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

ARBITRATION UNDER ARTICLE 25 OF THE DSU

AWARD OF THE ARBITRATORS

(22-5590)

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# ABBREVIATIONS USED IN THIS AWARD

Abbreviation	Description
Agreed Procedures	Agreed Procedures for Arbitration under Article 25 of the DSU, notified by the parties to the Dispute Settlement Body on 22 March 2022 (WT/DS583/10)
DSB	Dispute Settlement Body
DSU	Understanding on Rules and Procedures Governing the Settlement of Disputes
GATS	General Agreement on Trade in Services
GATT 1994	General Agreement on Tariffs and Trade 1994
GPA	Agreement on Government Procurement
Panel Report	Final Panel Report as issued to the parties in <i>Turkey – Certain Measures</i> <i>Concerning the Production, Importation and Marketing of Pharmaceutical</i> <i>Products</i> , attached to Türkiye's notice of recourse to arbitration (WT/DS583/12 and WT/DS583/12/Add.1)
SCM Agreement	Agreement on Subsidies and Countervailing Measures
SSI	Social Security Institution
TMMDA	Turkish Medicines and Medical Devices Agency
ТРА	Turkish Pharmacists' Association
TRIMs Agreement	Agreement on Trade-Related Investment Measures
Vienna Convention	Vienna Convention on the Law of Treaties, done at Vienna, 23 May 1969, UN Treaty Series, Vol. 1155, p. 331
Working Procedures	Working Procedures for Arbitration under Article 25 of the DSU, adopted by the Arbitrators on 10 May 2022
WTO	World Trade Organization

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# CASES CITED IN THIS AWARD

Short title	Full case title and citation
Australia – Salmon	Appellate Body Report, Australia – Measures Affecting Importation of Salmon, <u>WT/DS18/AB/R</u> , adopted 6 November 1998, DSR 1998:VIII, p. 3327
Brazil – Retreaded Tyres	Appellate Body Report, <i>Brazil – Measures Affecting Imports of Retreaded Tyres</i> , <u>WT/DS332/AB/R</u> , adopted 17 December 2007, DSR 2007:IV, p. 1527
Brazil – Retreaded Tyres	Panel Report, <i>Brazil – Measures Affecting Imports of Retreaded Tyres</i> , <u>WT/DS332/R</u> , adopted 17 December 2007, as modified by Appellate Body Report WT/DS332/AB/R, DSR 2007:V, p. 1649
Brazil – Taxation	Panel Reports, <i>Brazil – Certain Measures Concerning Taxation and Charges</i> , <u>WT/DS472/R</u> , Add.1 and Corr.1 / <u>WT/DS497/R</u> , Add.1 and Corr.1, adopted 11 January 2019, as modified by Appellate Body Reports WT/DS472/AB/R / WT/DS497/AB/R, DSR 2019:II, p. 345
Canada – Aircraft	Appellate Body Report, <i>Canada – Measures Affecting the Export of Civilian Aircraft</i> , <u>WT/DS70/AB/R</u> , adopted 20 August 1999, DSR 1999:III, p. 1377
Canada – Renewable Energy / Canada – Feed-in Tariff Program	Appellate Body Reports, <i>Canada – Certain Measures Affecting the Renewable Energy Generation Sector / Canada – Measures Relating to the Feed-in Tariff Program</i> , <u>WT/DS412/AB/R</u> / <u>WT/DS426/AB/R</u> , adopted 24 May 2013, DSR 2013:I, p. 7
Canada – Renewable Energy / Canada – Feed-in Tariff Program	Panel Reports, <i>Canada – Certain Measures Affecting the Renewable Energy</i> <i>Generation Sector / Canada – Measures Relating to the Feed-in Tariff Program</i> , <u>WT/DS412/R</u> and Add.1 / <u>WT/DS426/R</u> and Add.1, adopted 24 May 2013, as modified by Appellate Body Reports WT/DS412/AB/R/ WT/DS426/AB/R, DSR 2013:I, p. 237
China – HP-SSST (EU)	Appellate Body Reports, <i>China – Measures Imposing Anti-Dumping Duties on High-</i> <i>Performance Stainless Steel Seamless Tubes ("HP-SSST") from Japan / China –</i> <i>Measures Imposing Anti-Dumping Duties on High-Performance Stainless Steel</i> <i>Seamless Tubes ("HP-SSST") from the European Union</i> , <u>WT/DS454/AB/R</u> and Add.1 / <u>WT/DS460/AB/R</u> and Add.1, adopted 28 October 2015, DSR 2015:IX, p. 4573
China – Rare Earths	Appellate Body Reports, <i>China – Measures Related to the Exportation of Rare Earths, Tungsten, and Molybdenum</i> , <u>WT/DS431/AB/R</u> / <u>WT/DS432/AB/R</u> / <u>WT/DS433/AB/R</u> , adopted 29 August 2014, DSR 2014:III, p. 805
China – Rare Earths	Panel Reports, <i>China – Measures Related to the Exportation of Rare Earths,</i> <i>Tungsten, and Molybdenum</i> , <u>WT/DS431/R</u> and Add.1 / <u>WT/DS432/R</u> and Add.1 / <u>WT/DS433/R</u> and Add.1, adopted 29 August 2014, upheld by Appellate Body Reports WT/DS431/AB/R / WT/DS432/AB/R / WT/DS433/AB/R, DSR 2014:IV, p. 1127
Colombia – Textiles	Appellate Body Report, <i>Colombia – Measures Relating to the Importation of Textiles, Apparel and Footwear</i> , <u>WT/DS461/AB/R</u> and Add.1, adopted 22 June 2016, DSR 2016:III, p. 1131
EC – Asbestos	Appellate Body Report, <i>European Communities – Measures Affecting Asbestos and Asbestos-Containing Products</i> , <u>WT/DS135/AB/R</u> , adopted 5 April 2001, DSR 2001:VII, p. 3243
EC – Asbestos	Panel Report, <i>European Communities – Measures Affecting Asbestos and Asbestos-Containing Products</i> , <u>WT/DS135/R</u> and Add.1, adopted 5 April 2001, as modified by Appellate Body Report WT/DS135/AB/R, DSR 2001:VIII, p. 3305
EC – Fasteners (China)	Appellate Body Report, <i>European Communities – Definitive Anti-Dumping Measures</i> on Certain Iron or Steel Fasteners from China, <u>WT/DS397/AB/R</u> , adopted 28 July 2011, DSR 2011:VII, p. 3995
EC – Hormones	Appellate Body Report, <i>European Communities – Measures Concerning Meat and Meat Products (Hormones)</i> , <u>WT/DS26/AB/R</u> , <u>WT/DS48/AB/R</u> , adopted 13 February 1998, DSR 1998:I, p. 135
EC – Seal Products	Appellate Body Reports, <i>European Communities – Measures Prohibiting the Importation and Marketing of Seal Products</i> , <u>WT/DS400/AB/R</u> / <u>WT/DS401/AB/R</u> , adopted 18 June 2014, DSR 2014:I, p. 7
EC – Tariff Preferences	Panel Report, <i>European Communities – Conditions for the Granting of Tariff</i> <i>Preferences to Developing Countries</i> , <u>WT/DS246/R</u> , adopted 20 April 2004, as modified by Appellate Body Report WT/DS246/AB/R, DSR 2004:III, p. 1009
EC and certain member States – Large Civil Aircraft	Appellate Body Report, <i>European Communities and Certain Member States –</i> <i>Measures Affecting Trade in Large Civil Aircraft</i> , <u>WT/DS316/AB/R</u> , adopted 1 June 2011, DSR 2011:I, p. 7

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Short title	Full case title and citation
EU – Biodiesel (Argentina)	Appellate Body Report, <i>European Union – Anti-Dumping Measures on Biodiesel from Argentina</i> , <u>WT/DS473/AB/R</u> and Add.1, adopted 26 October 2016, DSR 2016:VI, p. 2871
EU – Energy Package	Panel Report, <i>European Union and its member States – Certain Measures Relating to the Energy Sector</i> , <u>WT/DS476/R</u> and Add.1, circulated to WTO Members 10 August 2018 [appeal/adoption pending]
India – Agricultural Products	Appellate Body Report, <i>India – Measures Concerning the Importation of Certain Agricultural Products</i> , <u>WT/DS430/AB/R</u> , adopted 19 June 2015, DSR 2015:V, p. 2459
India – Solar Cells	Appellate Body Report, <i>India – Certain Measures Relating to Solar Cells and Solar Modules</i> , <u>WT/DS456/AB/R</u> and Add.1, adopted 14 October 2016, DSR 2016:IV, p. 1827
India – Solar Cells	Panel Report, <i>India – Certain Measures Relating to Solar Cells and Solar Modules</i> , <u>WT/DS456/R</u> and Add.1, adopted 14 October 2016, as modified by Appellate Body Report WT/DS456/AB/R, DSR 2016:IV, p. 1941
Indonesia – Chicken	Panel Report, Indonesia – Measures Concerning the Importation of Chicken Meat and Chicken Products, <u>WT/DS484/R</u> and Add.1, adopted 22 November 2017, DSR 2017:VIII, p. 3769
Indonesia – Import Licensing Regimes	Appellate Body Report, <i>Indonesia – Importation of Horticultural Products, Animals and Animal Products</i> , <u>WT/DS477/AB/R</u> , <u>WT/DS478/AB/R</u> , and Add.1, adopted 22 November 2017, DSR 2017:VII, p. 3037
Japan – Alcoholic Beverages II	Appellate Body Report, Japan – Taxes on Alcoholic Beverages, <u>WT/DS8/AB/R</u> , <u>WT/DS10/AB/R</u> , <u>WT/DS11/AB/R</u> , adopted 1 November 1996, DSR 1996:I, p. 97
Mexico – Taxes on Soft Drinks	Appellate Body Report, <i>Mexico – Tax Measures on Soft Drinks and Other Beverages</i> , <u>WT/DS308/AB/R</u> , adopted 24 March 2006, DSR 2006:I, p. 3
Peru – Agricultural Products	Appellate Body Report, <i>Peru – Additional Duty on Imports of Certain Agricultural</i> <i>Products</i> , <u>WT/DS457/AB/R</u> and Add.1, adopted 31 July 2015, DSR 2015:VI, p. 3403
Philippines – Distilled Spirits	Appellate Body Reports, <i>Philippines – Taxes on Distilled Spirits</i> , <u>WT/DS396/AB/R</u> / <u>WT/DS403/AB/R</u> , adopted 20 January 2012, DSR 2012:VIII, p. 4163
US – COOL (Article 21.5 – Canada and Mexico)	Appellate Body Reports, United States – Certain Country of Origin Labelling (COOL) Requirements – Recourse to Article 21.5 of the DSU by Canada and Mexico, <u>WT/DS384/AB/RW</u> / <u>WT/DS386/AB/RW</u> , adopted 29 May 2015, DSR 2015:IV, p. 1725
US – Gasoline	Appellate Body Report, United States – Standards for Reformulated and Conventional Gasoline, <u>WT/DS2/AB/R</u> , adopted 20 May 1996, DSR 1996:I, p. 3
US – Gasoline	Panel Report, United States – Standards for Reformulated and Conventional Gasoline, <u>WT/DS2/R</u> , adopted 20 May 1996, as modified by Appellate Body Report WT/DS2/AB/R, DSR 1996:I, p. 29
US – Shrimp (Article 21.5 – Malaysia)	Appellate Body Report, United States – Import Prohibition of Certain Shrimp and Shrimp Products – Recourse to Article 21.5 of the DSU by Malaysia, <u>WT/DS58/AB/RW</u> , adopted 21 November 2001, DSR 2001:XIII, p. 6481
US – Sonar Mapping	GATT Panel Report, <i>United States – Procurement of a Sonar Mapping System</i> , GPR.DS1/R, 23 April 1992, unadopted [91SONARM]
US – Tuna II (Mexico) (Article 21.5 – Mexico)	Appellate Body Report, United States – Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products – Recourse to Article 21.5 of the DSU by Mexico, WT/DS381/AB/RW and Add.1, adopted 3 December 2015, DSR 2015:X, p. 5133

Parties:

European Union Türkiye<sup>1</sup>

Third Parties:

Japan
Russian Federation
Switzerland
Ukraine
United States

Arbitrators:

Mateo Diego-Fernández Andrade, Chairperson Seung Wha Chang Guohua Yang

# **1 INTRODUCTION**

1.1. This Arbitration concerns issues of law and legal interpretations developed in the Panel Report, *Turkey – Certain Measures Concerning the Production, Importation and Marketing of Pharmaceutical Products.*<sup>2</sup> These issues of law and legal interpretations relate to certain provisions of the General Agreement on Tariffs and Trade 1994 (GATT 1994) applied in the context of Türkiye's "localisation requirement".

1.2. The Panel was established on 30 September 2019 to consider a complaint by the European Union with respect to the consistency of the localisation requirement and certain other measures for pharmaceutical products adopted by Türkiye with provisions of the GATT 1994, the Agreement on Subsidies and Countervailing Measures (SCM Agreement), and the Agreement on Trade-Related Investment Measures (TRIMs Agreement).<sup>3</sup>

1.3. The Panel Report was issued to the parties on 11 November 2021. In ruling on the European Union's claims regarding the localisation requirement, the Panel found that:

- a. the European Union had established the existence of the localisation requirement as a "single measure", whereby (i) Türkiye required foreign producers to commit to localise in Türkiye their production of certain pharmaceutical products; and (ii) where commitments were not given, accepted, or fulfilled, relevant products were no longer reimbursed by Türkiye's Social Security Institution (SSI)<sup>4</sup>;
- b. the localisation requirement was not covered by the government procurement derogation in Article III:8(a) of the GATT 1994, and was therefore subject to the national treatment obligation in Article III:4 of the GATT 1994 and Article 2.1 of the TRIMs Agreement<sup>5</sup>;
- c. the localisation requirement was inconsistent with the national treatment obligation in Article III:4 of the GATT 1994<sup>6</sup>; and

<sup>&</sup>lt;sup>1</sup> Formerly "Turkey". (See Membership of the World Trade Organization (Revision), WT/INF/43/Rev.23, 4 June 2022) For ease of reference, we refer to Türkiye in this Award, except when quoting from the Panel Report or submissions preceding this change of name and when referring to the title of a Panel Exhibit.

<sup>&</sup>lt;sup>2</sup> We refer to the Final Report issued by the Panel to the parties on 11 November 2021 as the "Panel Report". In accordance with paragraph 5 of the Agreed Procedures for Arbitration under Article 25 of the

DSU (Agreed Procedures), the Panel Report in the three working languages of the WTO was attached to Türkiye's notice of recourse to arbitration. (WT/DS583/12 and WT/DS583/12/Add.1)

<sup>&</sup>lt;sup>3</sup> Request for the Establishment of a Panel by the European Union, WT/DS583/3.

<sup>&</sup>lt;sup>4</sup> Panel Report, para. 8.1.b.i.

<sup>&</sup>lt;sup>5</sup> Panel Report, para. 8.1.b.ii.

<sup>&</sup>lt;sup>6</sup> Panel Report, para. 8.1.b.iii.

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- d. Türkiye had not established that the localisation requirement was justified under Article XX(b) or Article XX(d) of the GATT 1994.<sup>7</sup>

1.4. The Panel also made findings of inconsistency with the GATT 1994 in respect of another measure challenged by the European Union, namely Türkiye's "prioritization measure". In this respect, the Panel found that:

- a. the European Union had established the existence of an overarching measure whereby Turkish authorities gave priority to the review of applications for inclusion in the "Annex 4/A list"<sup>8</sup> and to good manufacturing practices and marketing authorization applications concerning domestic pharmaceutical products over the review of applications of like imported products<sup>9</sup>; and
- b. the prioritization measure was inconsistent with Article III:4 of the GATT 1994.<sup>10</sup>

1.5. The Panel concluded that, to the extent that they were inconsistent with the GATT 1994, the measures at issue nullified or impaired benefits accruing to the European Union under that Agreement.<sup>11</sup> The Panel recommended that Türkiye bring its measures into conformity with its obligations under the GATT 1994.<sup>12</sup>

1.6. At the request of the parties, the Panel suspended its work before the circulation of the Panel Report to Members. $^{13}$ 

1.7. On 22 March 2022, Türkiye and the European Union notified Agreed Procedures for Arbitration under Article 25 of the DSU (Agreed Procedures) to the Dispute Settlement Body (DSB).<sup>14</sup> Under the Agreed Procedures, "[t]aking into account that the Appellate Body is not presently able to hear an appeal in this dispute", the parties agreed "to enter into arbitration under Article 25 of the DSU to decide any appeal from any final panel report as issued to the parties in dispute DS583".<sup>15</sup> The parties further agreed to "abide by the arbitration award, which shall be final" <sup>16</sup>, with the understanding that "un-appealed" panel findings would form an integral part of such an award.<sup>17</sup>

- <sup>10</sup> Panel Report, para. 8.1.d.ii.
- <sup>11</sup> Panel Report, para. 8.2.

<sup>&</sup>lt;sup>7</sup> Panel Report, para. 8.1.b.iv. In light of these findings, the Panel declined to rule on the European Union's alternative and conditional claim under Article 3.1(b) of the SCM Agreement and exercised judicial economy over the European Union's additional claims under Article 2.1 of the TRIMs Agreement and Article X:1 of the GATT 1994. In addition, the Panel exercised judicial economy over the European Union's claim that the localisation requirement applied in conjunction with the Turkish rules for approving the importation and marketing of pharmaceutical products (which had been referred to by the European Union as the "import ban on localised products") was inconsistent with Article XI:1 of the GATT 1994. (Ibid., paras. 8.1.b.v and 8.1.c)

<sup>&</sup>lt;sup>8</sup> As explained further below, to be reimbursable, a pharmaceutical product must be included as "active" in the list in Annex 4/A to the Health Implementation Communiqué. (See para. 6.4. below)

<sup>&</sup>lt;sup>9</sup> Panel Report, para. 8.1.d.i.

<sup>&</sup>lt;sup>12</sup> Panel Report, para. 8.3. The Panel also made findings regarding a request for a preliminary ruling by Türkiye pertaining to its terms of reference. In that regard, the Panel found that: (i) Türkiye's request for a preliminary ruling was not untimely; (ii) the localisation requirement, the import ban on localised products, and the prioritization measure had been identified with sufficient specificity to comply with Article 6.2 of the DSU; and (iii) the European Union had provided a brief summary of the legal basis of the complaint sufficient to present the problem clearly with respect to its claims under Article X:1 of the GATT 1994 and Article 3.1(b) of the SCM Agreement, so that both claims were properly within the Panel's terms of reference. (Ibid., para. 8.1.a.i-iii)

<sup>&</sup>lt;sup>13</sup> On 22 December 2021, the Panel informed the parties that it had granted the European Union's request that the Panel suspend its work, pursuant to Article 12.12 of the DSU, for a period of one month. (WT/DS583/6) On 21 January 2022, 10 February 2022, and 24 February 2022, the Panel informed the parties that it had agreed to the European Union's requests for extensions of the suspension of the Panel's work. (WT/DS583/7, WT/DS583/8, and WT/DS583/9) On 24 March 2022, the Panel agreed to the parties' joint request for a further indefinite suspension of the panel proceedings, and extended the suspension of the Panel's work indefinitely. (WT/DS583/11)

<sup>&</sup>lt;sup>14</sup> WT/DS583/10.

<sup>&</sup>lt;sup>15</sup> Agreed Procedures, para. 1. (fns omitted)

<sup>&</sup>lt;sup>16</sup> Agreed Procedures, para. 15.

<sup>&</sup>lt;sup>17</sup> Agreed Procedures, para. 9.

1.8. On 25 April 2022, Türkiye notified the DSB of its decision to initiate an arbitration under Article 25 of the DSU through a notice of recourse to arbitration, attaching the Panel Report, in accordance with paragraph 5 of the Agreed Procedures.<sup>18</sup> On the same day, Türkiye filed its written submission.

1.9. On 28 April 2022, three arbitrators were selected in accordance with paragraph 7 of the Agreed Procedures. On 30 April, 1 May, and 3 May 2022, we accepted our appointment and confirmed that we had no conflict of interest. On 4 May 2022, Members were informed of our appointment as Arbitrators.<sup>19</sup> On 5 May 2022, Mr Diego-Fernández Andrade was elected as Chairperson for the Arbitration.<sup>20</sup> The next day, the parties were informed that he would act as Chairperson.

1.10. Following an organizational meeting with the parties on 10 May 2022, we adopted Working Procedures for Arbitration under Article 25 of the DSU (Working Procedures)<sup>21</sup>, including a Working Schedule for the Arbitration, to be read in conjunction with the DSU, the Agreed Procedures, and relevant provisions of the Working Procedures for Appellate Review.<sup>22</sup> Annex A-2 of the Addendum to this Award, WT/DS583/ARB25/Add.1, contains these Working Procedures, including the Working Schedule.

1.11. In accordance with the adopted Working Schedule, the European Union filed its written submission on 13 May 2022. On 16 May 2022, the Russian Federation (Russia) and Switzerland each filed a third party's written submission.<sup>23</sup> On the same day, Brazil, Canada, China, Japan, Ukraine, and the United States each notified its intention to appear at the hearing as a third party.<sup>24</sup> Subsequently, on 15 June 2022, Indonesia notified its intention to appear at the hearing as a third party.<sup>25</sup>

1.12. On 3 June 2022, the Chairperson sent a letter to the parties and third parties with relevant preliminary information regarding the hearing. In this letter, among other things, the Chairperson confirmed that the hearing would be held in-person, with a possibility to attend remotely via Webex. In this connection, the Chairperson informed that Mr Yang would participate in the hearing remotely since, due to COVID-19-related restrictions, he would have difficulties travelling to Geneva for the hearing. The Chairperson also indicated that we would endeavour to send parties and third parties a list of questions or topics in advance of the hearing. On 10 June 2022, the Chairperson sent a subsequent letter to the parties and third parties providing additional information regarding remote access to the hearing.

1.13. On 15 June 2022, parties and third parties shared their delegation lists, indicating in-person and remote participants.<sup>26</sup> On 16 June 2022, we shared a list of questions with the parties and third parties to facilitate the conduct of the hearing and assist them in preparing for the hearing.

1.14. The hearing was held on 21-22 June 2022. The parties and eight third parties (Brazil, Canada, China, Japan, Russia, Switzerland, Ukraine, and the United States) made oral statements and/or responded to questions.

1.15. The Award is being issued to the parties in English on 21 July 2022, within 90 days of the commencement of the Arbitration. Pursuant to Article 25.3 of the DSU, we will notify the Award in English, French, and Spanish to the DSB, the Council for Trade in Goods, the Committee on Subsidies and Countervailing Measures, and the Committee on Trade-Related Investment Measures.

<sup>&</sup>lt;sup>18</sup> WT/DS583/12 and WT/DS583/12/Add.1.

<sup>&</sup>lt;sup>19</sup> WT/DS583/13.

<sup>&</sup>lt;sup>20</sup> Pursuant to paragraph 7 of the Agreed Procedures and paragraph 7 of the Working Procedures.

<sup>&</sup>lt;sup>21</sup> Pursuant to paragraph 11 of the Agreed Procedures.

<sup>&</sup>lt;sup>22</sup> WT/AB/WP/6.

<sup>&</sup>lt;sup>23</sup> Pursuant to paragraph 16 of the Agreed Procedures and paragraph 23 of the Working Procedures.

<sup>&</sup>lt;sup>24</sup> Pursuant to paragraph 16 of the Agreed Procedures and paragraph 24 of the Working Procedures.

<sup>&</sup>lt;sup>25</sup> Pursuant to paragraph 16 of the Agreed Procedures and paragraph 26 of the Working Procedures.

<sup>&</sup>lt;sup>26</sup> Canada, the European Union, and Japan subsequently updated their delegation lists.

### **2 MEASURES TAKEN TO STREAMLINE THE PROCEEDINGS**

2.1. Paragraphs 12 and 13 of the Agreed Procedures read<sup>27</sup>:

12. The parties request the arbitrators to issue the award within 90 days following the filing of the Notice of Appeal. To that end, the arbitrators may take appropriate organizational measures to streamline the proceedings, without prejudice to the procedural rights and obligations of the parties and due process. Such measures may include decisions on page limits, time limits and deadlines as well as on the length and number of hearings required.

13. If necessary in order to issue the award within the 90 day time-period, the arbitrators may also propose substantive measures to the parties, such as an exclusion of claims based on the alleged lack of an objective assessment of the facts pursuant to Article 11 of the DSU.[\*]

[\* fn original] <sup>5</sup> For greater certainty, the proposal of the arbitrators is not legally binding and it will be up to the party concerned to agree with the proposed substantive measures. The fact that the party concerned does not agree with the proposed substantive measures shall not prejudice the consideration of the case or the rights of the parties.

2.2. In accordance with paragraph 12 of the Agreed Procedures, we adopted organizational measures to streamline the proceedings. These organizational measures included setting up an organizational meeting with the parties to consider a draft set of Working Procedures at the outset of the Arbitration, decisions on page limits for submissions<sup>28</sup>, decisions on time limits for opening and closing statements at the hearing<sup>29</sup>, sending questions to parties and third parties in advance of the hearing to facilitate the conduct of the hearing, and adopting a tight hearing schedule. We also took internal organizational steps to streamline our work and ensure that our Award could be issued within 90 days of the commencement of the Arbitration.<sup>30</sup>

2.3. Moreover, at the organizational meeting with the parties as well as at the hearing, we consulted with the parties about the possibility of excluding Türkiye's claims raised under Article 11 of the DSU from the scope of the Arbitration. We eventually did not consider it necessary to propose formally that these claims be excluded from the scope of the Arbitration for the purpose of issuing our Award within 90 days.

### **3 MANDATE OF THE ARBITRATORS**

3.1. These Arbitration proceedings took place under Article 25 of the DSU. The Agreed Procedures define our mandate in this particular dispute. They make clear that the Arbitration is "to decide any appeal from any final panel report as issued to the parties in dispute DS583".<sup>31</sup> In accordance with the Agreed Procedures, unless otherwise provided for therein, the Arbitration is governed, *mutatis mutandis*, by the provisions of the DSU and other rules and procedures applicable to appellate review.<sup>32</sup>

3.2. The scope of the Arbitration is further set out in paragraphs 9 and 10 of the Agreed Procedures, which provide:

9. An appeal shall be limited to issues of law covered by the panel report and legal interpretations developed by the panel. The arbitrators may uphold, modify or reverse the legal findings and conclusions of the panel. Where applicable, the arbitration award

<sup>31</sup> Agreed Procedures, para. 1. (fn omitted)

<sup>&</sup>lt;sup>27</sup> Agreed Procedures, paras. 12-13. Paragraph 28 of the Working Procedures reads: The arbitrators shall issue the award within 90 days following the commencement of this arbitration. If necessary, in order to issue the award within the 90-day time-period, the arbitrators may propose substantive measures to the parties. (fn omitted)

<sup>&</sup>lt;sup>28</sup> See paragraphs 13, 14, and 25 of the Working Procedures.

<sup>&</sup>lt;sup>29</sup> See paragraph 33 of the Working Procedures. Additional time limits were subsequently set for the closing statements of third parties.

<sup>&</sup>lt;sup>30</sup> These included meeting frequently, drafting descriptive parts of the Award early in the proceedings, and setting up a working schedule for the timely exchange of drafts and written comments for the purposes of preparing questions, conducting our deliberations, and finalizing the Award.

<sup>&</sup>lt;sup>32</sup> Agreed Procedures, para. 11.

shall include recommendations, as envisaged in Article 19 of the DSU. The findings of the panel which have not been appealed shall be deemed to form an integral part of the arbitration award together with the arbitrators' own findings.

10. The arbitrators shall only address those issues that are necessary for the resolution of the dispute. They shall address only those issues that have been raised by the parties, without prejudice to their obligation to rule on jurisdictional issues.<sup>33</sup>

3.3. We are mindful that our task as Arbitrators under Article 25 of the DSU is to facilitate the solution of the dispute that has been submitted to arbitration by the parties. Our Award, to which the parties agreed to abide<sup>34</sup>, will not go through the process of being adopted by the DSB. We are also mindful that the Agreed Procedures mandate us to address only those issues raised by the parties that are necessary for the resolution of the dispute.<sup>35</sup>

- 3.4. The following issues are raised in this Arbitration:
  - a. whether the Panel erred in its interpretation and/or application of Article III:8(a) of the GATT 1994 in finding that the localisation requirement was not covered by the government procurement derogation in this provision, and was therefore subject to the national treatment obligation under Article III:4 of the GATT 1994 and Article 2.1 of the TRIMs Agreement;
  - b. whether the Panel's findings under Article III:4 of the GATT 1994 should be declared moot and of no legal effect or, alternatively, be reversed;
  - c. whether the Panel erred in its interpretation and/or application of Article XX(b) of the GATT 1994 in finding that Türkiye had not established that the localisation requirement was justified under this provision;
  - d. whether the Panel failed to make an objective assessment of the matter before it pursuant to Article 11 of the DSU when addressing Türkiye's claim that the localisation requirement was justified under Article XX(b) of the GATT 1994; and
  - e. whether the Panel erred in its application of Article XX(d) of the GATT 1994 in finding that Türkiye had not established that the localisation requirement was justified under this provision.

3.5. It is within these parameters that we issue our Award. In reaching our conclusions, we thoroughly considered all the arguments made by the parties and third parties. Not all these arguments are explicitly discussed in this Award and issues are addressed only to the extent necessary for the resolution of the dispute before us.

#### 4 ARGUMENTS OF THE PARTIES

4.1. The claims and arguments of the parties are reflected in the executive summaries of their written submissions.<sup>36</sup> Türkiye's notice of recourse to arbitration and the executive summaries of the parties' claims and arguments are contained in Annexes B and C of the Addendum to this Award, WT/DS583/ARB25/Add.1.

# **5 ARGUMENTS OF THE THIRD PARTIES**

5.1. The arguments of the third parties that filed a written submission (Russia and Switzerland) are reflected in the executive summaries of their written submissions<sup>37</sup>, and are contained in Annex D of the Addendum to this Award, WT/DS583/ARB25/Add.1.

<sup>&</sup>lt;sup>33</sup> Agreed Procedures, paras. 9-10.

<sup>&</sup>lt;sup>34</sup> Agreed Procedures, para. 15.

<sup>&</sup>lt;sup>35</sup> Agreed Procedures, para. 10.

<sup>&</sup>lt;sup>36</sup> Pursuant to paragraph 15 of the Working Procedures.

<sup>&</sup>lt;sup>37</sup> Pursuant to paragraph 15 of the Working Procedures.

#### 6 ANALYSIS

6.1. In this Award, we address claims and arguments pertaining to the Panel's findings under Articles III:4 and III:8(a) of the GATT 1994, before turning to claims and arguments pertaining to the Panel's findings under Article XX(b) and those under Article XX(d). We first provide a brief overview of relevant background information, including a short description of the localisation requirement.<sup>38</sup>

#### 6.1 Relevant background information and the localisation requirement

#### 6.1.1 Reimbursement of pharmaceutical products active in the Annex 4/A list

6.2. Türkiye's Universal Health Insurance Scheme "provides 'comprehensive, fair and equitable access to healthcare services', including access to pharmaceutical products, to virtually anyone residing in Turkey".<sup>39</sup> Within the Ministry of Health, the Turkish Medicines and Medical Devices Agency (TMMDA) is responsible for the registration, marketing approval and authorization, pricing, legal classification, and inspection of all human medicinal products.<sup>40</sup> For its part, the SSI, which is affiliated with the Ministry of Family, Labour and Social Services, is in charge of implementing social security policies and is responsible for, *inter alia*, paying for pharmaceuticals.<sup>41</sup>

6.3. Pharmaceutical products are prescribed by medical doctors and distributed to outpatients<sup>42</sup> by retail pharmacies, which are private entities. All retail pharmacies are members of the Turkish Pharmacists' Association (TPA).<sup>43</sup>

6.4. To be "reimbursable" by the SSI, a pharmaceutical product must be included as "active"<sup>44</sup> in a list included in Annex 4/A to the Health Implementation Communiqué<sup>45</sup> (the Annex 4/A list). The SSI determines which pharmaceutical products are included in the Annex 4/A list.<sup>46</sup> Products in the Annex 4/A list are put in equivalent groups, and a single "reimbursement price" set for each equivalent group (the lowest price in the equivalent group increased by 10%).<sup>47</sup>

6.5. The amounts charged by pharmacies for pharmaceutical products covered by the social security system are met from payments made by the SSI and out-of-pocket payments by outpatients.<sup>48</sup> According to a Protocol concluded between the SSI and the TPA<sup>49</sup>, individual retail pharmacies sign (and annually renew) standard contracts with the SSI. On the basis of these contracts, pharmacies periodically invoice the SSI for all pharmaceutical products included in the Annex 4/A list that they have provided to outpatients during the relevant period. The SSI reviews these invoices using a sampling method and reimburses the reimbursement price.<sup>50</sup> If the public price of a pharmaceutical product is greater than a maximum reimbursement price set by the SSI, outpatients must pay the

<sup>&</sup>lt;sup>38</sup> This overview is based on the Panel's account of the factual aspects of the dispute.

 <sup>&</sup>lt;sup>39</sup> Panel Report, para. 2.2 (quoting SSI, "Universal Health Insurance" (Panel Exhibit EU-2) and referring to Social Insurance and Universal Health Insurance Law, Law No. 5510 (31 May 2006), Official Gazette
 No. 26200 of 16 June 2006 (Panel Exhibits EU-1, TUR-2); referring to M. Tatar, "Short PPRI Pharma Profile, Turkey 2017", WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policy (Panel Exhibit EU-3), p. 7; Social Security Institution Activity Report 2018 (Panel Exhibits EU-109, TUR-7), p. 1; Türkiye's first written submission to the Panel, para. 28).
 <sup>40</sup> Panel Report, para. 2.3 (referring to G. Oner and M. Kecik, "Turkish Medicines and Medical Devices

<sup>&</sup>lt;sup>40</sup> Panel Report, para. 2.3 (referring to G. Oner and M. Kecik, "Turkish Medicines and Medical Devices Agency", presentation at 2014 WHO Technical Briefing Seminar (Panel Exhibit EU-5); Türkiye's first written submission to the Panel, para. 40).

<sup>&</sup>lt;sup>41</sup> Panel Report, para. 2.4 (referring to Law on Social Security Institution, Law No. 5502 (16 May 2006), Official Gazette No. 26173 of 20 May 2006 (Panel Exhibits EU-4, TUR-3), Article 3; Türkiye's first written submission to the Panel, para. 39; second written submission to the Panel, para. 19).

 <sup>&</sup>lt;sup>42</sup> Outpatients are distinguished from inpatients, who receive pharmaceutical products in hospitals.
 <sup>43</sup> Panel Report, paras. 2.7 and 2.14 (referring to Law on Turkish Pharmacists Association No. 6643)

<sup>(25</sup> January 1956), Official Gazette No. 9223 of 2 February 1956 (Panel Exhibit TUR-27), Article 1). <sup>44</sup> Panel Report, paras. 2.8 and 2.13.

<sup>&</sup>lt;sup>45</sup> Panel Report, para. 2.8 (referring to Social Security Institution Health Implementation Communiqué, Official Gazette No. 28597 of 24 March 2013 (Panel Exhibits EU-95, TUR-10)).

<sup>&</sup>lt;sup>46</sup> Panel Report, paras. 2.8 and 2.10-2.12, and fn 79 to para. 2.21.

<sup>&</sup>lt;sup>47</sup> Panel Report, para. 2.9.

<sup>&</sup>lt;sup>48</sup> Panel Report, para. 2.7.

<sup>&</sup>lt;sup>49</sup> TPA Protocol (Panel Exhibits EU-52, TUR-20).

<sup>&</sup>lt;sup>50</sup> Panel Report, para. 2.14 and fn 59 thereto. The reimbursement price of medicines is further detailed at paragraph 2.15 of the Panel Report.

difference, unless they decide to opt for an equivalent product. In addition, outpatients generally also pay a contribution fee and a prescription fee to retail pharmacies.<sup>51</sup>

6.6. Retail pharmacies and the SSI use an electronic information system, the "Medula system", which "enables the registration, tracking and invoicing of medicines that are obtained from pharmacies through a single application".52

### 6.1.2 The localisation requirement

6.7. The localisation requirement is a measure, whereby: (i) Türkiye requires foreign producers to commit to localise in Türkiye their production of certain pharmaceutical products; and (ii) where commitments are not given, accepted, or fulfilled, products are no longer reimbursed by the SSI.<sup>53</sup> It has different phases, which progressively target different products depending on their market share and the existence of equivalent products in the domestic market.<sup>54</sup>

6.8. The localisation process starts with the identification of the relevant products by the Turkish authorities. Pharmaceutical companies producing these products are informed that their products are to be included in the scope of the localisation requirement. The pharmaceutical companies then enter into discussions with the competent authorities with a view to preparing a transition plan and submitting commitments to produce locally. Any commitments made by pharmaceutical companies that have been accepted are followed up through regular progress reports presented by the pharmaceutical companies to the TMMDA. If a company does not submit a localisation commitment, the relevant products are no longer reimbursed by the SSI. This is also the case if a commitment is considered not to be appropriate, or if a company does not fulfil its commitment.<sup>55</sup>

6.9. The localisation requirement relates to Türkiye's policy objective of achieving the gradual transition from imports to domestic manufacturing of pharmaceuticals.<sup>56</sup> The objective is to meet 60% of domestic pharmaceutical demand through domestic production, 60% being the share of locally produced medicines in terms of sales value of the total domestic demand for medicines.<sup>57</sup>

#### 6.2 Articles III:4 and III:8(a) of the GATT 1994

6.10. Türkiye's first grounds of challenge in this Arbitration pertains to Article III:8(a) of the GATT 1994. Türkiye claims that the Panel erred in the interpretation and application of Article III:8(a) in finding that the localisation requirement did not involve a "purchase" and thus did not fall within the ambit of this provision.<sup>58</sup> Türkiye requests us to reverse relevant findings of the Panel, including its finding that the localisation requirement is not covered by Article III:8(a), and is therefore subject to the national treatment obligation under Article III:4 of the GATT 1994 and Article 2.1 of the TRIMs Agreement.<sup>59</sup> Türkiye also requests us to declare moot and of no legal effect, or reverse<sup>60</sup>, the Panel's findings under Article III:4, including its finding that the localisation requirement is inconsistent with that provision.<sup>61</sup>

<sup>59</sup> Türkiye requests us to reverse the conclusions and findings in paragraphs 7.61-7.107 and 8.1.b.ii of the Panel Report. (Türkiye's notice of recourse to arbitration, pp. 1-2)

<sup>&</sup>lt;sup>51</sup> Panel Report, para. 2.16.

<sup>&</sup>lt;sup>52</sup> Panel Report, para. 2.17 (quoting Social Security Institution, Directorate General for Provision of Services Healthcare Software Department, "Medula Project" presentation, 2019 (Panel Exhibit TUR-112), p. 17). <sup>53</sup> Panel Report, para. 7.31.

<sup>&</sup>lt;sup>54</sup> Panel Report, paras. 2.23-2.24.

<sup>&</sup>lt;sup>55</sup> Panel Report, paras. 2.25-2.26.

<sup>&</sup>lt;sup>56</sup> Panel Report, para. 2.20.

<sup>&</sup>lt;sup>57</sup> Panel Report, fn 75 to para. 2.20 (referring to Republic of Turkey, Ministry of Development, Tenth Development Plan 2014-2018 (2014), approved by Decision No. 1041 of the Grand National Assembly of Turkey of 2 July 2013 (Tenth Development Plan 2014-2018) (Panel Exhibit EU-12), point 1.16; Türkiye's responses to the Panel's second set of questions, para. 72).

<sup>&</sup>lt;sup>58</sup> Türkiye's notice of recourse to arbitration, pp. 1-2.

 $<sup>^{60}</sup>$  In this connection, Türkiye asks us to complete the legal analysis and find that all the elements of Article III:8(a) are met, although Türkiye considers that the Panel's findings under Article III:4 should be reversed, irrespective of any completion of legal analysis. (Türkiye's notice of recourse to arbitration, pp. 1-2; written submission, paras. 8-9 and 114-115)

<sup>&</sup>lt;sup>61</sup> Türkiye's notice of recourse to arbitration, pp. 1-2. Türkiye refers to the Panel's findings in paragraphs 7.121-7.127 and 8.1.b.iii of the Panel Report. (Ibid, p. 2.)

6.11. The European Union requests that we reject Türkiye's claims and find that the Panel did not err in its interpretation or application of Article III:8(a).<sup>62</sup> Should we find error with the Panel's interpretation or application of Article III:8(a), the European Union submits that there would be no basis to declare moot or reverse the Panel's findings under Article III:4, unless we complete the legal analysis and make a positive finding that the localisation requirement is covered by Article III:8(a).<sup>63</sup> Should we find it appropriate to complete the legal analysis, we should conclude that Article III:8(a) does not apply to the localisation requirement.64

6.12. We begin by briefly summarizing key Panel findings, before turning to consider relevant interpretation and application issues raised in this Arbitration.

### 6.2.1 Panel findings

6.13. Before the Panel, the European Union claimed that the localisation requirement was inconsistent with Article III:4 of the GATT 1994 and Article 2.1 of the TRIMs Agreement.<sup>65</sup> Türkiye responded that the localisation requirement fell within the scope of Article III:8(a) of the GATT 1994 and was thus not subject to the provisions invoked by the European Union.<sup>66</sup>

6.14. In the Panel's own words, the following elements need to be satisfied for a measure to fall within the scope of Article III:8(a)<sup>67</sup>: (i) the challenged measure must qualify as "laws, regulations, or requirements governing ... procurement"; (ii) the challenged measure "must involve a 'purchase' of products by a 'governmental agency'"; (iii) "the products must be purchased 'for governmental purposes'"; and (iv) "the products must not be purchased 'with a view to commercial resale or with a view to use in the production of goods for commercial sale'."<sup>68</sup> The Panel started its assessment with the second element. The Panel proceeded to set out its interpretation of the term "purchased" in the context of the phrase "products purchased by governmental agencies"<sup>69</sup> and look at whether the localisation requirement involved "the 'purchase' of pharmaceutical products included in the Annex 4/A list by governmental agencies".<sup>70</sup>

#### 6.2.1.1 The Panel's interpretation of the term "products purchased" as requiring a governmental agency to acquire ownership of the products at issue

6.15. Beginning with the ordinary meaning of the words "products purchased", the Panel considered that "in everyday usage a person or entity [was] said to purchase a product at the moment that the person or entity acquire[d] ownership of a product through some kind of payment."<sup>71</sup> To the Panel, the acquisition of ownership (i.e. property rights) was a purchase's defining characteristic, distinguishing it from renting or leasing a product.<sup>72</sup> Turning to contextual elements, the Panel recalled that "'procurement' refer[red] to 'the process pursuant to which a government acquire[d] products', and that the word 'purchased' ... refer[red] to 'the type of transaction used to put into effect' that acquisition."<sup>73</sup> Thus, the concept of "purchase" covered only a subset of the various types of transactions that could be used to put into effect "procurement". The Panel considered that interpreting the term "purchased" in accordance with its ordinary meaning, i.e. as covering only the type of transaction through which the government acquired ownership of the products, gave the term "purchase" a meaning distinct from the broader concept of "procurement" that could involve

<sup>&</sup>lt;sup>62</sup> European Union's written submission, para. 2.

<sup>&</sup>lt;sup>63</sup> European Union's written submission, paras. 88 and 104-105.

<sup>&</sup>lt;sup>64</sup> European Union's written submission, paras. 3 and 89.

<sup>&</sup>lt;sup>65</sup> Panel Report, para. 3.2.

<sup>&</sup>lt;sup>66</sup> Panel Report, paras. 3.3.b and 7.32.

<sup>&</sup>lt;sup>67</sup> The Panel addressed the "government procurement derogation" in Article III:8(a) before making any findings under Article III:4 of the GATT 1994 or Article 2.1 of the TRIMs Agreement, on account that measures satisfying the requirements of Article III:8(a) were not subject to the national treatment obligations set out in other paragraphs of Article III. (Panel Report, fn 239 to para. 7.32)

<sup>68</sup> Panel Report, para. 7.37. <sup>69</sup> Panel Report, para. 7.65. (emphasis added)

<sup>&</sup>lt;sup>70</sup> Panel Report, para. 7.63.

<sup>&</sup>lt;sup>71</sup> Panel Report, para. 7.70.

<sup>&</sup>lt;sup>72</sup> Panel Report, para. 7.70.

<sup>&</sup>lt;sup>73</sup> Panel Report, para. 7.71 (quoting Appellate Body Reports, Canada – Renewable Energy /

*Canada – Feed-in Tariff Program*, para. 5.59). (emphasis added by the Panel)

other types of transactions by which products might be procured (e.g. leasing).<sup>74</sup> The Panel further noted the requirement in Article III:8(a) that the products purchased must be for a governmental purpose. The Panel recalled that this referred to what was consumed by the government or provided by the government to recipients in the discharge of its public functions.<sup>75</sup> The Panel considered that both of those actions presupposed that the government acquired ownership of the product being consumed.<sup>76</sup>

6.16. Next, the Panel considered that, if situations in which a government paid for products used by non-governmental consumers were treated as "purchases" by the government simply on the basis that the government paid for the products, Article III:8(a) would extend to an open-ended range of protectionist measures. A purchase could then include coupons for food, subsidies for renovating real estate, and tax credits for environmentally friendly purchases. Recalling that Article III:8(a) was a limited derogation from the national treatment obligation under Article III, the Panel considered that such a result would undermine the object and purpose of the GATT 1994.<sup>77</sup>

6.17. The Panel concluded that, in the context of Article III:8(a), a product was "purchased" by a government only if the government acquired ownership of that product through some kind of payment. The Panel thus disagreed with Türkiye's assertion that the SSI "pa[id] for the pharmaceutical products and thus [was] the ultimate buyer (or the purchaser)" regardless of whether the SSI ever acquired ownership of those products.<sup>78</sup>

#### 6.2.1.2 The Panel's finding that the SSI does not purchase pharmaceutical products from retail pharmacies

6.18. The Panel next assessed whether Türkiye's pharmaceutical reimbursement system involved a purchase by the SSI, i.e. whether the SSI acquired ownership of pharmaceutical products included in the Annex 4/A list, whether at the time of approval in the Medula system or otherwise.<sup>79</sup> Specifically, the Panel sought to determine whether the SSI acquired any legal rights, of the type typically associated with ownership of goods, over the products, taking into account rights acquired by the retail pharmacies (that acquired ownership of pharmaceutical products when purchasing them from wholesalers) and outpatients (who acquired ownership of pharmaceutical products when obtaining them from pharmacies).80

6.19. The Panel was unable to discern any basis upon which it could conclude that the SSI acquired any legal rights over the pharmaceutical products it paid for, let alone that it acquired the type of legal rights typically associated with ownership of goods. The Panel did not see anything to suggest that the SSI acquired "any right of possession, any right of control, any right of exclusion, any right to derive income, or any right to freely dispose of the pharmaceutical products".<sup>81</sup> By way of example, the Panel noted that the SSI did not ever acquire the right to take physical possession of the pharmaceutical products. While acknowledging that physical possession of goods was not a constitutive element of a purchase<sup>82</sup>, the Panel considered the absence of any such right to take physical possession to be a strong indicator that the entity paying for these goods had not acquired any right of ownership. The Panel considered that this was a particularly strong indicator with goods that could freely be transported and stored, such as pharmaceutical products.<sup>83</sup>

<sup>&</sup>lt;sup>74</sup> Panel Report, para. 7.71. The Panel agreed with the European Union that the common element of these other contractual arrangements was that, "while they may lead to the acquisition of products (for example, in the case of rental, the acquirer takes possession and has the right to use the product for a certain period of time), they d[id] not lead to the acquisition of property over products." (Ibid. (quoting European Union's first written submission to the Panel, para. 202) (emphasis original))

<sup>&</sup>lt;sup>75</sup> Panel Report, para. 7.72 (referring to Appellate Body Reports, Canada – Renewable Energy / Canada – Feed-In Tariff Program, para. 5.68). <sup>76</sup> Panel Report, para. 7.72.

<sup>&</sup>lt;sup>77</sup> Panel Report, para. 7.73.

<sup>&</sup>lt;sup>78</sup> Panel Report, paras. 7.74 and 7.81 (quoting Türkiye's first written submission to the Panel, paras. 206-208).

<sup>&</sup>lt;sup>79</sup> Panel Report, para. 7.82.

<sup>&</sup>lt;sup>80</sup> Panel Report, para. 7.84.

<sup>&</sup>lt;sup>81</sup> Panel Report, para. 7.85.

<sup>&</sup>lt;sup>82</sup> Panel Report, paras. 7.75, 7.79, 7.83, and 7.86.

<sup>&</sup>lt;sup>83</sup> Panel Report, para. 7.86.

6.20. In addition, the Panel found no basis to support Türkiye's assertion that the SSI obtained the right to dispose of the pharmaceutical products that it paid for, according to its own choices. In this connection, the Panel observed that, following approval in the Medula system, the pharmaceutical product needed to be provided to the individual outpatient named in the prescription. All relevant decisions and choices associated with the disposition of pharmaceutical products were made by the prescribing doctor, the pharmacy, and the outpatient. The Panel did not discern any SSI involvement in choosing who received and consumed pharmaceutical products that the SSI paid for: "Neither the SSI nor any other governmental agency played any role in directing, or redirecting, pharmaceutical products to recipients of their choosing."<sup>84</sup>

6.21. The Panel was not persuaded by Türkiye's argument that the SSI could be deemed to acquire title to pharmaceutical products included in the Annex 4/A list and prescribed to patients at the time of approval in the Medula system. The Panel observed that approval through the Medula system served as confirmation that the patient was within SSI coverage and that the prescribed pharmaceutical products were in the Annex 4/A list. That approval confirmed, *inter alia*, that the pharmaceutical product may be invoiced by the pharmacy to the SSI at the previously set price.<sup>85</sup> In the Panel's view, it would require an artificial and strained construction of the facts to characterize this confirmation as a transaction through which "the SSI acquire[d] the right to dispose of those medicines by dispensing them, through the retail pharmacies, to patients", and "the title to those medicines [was] then immediately transferred to patients."<sup>86</sup> The Panel also observed that Türkiye had not pointed to any reference to the SSI acquiring "title" over pharmaceutical products in the Protocol signed between the SSI and the TPA or any other evidence on record.<sup>87</sup> The Panel concluded that the SSI did not acquire ownership of pharmaceutical products included in the Annex 4/A list and therefore the SSI's reimbursement of part or all of the cost of those products did not qualify as a "purchase" by the SSI in the context of Article III:8(a).<sup>88</sup>

# **6.2.1.3** The Panel's finding that retail pharmacies are not governmental agencies purchasing products on behalf of the SSI

6.22. The Panel next addressed Türkiye's alternative argument that there was a "purchase" covered by Article III:8(a) of the GATT 1994 because retail pharmacies purchased medicines from wholesalers on behalf of the SSI, and were, to that extent, "governmental agencies".<sup>89</sup>

6.23. The Panel agreed with Türkiye that Article III:8(a) did not necessarily preclude a governmental agency from purchasing products through an intermediary. However, to fall within the scope of Article III:8(a), a governmental purchase effected through an intermediary needed to lead to the government acquiring ownership of the product purchased.<sup>90</sup>

6.24. In the circumstances of this case, it was clear that the pharmacies' purchases of pharmaceutical products from wholesalers did not entail, or result in, the acquisition of ownership of those products by the SSI. The Panel recalled that the SSI did not acquire ownership of pharmaceutical products and, therefore, the SSI's reimbursements of part or all of the cost of those products did not qualify as a "purchase" by the SSI. Rather, the retail pharmacies acquired and retained ownership until it was transferred to outpatients. To the Panel, this sufficed to establish that retail pharmacies did not qualify as "governmental agencies".<sup>91</sup> The Panel noted the parties' arguments about the extent to which the SSI controlled the actions of retail pharmacies. To the Panel, even if it could be said that the SSI instructed and directed pharmacies what to do, this would not make them "governmental agencies" or mean that there are purchases by the government, so

<sup>87</sup> Panel Report, para. 7.88.

<sup>&</sup>lt;sup>84</sup> Panel Report, para. 7.87.

<sup>&</sup>lt;sup>85</sup> Panel Report, para. 7.88 (referring to Türkiye's responses to the Panel's first set of questions, para. 26; European Union's responses to the Panel's first set of questions, paras. 10-22; opening statement at

the Panel meeting, para. 24).

<sup>&</sup>lt;sup>86</sup> Panel Report, para. 7.88 (quoting and referring to Türkiye's second written submission to the Panel, para. 73; responses to the Panel's first set of questions, paras. 32-34; closing statement at the Panel meeting, para. 23; responses to the Panel's second set of questions, para. 43).

<sup>&</sup>lt;sup>88</sup> Panel Report, para. 7.90.

<sup>&</sup>lt;sup>89</sup> Panel Report, paras. 7.92 and 7.94.

<sup>&</sup>lt;sup>90</sup> Panel Report, para. 7.96.

<sup>&</sup>lt;sup>91</sup> Panel Report, para. 7.98.

long as the pharmacies acquired ownership of pharmaceutical products independently of the government.  $^{\rm 92}$ 

6.25. Based on the foregoing and recalling its earlier finding that the SSI never acquired ownership of the pharmaceutical products that it paid for, the Panel concluded that the private retail pharmacies did not qualify as "governmental agencies" in the context of Article III:8(a).<sup>93</sup>

# 6.2.1.4 The Panel's conclusion

6.26. Having found that the localisation requirement did not involve the "purchase" of relevant pharmaceutical products by governmental agencies, the Panel found that "the localisation requirement [was] not covered by the government procurement derogation in Article III:8(a) of the GATT 1994, and [was] therefore subject to the national treatment obligation in Article III:4 of the GATT 1994 and Article 2.1 of the TRIMs Agreement".<sup>94</sup> The Panel ultimately found the localisation requirement to be inconsistent with Article III:4 of the GATT 1994.<sup>95</sup>

#### 6.2.2 Whether the Panel erred in its interpretation of Article III:8(a) of the GATT 1994

6.27. In this Arbitration, Türkiye claims that the Panel erred in its interpretation of the "purchase requirement" in Article III:8(a) of the GATT 1994, which led to errors in the application of that provision to the facts of the case. Türkiye alleges two interpretation errors. First, the Panel erred in considering that Article III:8(a) required that a purchase be made *by* a governmental agency. Second, the Panel erred in finding that a purchase necessarily implied a transfer of ownership of the product from the seller to the entity purchasing the products.<sup>96</sup>

6.28. The European Union requests us to dismiss these claims. The European Union notes that the interpretative arguments made by Türkiye in this Arbitration were not before the Panel.<sup>97</sup> The European Union also contends that Article III:8(a) only applies to purchases *by* a governmental agency.<sup>98</sup> Therefore, the Panel was correct to consider whether there was governmental purchasing for the purposes of its analysis under Article III:8(a). The Panel was also correct to find that the concept of "purchase" entailed a transfer of ownership to the purchaser.<sup>99</sup>

#### 6.2.2.1 Overview of Article III:8(a) of the GATT 1994

6.29. Article III is a cornerstone of the multilateral trading system. The general principle, which is articulated in the first paragraph, postulates that internal measures "should not be applied so as to afford protection to domestic production".<sup>100</sup> Other paragraphs of Article III constitute specific expressions of this overarching, general principle.<sup>101</sup> Article III:4 of the GATT 1994, in particular, prohibits Members from treating imported products less favourably than like products of national origin in respect of all laws, regulations, and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution, or use.

6.30. Article III:8(a) of the GATT 1994 establishes a derogation from the national treatment obligation under Article III<sup>102</sup>, including Article III:4. As such, Article III:8(a) provides for a carve-out from a cornerstone principle of the GATT 1994, but does so only for specific types of measures dealing with government procurement. It reads:

<sup>&</sup>lt;sup>92</sup> Panel Report, para. 7.100.

<sup>&</sup>lt;sup>93</sup> Panel Report, para. 7.103.

<sup>&</sup>lt;sup>94</sup> Panel Report, para. 8.1.b.ii. See also ibid., paras. 7.104 and 7.107.

<sup>&</sup>lt;sup>95</sup> Panel Report, para. 8.1.b.iii. See also ibid., para. 7.127. In light of this finding and other findings under Article XX of the GATT 1994, the Panel exercised judicial economy over the European Union's claim under Article 2.1 of the TRIMs Agreement. (Ibid., paras. 7.245 and 8.1.b.v)

<sup>&</sup>lt;sup>96</sup> Türkiye's written submission, paras. 8 and 19. See also Türkiye's notice of recourse to arbitration, pp. 1-2; written submission, paras. 31-32 and 50.

<sup>&</sup>lt;sup>97</sup> European Union's written submission, para. 32; opening statement at the hearing, para. 12.

<sup>&</sup>lt;sup>98</sup> European Union's written submission, para. 33.

<sup>&</sup>lt;sup>99</sup> European Union's written submission, para. 53.

<sup>&</sup>lt;sup>100</sup> Appellate Body Report, Japan – Alcoholic Beverages II, p. 18, DSR 1996:I, p. 111.

<sup>&</sup>lt;sup>101</sup> Appellate Body Report, *EC – Asbestos*, para. 93.

<sup>&</sup>lt;sup>102</sup> Appellate Body Reports, Canada – Renewable Energy / Canada – Feed-in Tariff Program, para. 5.56.

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

6.31. Article III:8(a) contains several elements describing the types and the context of measures falling within the ambit of this provision. It describes the types of measures falling within its ambit as "laws, regulations or requirements governing the procurement" of products. Article III:8(a) also specifies what is procured and by whom. The subject matter of the procurement is a "product", and it is being procured "by governmental agencies". Moreover, there needs to be procurement of "products purchased for governmental purposes". Finally, Article III:8(a) refers to procurement of products purchased "not with a view to commercial resale or with a view to use in the production of goods for commercial sale".

6.32. These various elements inform each other and Article III:8(a) should be interpreted holistically.<sup>103</sup> These elements are also cumulative in nature, such that a measure failing to meet any one of those requirements will not be exempted from the national treatment obligations of Article III:4 of the GATT 1994 and Article 2.1 of the TRIMs Agreement.<sup>104</sup>

# 6.2.2.2 Whether the Panel wrongly assumed Article III:8(a) of the GATT 1994 to require a purchase *by* governmental agencies

6.33. As summarized above, the Panel focused its analysis on whether the localisation requirement involved a "purchase" of pharmaceutical products included in the Annex 4/A list by governmental agencies (i.e. the SSI or retail pharmacies on behalf of the SSI). The Panel did not elaborate on whether Article III:8(a) of the GATT 1994 should be interpreted as requiring a purchase by governmental agencies or whether a purchase could be made by a different entity. We understand the Panel to have simply assumed that Article III:8(a) required a purchase by governmental agencies.<sup>105</sup>

6.34. The Panel's approach seems to have been guided by the manner in which Türkiye presented its arguments in the panel proceedings. Before the Panel, Türkiye submitted that the SSI purchased pharmaceutical products included in the Annex 4/A list because the SSI paid for those pharmaceutical products or because it acquired title to those products. In the alternative, Türkiye argued that the purchase of pharmaceutical products from wholesalers by retail pharmacies was made on behalf of the SSI and this meant that the retail pharmacies were themselves "governmental agencies" purchasing pharmaceutical products.<sup>106</sup>

6.35. In this connection, the European Union argues that the Panel cannot be faulted for focusing on whether there was governmental purchasing since Türkiye's case before the Panel was either that the SSI purchases products as a governmental agency or that pharmacies purchase products as governmental agencies on behalf of the SSI.<sup>107</sup> The European Union noted that new arguments are not *per se* excluded from the scope of our review. However, to the European Union, we would need to exclude new arguments that, like those of Türkiye, would require us to solicit, receive, and review new facts.<sup>108</sup>

6.36. Under paragraph 9 of the Agreed Procedures, "[a]n appeal shall be limited to issues of law covered by the panel report and legal interpretations developed by the panel." Having reviewed the parties' submissions before the Panel, we agree with the European Union that the first interpretative

<sup>108</sup> The European Union referred to the Appellate Body Report in *Canada – Aircraft.* (European Union's responses to questions at the hearing)

<sup>&</sup>lt;sup>103</sup> Appellate Body Reports, Canada - Renewable Energy / Canada - Feed-in Tariff Program, para. 5.57.

<sup>&</sup>lt;sup>104</sup> Appellate Body Reports, Canada – Renewable Energy / Canada – Feed-In Tariff Program,

paras. 5.57, 5.69, and 5.74.

<sup>&</sup>lt;sup>105</sup> By way of example, the Panel referred to: Article III:8(a) as requiring "a 'purchase' of products by a 'governmental agency'"; "the phrase 'products purchased by governmental agencies'" in Article III:8(a); "the term 'purchase' in Article III:8(a)"; "the concept of a 'purchase' by a government"; "the limitation in Article III:8(a) that a product is 'purchased' by a government if the government acquires ownership of it"; and "the fact that Article III:8(a) is limited to the acquisition of products, through procurement and 'purchase' by the government". (Panel Report, paras. 7.37, 7.65, 7.71, 7.73, and 7.97)

<sup>&</sup>lt;sup>106</sup> Panel Report, para. 7.64.

<sup>&</sup>lt;sup>107</sup> European Union's written submission, para. 32; opening statement at the hearing, para. 12.

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issue raised by Türkiye in this Arbitration was not raised as such in the panel proceedings. Türkiye's argument at the panel stage was that there was a purchase by governmental agencies: the SSI or retail pharmacies acting on behalf of the SSI.<sup>109</sup> In this Arbitration, Türkiye argues more broadly on interpretation that the purchase does not need to be made by a governmental agency.<sup>110</sup> At the same time, Türkiye is raising a legal argument relating to the proper interpretation of the words "products purchased" in Article III:8(a), which were before the Panel and which the Panel interpreted and applied. Since the Panel considered that the words "products purchased" in Article III:8(a), which were properly before it, implied a purchase by a governmental agency, Türkiye's first interpretation claim in the Arbitration covers an issue of law covered by the Panel Report. Importantly, the arguments raised by Türkiye relate to the proper interpretation of Article III:8(a) and do not require us to solicit, receive, or review new facts. We thus proceed to analyse, in accordance with customary rules of interpretation of public international law as foreseen in Article 3.2 of the DSU, whether the Panel wrongly assumed that a purchase of products for governmental purposes must be made by a governmental agency.<sup>111</sup>

6.37. According to Türkiye, "the plain reading of Article III:8(a) indicates that it is the *procurement* that must be made by [a] governmental agency", not the purchase.<sup>112</sup> Therefore, provided procurement is made by a governmental agency, the relevant products might be purchased by another entity.<sup>113</sup> Türkiye further argues that the words "procurement" and "purchase" necessarily have different meanings, or Article III:8(a) would have referred to "laws, regulations or requirements governing the purchase by governmental agencies of products for governmental purposes".<sup>114</sup> Türkiye concludes "[p]recisely because all essential elements of the purchase transaction have already been set by the procuring governmental agency, the actual purchase can be entrusted to a non-governmental agency.<sup>115</sup>

6.38. The European Union considers that, by its own terms, and as was confirmed by the Appellate Body in prior disputes<sup>116</sup>, Article III:8(a) only applies to purchases by government agencies.<sup>117</sup> The European Union argues that "procurement" refers to the process pursuant to which the government acquires or obtains products while "purchase" refers to the specific transaction by which the government acquires or obtains the products. It follows that the entity purchasing the products must also be the government.<sup>118</sup> To the European Union, the mere fact that a government closely regulates certain products, or their price, does not mean that it procures or purchases them.<sup>119</sup> The European Union also finds it telling that Türkiye fails to clearly specify which other entity, other than the government itself, purchases in a government procurement scenario.<sup>120</sup>

<sup>&</sup>lt;sup>109</sup> Türkiye's main argument was that the SSI, as a governmental agency, purchased medicines itself. Türkiye also stated that the purchase did not necessarily need to be made by a governmental agency in the sense that "nothing in Article III:8(a) precludes the intervention of another entity as long as that entity intervenes on behalf of the relevant governmental agency." This was in the context of Türkiye's alternative argument that retail pharmacies purchased medicines on behalf of the SSI and were therefore themselves governmental agencies. (Türkiye's first written submission to the Panel, para. 209; responses to the Panel's second set of questions, paras. 44 and 47-49. See also Panel Report, paras. 7.64 and 7.93-7.94)

<sup>&</sup>lt;sup>110</sup> Türkiye's notice of recourse to arbitration, pp. 1-2; written submission, paras. 8, 19, 31, and 50. In Türkiye's view, the entity purchasing products can be any entity, not necessarily an entity acting as an intermediary on behalf of the government, as long as the other elements of Article III:8(a) are met. (Türkiye's written submission, para. 31; responses to questions at the hearing)

<sup>&</sup>lt;sup>111</sup> Our approach accords with that of the Appellate Body, which considered that new arguments are not *per se* excluded from the scope of appellate review to the extent they do not require the consideration of new facts. (Appellate Body Reports, *Canada – Aircraft*, para. 211; Peru – *Agricultural Products*, para. 5.88) In *US – COOL (Article 21.5)*, it considered the argument that Article IX of the GATT 1994 constituted relevant context for the interpretation of Article III:4 of the GATT 1994. While this was a new argument on appeal, the Appellate Body considered that it related to the proper interpretation of the term "treatment no less favourable" in Article III:4, which was before the panel and addressed in the panel report. (Appellate Body Reports, *US – COOL (Article 21.5)*, para. 5.350)

<sup>&</sup>lt;sup>112</sup> Türkiye's written submission, para. 21. (emphasis original)

<sup>&</sup>lt;sup>113</sup> Türkiye's written submission, para. 26.

<sup>&</sup>lt;sup>114</sup> Türkiye's written submission, para. 28.

<sup>&</sup>lt;sup>115</sup> Türkiye's written submission, para. 29.

<sup>&</sup>lt;sup>116</sup> European Union's written submission, paras. 18-25 and 28.

<sup>&</sup>lt;sup>117</sup> European Union's written submission, para. 33.

<sup>&</sup>lt;sup>118</sup> European Union's written submission, para. 26.

<sup>&</sup>lt;sup>119</sup> European Union's written submission, para. 31.

<sup>&</sup>lt;sup>120</sup> European Union's written submission, para. 17.

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6.39. The interpretative issue raised by Türkiye is framed as one concerning the words "products purchased", the notion of "purchase", or what Türkiye has called the "purchase requirement".<sup>121</sup> At the outset, we note that the noun "purchase" is not found in Article III:8(a). In addition, we recall that the words of Article III:8(a) should not be read in isolation from the remaining text of that provision.

6.40. Starting our interpretation with the text of Article III:8(a), this provision excludes from the scope of the national treatment obligation under Article III, "laws, regulations or requirements governing the procurement by governmental agencies of products purchased for governmental purposes...". In relevant part, the French text of Article III:8(a) refers to "l'acquisition, par des organes gouvernementaux, de produits achetés pour les besoins des pouvoirs publics". The Spanish text refers to "la adquisición, por organismos gubernamentales, de productos comprados para cubrir las necesidades de los poderes públicos".<sup>122</sup>

6.41. The phrase "products purchased *by* governmental agencies" that the Panel proceeded to interpret<sup>123</sup> is not found verbatim in Article III:8(a). In the English, French, and Spanish versions of Article III:8(a), the noun "procurement" is directly followed by the term "by governmental agencies". The plain reading of Article III:8(a) indicates that it is the procurement that is qualified by the proposition "by governmental agencies". Considering the text and grammatical structure of the provision, we are of the view that the reference to "governmental agencies" relates to the identity of the entity carrying out the procurement. This reading of Article III:8(a) accords with the Appellate Body's observations in the context of its interpretation of various elements of this provision. The Appellate Body observed that "procurement' is the operative word in Article III:8(a) describing the process and conduct of the governmental agency", and "[t]he reference to 'governmental agencies' defines the identity of the entity carrying out the procurement."<sup>124</sup>

6.42. The text of Article III:8(a) also suggests that "procurement" is to be distinguished from a "purchase".<sup>125</sup> Conceptually, procurement may be put into effect through different types of transactions, such as purchase, lease, or rent.<sup>126</sup> In other words, not every procurement needs to be effectuated by way of a purchase. We thus agree with the Panel that the concept of "purchase" covers only a subset of the various types of transactions that could be used to put into effect "procurement".<sup>127</sup>

6.43. Procurement refers generally to "[t]he action of obtaining something; acquisition; an instance of this".<sup>128</sup> The words "*acquisition*, par des organes gouvernementaux" and "*adquisición*, por organismos gubernamentales" in the French and Spanish versions of Article III:8(a) confirm that, in the context of that provision, "procurement" refers to a governmental agency *acquiring* products.<sup>129</sup> The express reference to "the procurement ... of products purchased" ("acquisition ... de produits achetés" and "adquisición ... de productos comprados") indicates that, for the purposes of Article III:8(a), such acquisition has to be put into effect through a purchase transaction. This also stems from the lack of any reference to other types of transactions (such as lease or rent). The word "procurement" in Article III:8(a) therefore refers to the process pursuant to which the government

<sup>&</sup>lt;sup>121</sup> Türkiye's notice of recourse to arbitration, pp. 1-2; written submission, paras. 2 and 18-19.

<sup>&</sup>lt;sup>122</sup> The WTO Agreement provides that the English, French, and Spanish languages each are authentic. According to Article 33 of the Vienna Convention, "[w]hen a treaty has been authenticated in two or more languages, the text is equally authoritative in each language" and "[t]he terms of the treaty are presumed to have the same meaning in each authentic text."

<sup>&</sup>lt;sup>123</sup> Panel Report, para. 7.65. (emphasis added) See para. 6.14. above.

<sup>&</sup>lt;sup>124</sup> Appellate Body Reports, Canada – Renewable Energy / Canada – Feed-in Tariff Program, para. 5.59.

 $<sup>^{125}</sup>$  The principle of effective treaty interpretation requires us to give meaning to every term of the provision. (Appellate Body Report, *US – Gasoline*, p. 23, DSR 1996:I, p. 21)

<sup>&</sup>lt;sup>126</sup> This is, for example, reflected in the Agreement on Government Procurement (GPA). Article II.2 of the GPA, which deals with the scope of that Agreement, indicates that "covered procurement means procurement for governmental purposes ... by any contractual means, including: purchase; lease; and rental or hire purchase, with or without an option to buy". We are mindful of the fact that the GPA is plurilateral in nature and that Türkiye is not a party to that Agreement. We consider, however, that the GPA reflects some general understanding that a purchase is one of the ways in which procurement may occur.

<sup>&</sup>lt;sup>127</sup> Panel Report, para. 7.71.

<sup>&</sup>lt;sup>128</sup> Oxford English Dictionary online, <u>https://www.oed.com/view/Entry/151913</u>, accessed on

<sup>1</sup> July 2022. <sup>129</sup> Emphasis added. In its French and Spanish versions, Article III:8(a) does not refer to "marchés

publics" and "contratación pública", but to "acquisition" and "adquisición".

acquires or obtains products and the words "products purchased" are used to describe the type of transaction used to put into effect that procurement.130

6.44. The verb in the past participle form "purchased" links the "products" being procured by governmental agencies with the remaining part of Article III:8(a), namely the phrase "for governmental purposes and not with a view of commercial resale ...". The French version refers to "l'acquisition ... de produits achetés pour les besoins des pouvoirs publics". The Spanish version refers to "la adquisición ... de productos comprados para cubrir las necesidades de los poderes públicos". The wording "for governmental purposes" can be contrasted with the wording of Article XVII:2 of the GATT 1994 on State Trading Enterprises.<sup>131</sup> Article XVII:1 stipulates obligations for state trading enterprises and Article XVII:2 sets out a derogation from those obligations for certain government procurement transactions. Article XVII:2 provides that "[t]he provisions of paragraph 1 of this Article shall not apply to imports of products for immediate or ultimate consumption in governmental use and not otherwise for resale or use in the production of goods for sale." Article XVII:2 thus more narrowly refers to "imports of products for immediate or ultimate consumption in governmental use". Article III:8(a) does not refer to governmental use or governmental consumption. In our view, the broader language "for governmental purposes" does not necessarily refer to government as the end to which the products procured and purchased are directed. It rather refers to the products procured and purchased for the needs ("purposes", "besoins", "necesidades") of the government. We agree with the statement in the Appellate Body reports cited by the parties that the phrase procurement of products purchased "for governmental purposes" in Article III:8(a) refers to what is consumed by the government or what is provided by the government to recipients in the discharge of its public functions.<sup>132</sup>

6.45. In its analysis of the words "products purchased", the Panel noted, and we agree, that cases of governmental procurement will typically involve situations where a government obtains products for its own use or consumption.<sup>133</sup> An obvious example is where a governmental agency purchases a good, uses it to discharge its governmental functions, and the good is totally consumed in the process. This would typically involve a purchase by the government. Government procurement through a purchase of products to be provided by the government to recipients in the discharge of its public function (when the government is not the end user of the products) may also typically, but not necessarily, involve a purchase by the government of those products.

6.46. Importantly, nothing in the text of Article III:8(a) explicitly specifies which entity purchases products for the purposes of government procurement. When a provision omits to further qualify an action, this can serve as an indication that no limitation is intended to be imposed on the manner or circumstances in which such action may be taken. If we were to read into Article III:8(a) a requirement that a purchase necessarily needs to be made by a governmental agency, we would be adding to the text of Article III:8(a) or moving the preposition "by governmental agencies" to relate to the words "products purchased" in this provision. The text and structure of the phrase "procurement by governmental agencies of products purchased" together with the contextual elements discussed above suggest to us that while a typical government procurement scenario under Article III:8(a) would involve a purchase by governmental agencies of the products being procured, there is no such requirement in Article III:8(a). We cannot exclude that another entity may purchase the relevant products, so long as there is procurement by a governmental agency and procurement of products purchased for governmental purposes.

<sup>&</sup>lt;sup>130</sup> This accords with the Appellate Body's interpretation of Article III:8(a). It understood "the word 'procurement' to refer to the process pursuant to which a government acquires products" and "[t]he word 'purchased' ... to describe the type of transaction used to put into effect that procurement". (Appellate Body Reports, Canada - Renewable Energy / Canada - Feed-in Tariff Program, para. 5.59) It also accords with the parties' understanding of the concept of procurement. According to Türkiye, procurement is "the process of obtaining products". (Türkiye's written submission, para. 27; responses to questions at the hearing) The European Union understands procurement as the governmental agency obtaining or acquiring products. (European Union's written submission, para. 29; responses to questions at the hearing)

<sup>&</sup>lt;sup>131</sup> We consider that Article XVII:2 of the GATT 1994 provides relevant interpretative context. This is consistent with the Appellate Body's approach. (Appellate Body Reports, Canada - Renewable Energy / Canada - Feed-in Tariff Program, para. 5.68)

<sup>&</sup>lt;sup>132</sup> Appellate Body Reports, Canada - Renewable Energy / Canada - Feed-in Tariff Program, para. 5.68. See also Türkiye's written submission, para. 99; European Union's written submission, para. 97. <sup>133</sup> Panel Report, para. 7.66.

6.47. We emphasize that, for the derogation in Article III:8(a) to apply, different requirements need to be met. In particular, Article III:8(a) requires a *procurement by governmental agencies* of products purchased *for governmental purposes*. Our interpretation set out above does not extend the scope of the derogation contained in Article III:8(a) beyond what is set by the provision itself.<sup>134</sup> In other words, Article III:8(a) would not extend to an open-ended range of protectionist measures and allow Members to circumvent their national treatment obligations, simply because the possibility is not excluded that, in certain circumstances, the relevant purchase transaction might be entered into by a non-governmental agency. Our understanding takes into account the fundamental purpose of Article III to avoid protectionism in the application of internal tax and regulatory measures<sup>135</sup> and reflects the carefully drafted balance between the national treatment obligation under Article III and the derogation contained in Article III:8(a).

6.48. Both parties extensively refer to the Appellate Body reports in Canada - Renewable Energy / Canada - Feed-in Tariff Program and India - Solar Cells.<sup>136</sup> In particular, the European Union considers the Appellate Body to have clarified that the entity purchasing products needs to be a governmental agency.<sup>137</sup> We carefully read the panel and Appellate Body reports in these two disputes. In Canada - Renewable Energy / Canada - Feed-in Tariff Program, the Appellate Body considered that "[t]he reference to 'governmental agencies' defines the identity of the entity carrying out the procurement" and "'procurement' is the operative word in Article III:8(a) describing the process and conduct of the governmental agency."<sup>138</sup> The word "purchased" is then used to describe the type of transaction used to put into effect that procurement. <sup>139</sup> Our understanding of Article III:8(a) properly accords with these observations. The Appellate Body in India - Solar Cells "recall[ed]", without more, that "the entity purchasing products needs to be a 'governmental agency'."<sup>140</sup> This statement was not the result of an interpretation of Article III:8(a) by the Appellate Body. It is found in a short paragraph briefly summarizing the various elements of Article III:8(a) in reference to the Appellate Body reports in Canada - Renewable Energy / Canada - Feed-in Tariff Program. Yet, whether a non-governmental entity could be the purchasing entity for the purposes of Article III:8(a) was not at issue in either of these two disputes. The Appellate Body did not discuss the proper interpretation of the words "products purchased" with respect to the interpretative issue raised by Türkiye in this Arbitration. The key interpretative issue in both disputes related to the word "products" in Article III:8(a), not to the notion of "purchase" or who purchases products.<sup>141</sup> While certain statements, taken out of context, could arguably suggest that the Appellate Body read Article III:8(a) to cover only purchases by governmental agencies, these statements are, in our reading, a reflection that, in those disputes, governmental agencies were both procuring and purchasing the product at issue. To that extent, these Appellate Body reports provide only limited assistance to the interpretative issue raised in this Arbitration.<sup>142</sup>

 $<sup>^{134}</sup>$  We also consider that merely characterizing a treaty provision as a "derogation" does not justify a stricter or narrower interpretation of that provision than would be warranted by applying the normal rules of treaty interpretation. (See e.g. Appellate Body Report, *EC – Hormones*, para. 104)

<sup>&</sup>lt;sup>135</sup> See e.g. Appellate Body Report, *Japan – Alcoholic Beverages II*, pp. 16-17, DSR 1996:I, pp. 109-110.

<sup>&</sup>lt;sup>136</sup> See e.g. Türkiye's written submission, para. 25; European Union's written submission, para. 19 et seq.; parties' responses to questions at the hearing.

<sup>&</sup>lt;sup>137</sup> European Union's written submission, paras. 18-19. To the European Union, the Appellate Body made a general interpretative finding that is directly relevant to this dispute, and it was appropriate for the Panel to follow this clear legal interpretation. (Ibid., paras. 21-22 and fn 18 to para. 22 (referring to Appellate Body Report, *US – Shrimp (Article 21.5 – Malaysia)*, paras. 108-109); opening statement at the hearing, para. 15)

<sup>&</sup>lt;sup>138</sup> Appellate Body Reports, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, paras. 5.59 and 5.66.

<sup>&</sup>lt;sup>139</sup> Appellate Body Reports, Canada – Renewable Energy / Canada – Feed-in Tariff Program, para. 5.59.

<sup>&</sup>lt;sup>140</sup> Appellate Body Report, *India – Solar Cells*, para. 5.18 (referring to Appellate Body Reports, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 5.74).

<sup>&</sup>lt;sup>141</sup> The disputes concerned the imposition of domestic content requirements, which mandated electricity generators to source a certain amount of renewable energy equipment domestically. The discrimination relating to generation equipment contained in the domestic content requirements was found not to be covered by the derogation of Article III:8(a) on the basis that the product discriminated against under Article III:4 (the electricity generation equipment) was not in a competitive relationship with the product procured by way of purchase under Article III:8(a) (electricity). (Appellate Body Reports, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, paras. 5.63, 5.79, and 5.84; *India – Solar Cells*, para. 5.40)

<sup>&</sup>lt;sup>142</sup> As indicated in paragraph 6.44. and fn 130 above, our interpretation accords with the observations that the Appellate Body made on interpretation with respect to the words "procurement" and "products purchased".

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6.49. For the reasons set out above, we consider that the "procurement by governmental agencies of products purchased for governmental purposes" would typically involve the procurement of products through a *purchase by* a governmental agency. However, Article III:8(a) does not contain an unequivocal requirement to that effect. We do not foreclose the possibility that, in certain circumstances, the relevant purchase transaction may be entered into by a non-governmental entity so long as the products are *procured by* a governmental agency and procurement is of products purchased for governmental purposes. We therefore find that the Panel erred in considering, as a starting point for its analysis in paragraph 7.65 of the Panel Report, that Article III:8(a) required a *purchase by* governmental agencies.

6.50. As further explained in paragraph 6.70. below, having agreed with Türkiye in respect of its first interpretation challenge, and given our analysis of Türkiye's related application claim, we do not consider it necessary for the resolution of this dispute to address Türkiye's second interpretation challenge in this Arbitration.

#### 6.2.3 Application of Article III:8(a) of the GATT 1994

6.51. Türkiye makes several claims regarding the Panel's application of Article III:8(a) of the GATT 1994. Türkiye's first application claim is that, as a result of its erroneous interpretation that there needed to be a purchase *by* a governmental agency, the Panel erred in finding that Article III:8(a) did not apply on the basis that there was no purchase of pharmaceutical products *by* the SSI.<sup>143</sup> Türkiye raises three additional application claims. Türkiye submits that, as a result of its erroneous interpretation that a purchase implied a transfer of ownership to the purchaser, the Panel erred in finding that there was no purchase of pharmaceutical products by the SSI did not acquire ownership of those products. In addition, Türkiye submits that, even if the Panel's interpretation were correct, the Panel should have concluded that there was a transfer of ownership to the SSI through the Medula system and thus a purchase by the SSI. Finally, in the alternative, Türkiye claims that the Panel erred in finding that retail pharmacies did not purchase pharmaceutical products from wholesalers on behalf of the SSI.<sup>144</sup>

6.52. The European Union requests us to reject these claims. The European Union considers Türkiye to be mostly taking issue with factual findings of the Panel. Since Türkiye has not invoked Article 11 of the DSU, the European Union considers that any challenge of factual findings by the Panel is outside the scope of our review. The European Union also disputes the allegations put forward by Türkiye in support of each of its application claims.<sup>145</sup>

6.53. Starting with Türkiye's first application claim, we note that this claim is premised on us disagreeing with the Panel's assumption that Article III:8(a) required a purchase *by* governmental agencies. We concluded above that "procurement by governmental agencies of products purchased for governmental purposes" would typically involve the procurement of products through a purchase by a governmental agency. However, Article III:8(a) does not contain an unequivocal requirement to that effect.<sup>146</sup> We thus agreed with Türkiye that the Panel's assumption that Article III:8(a) required a purchase *by* governmental agencies was incorrect.

6.54. According to Türkiye, Article III:8(a) applies in this case because retail pharmacies purchase the medicines included in Annex 4/A list, and the procurement is made by the SSI.<sup>147</sup> Türkiye argues that the SSI and other governmental agencies (the TMMDA) decide the legal framework governing the acquisition of medicines to be provided in the discharge of their public function, leaving no room for market-based or profit-maximizing price negotiations. Türkiye contends that the SSI: (i) decides which medicines are included in the Annex 4/A list; (ii) sets the price of those medicines (together with the TMMDA); (iii) signs the Protocol with the TPA and individual contracts with the retail pharmacies tasking them with ensuring the availability and distribution of those medicines throughout the country; (iv) approves the provision of medicines to be dispensed to patients through

<sup>&</sup>lt;sup>143</sup> Türkiye's notice of recourse to arbitration, pp. 1-2; written submission, para. 52.

<sup>&</sup>lt;sup>144</sup> Türkiye's notice of recourse to arbitration, pp. 1-2; written submission, paras. 56, 61, and 75.

<sup>&</sup>lt;sup>145</sup> European Union's written submission, paras. 3, 13-16, 58-59, 62-64, 67-75, and 78-84.

<sup>&</sup>lt;sup>146</sup> See para. 6.49. above.

<sup>&</sup>lt;sup>147</sup> Türkiye's written submission, paras. 52 and 55 (referring to Panel Report, para. 7.98;

European Union's first written submission to the Panel, para. 15; second written submission to the Panel, para. 101).

the Medula system; and (v) pays for the dispensed medicines based on invoices it receives from retail pharmacies.  $^{\rm 148}$ 

6.55. The European Union responds that no governmental agency of Türkiye engages in procurement since no governmental agency obtains or acquires the medicines included in the Annex 4/A list.<sup>149</sup> To the European Union, whether the SSI or other governmental agencies decide which medicines to reimburse, set the price of medicines, enter into contracts with pharmacies, approve reimbursements in the Medula system, and pay pharmacies' invoices for reimbursement, or more generally decide the legal framework for medicines does not show that they engage in the *procurement* of those medicines.<sup>150</sup> The European Union emphasizes that "procurement" refers to "the process pursuant to which the government *acquires* or obtains products, as opposed to merely financing or regulating their acquisition".<sup>151</sup>

6.56. Central to Türkiye's first application claim is whether there is *procurement* by a governmental agency of products purchased for governmental purposes within the meaning of Article III:8(a), i.e. whether the SSI procures the pharmaceutical products included in the Annex 4/A list.<sup>152</sup> The Panel did not make a finding on this issue. As summarized above, the Panel noted that there were several elements in Article III:8(a) and decided to start its analysis with the second element it had identified, looking at whether the localisation requirement involved "the 'purchase' of pharmaceutical products included in the Annex 4/A list by governmental agencies".<sup>153</sup> The Panel did not consider it necessary to assess the other elements of Article III:8(a), including that relating to procurement. Given that the issue of procurement is central to Türkiye's first application claim, for us to determine whether this claim has merit, we must ascertain whether the SSI procures the pharmaceutical products included in the Annex 4/A list.<sup>154</sup> The parties agree that there are sufficient Panel factual findings or uncontested facts on the panel record for us to complete the analysis in this respect.<sup>155</sup> In addition, neither party has raised any due process concerns. The parties, however, disagree on the conclusion we should reach upon completion of our analysis.<sup>156</sup>

# **6.2.3.1** Whether there is procurement by the SSI of pharmaceutical products included in the Annex 4/A list

6.57. As reflected in paragraphs 6.41. -6.44. above, "procurement" is the operative word in Article III:8(a) of the GATT 1994 describing the process and conduct of the governmental agency. It is to be distinguished from a "purchase", which refers to the type of transaction to put into effect procurement under Article III:8(a). As further discussed above, conceptually, procurement may be put into effect through different types of transactions, but Article III:8(a) specifically refers to

<sup>&</sup>lt;sup>148</sup> Türkiye's written submission, para. 53.

<sup>&</sup>lt;sup>149</sup> European Union's written submission, para. 59 (referring to Panel Report, paras. 7.84, 7.86-7.88, and 7.100).

<sup>&</sup>lt;sup>150</sup> Éuropean Union's written submission, para. 59.

<sup>&</sup>lt;sup>151</sup> European Union's written submission, para. 29. (emphasis original)

<sup>&</sup>lt;sup>152</sup> Türkiye does not clearly identify the purchase transactions through which procurement allegedly occurs. In the context of its first application claim, Türkiye refers to procurement by the SSI through the purchase by retail pharmacies from wholesalers. (Türkiye's written submission, para. 55) Elsewhere in its submission, Türkiye refers to the procurement by the SSI "through purchase transactions by the retail pharmacies or between the SSI and the retail pharmacies". (Ibid., para. 98) At the hearing, Türkiye stated that procurement is the process whereby the SSI obtains medicines for governmental purposes through the private retail pharmacies acting as an intermediary between the wholesalers and the outpatients. (Türkiye's responses to questions at the hearing)

<sup>&</sup>lt;sup>153</sup> Panel Report, para. 7.63.

<sup>&</sup>lt;sup>154</sup> The Panel noted that the work of the Appellate Body had been suspended for nearly two years and that Members remained unable to reach consensus on any selection process to fill the vacancies required for the Appellate Body to function. (Panel Report, para. 7.104 and fn 436 thereto) In the present case, given the Panel's factual findings and uncontested facts on the record, we find that we can complete the analysis on the issue of procurement. (See para. 6.59. et seq. below.) We are wary of the systemic concerns raised by Türkiye and Switzerland. Türkiye submits that the Panel's approach, should it have led us to decline completing the analysis, would have effectively precluded its right to have effective recourse to the WTO dispute settlement, "including an appeal review through Article 25 arbitration or otherwise". (Türkiye's written submission, para. 91) Switzerland notes the parties' right to appeal, including through an "appeal arbitration" under Article 25 of the DSU. (Switzerland's third party's submission, para. 15)

 <sup>&</sup>lt;sup>155</sup> The parties confirmed that our mandate includes the possibility of completing the legal analysis.
 (Parties' responses to questions at the hearing)
 <sup>156</sup> See e.g. Türkiye's written submission, paras. 55 and 94-95; European Union's written submission,

<sup>&</sup>lt;sup>156</sup> See e.g. Türkiye's written submission, paras. 55 and 94-95; European Union's written submission, paras. 59 and 91-92.

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"products purchased". We also noted that procurement refers generally to "[t]he action of obtaining something; acquisition; an instance of this".<sup>157</sup> To us, the words "*acquisition*, par des organes gouvernementaux" and "*adquisición*, por organismos gubernamentales" in the French and Spanish versions of Article III:8(a) confirm that, in the context of that provision, "procurement" refers to a governmental agency *acquiring* products.<sup>158</sup> Therefore, as we concluded above, "procurement" refers to the process pursuant to which a government acquires or obtains products. This is in line with the parties' own understanding of procurement.<sup>159</sup>

6.58. The parties both consider, and we agree, that procurement is not limited to scenarios of ownership acquisition of the products.<sup>160</sup> A governmental agency *acquiring* or *obtaining* products means that the governmental agency would, however, need to have a certain level of control over the products purchased for governmental purposes. Depending on the particular circumstances of each case, the following elements could be relevant to whether there is procurement by a governmental agency: ownership of the products by the governmental agency or other property rights or title over the products; the governmental agency holding or exercising other legal or contractual rights associated with the products; price setting and payment by the governmental agency; use of the products by the governmental agency over the products; ultimate benefit of the products by the governmental agency; and the governmental agency bearing risks, such as commercial risks, associated with the products. We consider this list to be non-exhaustive and relevant elements should be taken into account in a holistic manner. We also emphasize that acquiring or obtaining products cannot be equated with merely financing or regulating the acquisition of products.<sup>161</sup>

6.59. Having carefully reviewed the Panel Report and having engaged with the parties at the hearing regarding the nature of certain Panel findings, we consider that the Panel made a number of factual findings relevant to the issue of procurement. The Panel made these factual findings in the context of its assessment of whether the SSI (itself or through retail pharmacies) *purchased* pharmaceutical products. Although procurement cannot be equated with purchase, given the Panel's understanding of the concept of "purchase" as requiring a transfer of ownership to the purchaser and our understanding of the word "procurement" in the context of Article III:8(a) as requiring a certain

understanding of government procurement in the (unadopted) GATT panel report in US - Sonar Mapping. In the context of Article I:1(a) of the Tokyo Round Government Procurement Code, the GATT panel stated that "the following characteristics, none of which alone could be decisive, provide guidance as to whether a transaction should be regarded as government procurement", namely "payment by government, governmental use of or benefit from the product, government possession and government control over the obtaining of the product". (GATT Panel Report, US - Sonar Mapping, para. 4.7) There were a number of factors which, taken together, led the GATT panel to conclude that the purchase of a sonar mapping system by a private company was in fact government procurement: (i) payment for the system would be made with government money, and the amount of the purchase was determined by the government; (ii) a government agency would take title to the sonar mapping system; that agency, at the expiry of the contract, would be able to choose whether to continue to use, or to dispose of, the system; and that agency would enjoy the benefits of the system's purchase; (iii) the selection of the system was subject to the final approval of the government agency, which also retained the right to cancel the contract between the purchaser and the supplier of the sonar mapping system, with compensation, at its convenience; and (iv) the private entity would have no commercial interest in the transaction in the sense of a profit motive or a commercial risk. The GATT panel concluded that, in light of the government's payment for, ownership of, and use of the sonar mapping system and given the extent of its control over the obtaining of the system, there was government procurement. (Ibid., paras. 4.9-4.13)

<sup>&</sup>lt;sup>157</sup> Oxford English Dictionary online, <u>https://www.oed.com/view/Entry/151913</u>, accessed on 1 July 2022.

<sup>&</sup>lt;sup>158</sup> Emphasis added.

<sup>&</sup>lt;sup>159</sup> Türkiye's written submission, para. 27; European Union's written submission, para. 29; parties' responses to questions at the hearing. See also fn 130 above.

<sup>&</sup>lt;sup>160</sup> At the hearing, Türkiye noted that what matters is that, through procurement, the government obtains goods for governmental purposes. The European Union stated that acquiring or obtaining products could mean different things in different contexts. Typically, for movable goods, acquiring goods would mean taking physical possession of the goods, but there could be other ways in which the government acquires products (e.g. through an entitlement). Japan also considered that governmental agencies procuring products needed to acquire a certain entitlement over the product, but that this was not necessarily limited to property rights. Japan referred to the right to bring a legal action for non-performance of a contract. (Parties' and third parties' responses to questions at the hearing)
<sup>161</sup> Our understanding of "procurement by governmental agencies" accords with the GATT panel's

level of control over products, factual elements explored by the Panel for the purpose of looking at the issue of purchase are equally relevant to our assessment of the issue of procurement.

6.60. On the facts, and as summarized in paragraphs 6.2. -6.5. above, the Panel found that to be reimbursable, a pharmaceutical product needed to be included in the Annex 4/A list and the SSI determined which pharmaceutical products are included in that list.<sup>162</sup> Pharmaceutical products included in the Annex 4/A list are distributed to outpatients by retail pharmacies, which are private entities.<sup>163</sup> The SSI signed a Protocol with the TPA. According to the Protocol, individual retail pharmacies sign and annually renew standard contracts with the SSI. The amounts charged by pharmacies for pharmaceutical products covered by the social security system are met from payments by the SSI and out-of-pocket payments by outpatients. On the basis of their individual contracts with the SSI, pharmacies periodically invoice the SSI for all pharmaceutical products included in the Annex 4/A list that they have provided to outpatients during the relevant period. The SSI reviews invoices using a sampling method and reimburses the reimbursement price.<sup>164</sup> If the public price of a pharmaceutical product is greater than a maximum reimbursement price, outpatients must pay the difference, unless they decide to opt for an equivalent product. Outpatients generally also pay a contribution fee and a prescription fee to retail pharmacies.<sup>165</sup>

6.61. The Panel further found, as a matter of fact, that the SSI did not take physical possession of the products at any stage; retail pharmacies took physical possession of the products when purchasing pharmaceutical products from warehouses, with outpatients subsequently taking physical possession when receiving those products from the retail pharmacies.<sup>166</sup> It was undisputed before the Panel and is undisputed in this Arbitration that the SSI does not ever acquire the right to take physical possession of the pharmaceutical products that it pays for.<sup>167</sup>

6.62. The Panel also made factual findings regarding the electronic information system (the Medula system) used by the SSI and retail pharmacies to register, track, and invoice medicines.<sup>168</sup> Following approval in the Medula system, the pharmaceutical product must be provided to the individual consumer (i.e. outpatient) named in the prescription.<sup>169</sup> Importantly:

[A]II relevant decisions and choices associated with the disposition of pharmaceutical products are made by the prescribing doctor, the pharmacy, and the ultimate consumer (i.e. the outpatient). The Panel is unable to discern any SSI involvement in choosing who receives and consumes any of the pharmaceutical products that the SSI pays for. Put differently, all of the pharmaceutical products paid for by the SSI would be disposed of in exactly the same manner in a counterfactual scenario in which the SSI did not pay for all or part of the cost of those products. Neither the SSI nor any other governmental agency plays any role in directing, or redirecting, pharmaceutical products to recipients of their choosing.<sup>170</sup>

6.63. The Panel emphasized that "[a]pproval through the Medula system [was] essentially a confirmation that the patient is within SSI coverage and that the prescribed pharmaceutical products [were] on the Annex 4/A list." <sup>171</sup> That approval confirms, among other things, that the pharmaceutical product may be invoiced by the pharmacy to the SSI at the previously set price.<sup>172</sup> In light of these factual elements, the Panel found no basis to support Türkiye's assertion that the SSI obtained the right to dispose of the pharmaceutical products that it paid for according to its own

para. 26; European Union's responses to the Panel's first set of questions, paras. 10-22, opening statement at the Panel meeting, para. 24).

<sup>&</sup>lt;sup>162</sup> Panel Report, para. 2.8.

<sup>&</sup>lt;sup>163</sup> Panel Report, para. 2.7.

<sup>&</sup>lt;sup>164</sup> Panel Report, para. 2.14 and fn 59 thereto.

<sup>&</sup>lt;sup>165</sup> Panel Report, para. 2.16.

<sup>&</sup>lt;sup>166</sup> Panel Report, para. 7.86.

<sup>&</sup>lt;sup>167</sup> Panel Report, para. 7.86. In the Arbitration, Türkiye takes issue with the Panel's approach to look at whether the SSI acquired possession over the products in the context of its analysis of "products purchased", but does not challenge the Panel's finding that the SSI did not acquire the right to take physical possession of the pharmaceutical products. (Türkiye's written submission, paras. 64-65. See also paragraph 6.65. below)

<sup>&</sup>lt;sup>168</sup> Panel Report, para. 2.17.

<sup>&</sup>lt;sup>169</sup> Panel Report, para. 7.87.

<sup>&</sup>lt;sup>170</sup> Panel Report, para. 7.87.

<sup>&</sup>lt;sup>171</sup> Panel Report, para. 7.88.

<sup>&</sup>lt;sup>172</sup> Panel Report, para. 7.88 (referring to Türkiye's responses to the Panel's first set of questions,

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choices.<sup>173</sup> The Panel observed that "Turkey ha[d] not directed the Panel to any reference to the SSI acquiring 'title' to pharmaceutical products in the Protocol signed between the SSI and the Turkish Pharmacists Association or to any other evidence on record."<sup>174</sup> More generally, the Panel found that "there [was] nothing in the parties' description of Turkey's pharmaceutical reimbursement system to suggest that the SSI acquire[d] any right of possession, any right of control, any right of exclusion, any right to derive income, or any right to freely dispose of the pharmaceutical products that it acquire[d]."<sup>175</sup>

6.64. In addition to these Panel findings, there are uncontested facts on the record that could potentially be relevant to the issue of procurement. In particular, we understand the parties to have both relied on the fact, before the Panel, that pharmacies control their own stock<sup>176</sup>, although wholesale prices are regulated.<sup>177</sup>

6.65. Moreover, we observe that it was undisputed before the Panel that retail pharmacies acquire ownership of medicines when obtaining them from wholesalers 178 and final consumers (i.e. outpatients) subsequently acquire ownership when obtaining pharmaceutical products from retail pharmacies.<sup>179</sup> Türkiye does not challenge this in the Arbitration but argues that the Panel should have nonetheless concluded that there is a transfer of ownership from the pharmacies to the SSI through the Medula system.<sup>180</sup> In this context, Türkiye argues that the Panel unduly focused on the *physical possession* of the products, thereby contradicting its finding that physical possession is not a constitutive element of a purchase.<sup>181</sup> As summarized above, the Panel assessed whether the SSI acquired ownership of pharmaceutical products. The Panel was unable to discern any basis upon which it could conclude that the SSI acquired any legal rights over the pharmaceutical products it paid for. Only by way of example, did the Panel note that the SSI did not ever acquire the right to take physical possession of the pharmaceutical products. The Panel then proceeded to address, in some detail, Türkiye's assertion that the SSI obtained the right to dispose of the pharmaceutical products. Ultimately, the Panel found that the SSI did not acquire such right or any other right typically associated with a transfer of ownership.<sup>182</sup> We do not see any contradiction in the Panel's reasoning, nor do we consider that the Panel would have focused on who acquires the physical possession of the medicines to draw decisive guidance from it. In relation to the Panel's conclusion that there is no transfer of ownership of the pharmaceutical products to the SSI, Türkiye otherwise makes allegations that go to the Panel's assessment of the facts and its appreciation of evidence. In the absence of a claim under Article 11 of the DSU, these allegations are outside of the scope of our

 $^{176}$  Panel Report, fn 411 to para. 7.84 (referring to European Union's second written submission to the Panel, paras. 106-107; Türkiye's closing statement at the Panel meeting, para. 23).

<sup>177</sup> Parties' responses to questions at the hearing.

<sup>178</sup> Panel Report, paras. 7.84 and 7.98.

<sup>179</sup> Panel Report, paras. 7.84 and 7.98. We also note Türkiye's statement in the context of its first application claim in this Arbitration that "it is not disputed that the retail pharmacies purchase the medicines included in Annex 4/A." (Türkiye's written submission, para. 55 (referring to Panel Report, para. 7.98; European Union's first written submission to the Panel, para. 15; second written submission to the Panel, para. 101))

<sup>180</sup> Türkiye's written submission, para. 61.

<sup>181</sup> Türkiye's written submission, paras. 62-65 (referring to Panel Report, paras. 7.83 and 7.86; Panel Reports, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 7.228).

<sup>182</sup> Panel Report, para. 7.84 et seq.

<sup>&</sup>lt;sup>173</sup> Panel Report, para. 7.87.

<sup>&</sup>lt;sup>174</sup> Panel Report, para. 7.88.

<sup>&</sup>lt;sup>175</sup> Panel Report, para. 7.85. This particular finding rests on the Panel's review of Türkiye's

pharmaceutical reimbursement system, as described by the parties. We read this finding to be an intermediate finding of fact by the Panel, which led the Panel to conclude that the SSI does not acquire ownership over the pharmaceutical products. We note that Türkiye takes issue with the Panel's finding that the SSI does not obtain the right to dispose of medicines. In this context, Türkiye takes issue with the Panel's description of the Medula system and asserts that the Panel "completely disregarded ... evidence" reflected in Panel Exhibit TUR-117 as well as "completely ignored [the] fact" that the SSI pays a service fee to retail pharmacies for dispensing medicines to approved patients. (Türkiye's written submission, paras. 69 (referring to Panel Report, para. 7.87) and 71-73) With these allegations, Türkiye is in effect challenging the Panel's assessment of the facts and its appreciation of evidence. In the absence of a claim under Article 11 of the DSU, these challenges are outside of the scope of our review.

review.<sup>183</sup> We thus see no reason to disturb the Panel's conclusion that there is no transfer of ownership of the pharmaceutical products to the SSI.<sup>184</sup>

6.66. A close reading of the Panel Report further makes clear that the Panel considered the pharmacies to acquire ownership over pharmaceutical products "independently" of the government.<sup>185</sup> At the hearing, the parties extensively discussed paragraphs 7.99 and 7.100 of the Panel Report and the Panel's statement that even if the Panel were to accept Türkiye's assertion that the SSI controls all the elements concerning the acquisition of pharmaceutical products, "this would not make pharmacies 'governmental agencies' for the purposes of Article III:8(a), or transform their purchases into purchases by the government, so long as the pharmacies acquire ownership over pharmaceutical products independently of the government."<sup>186</sup> In our view, this statement has to be read in conjunction with the remaining analysis of the Panel regarding whether the SSI acquired ownership of the products. Given the Panel's detailed assessment of the facts of the case, including its factual findings recalled above, we consider the Panel to have reached the correct conclusion that pharmacies acquire ownership of the pharmaceutical products *independently* from the government. It is on this basis that the Panel concluded that the SSI did not acquire ownership of the pharmaceutical products through the purchase by retail pharmacies of those products from wholesalers.

6.67. Türkiye points to the level of control of the SSI over the retail pharmacies.<sup>187</sup> Türkiye argues that "the SSI controls the entire process of obtaining and dispensing medicines included in Annex 4/A to patients."<sup>188</sup> While we do not exclude that procurement by a governmental agency may occur through an intermediary, it remains that, for the purposes of the derogation under Article III:8(a), there needs to be a process whereby governmental agencies acquire or obtain products purchased for governmental purposes.<sup>189</sup> Türkiye did not explain how, through any such alleged control, the SSI would acquire or obtain medicines through a purchase of medicines. Türkiye has not pointed to elements showing a sufficient level of control by the SSI over the pharmaceutical products included in the Annex 4/A list when they are purchased by the retail pharmacies or otherwise. The fact that the SSI decides which pharmaceutical products are included in the Annex 4/A list and sets their price, enters into individual contracts with retail pharmacies, and pays the invoices that are periodically sent by the retail pharmacies<sup>190</sup> does not show, in light of the Panel's findings set out above, that there is procurement by the SSI. We note Türkiye's argument, as clarified at the hearing, that the SSI signs a Protocol with the TPA and individual contracts with the retail pharmacies tasking them with the distribution of those medicines and that, to comply with their obligations regarding such provision of medicines, retail pharmacies need to purchase the medicines.<sup>191</sup> This element most directly relates to the provision of medicines to outpatients, rather than to procurement through a purchase of medicines. We also recall the Panel's factual finding that all relevant decisions and choices associated with the disposition of pharmaceutical products are made by the prescribing doctor, the pharmacy, and the ultimate consumer, without SSI involvement: "[A]II of the pharmaceutical products paid for by the SSI would be disposed of in exactly the same manner in a counterfactual scenario in which the SSI did not pay for all or part of the cost of those products."<sup>192</sup>

6.68. In our view, the various elements set out above, taken together, indicate that there is no procurement by the SSI of products purchased for governmental purposes, whether at the moment when retail pharmacies purchase products from wholesalers or otherwise. While the SSI pays for pharmaceutical products when they are obtained by outpatients subject to certain conditions, sets their price, and decides which pharmaceutical products are included in the Annex 4/A list, retail

<sup>&</sup>lt;sup>183</sup> See fn 175 above. Türkiye also argues that medicines are "essential for human health, require specific storage conditions" and their provision must be "ensured by trained professionals". (Türkiye's appellant submission, para. 60) Türkiye has, however, not explained how this should affect our analysis of whether there is procurement by the SSI.

<sup>&</sup>lt;sup>184</sup> Panel Report, paras. 7.84-7.88.

<sup>&</sup>lt;sup>185</sup> Panel Report, para. 7.100.

<sup>&</sup>lt;sup>186</sup> Panel Report, para. 7.100.

<sup>&</sup>lt;sup>187</sup> Türkiye's written submission, paras. 42, 53-54, and 95; responses to questions at the hearing.

<sup>&</sup>lt;sup>188</sup> Türkiye's written submission, para. 95.

<sup>&</sup>lt;sup>189</sup> We recall that the Appellate Body understood a "governmental agency" within the meaning of Article III:8(a) to be "an entity acting for or on behalf of government and performing governmental functions within the competences conferred on it". (Appellate Body Reports, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, paras. 5.60-5.61)

<sup>&</sup>lt;sup>190</sup> These factual elements appear uncontested between the parties.

<sup>&</sup>lt;sup>191</sup> Türkiye's written submission, paras. 53 and 79; responses to questions at the hearing.

<sup>&</sup>lt;sup>192</sup> Panel Report, para. 7.87.

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pharmacies and/or outpatients, rather than the SSI, obtain physical possession of the products, dispose of and control the products, benefit from and use the products, obtain ownership of the products, and manage the stocks of products. We also recall the Panel's finding that "there [was] nothing in the parties' description of Turkey's pharmaceutical reimbursement system to suggest that the SSI acquire[d] any right of possession, any right of control, any right of exclusion, any right to derive income, or any right to freely dispose of the pharmaceutical products that it acquire[d]."<sup>193</sup> Therefore, we conclude that there is no procurement, within the meaning of Article III:8(a) of the GATT 1994, by the SSI of the pharmaceutical products included in the Annex 4/A list.

## 6.2.4 Conclusion

6.69. In light of the considerations above, we find that the localisation requirement does not fall within the ambit of the derogation in Article III:8(a) of the GATT 1994 on the basis that there is no procurement by governmental agencies within the meaning of that provision. Consequently, we uphold, albeit for different reasons, the Panel's finding, in paragraphs 7.107 and 8.1.b.ii of the Panel Report, that the localisation requirement is not covered by the government procurement derogation in Article III:8(a) of the GATT 1994, and is therefore subject to the national treatment obligation in Article III:4 of the GATT 1994 and Article 2.1 of the TRIMs Agreement.

6.70. We do not consider it necessary, for the purpose of resolving this dispute, to address further Türkiye's remaining claims under Article III:8(a) set out in paragraph 6.51. above. Procurement is an essential element of Article III:8(a) and our finding on procurement is sufficient to conclude that the localisation requirement is not covered by Article III:8(a). Addressing further Türkiye's remaining application claims, as they pertain to the issue of "products purchased" within the meaning of Article III:8(a), would not alter our conclusion that there is no procurement by the SSI of the pharmaceutical products included in the Annex 4/A list, whether at the time when retail pharmacies purchase pharmaceutical products from wholesalers or otherwise. Accordingly, the Panel's intermediate findings, in paragraphs 7.66-7.81 of the Panel Report, regarding the interpretation of the term "products purchased", as well as its intermediate finding, in paragraphs 7.90, 7.103, and 7.104, that the localisation requirement does not involve the purchase of pharmaceutical products included in the Annex 4/A list, are moot.<sup>194</sup>

6.71. We also do not consider it necessary to address Türkiye's request that we moot or reverse the Panel's findings under Article III:4 of the GATT 1994 as this request was conditional upon a reversal of the Panel's finding under Article III:8(a). Therefore, the Panel's finding, in paragraph 8.1.b.iii of the Panel Report, that the localisation requirement is inconsistent with the national treatment obligation in Article III:4 of the GATT 1994, remains undisturbed. Since this finding of inconsistency with Article III:4 stands, we proceed to address Türkiye's claims pertaining to the general exceptions in Article XX of the GATT 1994.

#### 6.3 Article XX(b) of the GATT 1994

6.72. In the event that we "do not conclude that the localisation [requirement] is covered by the government procurement derogation under Article III:8(a) of the GATT 1994 and/or do not reverse the Panel's findings under Article III:4 of the GATT 1994", Türkiye requests us to find that the Panel erred in concluding that the localisation requirement is not justified under Article XX(b) of the GATT 1994.<sup>195</sup> Türkiye claims that the Panel erred in the interpretation and application of Article XX(b) in finding that the localisation requirement is not "designed to" protect human, animal, or plant life or health.<sup>196</sup> Türkiye also claims that the Panel failed to make an objective assessment of the matter before it, as required by Article 11 of the DSU, when addressing Türkiye's claim that the localisation requirement is justified under Article XX(b).<sup>197</sup> Türkiye requests us to reverse relevant findings by the Panel, including its finding that the localisation requirement is not justified

<sup>&</sup>lt;sup>193</sup> Panel Report, para. 7.85.

<sup>&</sup>lt;sup>194</sup> The parties confirmed that our mandate includes the possibility to moot Panel findings. (Parties' responses to questions at the hearing)

<sup>&</sup>lt;sup>195</sup> Türkiye's written submission, para. 116.

<sup>&</sup>lt;sup>196</sup> Türkiye's notice of recourse to arbitration, p. 2; written submission, paras. 5-6 and 116.

<sup>&</sup>lt;sup>197</sup> Türkiye's notice of recourse to arbitration, p. 3; written submission, paras. 6, 116, 129, and 196-209.

under Article XX(b).<sup>198</sup> Türkiye also requests us to complete the legal analysis and find that the localisation requirement is justified under Article XX(b).<sup>199</sup>

6.73. The European Union disagrees with Türkiye's claims and requests us to find that the Panel did not err in its interpretation and application of Article XX(b).<sup>200</sup> In the alternative, the European Union argues that Türkiye's claims regarding the application of Article XX(b) implicate the Panel's appreciation of facts and evidence and therefore fall outside the scope of our review to the extent that Türkiye has not alleged a violation of Article 11 of the DSU in respect of these claims.<sup>201</sup> The European Union also argues that the Panel did not act inconsistently with Article 11 of the DSU in its assessment of the matter before it, when addressing Türkiye's claim that the localisation requirement is justified under Article XX(b).<sup>202</sup>

6.74. We begin by briefly summarizing key Panel findings, before turning to consider relevant interpretation and application issues raised in this Arbitration.

#### 6.3.1 Panel findings

6.75. With respect to Türkiye's invocation of the general exception in Article XX(b) of the GATT 1994, the Panel found that the localisation requirement was not a measure taken to protect human, animal, or plant life or health.<sup>203</sup>

## 6.3.1.1 Order of analysis

6.76. In its analysis of Türkiye's defence under Article XX(b) of the GATT 1994, the Panel proceeded in the following order. First, the Panel looked at whether the objective invoked by Türkiye (ensuring adequate access to affordable medicines) was an objective that related to the protection of "human life or health" under Article XX(b).<sup>204</sup> Second, the Panel considered whether the measure at issue was taken to (i.e. was designed to) protect human life or health. This part of the analysis consisted of two steps: (i) whether there was evidence of the existence of the risk to human life or health (health risk) that the measure aimed to reduce; and (ii) if the alleged health risk was found to exist, whether the measure was taken for the purpose of protecting human life or health by reducing that risk, or was instead taken for other reasons.<sup>205</sup> Third, assuming that the measure was found to be "designed to" protect human life or health, the Panel would have considered whether the measure was "necessary" to protect human life or health. This part of the analysis would have required the Panel weighing and balancing several factors, including the importance of the objective sought, the contribution of the measure to the achievement of that objective, and the trade-restrictiveness of the measure, as well as comparing the measure with possible alternative measures identified by the European Union.<sup>206</sup> Fourth, assuming that the measure was found to be provisionally justified under subparagraph (b), the Panel would have considered whether it also satisfied the requirements of the chapeau of Article XX (i.e. whether the measure was applied in a manner that did not constitute arbitrary or unjustifiable discrimination between countries where the same conditions prevailed and whether the measure was a disguised restriction on international trade).<sup>207</sup>

#### **6.3.1.2** The declared objective of the measure and its importance

6.77. With respect to the first issue, looking at the GATT 1994 and other covered agreements, as well as previous statements by panels and the Appellate Body, the Panel noted that the preservation of human life and health was an objective that was "both vital and important in the highest

<sup>&</sup>lt;sup>198</sup> Türkiye requests us to reverse the Panel's findings in paragraphs 7.157-7.214, 7.219, and 8.1.b.iv of the Panel Report. (Türkiye's notice of recourse to arbitration, p. 3; written submission, paras. 117 and 250)

<sup>&</sup>lt;sup>199</sup> Türkiye's notice of recourse to arbitration, p. 3; written submission, paras. 117, 210-213, and 250.

 $<sup>^{\</sup>rm 200}$  European Union's written submission, paras. 2, 4, 112, 114-158, and 163-176.

<sup>&</sup>lt;sup>201</sup> European Union's written submission, paras. 159-162.

<sup>&</sup>lt;sup>202</sup> European Union's written submission, paras. 4 and 177-181.

<sup>&</sup>lt;sup>203</sup> Panel Report, para. 7.211.

<sup>&</sup>lt;sup>204</sup> Panel Report, paras. 7.157-7.161.

<sup>&</sup>lt;sup>205</sup> Panel Report, paras. 7.134-7.135 and 7.165 et seq.

<sup>&</sup>lt;sup>206</sup> Panel Report, para. 7.136.

<sup>&</sup>lt;sup>207</sup> Panel Report, para. 7.138.

degree". <sup>208</sup> The Panel then referred to the more specific objective of ensuring access to pharmaceutical products, which it found to be recognized in the WTO covered agreements, as well as by various international authorities through different international instruments, and through multiple international initiatives and publications by international organizations.<sup>209</sup> The Panel noted no disagreement between the parties that: (i) the lack of access to pharmaceutical products posed a risk to human life and health; (ii) the objective of ensuring adequate access to pharmaceutical products was one that related to the protection of human life or health under Article XX(b) of the GATT 1994, and was vital and important; (iii) WTO Members were free to decide how to organize their social security and healthcare systems; (iv) governmental policies of covering all or part of the cost of pharmaceutical products were linked to the objective of providing universal healthcare, ensuring access to pharmaceutical products and protecting human health; and (v) Members may, in the context of Article XX(b), take measures to address the risk of future shortages of supplies before such shortages actually arise.<sup>210</sup>

# **6.3.1.3** The Panel's finding that the measure was not taken to (not designed to) pursue the declared objective

6.78. The Panel subsequently turned to the second issue, namely, whether Türkiye had demonstrated that the localisation requirement was a measure that was taken to protect human life or health and, more specifically, taken to prevent a risk of long-term shortage of supply of safe, effective, and affordable medicines.

6.79. The Panel focused first on whether Türkiye had properly identified a risk to human life or health (health risk) that the localisation requirement aimed to reduce. In this respect, the Panel noted that "[w]here there is no sufficient evidence as to the existence of a health risk, a challenged measure is not necessary to *protect* human, animal or plant life or health."<sup>211</sup>

6.80. The Panel referred to Türkiye's argument that its over-reliance on imported pharmaceutical products created a risk of long-term shortage of supply of safe, effective, and affordable medicines because of several factors relating to the cost of imported pharmaceutical products in Türkiye. These factors included, most notably: (i) low prices of medicines on the Turkish market carried the risk that foreign producers might decide to supply other countries where they could receive a higher price for their products; and (ii) imported pharmaceutical products might become unaffordable for the SSI if a foreign currency gained in value or the Turkish lira depreciated.<sup>212</sup> By localising the production of pharmaceutical products, the localisation requirement would be a measure designed to address this risk and to ensure uninterrupted access to safe, effective, and affordable pharmaceutical products for all patients in Türkiye.<sup>213</sup>

6.81. In the Panel's view, the risk identified by Türkiye (a risk of long-term shortage of supply of safe, effective, and affordable pharmaceutical products caused by an over-reliance on imported pharmaceutical products), without establishing any substantial degree of probability, appeared to be theoretical, abstract, and hypothetical.<sup>214</sup> Looking at the evidence provided by Türkiye, the Panel found that Türkiye had not identified any instance of shortage of supply of a specific product caused by foreign producers deciding to stop supplying medicines to Türkiye to instead sell in other countries where they can receive a higher price for their products, or caused by a medicine becoming unaffordable for the SSI because of a foreign currency gaining in value or the Turkish lira depreciating.<sup>215</sup>

6.82. In addition to the situation described by Türkiye being merely hypothetical, the Panel found that this situation could be present in any sector and concern any market. It was not specific to the pharmaceutical sector or to Türkiye, and was therefore characterized by a level of temporal and

Indonesia - Chicken, para. 7.225).

<sup>&</sup>lt;sup>208</sup> Panel Report, para. 7.157 (quoting Appellate Body Reports, *EC – Asbestos*, para. 172; *Brazil – Retreaded Tyres*, para. 179; Panel Reports, *Brazil – Retreaded Tyres*, para. 7.210;

<sup>&</sup>lt;sup>209</sup> Panel Report, paras. 7.158-7.160.

<sup>&</sup>lt;sup>210</sup> Panel Report, paras. 7.161-7.162.

<sup>&</sup>lt;sup>211</sup> Panel Report, para. 7.134 (referring to Panel Report, *EC – Asbestos*, para. 8.170; Appellate Body Reports, *EC – Seal Products*, para. 5.197). (emphasis original)

<sup>&</sup>lt;sup>212</sup> Panel Report, paras. 7.165 and 7.172.

<sup>&</sup>lt;sup>213</sup> Panel Report, paras. 7.165 and 7.170.

<sup>&</sup>lt;sup>214</sup> Panel Report, para. 7.180. See also ibid., para. 7.173.

<sup>&</sup>lt;sup>215</sup> Panel Report, paras. 7.173-7.177.

sectoral generality that was at odds with the concept of risk under Article XX(b). In the Panel's view, the generality of Türkiye's underlying argument would lead to the conclusion that there was a permanent risk of shortage of products concerning every sector of any WTO Member's economy. Following this logic, international trade liberalization in products and sectors that are necessary for the protection of human life or health created a permanent risk to human life or health under Article XX(b).<sup>216</sup>

6.83. In the Panel's view, the hypothetical and overly general nature of the alleged risk casts serious doubt on Türkiye's assertion that the localisation requirement was taken to protect against a future shortage of supply of safe, effective, and affordable pharmaceutical products in Türkiye.<sup>217</sup> The Panel considered further that most of the legal instruments putting into place the localisation requirement did not refer to a public health objective or, to the extent that some of them did, such references were cast at a general level and were not linked with the localisation requirement or the declared objective of preventing a shortage of supply of safe, effective, and affordable medicines arising from an over-reliance on imports.<sup>218</sup> The Panel found that those same documents, as well as other documents pertaining to the implementation of the localisation requirement, did not contain any contemporaneous references to a public health objective that could support the argument that the localisation requirement was a measure taken to protect human health or life. They suggested instead that the localisation requirement appeared to pursue an industrial policy objective.<sup>219</sup>

6.84. The Panel acknowledged Türkiye's ongoing aim to improve the performance of its domestic pharmaceutical industry by meeting a higher share of domestic demand for pharmaceutical products. In the Panel's view, however, the evidence did not seem to relate this objective to specific public health concerns such as improving the safety or affordability of available pharmaceutical products, or addressing a risk that domestic pharmaceutical demand may not be met by supply from the international market.<sup>220</sup> The Panel found that this cast further doubt on Türkiye's assertion that the localisation requirement was taken to protect against a future shortage of supply of safe, effective, and affordable pharmaceutical products in Türkiye.<sup>221</sup>

6.85. The Panel found further support for its view in the fact that the objective of the localisation requirement, as it appeared in several official documents, had no rational relationship to the invoked objective of ensuring a continuous supply of safe, effective, and affordable pharmaceutical products.<sup>222</sup> The Panel did not find evidence of such rational relationship between the stated objective of the localisation requirement (increasing domestic production from meeting 40% to covering 60% of domestic demand) and the declared objective of ensuring a continuous supply of safe, effective, and affordable pharmaceutical products.<sup>223</sup> In the Panel's view, a measure adopted in pursuit of developing a WTO Member's pharmaceutical sector could only be seen as having a public health objective if there was a rational relationship between the objective set by that WTO Member for developing its pharmaceutical sector and the specific public health objective invoked.<sup>224</sup> The lack of such rational relationship was, in the Panel's view, a further indication that the localisation requirement was not a measure taken to protect human life or health.<sup>225</sup>

#### 6.3.1.4 The Panel's conclusion

6.86. Having found that the localisation requirement was not a measure taken to protect human, animal, or plant life or health<sup>226</sup>, the Panel considered it did not need to assess the remaining legal elements of Article XX(b) of the GATT 1994 to determine the applicability of this exception.<sup>227</sup> Because the localisation requirement did not fall under Article XX(b) and therefore was not provisionally justified under this subparagraph, the Panel also found it unnecessary to assess whether the localisation requirement had been applied consistently with the requirements of the

- <sup>217</sup> Panel Report, para. 7.180.
- <sup>218</sup> Panel Report, paras. 7.184-7.191.
- <sup>219</sup> Panel Report, paras. 7.191-7.198.
- <sup>220</sup> Panel Report, para. 7.199.
- <sup>221</sup> Panel Report, para. 7.200.
- <sup>222</sup> Panel Report, para. 7.201.
- <sup>223</sup> Panel Report, paras. 7.201-7.208.
- <sup>224</sup> Panel Report, para. 7.203.
- <sup>225</sup> Panel Report, para. 7.208.
- <sup>226</sup> Panel Report, para. 7.211.
- <sup>227</sup> Panel Report, para. 7.212.

<sup>&</sup>lt;sup>216</sup> Panel Report, para. 7.178.

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*chapeau* of Article XX.<sup>228</sup> The Panel refrained from making additional findings or observations on any disputed issues in respect of the remaining elements under Article XX(b).<sup>229</sup>

#### 6.3.2 Whether the Panel erred in its interpretation of Article XX(b) of the GATT 1994

6.87. Article XX(b) of the GATT 1994 provides:

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any Member of measures:

...

(b) necessary to protect human, animal or plant life or health[.]

6.88. With respect to the Panel's interpretation of Article XX(b), the following issues have been brought before us:

- a. whether the Panel erred by confusing the "design" and "necessity" steps of the legal test under Article XX(b);
- b. whether the Panel erred by requiring that a measure address a health risk that has "a substantial degree of probability" of materializing for that measure to be "designed to" protect human, animal, or plant life or health; and
- c. whether the Panel erred by relying on the legal tests under Articles XX(a) and XX(j) of the GATT 1994 and Article XIV(a) of the GATS, as interpreted by previous panels.

6.89. We note at the outset that Article XX(b) allows Members to maintain measures that are otherwise inconsistent with obligations under the GATT 1994, to the extent that those measures are necessary to protect human, animal, or plant life or health, and are applied in a manner that is compatible with the requirements in the *chapeau* of Article XX. For an exception such as that contained in Article XX(b) to apply, the responding party bears the burden of invoking the provision and demonstrating that the measure in question meets the requirements of that provision.

6.90. Starting with the text of the provision, to be justified under Article XX(b), a measure must be necessary to protect human, animal, or plant life or health. In order to assess whether a measure is "necessary" to achieve that objective, a panel may first assess, as an initial question, whether the measure is even related to, or not incapable of, protecting human, animal, or plant life or health. Logically, unless a measure is "not incapable" of protecting human, animal, or plant life or health, then the measure cannot be justified under Article XX(b), and this would be the end of the inquiry.

6.91. In order to ascertain whether a measure is not incapable of protecting human, animal, or plant life or health, a panel should focus on examining the relationship between the challenged measure, considering its design (including its content, structure, and expected operation) and the proclaimed objective. The prior examination is used to assess whether the measure can be considered to have been "taken to", or "designed to", protect human, animal, or plant life or health. If the response to this question is affirmative, a panel may move to assess whether the measure can be considered to be "necessary" for the proclaimed objective, considering factors such as the extent of the contribution to the achievement of the objective, the measure's trade-restrictiveness, and the importance of the interests or values at stake, as well as comparing the measure with possible alternative measures identified by the complainant.

6.92. This two-step analysis of the design and the necessity of a measure has been used in previous disputes<sup>230</sup> and corresponds to the manner in which parties articulated their arguments both before

<sup>&</sup>lt;sup>228</sup> Panel Report, para. 7.213.

<sup>&</sup>lt;sup>229</sup> Panel Report, para. 7.214.

<sup>&</sup>lt;sup>230</sup> See e.g. Panel Report, *EC – Tariff Preferences*, paras. 7.198-7.199.

the Panel as well as in the Arbitration.<sup>231</sup> Having said that, panels have been cautioned in the past not to structure their analysis of the "design" element in such a way as to lead it to truncate such analysis prematurely and thereby foreclose consideration of crucial aspects of the respondent's defence relating to the "necessity" of the measure.<sup>232</sup>

# **6.3.2.1** Whether the Panel erred by confusing the "design" and "necessity" steps of the legal test under Article XX(b) of the GATT 1994

6.93. Regarding the question under Article XX(b) of the GATT 1994 of whether a challenged measure is "designed" to protect human, animal, or plant life or health, Türkiye submits that the Panel erred in its interpretation of the provision, because it adopted an erroneous legal standard to assess the "design requirement". Türkiye argues that past panels and the Appellate Body have shown a significant degree of deference in accepting that the policy objective of a measure is to protect human life or health. In light of this deferential legal standard applied in the assessment of a measure's design, panels must simply determine if the policy at issue falls within the range of policies designed to protect human life or health.<sup>233</sup>

6.94. In Türkiye's view, the Panel's interpretation mixes the threshold analysis of a measure's "design" under Article XX(b) with that of the measure's "necessity" and thereby limits WTO Members' regulatory autonomy to pursue public health policies under this provision.<sup>234</sup>

6.95. In response, the European Union argues that the Panel did not err in its interpretation of Article XX(b) in finding that the localisation requirement is not "designed to" protect human life or health.<sup>235</sup>

6.96. In paragraph 7.135 of its report, the Panel articulated a reasonable legal standard to assess whether the challenged measure was "taken for" the purpose of protecting human, animal, or plant life or health or was instead taken for other reasons:

To determine whether a challenged measure is "designed to" protect human, animal or plant life or health, a panel must examine all the evidence before it, including the text of the relevant legal instruments, the legislative history, and other evidence regarding the design, structure and expected operation of the challenged measure. ... If this threshold enquiry reveals that the challenged measure is incapable of meeting the stated objective, the analysis need not go further to determine whether this measure is necessary to protect this objective.<sup>236</sup>

6.97. The Panel also noted in its report:

When assessing whether a measure is taken to protect human, animal or plant life or health, prior panels have often commenced their analysis by determining the existence of the risk to human, animal or plant life or health (health risk) that the challenged measure aims to reduce. Where there is no sufficient evidence as to the existence of a health risk, a challenged measure is not necessary to *protect* human, animal or plant life or health.<sup>237</sup>

6.98. In its assessment of whether the localisation requirement is a measure "taken to" protect human, animal, or plant life or health, the Panel made the following intermediate findings:

and 8.185-8.194; Brazil - Retreaded Tyres, paras. 7.42 and 7.53-7.93; China - Rare Earths,

paras. 7.149-7.156; *Brazil – Taxation*, para. 7.859; *Indonesia – Chicken*, para. 7.209; *US – Gasoline*, para. 6.21; *EC – Tariff Preferences*, paras. 7.180 and 7.200; Appellate Body Reports, *EC – Seal Products*, para. 5.197). (fns omitted)

<sup>&</sup>lt;sup>231</sup> Türkiye's first written submission to the Panel, paras. 419-420 and 441-463; second written submission to the Panel, paras. 162-174; written submission, paras. 165-195; European Union's second written submission to the Panel, paras. 143-157; written submission, para. 120.

<sup>&</sup>lt;sup>232</sup> See e.g. Appellate Body Report, *Colombia – Textiles*, para. 5.77.

<sup>&</sup>lt;sup>233</sup> Türkiye's written submission, paras. 135-138 and 168.

 $<sup>^{\</sup>rm 234}$  Türkiye's written submission, paras. 127 and 141-146.

<sup>&</sup>lt;sup>235</sup> European Union's written submission, paras. 4, 112, and 116.

<sup>&</sup>lt;sup>236</sup> Panel Report, para. 7.135. (fns omitted)

<sup>&</sup>lt;sup>237</sup> Panel Report, para. 7.134 (referring to Panel Reports, EC – Asbestos, paras. 8.170, 8.182,

- a. First, Türkiye, as the party invoking the general exception in Article XX(b), had failed to substantiate its assertion that its alleged over-reliance on imported pharmaceutical products created a risk of long-term shortage of supply of safe, effective, and affordable medicines. In the absence of evidence, the Panel found that the risk identified by Türkiye, more specifically the factors that gave rise to a risk of future shortages in respect of any and all pharmaceutical products, could only be characterized as theoretical, abstract, and hypothetical.<sup>238</sup>
- b. Second, considering the evidence before it, including the legal instruments serving as a basis for the localisation requirement and the documents pertaining to its implementation, there were no contemporaneous references to a specific public health objective that could directly support the argument that the localisation requirement was a measure taken to protect human health or life. In the Panel's view, no evidence related the implementation of the localisation requirement to specific public health concerns, such as improving the safety or affordability of available pharmaceutical products or addressing a risk that domestic pharmaceutical demand might not be met by supply from the international market. The relevant documents indicated instead that the localisation requirement appeared to pursue an industrial policy objective.<sup>239</sup>
- c. Third, there was no evidence of a rational relationship between the localisation requirement's stated objective of increasing domestic production from meeting 40% to covering 60% of domestic demand, and the declared objective of ensuring a continuous supply of safe, effective, and affordable pharmaceutical products.<sup>240</sup>

6.99. Based on those three intermediate findings, the Panel found that the localisation requirement was not a measure "taken to" protect human, animal, or plant life or health within the meaning of Article XX(b).<sup>241</sup> Accordingly, it found that it did not need to assess further whether the same measure was "necessary" to protect human, animal, or plant life or health within the meaning of Article XX(b) or whether it was being applied consistently with requirements of the *chapeau* of Article XX.<sup>242</sup>

6.100. Having described the Panel's approach, we turn our attention to considering whether, as argued by Türkiye, the Panel adopted an erroneous legal standard to assess the "design" element in Article XX(b).

6.101. We recall in this regard, first, that in its report the Panel articulated a reasonable standard to assess whether the challenged measure was "taken for" the purpose of protecting human, animal, or plant life or health.<sup>243</sup> Second, the Panel made three intermediate findings, all of which were relevant for its analysis, namely, that: (i) the risk identified by Türkiye could only be characterized as theoretical, abstract, and hypothetical; (ii) the implementation of the localisation requirement appeared to pursue an industrial policy objective rather than specific public health concerns; and (iii) there was no evidence of a rational relationship between the localisation requirement and the stated objective of ensuring a continuous supply of safe, effective, and affordable pharmaceutical products. Although the Panel did not explicitly indicate it in these terms, these findings could allow the Panel to reasonably conclude that the relevant legal standard for the design requirement under Article XX(b) had not been met, namely, that there was no evidence of the existence of the health risk that the localisation requirement was allegedly seeking to reduce and that the localisation requirement was incapable of meeting the alleged public health objective.

6.102. While it may be true, as Türkiye argues, that the Panel considered aspects relating to the manner in which the localisation requirement could contribute to its proclaimed objective, it seems to us that this was done in the context of examining the expected operation of the challenged

<sup>&</sup>lt;sup>238</sup> Panel Report, paras. 7.165-7.180.

<sup>&</sup>lt;sup>239</sup> Panel Report, paras. 7.181-7.200.

<sup>&</sup>lt;sup>240</sup> Panel Report, paras. 7.201-7.208.

<sup>&</sup>lt;sup>241</sup> Panel Report, para. 7.211.

<sup>&</sup>lt;sup>242</sup> Panel Report, paras. 7.212-7.214.

<sup>&</sup>lt;sup>243</sup> See para. 6.96. above. It should be noted that Türkiye has challenged in this Arbitration neither the two-step analysis of the design and the necessity of a measure nor the standard articulated by the Panel in paragraphs 7.134 and 7.135 of its report.

measure, which is relevant in the "design" analysis.<sup>244</sup> We note in this respect that the "design" and the "necessity" analyses are not entirely disconnected exercises and that there can be some overlap in the evidence and the considerations that are relevant for each step.<sup>245</sup>

6.103. For the reasons indicated above, we do not consider that the Panel committed legal error by confusing the "design" and the "necessity" steps of the legal analysis under Article XX(b) of the GATT 1994.<sup>246</sup>

# **6.3.2.2** Whether the Panel erred by requiring that a measure address a health risk that has "a substantial degree of probability" of materializing for that measure to be "designed to" protect human, animal, or plant life or health

6.104. According to Türkiye, "the Panel ... set out a legal standard requiring a 'substantial degree of probability' of risk and thereby erroneously introduced a quantitative dimension in the notion of risk under Article XX(b) of the GATT 1994."<sup>247</sup> In Türkiye's view, the Panel erroneously concluded that in cases where a responding party cannot demonstrate that there is a "substantial degree of probability" that the asserted risk to human life or health will materialize, the evidentiary threshold to be met for establishing that the challenged measure is taken to protect human life or health becomes more burdensome. Türkiye argues that this interpretation regarding the measure's "design" introduces a quantitative dimension to the notion of risk to human life or health that unduly limits the range of public health measures that fall within the scope of Article XX(b).<sup>248</sup>

6.105. With respect to the interpretation of Article XX(b), the European Union submits that the Panel did not say that, in order to prove that a measure was taken to prevent a certain risk, a responding party was required to demonstrate a substantial degree of probability of the asserted risk. Rather, the Panel stated that such demonstration would make it easier for the responding party to discharge its burden of proof; the responding party could, however, meet its burden of proof differently. In the European Union's view, the term "substantial degree of probability of risk" does not require the responding party to provide a quantitative assessment of the risk.<sup>249</sup>

6.106. The European Union also argues that, with respect to the application of this evidentiary standard, the Panel did not find that Türkiye had failed to discharge its burden of proof on the existence of the asserted risk because it had not provided a quantification of the alleged risk. Instead the Panel considered that Türkiye had asserted the existence of a risk without establishing any substantial degree of probability, such that the risk appeared to be theoretical, abstract, and hypothetical. This "hypothetical and overly general nature" was one of the factors relied upon by the Panel to conclude that Türkiye had not discharged its burden to prove that the measure was taken to protect human life or health.<sup>250</sup>

6.107. In the relevant sections of its report, the Panel noted Türkiye's assertion that "its over-reliance on imported pharmaceutical products create[d] a risk of long-term shortage of supply of safe, effective and affordable pharmaceutical products". Türkiye's argument in this regard was that "the localisation requirement, by localising the production of pharmaceutical products, [was] a measure designed to address this risk." The Panel indicated that, as the party invoking a general exception under Article XX(b), Türkiye had the burden of identifying "some degree of probability

<sup>249</sup> European Union's written submission, paras. 114-127.

<sup>&</sup>lt;sup>244</sup> As noted above, in order to ascertain whether a measure is not incapable of protecting human life or health, a panel should focus on examining the relationship between the challenged measure, considering its design (including its content, structure, and expected operation) and the proclaimed objective. See para. 6.91. above.

<sup>&</sup>lt;sup>245</sup> See e.g. Appellate Body Report, *Colombia – Textiles*, para. 5.76.

<sup>&</sup>lt;sup>246</sup> We are mindful that, in conducting its assessment of the design of a measure, a panel should not truncate its analysis prematurely and thereby foreclose consideration of crucial aspects of a respondent's defence relating to the "necessity" analysis. However, we do not consider that the Panel made such an error.

<sup>&</sup>lt;sup>247</sup> Türkiye's written submission, para. 137. (fn omitted)

 $<sup>^{248}</sup>$  Türkiye's written submission, paras. 127 and 130-140.

<sup>&</sup>lt;sup>250</sup> The other two factors considered by the Panel were that: (i) the documents pertaining to the implementation of the localisation requirement did not contain any contemporaneous references to the specific risk and objective invoked by Türkiye; and (ii) there was no rational relationship between the localisation requirement's stated objective of meeting 60% (by value) of domestic pharmaceutical demand through domestic production and the objective of ensuring a continuous supply of safe, effective, and affordable pharmaceutical products. (European Union's written submission, para. 129 (quoting Panel Report, para. 7.210))

that the alleged risk [existed]". More specifically, Türkiye had the burden of demonstrating "the existence of a risk of shortage of supply arising from its over-reliance on imported pharmaceutical products".<sup>251</sup>

6.108. The Panel further noted that there was no "rigid or pre-determined threshold or evidentiary standard that should be applied in this respect" and "[i]nsofar as a responding party present[ed] evidence and arguments demonstrating that there [was] a substantial degree of probability of a specified risk to human life or health materializing, it [would] be easier for [that] party to discharge its burden of proving that the challenged measure was taken to protect against that risk". It continued: "Conversely, insofar as a responding party assert[ed] the existence of a risk without establishing any substantial degree of probability, such that the risk appear[ed] to be theoretical, abstract or otherwise hypothetical, it [would] be more difficult for [that] party to discharge its burden of proving that the challenged measure was taken to protect against that risk."<sup>252</sup>

6.109. After having considered Türkiye's arguments and the available evidence, the Panel concluded that Türkiye had asserted "the existence of a risk without establishing any substantial degree of probability, such that the risk appear[ed] to be theoretical, abstract and hypothetical. In the Panel's view, the hypothetical and overly general nature of the alleged risk, as asserted by Turkey, cast[] serious doubt on Turkey's assertion that the localisation requirement was taken to protect against a future shortage of supply of safe, effective and affordable pharmaceutical products in Turkey".<sup>253</sup>

6.110. Looking at the statements of the Panel identified by Türkiye<sup>254</sup>, we do not consider that the Panel set out a legal standard requiring a substantial degree of probability of risk for assessing whether a measure has been taken to protect human, animal, or plant life or health, in accordance with Article XX(b). The reference to a "substantial degree of probability" of the existence of the risk alleged by the responding party was made by the Panel, not as a proposed legal standard, but rather as an indicator of the existence of a risk that is not merely theoretical, abstract, or hypothetical. The Panel did not foreclose the possibility" of the existence of the alleged risk, to show that a challenged measure was taken to protect human life or health under Article XX(b). The Panel only stated that, lacking such evidence, the task for the responding party to discharge its burden of proof that the challenged measure was taken to protect against that risk would be "more difficult".<sup>255</sup> We do not consider that this statement should be construed as setting out an incorrect legal standard and thereby constitutes an error of interpretation.

6.111. In the same vein, given that the Panel did not require a substantial degree of probability of risk as a legal standard for the "design" analysis, we are also unconvinced that the statements of the Panel identified by Türkiye and referred to above introduce any quantitative dimension to the notion of risk to human life or health that unduly limited the range of public health measures that fall within the scope of Article XX(b).

# **6.3.2.3** Whether the Panel erred by relying on previous panel reports dealing with other provisions

6.112. Türkiye claims that, despite the textual differences with Article XX(b) of the GATT 1994, the Panel erroneously relied on previous panel reports dealing with Articles XX(j) and XX(a) of the GATT 1994 and Article XIV(a) of the GATS to support its incorrect legal standard.<sup>256</sup>

6.113. Türkiye also argues that the Panel's reading of the report in *Brazil – Taxation* was incorrect and did not support the Panel's erroneous interpretation of Article XX(b). Türkiye notes that, in the relevant sections of this report (dealing with Article XX(a) of the GATT 1994), the panel had found that, notwithstanding its deep reservations regarding the design of the challenged measure, it was

<sup>&</sup>lt;sup>251</sup> Panel Report, para. 7.170. (fn omitted)

<sup>&</sup>lt;sup>252</sup> Panel Report, para. 7.171.

<sup>&</sup>lt;sup>253</sup> Panel Report, para. 7.180.

<sup>&</sup>lt;sup>254</sup> Türkiye's written submission, para. 137 (referring to Panel Report, paras. 7.165-7.171).

<sup>&</sup>lt;sup>255</sup> Panel Report, para. 7.171.

<sup>&</sup>lt;sup>256</sup> Türkiye's written submission, paras. 127 and 147-161.

not in a position to find that this measure was incapable of contributing to the proclaimed objective.  $^{\rm 257}$ 

6.114. The European Union responds that there are commonalities between Article XX(b) and the provisions addressed in the reports cited by the Panel in the context of the discussion of the assessment of the existence of a risk as part of the "design" analysis, so that the contextual relevance of those references cannot be excluded *per se*. The European Union adds that, even if the Panel's reference to those panel reports was incorrect, such error would be inconsequential because the Panel's interpretation of the relevant evidentiary standard under Article XX(b) was not dependent on a reference to those panel reports.<sup>258</sup> The European Union adds that the Panel also referred to panel reports relating to disputes concerning the interpretation of Article XX(b).<sup>259</sup>

6.115. The European Union also argues that the Panel's reference to the panel report in *Brazil – Taxation* is not incorrect as it is cited as an example of the type of enquiry to be conducted by panels for the purpose of evaluating the existence of a risk, when such evaluation is required by the applicable legal standard.<sup>260</sup>

6.116. We will consider first Türkiye's argument that the Panel set up an incorrect standard by improperly relying on prior panel and Appellate Body reports that dealt with provisions other than Article XX(b). We will subsequently turn, if necessary, to the additional argument that the Panel misinterpreted the findings in the panel report in *Brazil – Taxation*.

6.117. In the paragraphs identified by Türkiye<sup>261</sup>, the Panel referred to the findings in *India – Solar Cells* (under Articles XX(j) and XX(d) of the GATT 1994), *EU – Energy Package* (under Articles XIV(a) of the GATS and XX(j) of the GATT 1994), and *Brazil – Taxation* (under Article XX(a) of the GATT 1994). The Panel's citations to those reports were made in the context of the Panel's assertion that "[t]his is not the first case in which a responding party has argued that a challenged measure was taken to prevent a risk of supply-side disruptions that could arise from its alleged over-reliance on imports of essential goods and/or services, to ensure a continuous and affordable supply of those goods or services."<sup>262</sup>

6.118. The Panel noted that "[i]n prior cases, panels and the Appellate Body [had] consistently required the responding party to demonstrate, at a minimum, that the asserted risk arising from over-reliance on imports was more than a merely hypothetical possibility."<sup>263</sup> The Panel added, that "in the context of Article XX(b), as in the context of the other subparagraphs of Article XX, a party invoking a general exception must identify some degree of probability that the alleged risk exist[ed]."<sup>264</sup>

6.119. Looking at the references to previous panel reports that Türkiye has identified, we do not believe that these general observations made by the Panel are unreasonable or an incorrect description of the cited reports. We also recall that we have already found that the Panel articulated a proper legal standard to assess whether the challenged measure was "taken for" the purpose of protecting human, animal, or plant life or health.<sup>265</sup> We find no indication that the Panel's references to the cited panel reports, based on provisions other than Article XX(b), were determinative in the articulation of that standard.

6.120. Türkiye additionally argues that the Panel misread the report in *Brazil – Taxation* and, as a consequence, erroneously interpreted Article XX(b).<sup>266</sup>

 $^{\rm 259}$  European Union's written submission, paras. 151-152.

<sup>&</sup>lt;sup>257</sup> Türkiye's written submission, paras. 162-164 (referring to Panel Report, *Brazil – Taxation*, paras. 7.569, 7.571, 7.573-574, and 7.581-7.582).

<sup>&</sup>lt;sup>258</sup> European Union's written submission, para. 154.

<sup>&</sup>lt;sup>260</sup> European Union's written submission, para. 153.

<sup>&</sup>lt;sup>261</sup> Türkiye's written submission, paras. 147-148 (referring to Panel Report, paras. 7.167-7.171 and fn 609 to para. 7.170).

<sup>&</sup>lt;sup>262</sup> Panel Report, para. 7.166.

<sup>&</sup>lt;sup>263</sup> Panel Report, para. 7.166.

<sup>&</sup>lt;sup>264</sup> Panel Report, para. 7.170.

<sup>&</sup>lt;sup>265</sup> See para. 6.96. above.

<sup>&</sup>lt;sup>266</sup> Türkiye's written submission, paras. 162-164.

6.121. We note in this regard that the Panel Report's reference to *Brazil – Taxation* was made in the context of the discussion on whether the localisation requirement is a measure "designed to" protect human life or health. The Panel noted that in *Brazil – Taxation* the responding party had been found to have provided no evidence to substantiate its assertion regarding the alleged risk.<sup>267</sup>

6.122. The Panel's reference to that case as to how the responding party had been unable to demonstrate the existence of an alleged risk is not incorrect. Moreover, we have already noted that there is no indication that the Panel's references to panel reports cited by Türkiye, including the one in *Brazil – Taxation*, were determinative in the articulation by the Panel of the applicable standard to assess whether the challenged measure was "taken for" the purpose of protecting human, animal, or plant life or health.

6.123. For the reasons indicated, we do not consider that the Panel erred by relying on previous panel reports dealing with provisions other than Article XX(b).

# 6.3.3 Whether the Panel erred in its application of Article XX(b) of the GATT 1994

6.124. Türkiye submits that, "as a result of its erroneous interpretation of Article XX(b) of the GATT 1994, the Panel also failed to properly apply Article XX(b) to the localisation [requirement]" in finding that this measure was not designed to protect human life or health.<sup>268</sup> Türkiye also argues that the Panel erred "in the assessment of the risk to human life or health underlying the localisation [requirement]", by narrowing the health risk asserted by Türkiye and focusing on a narrower risk.<sup>269</sup>

6.125. In response, the European Union argues that Türkiye's contention that the Panel erred in the application of Article XX(b) is entirely predicated and dependent upon Türkiye's prior claim that the Panel made an erroneous interpretation of that provision. In the European Union's view, since the Panel did not make any of the errors of interpretation of Article XX(b) alleged by Türkiye, Türkiye's assertion that the Panel misapplied Article XX(b) should also be dismissed.<sup>270</sup> In the alternative, the European Union argues that Türkiye's claim regarding the application of Article XX(b) implicates the Panel's appreciation of facts and evidence and, absent a specific challenge on this issue under Article 11 of the DSU, falls outside the scope of our review.<sup>271</sup> The European Union adds, in the further alternative, that the Panel did not make the assessment errors alleged by Türkiye.<sup>272</sup>

6.126. We start by noting that, at the hearing, Türkiye asserted that its claim regarding the Panel's alleged errors in the application of Article XX(b) was independent from its claims regarding the Panel's interpretation of the provision. In Türkiye's words, "this claim is not entirely dependent on its claim of erroneous interpretation".<sup>273</sup>

6.127. Despite this assertion, the manner in which Türkiye has articulated its claim regarding the Panel's alleged erroneous application of Article XX(b) seems to be consequential to its claims regarding the Panel's interpretation of the same provision. Türkiye in essence repeats the arguments made with respect to the Panel's alleged errors of interpretation and argues that, had the Panel adopted and applied the correct legal standard requiring a determination of whether the localisation requirement is not incapable of protecting human life or health, it would have concluded that the localisation requirement was "designed to" protect human life or health.<sup>274</sup>

<sup>&</sup>lt;sup>267</sup> Panel Report, para. 7.168 (referring to Panel Report, *Brazil – Taxation*, paras. 7.573 and 7.582).

<sup>&</sup>lt;sup>268</sup> Türkiye's written submission, para. 128. See also ibid., paras. 165 and 195.

<sup>&</sup>lt;sup>269</sup> Türkiye's written submission, paras. 172-194.

<sup>&</sup>lt;sup>270</sup> European Union's written submission, paras. 156-158.

<sup>&</sup>lt;sup>271</sup> European Union's written submission, paras. 159-162.

<sup>&</sup>lt;sup>272</sup> European Union's written submission, paras. 163-176.

<sup>&</sup>lt;sup>273</sup> Türkiye's opening statement at the hearing, para. 32.

<sup>&</sup>lt;sup>274</sup> Türkiye's written submission, paras. 193-195. In support of this argument, Türkiye states that: (i) the assessment of the "design requirement" is a threshold examination and not a particularly demanding step and that panels and the Appellate Body have in the past shown a significant degree of deference in accepting that the policy objective of a measure is to protect human life or health; (ii) the Panel should have concluded that the localisation requirement falls within the range of policies designed to protect human life or health within the meaning of Article XX(b); (iii) the Panel erred in assessing the risk to human life or health; and (iv) the Panel should have concluded that the localisation requirement was *not incapable of* ensuring uninterrupted access to safe, effective, and affordable pharmaceutical products in Türkiye. (Ibid., paras. 166-183 and 187-192)

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6.128. The one notable exception to the above is Türkiye's allegation that "the Panel erred in the application of Article XX(b) because it re-defined the risk addressed by the localisation [requirement]".<sup>275</sup> Türkiye argues in this respect that the Panel failed to properly consider the arguments and evidence submitted by Türkiye with respect to the public health objective underlying the localisation requirement.<sup>276</sup> Türkiye specifically submits that, despite its "express and repeated statements, the Panel significantly narrowed the health risk asserted by Turkey and proceeded to assess whether the evidence presented by Turkey showed that the localisation [requirement] was taken to address that narrower risk".<sup>277</sup>

6.129. Türkiye's allegation that the Panel failed to consider its arguments and evidence with respect to the public health objective underlying the localisation requirement is not a mere claim that the Panel failed to properly apply the provision to the localisation requirement. It is instead a claim that goes to the Panel's appreciation of facts and evidence. This is an allegation that can be properly examined only in the context of a claim under Article 11 of the DSU, a provision that has not been invoked by Türkiye in this regard.<sup>278</sup>

6.130. For these reasons, to the extent that we have found no reversible error in the Panel's interpretation of Article XX(b), and considering the nature of Türkiye's application claims, we consider that Türkiye has failed to establish that the Panel erred in its application of Article XX(b).

# 6.3.4 Article 11 of the DSU

6.131. As an additional grounds of challenge, Türkiye submits that the Panel failed to make an objective assessment of the matter as required by Article 11 of the DSU.<sup>279</sup> Türkiye raises two arguments in this regard. First, Türkiye argues that the Panel looked only at the documents implementing the localisation requirement, but wilfully disregarded some arguments and relevant evidence put forward by Türkiye with respect to the measure's design and structure and with respect to the authorities responsible for its design and implementation. Second, Türkiye argues that the Panel looked individually at documents pertaining to the implementation of the localisation requirement but failed to make a "holistic assessment" of those documents when determining whether the measure was taken to protect human life or health.<sup>280</sup>

6.132. The European Union submits that the Panel did not make any of the errors alleged by Türkiye and, in any event, those errors, whether considered singly or together, would not amount to a breach of Article 11 of the DSU. The European Union recalls that panels enjoy a margin of discretion as triers of fact and are not required to accord to factual evidence of the parties the same meaning and weight as do the parties.<sup>281</sup> Moreover, the mere fact that the Panel did not address explicitly each and every component of the challenged measure does not amount to an error, let alone an egregious error.<sup>282</sup>

6.133. In relevant part, Article 11 of the DSU reads as follows:

# Article 11 Function of Panels

The function of panels is to assist the DSB in discharging its responsibilities under this Understanding and the covered agreements. Accordingly, a panel should make an objective assessment of the matter before it, including an objective assessment of the facts of the case and the applicability of and conformity with the relevant covered

<sup>&</sup>lt;sup>275</sup> Türkiye's opening statement at the hearing, paras. 32-33.

<sup>&</sup>lt;sup>276</sup> Türkiye's written submission, paras. 172-194.

<sup>&</sup>lt;sup>277</sup> Türkiye's written submission, para. 178.

<sup>&</sup>lt;sup>278</sup> We note that Türkiye invoked Article 11 of the DSU with respect to other aspects of the Panel's assessment. See Section 6.3.4 below.

<sup>&</sup>lt;sup>279</sup> Türkiye's written submission, paras. 6 and 116.

<sup>&</sup>lt;sup>280</sup> Türkiye's written submission, paras. 129, 196-202, 205, and 209.

<sup>&</sup>lt;sup>281</sup> European Union's written submission, paras. 177-179.

<sup>&</sup>lt;sup>282</sup> European Union's written submission, paras. 180-185.

agreements, and make such other findings as will assist the DSB in making the recommendations or in giving the rulings provided for in the covered agreements.

6.134. As has been indicated in the past, panels are required under Article 11 of the DSU to consider all evidence before them, assess its credibility, determine its weight, and ensure that their findings have a proper basis in that evidence.<sup>283</sup> It is generally within the discretion of panels, however, to decide which evidence to utilize in making findings, and, as long as they make an objective assessment of the matter before them, panels are not required to accord to factual evidence the same meaning and weight as do the parties.<sup>284</sup> In previous cases, the Appellate Body has highlighted the gravity of an allegation that a panel has failed to make an "objective assessment of the matter before it" and stated that it is incumbent on a party raising a claim under Article 11 of the DSU to identify specific errors regarding the objectivity of the panel's assessment and "to explain *why* the alleged error *meets* the standard of review under that provision".<sup>285</sup>

6.135. We will look first at Türkiye's argument that the Panel failed to examine all of the evidence relating to the design and structure of the localisation requirement and to the authorities responsible for its design and implementation.

6.136. With respect to the arguments and evidence related to the design and structure of the localisation requirement, we look at Türkiye's argument that the Panel failed to take into account the measure's implementation in five phases, which according to Türkiye pursued "[t]he aim of [encouraging] local production within a predictable period of time, rather than removing the imported products from reimbursement".<sup>286</sup>

6.137. The Panel noted in its report that, by design, the localisation requirement had five phases "which progressively target different products depending on their market share and the existence of equivalent products in the domestic market".<sup>287</sup> The Panel described the design of the measure and each of these phases, noting at the same time that, according to Türkiye, "only Phase 1 and Phase 2 [had] been implemented so far"<sup>288</sup> and that "the implementation of Phases 1 and 2 [had] already resulted in the identification of products that [would] no longer be reimbursed by the SSI."<sup>289</sup> There is extensive discussion in the Panel Report with respect to the localisation requirement and its implementation in phases, as well as to the respective arguments of the parties in this regard.

6.138. With respect to the authorities responsible for the localisation requirement's design and implementation, Türkiye argues that the Panel disregarded relevant evidence. According to Türkiye, "the public health objective of the localisation [requirement] is further evinced by the fact that it has been designed and implemented by the authorities responsible for public health policies."<sup>290</sup> The Panel Report notes the main legal instruments, as identified by the parties, that were the basis for the localisation requirement, namely: (i) the Tenth Development Plan 2014-2018; (ii) the Structural Transformation Program for Healthcare Industries Action Plan; and (iii) the 2016 Action Plan of the 64th Government.<sup>291</sup> The Panel also described the authorities responsible for implementing the localisation requirement, including the role of the TMMDA, the SSI, and the Ministry of Health.

<sup>&</sup>lt;sup>283</sup> Appellate Body Reports, *India – Solar Cells*, para. 5.87; *Philippines – Distilled Spirits*, para. 135; *Brazil – Retreaded Tyres*, para. 185; *EC – Hormones*, paras. 132-133.

<sup>&</sup>lt;sup>284</sup> Appellate Body Reports, *India – Solar Cells*, para. 5.87; *Australia – Salmon*, para. 267; *EC and certain member States – Large Civil Aircraft*, para. 1317.

<sup>&</sup>lt;sup>285</sup> Appellate Body Report, *Indonesia – Import Licensing Regimes*, para. 5.28 (quoting Appellate Body Reports, *China – Rare Earths*, para. 5.178; *EC – Fasteners (China)*, para. 442). (emphasis original) See also Appellate Body Reports, *EU – Biodiesel (Argentina)*, para. 6.200; *US – Tuna II (Mexico) (Article 21.5 – Mexico)*, para. 7.191; *China – HP-SSST (Japan) / China – HP-SSST (EU)*, para. 5.244; *Peru – Agricultural Products*, para. 5.179.

<sup>&</sup>lt;sup>286</sup> Türkiye's written submission, para. 203 (quoting Türkiye's first written submission to the Panel, paras. 452-453, in turn quoting Public Announcement concerning the Localisation Process of 4 March 2016 by the TMMDA, the SSI and the Ministry of Health (Panel Exhibit EU-49)).

<sup>&</sup>lt;sup>287</sup> Panel Report, para. 2.23. (fn omitted)

<sup>&</sup>lt;sup>288</sup> Panel Report, fn 89 to para. 2.24 (quoting Türkiye's first written submission to the Panel, para. 140).

<sup>&</sup>lt;sup>289</sup> Panel Report, fn 89 to para. 2.24. See also ibid., para. 7.22.

<sup>&</sup>lt;sup>290</sup> Türkiye's written submission, para. 204.

<sup>&</sup>lt;sup>291</sup> Panel Report, para. 7.185 (referring to Tenth Development Plan 2014-2018 (Panel Exhibit EU-12); Ministry of Hoalth and Ministry of Development. Structural Transformation Program for Hoalthcare Inductries

Ministry of Health and Ministry of Development, Structural Transformation Program for Healthcare Industries

6.139. Accordingly, there is no indication that the Panel disregarded arguments and relevant evidence put forward by Türkiye with respect to either the design and structure of the localisation requirement or the authorities responsible for its design and implementation.

6.140. We now turn to Türkiye's argument that, with respect to the documents pertaining to the implementation of the localisation requirement, the Panel focused on each document individually, instead of analysing the way these documents interacted with each other.<sup>292</sup> In this respect, Türkiye is not arguing that the Panel failed to examine documents pertaining to the implementation of the localisation requirement. Instead, Türkiye suggests that, by considering each of these documents individually, the Panel failed to ascertain the public health objective of the measure.

6.141. In essence, Türkiye's claim that the Panel failed to make an "objective assessment of the matter before it" is based on Türkiye's disagreement with the Panel's interpretation and application of Article XX(b) and with the Panel's assessment of the facts of the case. In this respect, the Panel derived different conclusions from the localisation requirement's design and structure and from the authorities responsible for its design and implementation than those proposed by Türkiye. Neither this fact nor the fact that the Panel considered documents pertaining to the implementation of the localisation requirement individually implies by itself that the Panel failed to make an objective assessment of the matter as required by Article 11 of the DSU. As noted above, it is generally within the discretion of a panel to decide which evidence to utilize in making its findings, and, as long as the panel makes an objective assessment of the matter before it, the panel is not required to accord to factual evidence the same meaning and weight as do the parties. Türkiye also fails to explain why and how a "holistic assessment" of the same documents would have resulted in a different result for the Panel's analysis.<sup>293</sup>

6.142. For the above reasons, we do not consider that the panel exceeded its authority as the trier of facts and thereby failed to make an objective assessment of the matter before it, as required by Article 11 of the DSU.

### 6.3.5 Conclusion

6.143. In light of the considerations above, we find that Türkiye has not established that the Panel erred in the interpretation or application of Article XX(b) of the GATT 1994 in finding that Türkiye had not demonstrated that the localisation requirement was a measure taken to protect human, animal, or plant life or health and was therefore justified under Article XX(b).

6.144. Having found that the localisation requirement was not a measure taken to protect human, animal, or plant life or health, the Panel did not need to assess the remaining legal elements of Article XX(b) to determine the applicability of this exception, namely, whether the measure was "necessary" to achieve that objective. Moreover, because the localisation requirement did not fall under Article XX(b) and therefore was not provisionally justified under this subparagraph, it was also unnecessary for the Panel to assess whether the localisation requirement was being applied consistently with the requirements of the *chapeau* of Article XX.

6.145. The Panel also did not fail to make an objective assessment of the matter before it. We therefore reject Türkiye's claim under Article 11 of the DSU.

Action Plan, November 2014 (Structural Transformation Program for Healthcare Industries Action Plan) (Panel Exhibits EU-14, TUR-37); Republic of Turkey, Office of the Prime Minister, 2016 Action Plan of the 64<sup>th</sup> Government (Implementation and Reforms), 10 December 2015 (2016 Action Plan of the 64<sup>th</sup> Government) (Panel Exhibit EU-15)). The Tenth Development Plan 2014-2018 was approved by Türkiye's Grand National Assembly, the Structural Transformation Program for Healthcare Industries Action Plan was coordinated by Türkiye's Ministry of Health and Ministry of Development, and the 2016 Action Plan of the 64<sup>th</sup> Government was approved by the Office of the Prime Minister. (Panel Report, fns 75 to para. 2.20, and 637 and 638 to para. 7.185. See also European Union's written submission, para. 187)

<sup>&</sup>lt;sup>292</sup> Türkiye's written submission, paras. 203-204 and 206-208.

<sup>&</sup>lt;sup>293</sup> Türkiye states that "[t]hese errors were material and affected the Panel's finding that the localisation [requirement] is not 'designed to' protect human life or health" but did not further elaborate on this assertion. (Türkiye's written submission, para. 6. See also ibid., paras. 206-208)

6.146. Consequently, we uphold the Panel's finding, in paragraphs 7.219 and 8.1.b.iv of the Panel Report, that Türkiye has not established that the localisation requirement is justified under Article XX(b) of the GATT 1994.

6.147. Having upheld the Panel's finding that the localisation requirement is not justified under Article XX(b), we proceed to address Türkiye's alternative claim pertaining to Article XX(d) of the GATT 1994.

# 6.4 Article XX(d) of the GATT 1994

6.148. In the event that we do not find that Türkiye has established that "the localisation [requirement] falls within the scope of Article III:8(a) of the GATT 1994 and/or is not inconsistent with Article III:4 of the GATT 1994", and if we also do not reverse the Panel's findings under Article XX(b) of the GATT 1994 and do not find that the measure is justified under Article XX(b), Türkiye submits that the Panel erred in finding that the localisation requirement is not justified under Article XX(d) of the GATT 1994.<sup>294</sup>

6.149. We begin by briefly summarizing the Panel's findings, before turning to consider relevant issues raised in this Arbitration.

#### 6.4.1 Panel findings

6.150. With respect to Türkiye's invocation of the general exception in Article XX(d) of the GATT 1994, the Panel found that Türkiye had failed to demonstrate that the localisation requirement was taken to (designed to) secure compliance with laws requiring Türkiye to ensure "accessible, effective and financially sustainable healthcare" for its population.<sup>295</sup>

6.151. In the Panel's view, Türkiye's argument under Article XX(d) was substantially the same as its argument under Article XX(b). The essence of Türkiye's arguments was that the localisation requirement was justified under Article XX(b) because it was necessary to ensure uninterrupted access to safe, effective, and affordable medicines in Türkiye, and under Article XX(d) because it was necessary to secure compliance with laws requiring Türkiye to ensure accessible, effective, and financially sustainable healthcare. The Panel found that, given the overlap, its assessment under Article XX(b) extended *mutatis mutandis* to the analysis of the defence under Article XX(d).<sup>296</sup>

# 6.4.2 Whether the Panel applied the wrong legal standard in rejecting Türkiye's defence under Article XX(d) of the GATT 1994

6.152. Türkiye submits that the Panel's finding that the localisation requirement is not justified under Article XX(d) of the GATT 1994 is vitiated by legal error because it is based on an incorrect legal standard.<sup>297</sup> By relying exclusively on its legal analysis under Article XX(b) when examining Türkiye's defence under Article XX(d), the Panel disregarded the important differences between these two subparagraphs and failed to address key elements of the legal test under Article XX(d).<sup>298</sup> Türkiye requests us to carry out the legal analysis under Article XX(d) and conclude that the localisation requirement is justified under that provision.<sup>299</sup>

6.153. The European Union disagrees with Türkiye's arguments and submits that the Panel did not err by relying on an incorrect legal standard under Article XX(d). In the European Union's view, the Panel correctly limited its analysis to whether the localisation requirement was designed to secure compliance with laws and regulations requiring Türkiye to ensure accessible, effective, and financially sustainable healthcare. The Panel correctly considered that it followed from its assessment of the

<sup>&</sup>lt;sup>294</sup> Türkiye's written submission, para. 251. Türkiye requests us to reverse the Panel's findings in paragraphs 7.217-7.219 and 8.1.b.iv of the Panel Report. (Türkiye's notice of recourse to arbitration, p. 3)

<sup>&</sup>lt;sup>295</sup> Panel Report, para. 7.218.

<sup>&</sup>lt;sup>296</sup> Panel Report, para. 7.217-7.218.

<sup>&</sup>lt;sup>297</sup> Türkiye's written submission, paras. 252, 256-260, and 279.

<sup>&</sup>lt;sup>298</sup> Türkiye's written submission, paras. 261-278. At the hearing, Türkiye referred to its assertion before the Panel that its defence under Article XX(d) is distinct from its defence under Article XX(b). (Türkiye's responses to questions at the hearing (referring to Türkiye's responses to the Panel's first set of questions, para. 72))

<sup>&</sup>lt;sup>299</sup> Türkiye's written submission, paras. 252 and 280-311.

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evidence under Article XX(b) that Türkiye had failed to demonstrate that the localisation requirement was designed to secure compliance with laws requiring Türkiye to ensure "accessible, effective and financially sustainable healthcare" for its population. The Panel was not required to analyse the other components of the analysis under Article XX(d).<sup>300</sup> Should we conclude that the Panel adopted an erroneous legal standard in examining Türkiye's defence under Article XX(d), the European Union submits in the alternative that the factual findings of the panel and the undisputed facts on the panel record do not provide us with a sufficient basis to complete the analysis under Article XX(d), the European Union submits in the further alternative that the localisation requirement is not justified under Article XX(d).<sup>302</sup>

6.154. Article XX(d) of the GATT 1994 provides:

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any Member of measures:

...

(*d*) necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those relating to customs enforcement, the enforcement of monopolies operated under paragraph 4 of Article II and Article XVII, the protection of patents, trade marks and copyrights, and the prevention of deceptive practices[.]

6.155. Article XX(d) allows Members to maintain measures that are otherwise inconsistent with obligations under the GATT 1994, to the extent that those measures are necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of the GATT 1994, and are applied in a manner that is compatible with the requirements in the *chapeau* of Article XX. Like in the case of Article XX(b), for an exception under Article XX(d) to apply, the responding party bears the burden of invoking the provision and demonstrating that the measure in question meets the requirements of that provision.

6.156. Starting with the text of the provision, to be justified under Article XX(d), a measure must be necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of the GATT 1994. In order to assess whether a measure can be justified under Article XX(d), a panel may first assess, as an initial question, whether the measure is even related to, or not incapable of, securing compliance with the specific rules, obligations, or requirements. Logically, unless a measure is "not incapable" of securing compliance with specific rules, obligations, or requirements under the relevant provisions of the relevant "laws or regulations", then the measure cannot be justified under Article XX(d), and this would be the end of the inquiry.

6.157. In order to ascertain whether a measure is not incapable of securing compliance with specific laws or regulations, a panel should focus on examining the relationship between the challenged measure, considering its design (including its content, structure, and expected operation) and the proclaimed objective. The prior examination is used to assess whether the measure can be considered to have been "taken to", or "designed to", secure compliance with relevant laws or regulations. If the response to this question is affirmative, a panel may move to assess whether the measure can be considered to be "necessary" for the proclaimed objective, considering factors such as the extent of the contribution to the achievement of the objective, the measure's trade-restrictiveness, and the importance of the interests or values at stake, as well as comparing the measure with possible alternative measures identified by the complainant.

<sup>&</sup>lt;sup>300</sup> European Union's written submission, paras. 209 and 211-223.

<sup>&</sup>lt;sup>301</sup> European Union's written submission, paras. 210 and 224-228.

<sup>&</sup>lt;sup>302</sup> European Union's written submission, paras. 210 and 229-241.

6.158. This two-step analysis of the design and the necessity of a measure has been used in previous disputes<sup>303</sup> and corresponds to the manner in which the parties articulated their arguments both before the Panel as well as in the Arbitration.<sup>304</sup>

6.159. As noted above, the Panel found that Türkiye had failed to establish that the localisation requirement was taken to (designed to) secure compliance with laws requiring Türkiye to ensure "accessible, effective and financially sustainable healthcare" for its population. In light of the required elements for analysis under Article XX(d), normally such a conclusion would have been preceded by an examination of: (i) whether Türkiye had properly identified relevant laws or regulations that can qualify as "laws or regulations" within the meaning of Article XX(d)<sup>305</sup>; (ii) whether those laws or regulations were not found to be "inconsistent with the provisions of the [GATT 1994]"; and (iii) whether there was a rational relationship between the localisation requirement and the proclaimed objective, namely, whether the localisation requirement was not incapable of securing compliance with the specific rules and obligations under the relevant laws or regulations. These elements are cumulative, so that the lack of even one of them would have been sufficient for the Panel to reject the Article XX(d) defence.

6.160. In our view, it would have been more prudent had the Panel followed the order of the relevant analysis and articulated the applicable legal standard in assessing Türkiye's invocation of Article XX(d) of the GATT 1994. In other words, logically and analytically, it would have been more reasonable for the Panel to consider first which specific legal instruments were identified by Türkiye as the relevant "laws or regulations", whether such instruments qualified as "laws or regulations" within the meaning of Article XX(d), and whether they were not inconsistent with provisions of the GATT 1994, before turning to the examination of the relationship between the localisation requirement and the specific laws or regulations for the purposes of its "design" analysis.

6.161. The Panel did not follow the order of analysis suggested above. Specifically, there is no express confirmation in the Panel Report of the relevant laws or regulations cited by Türkiye, nor any examination of the characteristics of those instruments to confirm whether they could qualify as "laws or regulations" within the meaning of Article XX(d). The Panel also did not address whether the relevant laws or regulations were not inconsistent with the GATT 1994. In addition, the Panel Report is silent on the applicable legal standard for the Article XX(d) defence.

6.162. In this connection, at the Panel stage, the European Union disputed that the legal instruments cited by Türkiye had the required degree of specificity and normativity to qualify as "laws or regulations" within the meaning of Article XX(d).<sup>306</sup> Nevertheless, the Panel seems to implicitly have assumed, for the sake of focusing its analysis on the relationship issue<sup>307</sup>, that the legal instruments cited by Türkiye could qualify as "laws or regulations" for the purposes of Türkiye's Article XX(d) defence<sup>308</sup> and that, as argued by Türkiye, the relevant obligation contained in those

<sup>&</sup>lt;sup>303</sup> See e.g. Appellate Body Report, *India – Solar Cells*, para. 5.58.

<sup>&</sup>lt;sup>304</sup> See e.g. Türkiye's first written submission to the Panel, paras. 539-548; second written submission to the Panel, paras. 235-246; written submission, paras. 258 and 268; European Union's second written submission to the Panel, paras. 202-203; written submission, paras. 213-214.

<sup>&</sup>lt;sup>305</sup> Some relevant elements in this regard could include: 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; the degree of specificity of the relevant rule; whether the rule is legally enforceable; whether the rule has been adopted or recognized by a competent authority possessing the necessary powers under the domestic legal system of a Member; the form and title given to any instrument or instruments containing the rule under the domestic legal system of a Member; and the penalties or sanctions that may accompany the relevant rule. (See e.g. Appellate Body Reports, *India – Solar Cells*, para. 5.106 et seq.; *Mexico – Taxes on Soft Drinks*, para. 70)

<sup>&</sup>lt;sup>306</sup> European Union's second written submission to the Panel, paras. 207-213.

<sup>&</sup>lt;sup>307</sup> At the Panel stage, when considering the justification of Türkiye's invocation of Article XX(d), the parties to an important degree focused on whether there was evidence of a relationship between the localisation requirement and the proclaimed objective (i.e. securing compliance with laws requiring Türkiye to ensure accessible, effective, and financially sustainable healthcare for its population). (European Union's second written submission to the Panel, paras. 203-206; Türkiye's second written submission to the Panel, paras. 235-246) In this Arbitration, Türkiye has not challenged the legal standard applicable under Article XX(d).

<sup>&</sup>lt;sup>308</sup> Panel Report, para. 7.218.

legal instruments was for Türkiye to ensure accessible, effective, and financially sustainable healthcare.  $^{\rm 309}$ 

6.163. On the basis of those assumptions, the Panel considered whether the localisation requirement could be found to be a measure taken to secure compliance with the laws and regulations cited by Türkiye. The Panel noted the overlap between the arguments advanced by Türkiye in its allegation that the localisation requirement is justified under Article XX(b) because it is necessary to ensure uninterrupted access to safe, effective, and affordable medicines in Türkiye, and those advanced in the allegation that the same measure is justified under Article XX(d) because it is necessary to secure compliance with laws requiring Türkiye to ensure accessible, effective, and financially sustainable healthcare.<sup>310</sup>

6.164. Given the overlap between both defences, the Panel was of the view that the considerations made in its assessment of Türkiye's defence under Article XX(b) in this case could be extended *mutatis mutandis* to the analysis of Türkiye's defence under Article XX(d).<sup>311</sup> To recall, the Panel had concluded that Türkiye had failed to demonstrate that the localisation requirement was a measure designed to (taken to) protect human life or health.<sup>312</sup> With respect to Türkiye's invocation of Article XX(d), the Panel concluded that Türkiye had failed to demonstrate that the localisation requirement was taken to secure compliance with laws requiring Türkiye to ensure "accessible, effective and financially sustainable healthcare" for its population.<sup>313</sup>

6.165. We now turn to examine whether the method of analysis followed by the Panel as described above constitutes a legal error. We do not consider that it does for the following reasons.

6.166. To begin with, the Panel appears to have taken Türkiye's description of the relevant legal instruments at face value, and assumed *arguendo* that the legal instruments cited could be said to "*require* Türkiye to ensure accessible, effective, and financially sustainable healthcare" for its population. <sup>314</sup> Considering this assumption, the Panel focused on whether the localisation requirement was taken to (designed to) secure compliance with laws requiring Türkiye to ensure the proclaimed objective.

6.167. On the basis of its prior finding under Article XX(b) that the localisation requirement pursues industrial policy rather than the alleged objective of ensuring a continuous supply of safe, effective, and affordable pharmaceutical products, and considering the equivalent arguments advanced by Türkiye in its Article XX(d) defence, the Panel seems to have implicitly but necessarily reached an intermediate finding that there is no rational relationship between the localisation requirement and the proclaimed objective of securing compliance with laws or regulations requiring Türkiye to ensure accessible, effective, and financially sustainable healthcare. We also understand the Panel's *mutatis mutandis* application to suggest that a similar intermediate finding may apply in the context of Article XX(d). In light of the manner in which Türkiye articulated its justification for the localisation requirement under Article XX(d), it does not seem to constitute a legal error for the Panel to have extended elements of its assessment under Article XX(b) *mutatis mutandis* to the analysis of Türkiye's defence under Article XX(d).

6.168. We note once again that all the conditions and relevant elements for Article XX(d) are cumulative in nature. Hence, even without the Panel's examination of the laws or regulations cited by Türkiye and their qualification under Article XX(d), the Panel's intermediate finding on the lack of rational relationship between the localisation requirement and the proclaimed objective, which was made on the basis of the Panel's *mutatis mutandis* application, was sufficient for the Panel to conclude that the localisation requirement was not taken to secure compliance with the relevant laws or regulations, even if taken at face value as described by Türkiye.

<sup>&</sup>lt;sup>309</sup> Panel Report, para. 7.217.

<sup>&</sup>lt;sup>310</sup> Panel Report, para. 7.218.

<sup>&</sup>lt;sup>311</sup> Panel Report, para. 7.218.

<sup>&</sup>lt;sup>312</sup> Panel Report, para. 7.211.

<sup>&</sup>lt;sup>313</sup> Panel Report, para. 7.218.

<sup>&</sup>lt;sup>314</sup> Türkiye's first written submission to the Panel, para. 515. (emphasis added) "The essence of Turkey's arguments is that the measure is justified ... under Article XX(d) because it is necessary to secure compliance with laws requiring Turkey to ensure accessible, effective and financially sustainable healthcare." (Panel Report, para. 7.218)

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# 6.4.3 Conclusion

6.169. In light of the considerations above, we find that Türkiye has not established that the Panel applied an incorrect legal standard under Article XX(d) in finding that Türkiye had failed to demonstrate that the localisation requirement was taken to secure compliance with laws requiring Türkiye to ensure accessible, effective, and financially sustainable healthcare and was therefore justified under Article XX(d) of the GATT 1994.

6.170. Having found that the localisation requirement was not a measure taken to secure compliance with laws or regulations, the Panel did not need to assess the remaining legal elements of Article XX(d) to determine the applicability of this exception, namely, whether the measure was "necessary" to secure such compliance. Moreover, because the localisation requirement did not fall under Article XX(d) and therefore was not provisionally justified under this subparagraph, it was also unnecessary for the Panel to assess whether the localisation requirement was being applied consistently with the requirements of the *chapeau* of Article XX.

6.171. Consequently, we uphold the Panel's finding, in paragraphs 7.219 and 8.1.b.iv of the Panel Report, that Türkiye has not established that the localisation requirement is justified under Article XX(d) of the GATT 1994.

# 7 AWARD

7.1. In light of the foregoing considerations, we make the following findings and conclusions. We recall that, pursuant to paragraph 9 of the Agreed Procedures, the findings of the Panel that have not been "appealed" in the context of this Arbitration shall be deemed to form an integral part of the Award together with our own findings.

### 7.1 Articles III:4 and III:8(a) of the GATT 1994

7.2. On interpretation, we consider that, under Article III:8(a) of the GATT 1994, "procurement by governmental agencies of products purchased for governmental purposes" would typically involve the procurement of products through a *purchase by* a governmental agency. However, Article III:8(a) does not contain an unequivocal requirement to that effect. We do not foreclose the possibility that, in certain circumstances, the relevant purchase transaction may be entered into by a non-governmental entity so long as the products are *procured by* a governmental agency and procurement is of products purchased for governmental purposes. We therefore <u>find</u> that the Panel erred in considering, as a starting point for its analysis in paragraph 7.65 of the Panel Report, that Article III:8(a) required a *purchase by* governmental agencies.

7.3. On application, central to Türkiye's first claim under Article III:8(a) is whether there is *procurement* by a governmental agency of products purchased for governmental purposes within the meaning of Article III:8(a). On the basis of the Panel's factual findings and uncontested facts on the panel record, we conclude that there is no procurement, within the meaning of Article III:8(a), by the SSI of the pharmaceutical products included in the Annex 4/A list.

7.4. For these reasons:

- a. we <u>find</u> that the localisation requirement does not fall within the ambit of the derogation in Article III:8(a) of the GATT 1994 on the basis that there is no procurement by governmental agencies within the meaning of that provision;
- b. consequently, we <u>uphold</u>, albeit for different reasons, the Panel's finding, in paragraphs 7.107 and 8.1.b.ii of the Panel Report, that the localisation requirement is not covered by the government procurement derogation in Article III:8(a) of the GATT 1994, and is therefore subject to the national treatment obligation in Article III:4 of the GATT 1994 and Article 2.1 of the TRIMs Agreement; and
- c. we <u>declare</u> the Panel's intermediate findings, in paragraphs 7.66-7.81 of the Panel Report, regarding the interpretation of the term "products purchased", as well as its intermediate finding, in paragraphs 7.90, 7.103, and 7.104, that the localisation requirement does not

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involve the purchase of pharmaceutical products included in the Annex 4/A list by governmental agencies to be <u>moot and of no legal effect</u>.

7.5. Having upheld the Panel's finding that the localisation requirement does not fall within the ambit of Article III:8(a), it is not necessary for us to address Türkiye's conditional requests that we moot or reverse the Panel's findings under Article III:4 of the GATT 1994. Therefore:

a. we <u>find</u> that the Panel's finding, in paragraph 8.1.b.iii of the Panel Report, that the localisation requirement is inconsistent with the national treatment obligation in Article III:4 of the GATT 1994, remains undisturbed.

# 7.2 Article XX(b) of the GATT 1994

7.6. On interpretation, we do not consider that the Panel committed legal error by confusing the "design" and the "necessity" steps of the legal analysis under Article XX(b) of the GATT 1994. We also do not consider that the Panel set out a legal standard requiring a substantial degree of probability of risk for assessing whether a measure has been taken to protect human, animal, or plant life or health, in accordance with Article XX(b) of the GATT 1994, nor that the Panel introduced any quantitative dimension to the notion of risk to human life or health that unduly limited the range of public health measures that fall within the scope of Article XX(b). Finally, we disagree that the Panel erred by relying on previous panel reports dealing with provisions other than Article XX(b).

7.7. On application, to the extent that we have found no reversible error in the Panel's interpretation of Article XX(b), and considering the nature of Türkiye's application claims, we consider that Türkiye failed to establish that the Panel erred in its application of Article XX(b).

7.8. With respect to Article 11 of the DSU, we do not consider that the Panel exceeded its authority as the trier of facts and thereby failed to make an objective assessment of the matter before it.

7.9. For these reasons:

a. we <u>uphold</u> the Panel's finding, in paragraphs 7.219 and 8.1.b.iv of the Panel Report, that Türkiye has not established that the localisation requirement is justified under Article XX(b) of the GATT 1994.

# 7.3 Article XX(d) of the GATT 1994

7.10. In light of the manner in which Türkiye articulated its justification for the localisation requirement under Article XX(d) of the GATT 1994, we consider that it did not constitute legal error for the Panel to have extended elements of its assessment under Article XX(b) *mutatis mutandis* to the analysis of Türkiye's defence under Article XX(d). Even without the Panel's examination of the laws or regulations cited by Türkiye and their qualification under Article XX(d), the Panel's intermediate finding on the lack of rational relationship between the localisation requirement and the proclaimed objective, which was made on the basis of the Panel's *mutandis* application, was sufficient for the Panel to conclude that the localisation requirement was not taken to secure compliance with the relevant laws or regulations, even if taken at face value as described by Türkiye.

7.11. For these reasons:

a. we <u>uphold</u> the Panel's finding, in paragraphs 7.219 and 8.1.b.iv of the Panel Report, that Türkiye has not established that the localisation requirement is justified under Article XX(d) of the GATT 1994.

# 7.4 Recommendation

7.12. Pursuant to Article 19.1 of the DSU<sup>315</sup>, we recommend that Türkiye bring into conformity with its obligations under the GATT 1994 its measures that were found to be inconsistent in this Award and in the Panel Report<sup>316</sup> as modified by this Award.

<sup>&</sup>lt;sup>315</sup> "Where applicable, the arbitration award shall include recommendations, as envisaged in Article 19 of

the DSU." (Agreed Procedures, para. 9) <sup>316</sup> In accordance with paragraph 5 of the Agreed Procedures, the Panel Report can be found as an attachment to Türkiye's notice of recourse to arbitration. (WT/DS583/12 and WT/DS583/12/Add.1)