priority lists of medical products;
- Improve the financing of health services for expanding the domestic market;
- Facilitate access to foreign markets;
- Facilitate development of regional pooled procurement mechanisms;
- Encourage regulatory harmonization;
- Introduce appropriate pricing policies;
- Facilitate relevant transfer of technology;
- Support incremental innovation and production;
- Develop appropriate intellectual property regimes;
- Develop appropriate investment policies and facilitate joint ventures;

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195 Turkey's first written submission, paras 585 and 592. See Article 2 g) and 4 j) of the Priority Assessment Guideline (Exhibit EU-97).

196 EU's first written submission, para. 105.

197 WHO, Local Production for Access to Medical Products: Developing a Framework to Improve Public Health (2011)pp. 54-60, Exhibit – 116. *See* also WHO and European Commission, Promoting and Supporting Local Manufacturing of Quality Medical Products in Developing Countries – The Business Case for Improving Access, 13 May 2015, p. 5, Exhibit TUR-90.

- Facilitate international cooperation for local production.

191. It will be noted that the above list does not include any measure resembling Turkey's Localisation Requirement.

192. Of particular relevance is the item entitled "Develop appropriate investment policies and facilitate joint ventures". The WHO elaborates on the measures to be taken under this heading as follows:

> Improving the investment climate: A well-tailored investment policy can bring more internal and external financing for local production. Elements of such a policy include simplifying the requirements for doing business in pharmaceutical and other medical products (e.g. business licensing), making it easier for expatriate experts to be dispatched to provide technology transfer (e.g. longer visas for highly skilled technicians sent by technology providers), and establishing high-technology parks with good infrastructure that can apply reliable power and clean water. Guidance for policy-makers is now available in this area. (United Nations, 2011e).
>
> Facilitating strategic joint ventures: Governments can facilitate strategic joint ventures for local production of important essential medical products between local companies and companies from industrialized countries and large developing countries. Such joint ventures in most cases are possible only with the political and direct and indirect fiscal support of governments. Apart from production of medical products that otherwise cannot be produced locally, such ventures can help to ensure complete technology transfer and build local capacity[198].

193. Again, there is nothing in the investment policies advocated by the WHO for supporting local production of pharmaceutical products that may be relied upon to justify trade-restrictive measures such as Turkey's Localisation Requirement.

2.6.2.5 The Localisation Requirement is not applied in accordance with the chapeau of Article XX

194. In the event that the Panel found that the Localisation Requirement is "necessary" to attain the objective alleged by Turkey, the European Union submits that the Localisation Requirement is not applied in a manner compatible with the requirements of the chapeau of Article XX of the GATT 1994.

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198 WHO, Local Production for Access to Medical Products: Developing a Framework to Improve Public Health (2011)pp. 59-60, Exhibit - 116.

195. The Appellate Body has stated that:

> "[o]ne of the most important factors' in the assessment of arbitrary or unjustifiable discrimination is the question of whether the discrimination can be reconciled with, or is rationally related to, the policy objective with respect to which the measure has been provisionally justified under one of the subparagraphs of Article XX ."[199]

196. The Localisation Requirement is applied in a manner which cannot be rationally reconciled with the public health objective alleged by Turkey and, as a result, leads to arbitrary or unjustifiable discrimination between domestic and imported products.

197. The application of the Localisation Requirement is not calibrated to reflect the difference in health risks that may arise in relation with different pharmaceutical products. In principle, the Localisation Requirement applies to all pharmaceutical products covered by the Reimbursement Scheme, regardless of how essential they are, and regardless of the degree of risk of shortage of supply of each group of equivalent products.

198. To the extent that Turkey modulates the application of the Localisation Requirement, by dividing its implementation into five phases, such modulation is at odds with the public health objective allegedly pursued by Turkey. Indeed, as explained above, Phase 1 and Phase 2, the only ones implemented so far by Turkey, cover pharmaceutical products where, by Turkey's own admission, there is no risk of shortage of supply and, hence, no health risk. In the absence of that risk, it becomes clear that the public health objective invoked by Turkey is but an excuse for promoting the economic development and industrial policy objectives pursued by Turkey in the pharmaceutical sector.

2.6.3. Conclusion

199. For the reasons set out above, the inconsistency of the Localisation Requirement with Article III:4 of the GATT 1994 and Article 2.1 of the TRIMS Agreement are not justified under Article XX(b) of the GATT 1994.

2.7. THE LOCALISATION REQUIREMENT IS NOT JUSTIFIED UNDER ARTICLE XX(D) OF THE GATT 1994

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199 Appellate Body Report, *US – Tuna II (Mexico)* (Article 21.5 – Mexico), para. 7.316 (quoting Appellate Body Reports, *EC – Seal Products*, para. 5.306.

200. In the alternative, Turkey submits that Article XX(d) of the GATT 1994 justifies the Localisation Requirement, "because the measure is necessary to secure compliance with the laws and regulations requiring Turkey to ensure accessible, effective and financially sustainable healthcare"[200].

201. More precisely, Turkey argues that the Localisation Requirement is necessary to ensure compliance with two obligations imposed by Turkey's laws and regulations: the obligation to guarantee access to medicines to the Turkish citizens; and the obligation to ensure the financial sustainability of Turkey's public health system.

202. For the reasons explained below, the European Union submits that the Localisation Requirement is not justified under Article XX(d) of the GATT 1994. The Localisation Requirement is not designed to achieve the objective alleged by Turkey, but rather to pursue Turkey's economic development and industry policy goals, and is very trade-restrictive. Turkey has failed to identify "laws and regulations" requiring to ensure the financial sustainability of Turkey's healthcare system with the requisite degree of specificity and normativity. Furthermore, the Localisation Requirement is not necessary to achieve the alleged objective: Turkey has not shown that the Localisation Requirement makes a contribution to that objective and, in any event, there are less trade-restrictive alternatives. In addition, the Localisation Requirements is not applied in accordance with the chapeau of Article XX of the GATT 1994.

2.7.1. The Localisation Requirement is not designed to ensure compliance with laws and regulations requiring Turkey to "ensure accessible, effective and financially sustainable healthcare"

203. The Localisation Requirement is not designed to ensure compliance with laws and regulations requiring Turkey to "ensure accessible, effective and financially sustainable healthcare".

204. Rather, as explained in section 2.6.1, the Localisation Requirement has been designed to promote the economic development and industrial policy objectives pursued by Turkey in the pharmaceutical sector.

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200 Turkey's first written submission, para. 504.

205. The European Union has already explained in section xxxx why the structure and design of the Localisation Requirement are inconsistent with the objective to ensure access to medicines.

206. In turn, that the Localisation Requirement is not designed to ensure the financial sustainability of Turkey's public health system is clearly revealed by the fact that the Localisation Requirement applies equally to all imported products, regardless of their price and irrespective of whether they are more costly than equivalent domestic products.

2.7.2. Turkey has failed to identify laws and regulations requiring to ensure the financial sustainability of Turkey's healthcare system

207. Turkey invokes several provisions included in Turkey's constitution and domestic legislation, as well as in international instruments, which, according to Turkey, would constitute "laws and regulations" within the meaning of Article XX(d) of the GATT 1994[201].

208. Most of those provisions concern the Governments' obligation to provide social security, including healthcare and access to medicines, and the corresponding right of citizens to receive those benefits[202].

209. In contrast, Turkey has identified just two provisions included in Article 405 of Presidential Decree No. 4, of 2018[203], as "laws or regulations" requiring Turkey to ensure the financial sustainability of the SSI.

210. Article 405 reads as follows:

> Purpose and Duties of the Institution
>
> ARTICLE 405- (1) The main purpose of the institution is to implement an effective, fair, easily accessible, actuarially and financially sustainable, social security system based on modern standards and social insurance principles.
>
> (2) The tasks of the Institution are as follows:
>
> a) To implement social security policies by taking into account national development strategies and policies and annual implementation programs, and to work on the development of these policies.

201 Turkey's first written submission, paras. 518-537.

202 Turkey's first written submission, paras. 519-520 (Articles 2 and 56 of the Turkish Constitution), para. 521 (Law No. 5510) para. 523 (Articles 9 and 12 of ICESCR) and para. 525 (Articles 11(1) and 12 ESC).

203 Turkey's first written submission, para. 523.

b) To inform the real and legal persons about their rights and obligations, to facilitate the exercise of their rights and fulfilment of their obligations.

c) On social security issues; to follow international developments, to cooperate with the European Union and international organizations, to carry out the necessary studies on social security agreements with foreign countries, to implement international agreements duly put into effect.

d) To conduct education, research and consultancy activities in the field of social security, to ensure coordination and cooperation between public administrations.

e) To perform duties assigned to the Institution by the legislation[204].

211. More specifically, Turkey relies on the two provisions of Article 405 underlined in the above quotation. However, having regard to the characteristics identified as relevant by the Appellate Body in previous cases[205], those two provisions cannot be considered as "laws" or "regulations" within the meaning of Article XX(d) of the GATT 1994.

212. As indicated by the title of Article 405 and by its own terms, Article 405(1) of Presidential No 4 is but an aspirational provision, whose only function is to set out the "main purpose" that should guide the functioning of the SSI. As such, Article 405(1) lacks the requisite degree of specificity and normativity to qualify as a "law" or "regulation" within the meaning of Article XX(d). Furthermore, Turkey has not shown that Article 405(1) is legally enforceable as such, let alone that its breach may result in any sanctions or penalties.

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204 Article 405 of Presidential Decree No. 4, Exhibit TUR-14. Underlining added.

205 *Cfr.* Appellate Body Report, *India – Solar Cells*, para. 5.113 ("To sum up, in determining whether a responding party has identified a rule that falls within the scope of "laws or regulations" under Article XX(d) of the GATT 1994, a panel should evaluate and give due consideration to all the characteristics of the relevant instrument(s) and should avoid focusing exclusively or unduly on any single characteristic. In particular, it may be relevant for a panel to consider, among others: (i) the degree of normativity of the instrument and the extent to which the instrument operates to set out a rule of conduct or course of action that is to be observed within the domestic legal system of a Member; (ii) the degree of specificity of the relevant rule; (iii) whether the rule is legally enforceable, including, e.g. before a court of law;(iv)whether the rule has been adopted or recognized by a competent authority possessing the necessary powers under the domestic legal system of a Member; (v) the form and title given to any instrument or instruments containing the rule under the domestic legal system of a Member; and (vi) the penalties or sanctions that may accompany the relevant rule.")

213. In turn, paragraph 2 a) of Article 405 limits itself to describe one of the SSI's "tasks" in very general terms. The "national development strategies and policies and annual implementation programs" mentioned in that provision are policy documents, which do not qualify by themselves as "laws" and "regulations" within the meaning of Article XX(d). Furthermore, pursuant to paragraph 2 a), the SSI is merely instructed to "take into account" those policy documents and "work on their development". Again, this provision lacks the requisite degree of specificity and normativity to qualify as a "law" or "regulation" within the meaning of Article XX(d). In addition, Turkey has not shown that Article 405(2) a) of Presidential Decree No 4 is legally enforceable, let alone that its breach may result in any sanctions or penalties.

2.7.3. The Localisation Requirement is not necessary to ensure compliance with laws and regulations requiring Turkey to "ensure accessible, effective and financially sustainable healthcare"

214. The European Union has already demonstrated that the Localisation Requirement is not necessary to ensure access to medicines as part of its response to Turkey's defence under Article XX(b) of the GATT 1994.

215. As regards the alleged obligation to ensure the financial sustainability of Turkey's social security system, the European Union will demonstrate here below that the Localisation Requirement is not necessary for that purpose. Turkey has not met its burden of proving that the Localisation Requirement contributes to achieving that objective and there are less trade restrictive measures.

2.7.3.1 Turkey has not met its burden of proving that local production of the products concerned contributes to achieve the alleged objective of ensuring "financially sustainable healthcare"

216. Turkey's allegation that the Localisation Requirement contributes to the alleged objective of ensuring the financial sustainability of Turkey's healthcare system rests entirely on the following paragraph of its submission:

> Turkey submits that for the financial sustainability, the healthcare system should rely more on domestic products, since the medicines which are domestically produced are less costly over the years and they are more easily supplied. In that sense, in light of the increasing burden of growing medical expenses, the localisation measure mitigates the risk of

> undermining the financial stability of the Turkish healthcare and social security system.[…][206]

217. Turkey has provided no evidence to support any of the assertions made in that paragraph. There is no reason to assume that production costs will be lower in Turkey than in any other WTO Member. To the contrary, the re-localization of the production of medicines from another WTO Member to Turkey may entail higher costs as a result of the ensuing loss of economies of scale and the need to amortize investment costs. Moreover, in the long term, localising the production of reimbursable medicines pursuant to the Localisation Requirement, in combination, with the import ban will lead to less competition on the Turkish market and higher prices.

218. The World Health Organization has observed that:

> If medicines are produced locally, then there is a higher expectation that their prices would be more in line with the purchasing parity of the local population; this may, however, not always be the case. Locally produced generic medicines may not be cheaper than their imported equivalents, or at least not in the initial stages of local production, unless a combination of efficiencies in production and economies of scale can achieved. Unaffordable prices of medicines can be a function of the high cost of local production or of weaknesses in the pricing policy regimes; more often, it is a combination of the two. In addition, the distribution network can significantly increase the final cost of the product to the patient. (Health Action International, 2011)[207]

219. In practice, according to a survey of published evidence conducted by the WHO, there is evidence that "some locally produced medicines are more expensive than foreign-made counterparts (e.g. Brazil, Jordan, Turkey, Malaysia, United Republic of Tanzania, Viet Nam)"[208].

2.7.3.2 The Localisation Requirement is very trade-restrictive

220. As explained above in section 2.6.2.3, the Localisation Requirement is extremely trade-restrictive because, in practice, it has the effect of excluding imported products from a very large part of the Turkish market.

2.7.3.3 There are adequate less trade-restrictive alternatives in order to achieve the objective alleged by

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206 Turkey's first written submission, para. 554.

207 WHO, Local Production for Access to Medical Products: Developing a Framework to Improve Public Health (2011), pp 46-47, Exhibit - 116.

208 WHO, Local Production for Access to Medical Products: Developing a Framework to Improve Public Health (2011), p. 20, Exhibit – 116.

Turkey the alleged objective of ensuring "financially sustainable healthcare"

221. In any event, there are many alternatives to ensure the financial sustainability of Turkey's health system without breaching Turkey's obligations under the WTO Agreement.

222. For example, Turkey could implement one or more of the following alternatives: improving the functioning of Turkey's SSI, with a view to making it more efficient and reducing unnecessary expenditure; increasing the co-payments of patients; increasing the overall tax revenue by raising tax rates or ensuring a more efficient collection; transferring funds from other budgetary lines to the financing of the SSI, etc.

2.7.4. The Localisation Requirement is not applied in accordance with the chapeau of Article XX

223. In the event that the Panel found that the Localisation Requirement is "necessary" to attain the objective alleged by Turkey, the European Union submits that the Localisation Requirement is not applied in a manner compatible with the requirements of the chapeau of Article XX of the GATT 1994.

224. As regards the objective to ensure compliance with laws and regulations requiring Turkey to guarantee access to medicines, reference is made to section xxx.

225. As regards the objective to ensure compliance with the obligation to ensure the financial sustainability of Turkey's SSI, the European Union observes that there is no "rational connection" between that objective and the manner in which the Localisation Requirement is applied[209]. Indeed, the Localisation Requirement applies equally to all imported products, regardless of their price. Even if an imported product is less costly to the SSI than its domestic counterpart, it will still be excluded from reimbursement. As a result, the Localisation Requirement may well have the effect of increasing the reimbursement costs for the SSI, thereby defeating the objective invoked by Turkey.

2.7.5. Conclusion

[209] *Cfr.* Appellate Body Report, *US – Tuna II (Mexico)* (Article 21.5 – Mexico), para. 7.316 (quoting Appellate Body Reports, *EC – Seal Products*, para. 5.306).

226. For the reasons set out above, the inconsistency of the Localisation Requirement with Article III:4 of the GATT 1994 and Article 2.1 of the TRIMS Agreement are not justified under Article XX (d) of the GATT 1994.

2.8. THE LOCALISATION REQUIREMENT IS INCONSISTENT WITH ARTICLE 2.1 OF THE TRIMS AGREEMENT

227. The European Union has submitted that the Localisation Requirement is an investment measure related to trade in goods that is inconsistent with Article III:4 of the GATT. For those reasons, the Localisation Requirement is incompatible with Article 2.1 of the TRIMS Agreement.

228. Turkey does not contest that the Localisation Requirement is an "investment measure" within the scope of the TRIMS Agreement.

229. Turkey limits itself to argue that "given that the localisation measure falls outside the scope of Article III, by virtue of Article III:8(a), it follows that such measure cannot be found to be inconsistent with Article 2.1 of the TRIMs Agreement".

230. As explained above in section 2.4, the Localisation Requirement is not excluded from the scope of Article III:4 by virtue of Article III:8(a). Therefore, the Localisation Requirement is inconsistent with Article 2.1 of the TRIMS Agreement.

2.9. THE LOCALISATION REQUIREMENT IS INCONSISTENT WITH ARTICLE 3.1(B) OF THE SCM AGREEMENT

231. The European Union has submitted that the Reimbursement Scheme operated by Turkey's Social Security Institution (SSI) involves the granting of a "subsidy" in the sense of Article 1.1 of the SCM Agreement. The Localisation Requirement makes the granting of that subsidy contingent upon "the use of domestic over imported goods", thereby violating Article 3.1(b) of the SCM Agreement.

232. The European Union recalls that it has submitted this claim in the alternative to its claim with regard to the Localisation Requirement under Article III:4 of the GATT 1994. In other words, the European Union requests the Panel to rule on this claim only in the event that the Panel were to conclude that the Localisation Requirement is not in breach of Article III:4 of the GATT 1994, or that such breach is justified under any other provision of the GATT 1994.

233. Here below, the European Union will address in turn the arguments made by Turkey in its first written submission with regard to: (i) the existence of a "financial contribution"; (ii) the existence of a "benefit"; and (iii) the contingency of the subsidy "upon the use of domestic over imported goods".

2.9.1. Financial contribution

2.9.1.1 Direct transfer of funds

234. The payments made by the SSI to the pharmacies under the Reimbursement Scheme involve a "direct transfer of funds" from the SSI to the pharmacies. Therefore, those payments constitute "financial contributions" within the meaning of item (i) of Article 1.1 (a) (1) of the SCM Agreement.

235. Turkey contends that the payments made by the SSI to the pharmacies do not involve a "direct transfer of funds" because Article 1.1 (a)(1)(i) of the SCM Agreement is concerned with "various forms of government capital or debt financing to an economic operator to the exclusion of normal payments for goods supplied on behalf of a government entity".

236. Turkey's reading of Article 1.1 (a) (1) (i) of the SCM is unduly narrow. The Appellate Body has clarified that the terms "direct transfer of funds" "captur[e] conduct on the part of the government by which money, financial resources, and/or financial claims are made available to a recipient". In the present case, it is beyond doubt that the SSI is part of the Turkish Government and that, through the Reimbursement Scheme, the SSI does make money available to the pharmacies.

237. The fact that such transfer of funds is part of a broader scheme, which, according to Turkey, involves a "procurement" or "purchase" by the SSI of pharmaceutical products, does not exclude the existence of a "direct transfer of funds".

238. According to the Appellate Body, the "government practice" referred to in Article 1.1 (a)(1)(i) "need not consist, or be comprised, solely of the transfer of funds, but may be a broader set of conduct in which such a transfer is implicated or included" . Furthermore, the transfer of funds may involve "reciprocal rights and obligations". The Appellate Body has further clarified that the fact that a transaction involves a purchase of goods does not exclude its legal characterization as a direct transfer of funds.

2.9.1.2 Entrustment or direction of the provision of goods

239. As explained above in section xxxx, the European Union considers that the Reimbursement Scheme does not involve a "procurement" or "purchase" of pharmaceutical products "for governmental purposes" within the meaning of Article III: 8(a) of the GATT 1994.

240. However, if the Panel agreed with Turkey that the SSI does "procure" and "purchase" pharmaceutical products "for governmental purposes", the European Union submits that the subsequent provision of those goods by the pharmacies to the out-patients would constitute, by itself, a "financial contribution" within the scope of Article 1.1(a)(1)(iv) of the SCM Agreement. Indeed, on that premise, it would have to be considered that: 1) the SSI "entrusts" or "directs" the pharmacies to perform the function of "providing goods" to the out-patients; and 2) such function is one "normally vested in the government and the practice, in no real sense, differs from practices normally followed by governments".

241. Turkey acknowledges that, according to its own construction of the Reimbursement Scheme, "it can be considered that pharmacies have been "entrusted" or "directed" by the SSI to dispense pharmaceutical products to out-patients"[210]. Turkey seeks to qualify this admission by stating this "this does not mean that the reimbursement scheme operated by the SSI amounts to a 'subsidy' within the meaning of the SCM Agreement"[211] and that "[a] holistic analysis of the measure at issue clearly shows that it does not fall within the scope of the SCM Agreement"[212].

242. At this stage of the analysis, however, the only relevant issue is whether the Reimbursement Scheme involves a financial contribution and Turkey has not put forward any argument to contest that the Reimbursement Scheme, as construed by Turkey, would involve a financial contribution within the meaning of Article 1.1 (a)(1)(iv) of the SCM Agreement.

2.9.2. Benefit

243. The financial contributions identified in the preceding section confer a direct "benefit", within the meaning of Article 1.1(b) of the SCM Agreement to the out-patients who receive the pharmaceutical products covered by the

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210 Turkey's first written submission, para. 370.

211 Turkey's first written submission, para. 371.

212 Turkey's first written submission, para. 371.

Reimbursement Scheme and, as a result, also an indirect benefit to the Turkish producers of those pharmaceutical products.

2.9.2.1 Direct benefit

244. The financial contributions identified in the previous section, whether considered each on its own or in combination, confer a direct "benefit", within the meaning of Article 1.1(b) of the SCM Agreement, upon the out-patients who are beneficiaries of the Turkish Social Security System.

245. It is beyond question that the out-patients are "better off"[213] as a result those financial contributions. As acknowledged by Turkey, "the payments made by the SSI to retail pharmacies cover the costs of pharmaceutical products and essentially replace the payments that would have been otherwise required from patients"[214]. In other words, in the absence of the financial contributions identified above, the out-patients would be required to pay to the pharmacies the full price of the pharmaceutical products included in the Reimbursement List in order to receive those products.

246. Turkey does not appear to contest the obvious fact that the financial contributions identified by the European Union confer a direct benefit to the out-patients. Rather, Turkey limits itself to argue such direct benefit "falls outside the scope of the SCM Agreement". By doing so, however, Turkey is responding to an argument that the European Union has not made. The European Union has shown 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[215].

2.9.2.2 Indirect benefit

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213 Appellate Body Report, *US – Large Civil Aircraft (2012)*, para. 662.

214 Turkey's first written submission, para. 364.

215 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.

247. By conferring a direct benefit to the out-patients, the Reimbursement Scheme also confers an indirect benefit to the Turkish producers of the pharmaceutical products covered by the Reimbursement Scheme.

248. Turkey contends that the European Union has failed to meet its burden of proving that the benefit has "passed through" from the out-patients to the Turkish producers of pharmaceutical products.[216]

249. Turkey purports to rely on the guidance provided by the Appellate Body in previous cases with regard to the situation where the producer of a subsidised input was not the same as the producer of the processed product subject to a countervailing duty.[217] That case-law, however, is inapposite because the present case concerns a very different situation. Previous panels have cautioned against extrapolating the case-law on the pass through of input subsidies invoked by Turkey to different situations[218].

250. It is far more relevant to consider the guidance provided by previous panels which have examined specifically the situation where, as in the present case, a subsidy is granted to a purchaser of goods on condition that she purchases goods from certain producers.

251. In *Brazil – Aircraft (Article 21.5 – Canada II)* the underlying subsidy took the form of payments made by the Brazilian Government to a commercial lender in support of export credit transactions. The subsidised export credits were granted to the purchasers of aircraft, rather than to the Brazilian producer of aircraft. The Panel held that the complainant bore the burden of proving that the benefit conferred to the lender had been passed through to the Brazilian producer of aircraft. Nevertheless, the Panel explained that proof that the lender had passed through the benefit conferred by the subsidy received from the Brazilian government to the purchaser of aircraft would, by itself, constitute, "at a minimum", prima facie proof of benefit to the producer:

> We note that PROEX III payments are made in support of export credits extended to the purchaser, and not to the producer, of Brazilian regional aircraft. In our view, however, to the extent Canada can establish that PROEX III payments allow the purchasers of a product to obtain export credits on terms more

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216 Turkey's first written submission, para. 387.

217 Turkey's first written submission, para. 388, referring to Appellate Body Report, *US – Softwood Lumber IV*, paras. 140-141.

218 Panel Report, *Mexico – Olive Oil*, paras. 7.143 and 7.144.

> favourable than those available to them in the market, this will, at a minimum, represent a prima facie case that the payments confer a benefit on the producers of that product as well, as it lowers the cost of the product to their purchasers and thus makes their product more attractive relative to competing products.[219]

252. The approach taken in *Brazil – Aircraft (Article 21.5 – Canada II)* was expressly endorsed by the Panel in *Canada – Aircraft Credits and Guarantees*[220].

253. Contrary to Turkey's suggestions, the decision of the Arbitrator in US-Upland Cotton does not involve a departure from the approach followed by the above-mentioned panels. The arbitrator in *US-Upland Cotton* did not rule on the type of proof required in order to prove that the benefit conferred by a subsidy granted to the purchaser is passed through to the producer. The only issue before the arbitrator was the quantification of the total amount of the benefits conferred by a subsidy for the purposes of determining the level of authorised retaliation. The arbitrator clarified that the benefit that passes through from the purchaser to the producer is not a separate benefit but part of the same benefit conferred upon the purchase. Therefore, the two benefits cannot be added for the purposes of quantifying the total amount of the benefit in view of determining the level of authorised retaliation.[221]

254. The issue before this Panel, however, is not the quantification of the total benefit conferred by the subsidy, but rather whether the direct benefit received by the out-patients confers an indirect benefit to the producers of domestic pharmaceutical products.

255. Turkey notes that, unlike in *Brazil – Aircraft (Article 21.5 – Canada II)*, in the present case there is no direct contractual relationship between the out-patients and the producers of pharmaceutical products. This difference, however, is irrelevant. The mere circumstance that pharmacies and the wholesalers act as intermediaries does not alter the essential fact that the financial contributions lower the costs to the out-patients, who, as final customers, drive the demand for the product. Nor, consequently, does that circumstance deprive the domestic producers from the advantage vis-à-vis

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219 Panel Report, *Brazil – Aircraft (Article 21.5 – Canada II)*, fn 42.

220 Panel Report, *Canada – Aircraft Credits and Guarantees*, para. 7.229.

221 Decision by the Arbitrator, *US – Upland Cotton* para. 4.148, fn.199 ("[…] Rather, the benefit conferred on the producers was simply part of the benefit conferred in the first instance on the recipients of the financial contribution that had passed-through, in the second instance, to the producers. In other words, the benefit

competing products on the market mentioned by the panel *Brazil – Aircraft (Article 21.5 – Canada II)*.

256. Turkey further contends that "the choice of the pharmaceutical product is not left to the patient"[222]. Rather, according to Turkey, "it is a decision made by a medical doctor motivated by the health needs of the patient"[223]. However, this is contradicted by Turkey's own description of the Reimbursement Scheme, which evidences that patients do have certain choices. In particular, where a product is a "generic" or belongs to a group of "equivalent products" (which is the case for the majority of the products, including all the products covered by phase 1 and phase 2 of the localisation measure[224], the only ones implemented so far), the out-patient is allowed to purchase the product of his choice among the generic or equivalent products.[225]

2.9.3. Contingency upon the use of domestic over imported goods

257. As explained in the EU' first written submission, the subsidy identified in the preceding sections is contingent upon the use of domestic over imported goods by the out-patients. Both the financial contributions and the benefits thereby conferred are conditional upon the out-patients being provided pharmaceutical products included in the Reimbursement List[226], for their personal use.[227] In turn, the inclusion of a product in the Reimbursement List is conditional upon the product being produced in Turkey.[228]

258. Turkey contends that "the use of pharmaceutical products by patients does not lead to contingency within the meaning of Article 3.1(b) of the SCM Agreement"[229]. According to Turkey, "in essence Article 3.1(b) prohibits the use of local content requirements"[230].

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222 Turkey's first written submission, para. 400.

223 Ibid.

224 Turkey's first written submission, para. 139

225 Turkey's first written submission, para. 87

226 European Union's first written submission, para. 293.

227 European Union's first written submission, para. 296.

228 European Union's first written submission, para. 295.

229 Turkey's first written submission, para. 406.

230 Turkey's first written submission, para. 406.

259. Turkey's reading of Article 3.1(b) of the SCM Agreement is not required by the text of that provision and is unduly narrow in view of the context and the specific object and purpose of that provision. While in practice "local content subsidies" may be the most usual form of subsidies contingent upon the use of domestic over imported goods, the terms of Article 3.1(b) of the SCM Agreement may encompass as well other types of subsidies.

260. Turkey's interpretation disregards the ordinary meaning of the term "goods", which includes not only inputs but also finished goods. In US – Tax Incentives, the Appellate Body noted that the term "goods" can be read as a synonym for "products".[231] The Appellate Body pointed out that this term may refer to "any type of good"[232].

261. The term "goods" is one of the most frequently used in the WTO Agreement. Yet nowhere in the WTO Agreement is the term "goods" used as excluding finished goods. Had the drafters of Article 3.1(b) intended to capture exclusively local content subsidies, they would have used another term such as "inputs" rather than "goods", or required that "goods" be "used" as "inputs" or "tools"[233].

262. In turn, in *US – Carbon Steel*, the Appellate Body interpreted the term "use" as "the action of using or employing something"[234]. The Appellate Body added, in *US – Tax Incentives*, that the meaning of this term would vary "depending on the particular circumstances":

> Article 3.1(b) does not elaborate on what constitutes 'use of … goods'; nor do other provisions of the SCM Agreement or other covered agreements define this term. In the absence of any further guidance, the term 'use' may, depending on the particular circumstances, refer to consuming a good in the process of manufacturing, but may also refer to, for instance, incorporating a component into a separate good, or serving as a tool in the production of a good.[235]

263. The above quoted passage confirms that the "uses" mentioned by Turkey[236] are just examples, derived from the local content subsidies addressed by

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231 Appellate Body Report, *US – Tax Incentives*, para. 5.9.

232 Appellate Body Report, *US – Tax Incentives*, para. 5.9.

233 The term "input" was well-known to the drafters of the SCM Agreement. It is used no less than 34 times in the SCM Agreement.

234 Appellate Body Report, *US – Carbon Steel (India)*, para. 4.374.

235 Appellate Body Report, *US – Tax Incentives*, para. 5.9. Underlining added.

236 Turkey's first written submission, para. 406.

the Appellate Body in the cases mentioned above, and do not exhaust the meaning of "use", which may be different in other circumstances.

264. The terms of Article 3.1(b) of the SCM Agreement only require the use of domestic over imported goods, without any further specification. Article 3.1(b) does not require that the goods be used by an enterprise, let alone by the same producer of goods who benefits from the subsidy. As illustrated by the present case, the recipient of a financial contribution, and direct beneficiary of a subsidy, may be a different enterprise or person from the producer of goods who is the ultimate beneficiary of the subsidy[237]. In that situation, a requirement that the recipient of the financial contribution and direct beneficiary of the subsidy uses domestic over imported goods may be sufficient to bring the subsidy within the scope of Article 3.1(b) of the SCM Agreement.

265. Article 3 of the SCM Agreement prohibits certain types of subsidies because they were regarded by the drafters as being particularly pernicious in light of the object and purpose pursued by the SCM Agreement and the WTO Agreement as a whole. The prohibition is not based on the amount of the subsidy, or on the actual or threatened trade effects of the subsidy. Rather, the prohibition is based on the sole fact that the subsidy is subject to a condition which is assumed, *a priori*, to be highly trade-distortive. Thus, Article 3.1(b) prohibits subsidies contingent upon the use of local goods over imported goods because that condition discriminates between domestic and imported goods. *A priori*, such form of discrimination is no less trade-distortive when the goods concerned are finished products than when they are inputs, as confirmed by the fact that Article III:4 of the GATT 1994 prohibits on equal terms discrimination between all imported and domestic goods, without making any distinction between inputs and other goods.

266. Turkey further contends that "the alleged subsidy, if anything, is conditional upon the domestic production of pharmaceutical products and not upon the *use* of domestic over imported goods"[238] and that "the fact that subsidies

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237 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

238 Turkey's first written submission, para. 411.

provided for domestic production are WTO-consistent is confirmed by Article III:8(b) of the GATT 1994"[239].

267. However, the subsidy identified by the European Union is not contingent upon domestic production alone. Unless an out-patient requests and is provided a product included in the Reimbursement List, no financial contribution is made by the SSI, and no benefit is thereby conferred, either directly to the patient or indirectly to the domestic producer.

268. Article III:(8)(b) of the GATT 1994 allows "the payment of subsidies exclusively to domestic producers". The subsidies at issue in this case do not involve "payments" made "exclusively to domestic producers". Rather, the SSI makes payments to the pharmacies, which are conditional upon the out-patients being provided and using domestic goods included in the Reimbursement List. In turn, those payments provide an indirect benefit to the domestic producers. It is well-established since the early years of the GATT 1948 that payments to the purchasers of domestic goods do not qualify as "payments" that are "made exclusively to domestic producers" within the meaning of Article III:8(b) of the GATT 1994[240].

2.9.4. Conclusion

269. The Reimbursement Scheme operated by Turkey's Social Security system involves the granting of a "subsidy" in the sense of Article 1.1 of the SCM Agreement. The Localisation Requirement makes the granting of that subsidy contingent upon "the use of domestic over imported goods", thereby violating Article 3.1(b) of the SCM Agreement.

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239 Turkey's first written submission, para. 412.

240 *See* GATT Panel Report on *Italian Discrimination against Agricultural Machinery*, L/833, adopted on 23 October 1958, 7S/60, 64, para. 14 ("The Panel agreed with the contention of the United Kingdom delegation that in any case the provisions of paragraph 8(b) would not be applicable to this particular case since the credit facilities provided under the Law were granted to the purchasers of agricultural machinery and could not be considered as subsidies accorded to the producers of agricultural machinery").

See also GATT Panel Report on *European Economic Community - Payments and Subsidies paid to Processors and Producers of Oilseeds and related Animal-Feed Proteins,* L/6627, adopted on 25 January 1990, 37S/86, 124, para. 137 ("The Panel noted that Article III:8(b) applies only to payments made exclusively to domestic producers and considered that it can reasonably be assumed that a payment not made directly to producers is not made 'exclusively' to them. It noted moreover that, if the economic benefits generated by the payments granted by the Community can at least partly be retained by the processors of Community oilseeds, the payments generate a benefit conditional upon the purchase of oilseeds of domestic origin inconsistently with Article III:4. Under these circumstances Article III:8(b) would not be applicable because in that case the payments would not be made exclusively to domestic producers but to processors as well".)

3. THE IMPORT BAN ON LOCALISED PRODUCTS

3.1.1. The European Union established the existence and content of the Import Ban on localised products

270. The European Union claims that there is an import ban on localised products and that this import ban is inconsistent with Article XI:1 of the GATT 1994.

271. Turkey replies that the European Union failed to establish the existence and precise content of the Import Ban because of the following:

i. the legal entity that has a marketing authorisation for a specific pharmaceutical product, may obtain another marketing authorisation for the same pharmaceutical product if that product has a slightly different composition (e.g. dosage) or is presented in a different form;

ii. a sister company may requesting a marketing authorisation for the same pharmaceutical product with the same composition and in the same pharmaceutical form;

iii. even where two products have the same qualitative and quantitative composition and same pharmaceutical form, if they are used for different indications (i.e. for different diseases), the two products can receive different marketing authorisations.

272. The European Union notes that Turkey's claims do not deny the existence of an import ban for the localized pharmaceutical product with respect to the marketing authorisation already granted (product with the same formulation and pharmaceutical form, already authorized by the Ministry, to the same real person or legal entity).

273. The evidence produced by Turkey confirms the existence of the Import Ban. A comparison[241] of the table with sales data 2018-2019 (IQVIA database)[242], relied on by Turkey to show that "pharmaceutical products which did not comply with the localisation measure continue to be sold on the Turkish market", with "the Reimbursement List", updated as of 5 May 2020[243] shows that, on average, imports of products in the list TUR-103 decreased by 61% in 2019 compared to 2018; that for 53% of the products in the list TUR-103, imports decreased by more than 95% in 2019 compared to 2018; and that for 31% of the products in the list TUR-103, imports fell to zero in 2019.

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241 Exhibit EU-113.

242 Exhibit TUR-103, para. 494 of Turkey's first written submission.

243 Exhibit EU-102.

274. Next, the European Union disagrees with Turkey's points ii. and iii. above.

275. First, sister companies cannot get different marketing authorisations.

276. According to Articles 4 aa) and 8 o) and ö) of the Regulation on Marketing Authorisation of Medicinal Products for Human Use[244], one product can have more than one MA holder (co-marketing), but this concerns a product with the same qualitative and quantitative composition, the same pharmaceutical form, the same manufacturing site and otherwise identical in all aspects, other than trade name, with the authorized product or the product for which an authorization application or co-application has been filed. Therefore, it is not possible to be granted an import and local marketing authorisation for a co-marketed product with the same trade name.

277. Second, two products with the same qualitative and quantitative composition and same pharmaceutical form are not granted two different marketing authorisations for different diseases. Additional therapeutic indications are submitted via variation applications to the same marketing authorisation already granted.

278. Specifically, Article 8 of the Regulation on Marketing Authorisation of Medicinal Products for Human Use provides that applications for marketing authorisations include information about "Therapeutic indications, contraindications and adverse reactions", meaning that a marketing authorisation may cover several indications, while Articles 1 and 7 of the Regulation on Variations provide that additions to or variations in therapeutic indications to products already registered or with registration pending make the object of Type II variation applications. Article 27 of the Regulation on Marketing Authorisation of Medicinal Products for Human Use also provides that all variations pertaining to the product, to be performed in consequence to the granting the marketing authorisation of a product, shall be submitted to the Ministry by the marketing authorisation holder.

279. Turkey also contends that the European Union failed to establish that the different components function together and form a single overarching measure, distinct from its parts, with the objective of prohibiting imports.

280. However, the EU has identified in its first written submission, the legal instruments which provide that when a pharmaceutical product has been localised in Turkey in accordance with the Localisation Requirement, it can

244 Exhibit EU-89.

no longer be imported because, following the required variation procedure, it lacks the import marketing authorisation necessary for importation. In particular, Article 20(2) of the Regulation on the Marketing Authorisation of Medicinal Products for Human Use[245], Article 4 of the Regulation on Variations[246] and several other documents[247] further showing that companies are required to change their marketing authorisation from import to local within the Localisation Requirement. As noted above, Turkey does not deny that the pharmaceutical products with the same formulation and pharmaceutical form as localised pharmaceutical products cannot be imported. This falls squarely within the definition of an import ban.

281. Further, Turkey essentially submits that the claim under Article XI:1 of the GATT 1994 must be rejected because the marketing authorisation rules do not fall within the scope of Article XI:1 as they constitute an internal measure within the meaning of Article III:4.[248]

282. This argument is unfounded.

283. Article XI:1 imposes an obligation on Members not to institute or maintain import and export prohibitions or restrictions. Previous panels have interpreted this provision in a broad manner so as to apply to any measures instituted or maintained by a Member prohibiting or restricting the importation or exportation of goods other than measures that take the form of duties, taxes or other charge. Article XI:1 does not distinguish among categories of import and export prohibitions or restrictions; instead, it refers to import and export prohibitions or restrictions in general.[249]

284. 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. The lack of an import marketing authorisation for a particular pharmaceutical products leads to the impossibility to import that product because a 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.

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245 European Union's first written submission, paras. 303-304.

246 European Union's first written submission, paras. 307-308.

247 European Union's first written submission, paras. 309-317.

248 Turkey's first written submission, paras. 608-616

249 Panel Report, *Argentina – Import Measures*, para. 6.440.

The importer is required to submit the inspection certificate when making a customs declaration at customs offices. According to the "Announcement on import applications for medical products" with Annexes and Model Statement of 31 December 2019, a marketing authorisation is a prerequisite for obtaining the inspection certificate.[250] In addition, the mere fact that marketing authorization rules also apply to domestic products cannot render Article XI:1 of the GATT 1994 inapplicable.

3.1.2. The import ban on localised products is cannot be justified under Article XX(d) of the GATT 1994

285. Turkey submits that the Import Ban is justified under Article XX(d) of the GATT 1994 because :

i. the effect of the measure is to ensure the effectiveness and compliance with the localisation measure which itself is not inconsistent with the GATT;

ii. it is necessary to secure that compliance, and

iii. it is applied in a manner consistent with the chapeau of Article XX.

286. Turkey argues that the Import Ban prevents pharmaceuticals manufacturers from circumventing the localisation measure by localizing a negligible part of production of a given product and supplying the remaining part by importation and that the Localisation Requirement is consistent with the GATT 1994.

287. The European Union has demonstrated that the Localisation Requirement is inconsistent with the GATT 1994. However, if the Panel were to find that the Localisation Requirement is consistent with the GATT 1994, the European Union submits that the Import Ban cannot be justified under Article XX(d).

3.1.3. The Import Ban is not a measure "to secure compliance" with the Localisation Requirement

288. It should be recalled that, it is well established in GATT/WTO jurisprudence that the phrase "to secure compliance with laws or regulations" in Article XX(d) means measures "to enforce obligations under laws or regulations", and not measures "to ensure the attainment of the objectives of the laws

250 See European Union's first written submission, paras. 301, 319-321, and Article 4 of the Regulations on Import Control and the "Announcement on import applications for medical products" with Annexes and Model Statement of 31 December 2019 (Exhibit EU-92) that refers to marketing authorisation as "licence".

and regulations". Therefore, prior panels have found that measures that may be consistent with or further the objectives of a law or regulation, but which do not enforce any obligations contained therein, do not fall within the scope of Article XX(d).[251]

289. For example, in *Canada – Periodicals*, Canada asserted that a prohibition on imported magazines containing domestic advertising was required to secure compliance with a tax measure that limited deductions to expenses incurred in advertising in domestic magazines. The panel concluded that although the ban on imported magazines might have the incidental consequence of ensuring that the tax deduction was not abused, and, therefore, the ban "may share the same policy objective" with the tax measure, that alone was insufficient to establish that the import ban was meant to "secure compliance" with tax legislation.[252] Likewise, in *Canada – Wheat Exports and Grain Imports*, the panel found that the measure "may allow Canada … to ensure the attainment of the objectives" of the Canada Grain Act, but that this did not suffice to establish that it was a measure designed to "secure compliance" with laws or regulations. Canada argued that if certain products, such as GMO grain not approved in Canada, were found in shipments of Canadian grain, this would have deleterious effects on Canadian exports, as it would have a negative impact on consumer confidence in Canada's quality assurance system. The Panel rejected this argument, stating:

> We note in this respect that Article XX(d) provides that the WTO-inconsistent measure that is sought to be justified must be "necessary to secure compliance with laws and regulations" that are not themselves inconsistent with the provisions of the GATT 1994. The panel in European Economic Community - Regulations on Imports of Parts and Components found this phrase to mean "to enforce obligations under laws and obligations" and not "to ensure the attainment of the objectives of the laws and regulations". Therefore, the fact that Section 57(c) of the Canada Grain Act may allow Canada to control for SPS and GMO problems and thus helps Canada preserve consumer confidence which, in turn, helps to ensure the attainment of the objectives of, say, the Canada Grain Act, would not be sufficient to bring Section 57(c) within the protective scope of Article XX(d).[253]

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251 Panel Report, *India — Solar Cells*, para. 7.330.

252 Panel Report, *Canada – Periodicals*, para. 5.10.

253 Panel Report, *Canada – Wheat Exports and Grain Imports*, para. 6.248.

290. In the present case, the Import Ban is not a mean "to enforce obligations"[254] under the Localisation Requirement to manufacture domestically as it does not oblige foreign producers to actually manufacture in Turkey. Although the Import Ban might have the incidental consequence of ensuring that the commitments of the foreign producers to produce domestically are not abused, and, therefore, the Import Ban "may share the same policy objective" with the Localisation Requirement, that alone is insufficient to establish that the Import Ban was meant to "secure compliance" with the Localisation Requirement. Further, it should be recalled that the Regulation on the Marketing Authorisation of Medicinal Products for Human Use predates the Localisation Requirement measure and its Article 20(2) prohibits the importation of all pharmaceutical products that are manufactured domestically, not only of the localised products.

3.1.4. The Import Ban is not "necessary" within the meaning of Article XX(d)

291. First, the European Union does, of course, agree that the alleged objective to ensure adequate access to medicines falls within the scope of Article XX(b) of the GATT 1994 and is "extremely vital and important". However, as explained above,[255] the Localisation Requirement is not designed to achieve the public health objective alleged by Turkey. Rather, the Localisation Requirement has been designed to promote the economic development and industrial policy objectives pursued by Turkey in the pharmaceutical sector.

292. Moreover, as explained above (section **Error! Reference source not found.**) Turkey has provided no relevant evidence of the existence of a risk of shortage of supply.

293. Second, even if the Panel were to consider that the objective of the Localisation Requirement is the uninterrupted access to safe, effective and affordable medicines for all patients in Turkey (*quod non*), the Import Ban cannot contribute to that objective precisely because it prohibits the import of localized pharmaceutical products thus contributing to a shortage of supply of medicines. The existence of the special import authorization[256] rather tends to confirm that the Import Ban may create shortages of localised pharmaceutical products.

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254 Panel Report, *Canada – Periodicals*, para. 5.9.

255 Section **Error! Reference source not found.**.

256 Turkey's first written submission, paras. 585, 592

294. Even if the Panel were to consider that the Import Ban may contribute to the establishment of a local production of pharmaceutical products, it is generally agreed, however, that local production of pharmaceutical products is not a panacea for improving access to medicines. In specific contexts, and subject to certain conditions, local production may be a useful tool, alongside other policy tools, for improving access to medicines. In other contexts, however, local production may fail to contribute to improving access to medicines. Indeed, depending on the circumstances, efforts to promote local production may well be counterproductive, by increasing unnecessarily the costs of medicines or lowering their quality.[257]

295. Third, the Import Ban, as a compliance measure for the Localisation Requirement, produces very restrictive effects on international trade since it prohibits any importation of the localized pharmaceutical products. The only exception is the "special import authorization" in case of difficulty in the supply of the pharmaceutical product concerned,[258] but this authorization is set out precisely to deal with already existing shortages of supply. As to the possibility to obtain a marketing authorization for a localized pharmaceutical product in a different dosage or form, these alternative products are not an option for patients.

296. In sum, the European Union concludes that the objective of the Localisation Requirement, the measure that the Import Ban is designed to ensure compliance with, is to promote the economic development and industrial policy objectives pursued by Turkey in the pharmaceutical sector and not to provide adequate access to medicine. Turkey has also failed to provide relevant evidence of the existence of a risk of shortage of supply. With regard to the trade-restrictiveness of the measures, the Import Ban is a very restricting measure as it prohibits importation of localised products. With regard to the contribution of the Localisation Requirement to the realization of Turkey's alleged objective to ensure uninterrupted access to medicine, the Import Ban undermines that objective by prohibiting importation of localised products.

3.2. Alternative measures

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257 See paras.**Error! Reference source not found.**-**Error! Reference source not found.** above.

258 Priority Assessment Guidelines, Article 2 g) and 4 j) (Exhibit EU-97).

297. The Appellate Body has clarified that a measure will not be considered "necessary" within the meaning of Article XX(d) of the GATT 1994 "if an alternative measure which [a Member]could reasonably be expected to employ and which is not inconsistent with other GATT provisions is available to it".[259] The alternative measure must be one that preserves for the responding Member its right to achieve its desired level of protection with respect to the objective pursued and is reasonably available to it.[260] Moreover, in addition to the difficulty of implementing a measure, consideration should be given to the following: (i) whether it is a WTO-consistent measure or entails a lesser degree of inconsistency; (ii) the extent to which it contributes to the realization of the end pursued; and (iii) whether it has effects less trade-restrictive than the measure at issue.[261]

298. In this case, the European Union considers that a labelling requirement for localized products indicating that they are domestically produced is an alternative measure that Turkey could reasonably be expected to employ and which is not inconsistent with other GATT provisions.

299. Such measure would preserve Turkey's right to achieve its desired level of compliance with the Localisation Requirement as pharmacies could easily distinguish between an imported and a domestically manufactured product to reimburse only the latter. Moreover, this alternative measure is significantly less trade-restrictive than the Import Ban since it allows the importation of localised products.

3.3. Conclusion

300. For the reasons set out above, the inconsistency of the Import Ban with Article XI:1 of the GATT 1994 is not justified under Article XX (d) of the GATT 1994.

4. THE PRIORITIZATION MEASURE

301. Turkey argues that the European Union failed to demonstrate the existence of the Prioritization Measure and its general nature because the legal

259 Appellate Body Report, *Korea – Various Measures on Beef*, paras. 162-164.

260 Appellate Body Report, *US – Gambling*, para. 308.

261 Appellate Body Report, *EC – Asbestos*, paras. 170-172.

instruments create the possibility of granting priority to certain applications, but is subject to the discretion of the relevant body.[262]

302. The European Union recalls that Turkish legislation 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. The Priority Assessment Guideline also enables giving priority, inter alia, to applications regarding pharmaceutical products manufactured in Turkey. No such possibility exist for imported products that are like local products.[263]

303. Specifically, the assessment criteria for priority show that Turkish legislation actually mandates giving priority to locally manufactured products. Annex 3 of the Priority Assessment Guideline regarding the Prioritization Assessment Criteria and Scoring Chart attributes a coefficient of 0.15 to applications concerning Local production. Article 10 d) also confirms this: "Total weighted score obtained in the event that the product is locally manufactured, domestic active substance is used, bioequivalence studies and clinical research are carried out in our country, multiply by coefficients stated in the related part (4, 5, 6)." Further, Article 10 ğ) indicates that locally manufactured product applications is not a mere factor to be assessed discretionarily but a mandatory criterion: "the priority matter of locally manufactured product applications relating to the transferring of production of imported medicines to our country is assessed by the Commission."

304. Turkey's actions plans and programmes further confirm that domestically produced medicines are granted priority for reimbursement, pricing policies and licensing procedures.[264] Turkey seeks to show that these action plans and programmes are not current anymore as shown by the absence to any prioritization in the 11th Development Plan for the period 2019-2023.[265] However, the 11th Development Plan is a general document with a short

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262 Turkey's first written submission, paras. 662-677.

263 Except for the imported products included on the "Foreign Price List of Medicinal Products" or covered by the special import permit applications needed to cover domestic shortage of supply.

264 European Union's first written submission, paras. 323-329.

265 Turkey's first written submission, para. 676.

section on pharmaceuticals and medical devices.[266] On the contrary, recent reports continue to refer to priority given to domestically manufactured products:

i. the Turkish healthcare market from September 2020 refers to priority granted for "Technology transfer to Turkey"; [267]

ii. SSI's 2018 report: "In reimbursement and pricing policies and in licensing procedures, the requisite arrangements and applications are to be put in place for priority assessment of medicines and medical devices produced in Turkey.";[268]

iii. TMMDA Administrative Operation Report 2019, published in February 2020 also provides that :"OBJECTIVE 3: To prioritise assessment of applications for medicines that contribute to public health and the national economy, and to support domestic [yerli, which can also mean local] production".[269]

305. Turkey's submission that "…while the action plan set out the objective to evaluate with priority the reimbursement applications filed for domestically produced products, this does not prejudge whether priority will be granted in each case"[270] actually concedes that in certain cases applications filed for domestically produced products will be granted priority.

306. Even if the applications for prioritization for product manufactured in Turkey are not granted in each and every case, it is well-established that that there is less favourable treatment even where the measure "will not give rise to less favourable treatment for like imported products in each and every case",[271] or where the coverage of the measure is partial.[272]

307. If the relevant bodies grant priority only for some applications involving domestically manufactured products, this might minimize the adverse effects on competitive opportunities as between imported and like domestic

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266 Exhbit EU-88, pages 87-88.

267 Exhibit EU-117, page 76.

268 Exhibit EU-109, page 29. The original report can be found at the following web link: http://www.sgk.gov.tr/2018FaaliyetRaporu.pdf (accessed on 29 October 2020)

269 Exhibit EU-111, pages 200-201. Excerpts from this document have been attached as Exhibit TUR-78. The entire report can be found here https://titck.gov.tr/storage/Archive/2020/dynamicModulesAttachment/dareFaaliyetRaporu2019_ff2cc850-3c5c-481f-b9d0-fa0697088549.pdf (accessed on 29 October 2020)

270 European Union's first written submission, para. 675.

271 Appellate Body Report, *US – FSC (Article 21.5)*, para. 221.

272 Panel Report, *India – Solar Cells*, para. 7.95.

products in general. For those specific domestic products which are given priority, though, the competitive opportunities are affected. Thus, the possibility to obtain priority is still only available for domestically manufactured products and amounts to less favourable treatment.[273]

308. The argument[274] that the European Union must demonstrate that Turkey effectively gives priority to domestic pharmaceutical products over imported products is unfounded as Article III:4 seeks to ensure effective equality of opportunities and showing "less favourable treatment" does not require proof of actual effects.[275]

309. Turkey also provides a table[276] purporting to show that locally manufactured products are not granted priority by the HMPPAC[277] compared to imported products.

310. The table splits pharmaceutical products between domestic and imported but fails to single out the number of applications for priority based on the being manufactured domestically which is the relevant issue here. The fact that, overall, the number of imported and domestic products that were granted priority is similar does not inform as to how frequently domestic products get priority because they are manufactured domestically. Imported and domestic products may get priority review for a series of reasons, such as being a first generic product, being innovative or making the object of special import permit applications/being included in the foreign medicine procurement list.[278] The mere fact that, overall, the imported and domestically manufactured products have similar rates of priority review does not show the absence of less favourable treatment for imported products. The WTO jurisprudence under Article III has rejected offsetting less favourable treatment of some imported products with more favourable treatment of other imported products.[279]

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273 Panel Report, *Canada — Wheat Exports and Grain Imports*, para. 6202: "In the Panel's view, if the CGC were to grant unconditional advance authorization for all imported grain, this might minimize the adverse effects on competitive opportunities as between imported and like domestic grain. However, there would still be a need to make a request for authorization. As already noted above, the requirement to make a request for authorization is an additional requirement that is imposed exclusively on imported grain and amounts to less favourable treatment."

274 Turkey's first written submission, para. 672.

275 Appellate Body Report, *Japan – Taxes on Alcoholic Beverages II*, para.35.

276 Exhibit TUR-106.

277 Human Medicinal Products Priority Assessment Commission.

278 Article 2(e) of the Priority Assessment Guideline.

279 Appellate Body Report, *India — Additional Import Duties*, footnote 405.

4.1. Prioritization Measure is a "law", "regulation" or "requirement"

311. According to Turkey the European Union failed to substantiate how or why the Prioritization Measure as an overarching measure is a "law" or "regulation" by merely referring to two legal instruments that are components of, or elements through which the measure is implemented, but do not constitute the measure at issue.[280]

312. The European Union replies that the Prioritization Measure is embodied, wholly or at least partly, as shown above and in the first written submission,[281] in formal legal instruments such as laws and guidelines. These instruments clearly qualify as "laws" or "regulations" resulting from "governmental action" and setting out rules with which compliance is necessary to obtain an advantage from a government.

313. In any case, Article III:4 applies not only to mandatory measures but also to conditions that an enterprise accepts in order to receive an advantage, including in cases where the advantage is in the form of a benefit with respect to the conditions of importation of a product.[282] The legal instruments in this case qualify at least as "requirements" within the meaning of Article III:4, because they set out the conditions and procedures that need to be followed to benefit from the priority for reimbursement, pricing policies and licensing procedures and they are issued by public authorities responsible for these matters.

314. Finally, in line with the findings of the panel in *Argentina–Import Measures*,[283] the governmental action plans and programmes in this case that presented the Prioritization Measure as a policy of the Turkish government also qualify as "requirement".

4.2. The Prioritization Measure accords less favourable treatment to imported like products

315. Turkey essentially claims that the Prioritization Measure does not accords less favourable treatment to imported like products given the discretion of the authorities when assessing the priority applications for inclusion in the

280 Turkey's first written submission, paras. 686-689.

281 European Union's first written submission, paras. 323-329.

282 Panel Report, Canada-Autos, para. 10.73.

283 Panel Report, *Argentina–Import Measures*

reimbursement scheme and the review of GMP and marketing authorization applications.[284]

316. The European Union refers to its explanations above that the legal instruments underpinning the Prioritization Measure do not confer unfettered discretion to the responsible bodies. The SSI Regulation on Drug Reimbursement and the Priority Assessment Guideline actually mandate as a favourable criterion in assessing priority the local manufacture of pharmaceutical products.

317. Contrary to Turkey's assertions,[285] the fact that imported products could get priority for other reasons is not sufficient to refute the existence of domestic manufacturing as criterion for priority. In the absence of this criterion, it is likely that fewer domestically manufactured products would get priority review. The priority review granted by the Turkish authorities to products of domestic origin means that these products are likely to be placed on the market faster than imported products.

318. Lastly, Turkey provides a table[286] showing the number of applications the Medical Reimbursement Commission included in the reimbursement list with a breakdown between domestic and imported products. The table has limited relevance as it does not mention the speed with which products are included in the reimbursement list in a given year. On the contrary, the table actually clearly shows that domestic products are included faster in the reimbursement list than imported products. For example, in the period 1 of 2017 (30.11.2016-02.10.2017) only 11 imported products out of 56 were included in the reimbursement list in 2017 compared with 85 out of 174 applications for domestic products. Likewise, in period 2 of 2017 (18.04.2017-02.10.2017) only 2 out of 30 imported products were included in the reimbursement list in 2017 compared with 39 out of 139 domestic products. In percentage terms, if one compares the shares of granted applications by year, the data shows for instance that from 24% to 92% of domestic applications were already granted by the Medical Reimbursement Commission within the first year following application, while only a share

284 Turkey's first written submission, paras. 690-697.

285 Turkey's first written submission, paras. 694.

286 Exhibit TUR-64.

from 8% to 58% of import applications were granted within the same period of time.[287]

5. CONCLUSIONS

319. For the reasons set out in this submission, the European Union requests the Panel to find that:

1) The Localisation Requirement is inconsistent with Turkey's obligations under Article III:4 of GATT 1994, Article X:1 of GATT 1994 and Article 2.1 of the TRIMs Agreement;

2) To the extent that the Panel found that the Localisation Requirement is not inconsistent with Article III:4 of the GATT 1994, that such measure is inconsistent with Article 3.1(b) of the SCM Agreement;

3) The Import Ban on localised products is inconsistent with Turkey's obligations under Article XI:1 of GATT 1994; and

4) The Prioritization Measure is inconsistent with Turkey's obligations under Article III:4 of GATT 1994.

[287] Exhibit EU-118 regarding the Share of granted applications local v imported products, see Table 3.