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

REPORT OF THE PANEL

*Addendum*

This *addendum* contains Annexes A to D to the Report of the Panel to be found in document WT/DS583/12.

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**ANNEX A**

WORKING PROCEDURES AND PRELIMINARY RULING

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## **ANNEX A-1**

### **WORKING PROCEDURES OF THE PANEL**

**As revised on 5 March 2021**

#### **General**

1. (1) In this proceeding, the Panel shall follow the relevant provisions of the Understanding on Rules and Procedures Governing the Settlement of Disputes ("DSU"). In addition, the following Working Procedures apply.  
  
(2) The Panel reserves the right to modify these procedures as necessary, after consultation with the parties.

#### **Confidentiality**

2. (1) In accordance with the DSU, the deliberations of the Panel shall be confidential and the documents submitted to it shall be treated as confidential but shall be made available to the parties and the third parties<sup>1</sup> to the dispute. Members shall treat as confidential information that is submitted to the Panel which the submitting Member has designated as confidential.  
  
(2) In accordance with the DSU, nothing in these Working Procedures shall preclude a party or third party from disclosing statements of its own positions to the public.  
  
(3) If a party submits a confidential version of its written submissions to the Panel, it shall also, upon request of a Member, provide a non-confidential summary of the information contained in its submissions that could be disclosed to the public. The Panel may, upon request, fix a time-limit within which the party should endeavour to provide such summary.  
  
(4) Upon request, the Panel may adopt appropriate additional procedures for the treatment and handling of confidential information after consultation with the parties.

#### **Submissions**

3. (1) Before the first substantive meeting of the Panel with the parties, each party shall submit a written submission in which it presents the facts of the case and its arguments, in accordance with the timetable adopted by the Panel.  
  
(2) Each party shall also submit to the Panel, before the first substantive meeting of the Panel, a written rebuttal, in accordance with the timetable adopted by the Panel.  
  
(3) Each third party that chooses to make a written submission before the first substantive meeting of the Panel with the parties shall do so in accordance with the timetable adopted by the Panel.  
  
(4) The Panel may invite the parties or third parties to make additional submissions during the proceeding, including with respect to requests for preliminary rulings in accordance with paragraph 4 below.

#### **Preliminary rulings**

4. (1) If Turkey considers that the Panel should make a ruling before the issuance of the Report that certain measures or claims in the panel request or the complainant's first written

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<sup>1</sup> To the extent provided for in Article 10.3 of the DSU.

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submission are not properly before the Panel, the following procedure applies. Exceptions to this procedure shall be granted upon a showing of good cause.

- a. Turkey shall submit any such request for a preliminary ruling at the earliest possible opportunity and in any event no later than in its first written submission to the Panel. The European Union shall submit its response to the request before the first substantive meeting of the Panel, at a time to be determined by the Panel in light of the request.
- b. The Panel may issue a preliminary ruling on the issues raised in such a preliminary ruling request before, during or after the first substantive meeting, or the Panel may defer a ruling on the issues raised by a preliminary ruling request until it issues its Report to the parties.
- c. If the Panel finds it appropriate to issue a preliminary ruling before the issuance of its Report, the Panel may provide reasons for the ruling at the time that the ruling is made, or subsequently in its Report.
- d. Any request for such a preliminary ruling by Turkey before the first meeting, and any subsequent submissions of the parties in relation thereto before the first meeting, shall be served on all third parties. The Panel may provide all third parties with an opportunity to provide comments on any such request, either in their submissions as provided for in the timetable or separately. Any preliminary ruling issued by the Panel before the first substantive meeting on whether certain measures or claims are properly before the Panel shall be shared with all third parties.

(2) This procedure is without prejudice to the parties' right to request other types of preliminary or procedural rulings during the proceeding, and to the procedures that the Panel may follow with respect to such requests.

#### **Evidence**

5. (1) Each party shall submit all evidence to the Panel no later than during the first substantive meeting, except evidence necessary for purposes of rebuttal, or evidence necessary for answers to questions or comments on answers provided by the other party. Additional exceptions may be granted upon a showing of good cause.  
  
(2) If any new evidence has been admitted upon a showing of good cause, the Panel shall accord the other party an appropriate period of time to comment on the new evidence submitted.
6. (1) If the original language of an exhibit or portion thereof is not a WTO working language, the submitting party or third party shall simultaneously submit a translation of the exhibit or relevant portion into the WTO working language of the Panel. The Panel may grant reasonable extensions of time for the translation of exhibits upon a showing of good cause.  
  
(2) Any objection as to the accuracy of a translation should be raised promptly in writing, preferably no later than the next submission or meeting (whichever occurs earlier) following the submission which contains the translation in question. Any objection shall be accompanied by an explanation of the grounds for the objection and an alternative translation.
7. (1) To facilitate the maintenance of the record of the dispute and maximize the clarity of submissions, each party and third party shall sequentially number its exhibits throughout the course of the dispute, indicating the submitting Member and the number of each exhibit on its cover page. Exhibits submitted by the European Union should be numbered EU-1, EU-2, etc. Exhibits submitted by Turkey should be numbered TUR-1, TUR-2, etc. If the last exhibit in connection with the first submission was numbered TUR-5, the first exhibit in connection with the next submission thus would be numbered TUR-6. If a party withdraws one or more exhibits, or submits one or more exhibits intentionally blank, it should indicate "exhibit withdrawn"; or "exhibit intentionally left blank", respectively.

(2) With each submission, oral statement, and response to questions, a party shall provide an updated list of exhibits (in Word or Excel format).

(3) If a party submits a document that has already been submitted as an exhibit by the other party, it should explain why it is submitting that document again.

(4) If a party includes a hyperlink to the content of a website in a submission and intends that the cited content form part of the official record, the cited content of the website shall be provided in the form of an exhibit along with the date that it was accessed.

### **Editorial Guide**

8. In order to facilitate the work of the Panel, each party and third party is invited to make its submissions in accordance with the WTO Editorial Guide for Panel Submissions (electronic copy provided).

### **Questions**

9. The Panel may pose questions to the parties and third parties at any time, including as follows in connection with the first substantive meeting:

a. Before the meeting, the Panel shall send written questions for advance written responses from the parties. The Panel shall ensure that the parties are afforded sufficient time to prepare their written responses, and that the responses are received sufficiently in advance of the meeting, so as to ensure that each party is able to provide comments on the other's responses at the meeting.

b. The Panel may also include questions for advance written responses from the third parties.

c. The Panel may put additional follow-up questions to the parties and third parties orally during the meeting, and in writing following the meeting, as provided for in paragraphs 15 and 21 below.

### **Substantive meetings**

10. The Panel shall meet in closed session.

11. The parties shall be present at the meetings only when the Panel invites them to appear before it.

12. (1) Each party has the right to determine the composition of its own delegation when meeting with the Panel.

(2) Each party shall have the responsibility for all members of its delegation and shall ensure that each member of its delegation acts in accordance with the DSU and these Working Procedures, particularly with regard to the confidentiality of the proceeding and the submissions of the parties and third parties.

13. Each party shall provide to the Panel the list of members of its delegation on a dedicated form to be provided by the Secretariat no later than 5.00 p.m. (Geneva time) on 6 April 2021.

14. A request for interpretation by any party should be made to the Panel as early as possible, preferably at the organizational stage, to allow sufficient time to ensure availability of interpreters.

15. The Panel shall hold at least one substantive meeting with the parties. Upon request by either party, the Panel may hold a second substantive meeting with the parties. The first and second substantive meetings of the Panel with the parties shall be conducted as follows:

a. At the first substantive meeting the Panel shall invite the European Union to make an opening statement to present its case first. Subsequently, the Panel shall invite Turkey to

present its point of view. Before each party takes the floor, it shall provide the Panel and other participants at the meeting with a provisional written version of its statement. At the second substantive meeting Turkey shall be given the opportunity to present its opening statement first. The party that presented its opening statement first shall present its closing statement first.

b. Each party should avoid lengthy repetition of the arguments in its submissions. Each party is allocated 75 minutes for its opening statement

c. After the conclusion of the opening statements and the third-party session, the Panel shall give each party the opportunity to make comments on the other party's opening statement, to make comments on the other party's written responses to advance written questions<sup>2</sup>, or to ask the other party questions, through the Panel.

d. The Panel may subsequently pose questions to the parties.

e. The parties and the Panel shall transmit any questions they expect to pose orally by no later than 16 April 2021. If the parties' opening statements raise any additional issues that the Panel wishes to address through oral questions, the Panel will transmit those questions in writing sufficiently well in advance of the interactive/Q&A session with the parties.

f. Either party may take the floor to make oral comments on the other party's oral responses to questions.

g. Once the questioning has concluded, the Panel shall afford each party an opportunity to present a closing statement of up to 45 minutes, with the European Union presenting its statement first. Before each party takes the floor, it shall provide the Panel and other participants at the meeting with a provisional written version of its closing statement.

h. Following the meeting:

i. Each party shall submit a final written version of its opening and closing statements no later than 5.00 p.m. (Geneva time) on 26 April 2021.

ii. Each party shall send in writing, by 30 April 2021, any questions to the other party to which it wishes to receive a response in writing.

iii. The Panel shall send in writing, by 30 April 2021, any questions to the parties to which it wishes to receive a response in writing.

iv. Each party shall respond in writing to the questions from the Panel, and to any questions posed by the other party, by 28 May 2021.

### **Third-party session**

17. Each third party may present its views orally during a session of the first substantive meeting with the parties set aside for that purpose.

18. Each third party shall provide to the Panel the list of the members of its delegation on a dedicated form to be provided by the Secretariat no later than 5:00 p.m. (Geneva time) on 6 April 2021, and each third party shall also indicate, by no later than 6 April 2021, whether it intends to make an oral statement at the meeting.

19. (1) Each third party has the right to determine the composition of its own delegation when meeting with the Panel.

(2) Each third party shall have the responsibility for all members of its delegation and shall ensure that each member of its delegation acts in accordance with the DSU and these Working

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<sup>2</sup> For greater clarity, each party shall be free to comment in its opening and/or closing statements on the other's responses to advance written questions.

Procedures, particularly with regard to the confidentiality of the proceeding and the submissions of the parties and third parties.

20. A request for interpretation by any third party should be made to the Panel as early as possible, preferably upon receiving the working procedures and timetable for the proceeding, to allow sufficient time to ensure availability of interpreters.

21. The third-party session shall be conducted as follows:

- a. The parties and third parties may be present during the entirety of this session.
- b. The Panel shall first hear the statements of the third parties, who shall speak in alphabetical order. Each third party making a statement at the third-party session shall provide the Panel and other participants with a provisional written version of its statement before it takes the floor.
- c. Each third party should limit the duration of its statement to 15 minutes and avoid repetition of the arguments already in its submission. If a third party considers that it requires more time for its statement, it should inform the Panel and the parties by no later than 14 April 2021, together with an estimate of the expected duration of its statement. The Panel will accord equal time to all third parties for their statements.
- d. After the third parties have made their statements, the parties shall be given the opportunity to pose questions to any third party, through the Panel, for clarification on any matter raised in that third party's submission or oral statement.
- e. The Panel may subsequently pose questions to any third party.
- f. The parties and the Panel shall transmit any questions they expect to pose orally to the third parties by no later than 16 April 2021.
- g. Following the third-party session:
  - i. Each third party shall submit the final written version of its statement no later than 5.00 p.m. (Geneva time) on 26 April 2021.
  - ii. Each party may send in writing, by 30 April 2021, any questions to one or more third parties to which it wishes to receive a response in writing.
  - iii. The Panel may send in writing, by 30 April 2021, any questions to one or more third parties to which it wishes to receive a response in writing.
  - iv. Each third party choosing to do so shall respond in writing to the questions from the Panel or a party by 28 May 2021.

#### **Descriptive part and executive summaries**

22. The description of the arguments of the parties and third parties in the descriptive part of the Panel report shall consist of executive summaries provided by the parties and third parties, which shall be annexed as addenda to the report. These executive summaries shall not in any way serve as a substitute for the submissions of the parties and third parties in the Panel's examination of the case.

23. Each party shall submit a single integrated executive summary of the facts and arguments as presented to the Panel in its written submissions and oral statement(s), in accordance with the timetable adopted by the Panel.

24. The integrated executive summary shall not exceed 30 pages.

25. The Panel may request the parties and third parties to provide executive summaries of facts and arguments presented in any other submissions to the Panel for which a deadline may not be specified in the timetable.

26. Each third party that submitted arguments (either in writing or at the third-party session) shall submit an integrated executive summary of its arguments as presented in its written submission and statement in accordance with the timetable adopted by the Panel. This integrated executive summary may also include a summary of responses to questions, if relevant. The executive summary to be provided by each third party shall not exceed six pages. If a third party's submission and statement do not exceed six pages in total, they shall serve as the executive summary of that third party's arguments. If the third party's submission and statement exceed six pages in total, the third party shall indicate if its submission or its statement should serve as its executive summary. If the third-party indicates that it does not wish for the submission or statement or both to serve as its executive summary, it shall submit a separate integrated executive summary.

### **Interim review**

27. Following issuance of the interim report, each party may submit a written request to review precise aspects of the interim report and request a further meeting with the Panel, in accordance with the timetable adopted by the Panel. The right to request such a meeting shall be exercised no later than at the time the written request for review is submitted.

28. If no further meeting with the Panel is requested, each party may submit written comments on the other party's written request for review. Such written comments shall be limited to the other party's written request for review and shall be submitted in accordance with the timetable adopted by the Panel.

### **Interim and Final Report**

29. The interim report, as well as the final report before its official circulation, shall be kept strictly confidential and shall not be disclosed.

### **Service of documents**

30. The following procedures regarding service of documents apply to all documents submitted by parties and third parties during the proceeding:

- a. Each party and third party shall send an email to the DS Registry attaching an electronic copy of all documents that it submits to the Panel, preferably in both Microsoft Word and PDF format. All such emails to the Panel shall be addressed to [DSRegistry@wto.org](mailto:DSRegistry@wto.org) and copied to other WTO Secretariat staff whose email addresses have been provided to the parties during the proceeding. If it is not possible to attach all the exhibits to one email, the submitting party or third party may send separate emails. If the number of emails necessary to transmit the exhibits would exceed 5 or any one exhibit is too large to be transmitted via email, the party shall upload the relevant exhibits to the Disputes On-line Registry Application (DORA). The email version sent to the DS Registry shall constitute the official version for the purposes of submission deadlines and the record of the dispute.
- b. In addition, each party is invited to submit all documents through DORA within 24 hours following the deadline for the submission of the paper versions. If the parties have any questions or technical difficulties relating to the WTO e-filing system, they are invited to contact the DS Registry at [DSRegistry@wto.org](mailto:DSRegistry@wto.org).
- c. If the parties or third parties have any questions or technical difficulties relating to DORA, they are invited to consult the User Guide available in the "Help" section of DORA and if necessary contact the DS Registry ([DSRegistry@wto.org](mailto:DSRegistry@wto.org)).
- d. Following email submission, each party and third party shall submit one courtesy paper copy of all documents it submits to the Panel, including the exhibits, with the DS Registry

(office No. 2047) by 5:00 p.m. (Geneva time) the next business day.<sup>3</sup> If the Member does not have a mission or representative in Geneva the submissions may be sent by post or courier and must have a postmark or proof that they were sent the next business day after the submission was due. The DS Registrar shall stamp the documents with the date and time of receipt. If an exhibit is in a format that is impractical to submit as a paper copy, then the party may submit such exhibit in electronic format (email or on a CD-ROM, DVD or USB key). In this case, the cover page of the exhibit should indicate that the exhibit is only available in electronic format.

- e. The receipt of the email by the DS Registry shall constitute service on the Panel. Each party shall serve any document submitted to the Panel directly on the other party. A party shall submit its documents to another party by email. Each party shall confirm, in writing, that it has served on the other party, as appropriate, at the same time it provides each document to the Panel, a copy of such documents. Each party shall, in addition, serve any document submitted in advance of the first substantive meeting with the Panel directly on the third parties. For greater clarity, this includes, in accordance with paragraph 3(b) of these Working Procedures, the parties' rebuttal submissions. This also includes the parties' written responses to questions sent in advance of the first substantive meeting. The receipt of the email by the other party and the third parties (where relevant) shall constitute service.<sup>4</sup>
- f. As a general rule, all communications from the Panel to the parties and third parties will be via email. The Panel shall provide the parties with a paper copy of the Interim Report and the Final Report upon request.

#### **Correction of clerical errors in submissions**

31. The Panel may grant leave to a party or third party to correct clerical errors in any of its submissions (including paragraph numbering and typographical mistakes). Any such request should identify the nature of the errors to be corrected and should be made promptly following the filing of the submission in question.

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<sup>3</sup> If, for any reason, the WTO building is extraordinarily closed, the "next business day" will mean the day that the Panel determines for such filings once normal operations have resumed.

<sup>4</sup> In light of the requirement that receipt of the email constitutes service, parties and third parties may wish to include a "read receipt" when sending emails to the DS Registry, the other party, or the third parties.

**ANNEX A-2**

**ADDITIONAL WORKING PROCEDURES CONCERNING PROTECTION OF  
BUSINESS CONFIDENTIAL INFORMATION  
(BCI PROCEDURES)**

**Adopted on 15 April 2020**

The following procedures apply to business confidential information (BCI) submitted during the panel proceedings.

1. For the purposes of these proceedings, BCI means information:
  - a. that is designated as such by the party submitting it;
  - b. that is not otherwise available in the public domain; and
  - c. that is commercially sensitive or, in the case of government, confidential information, the release of which could reasonably be considered to cause or threaten to cause harm to the public interest, including by impairing the ability of the government to conduct its work.
2. Each party and third party shall act in good faith and exercise restraint in designating information as BCI. The Panel shall have the right to intervene in any manner that it deems appropriate, if it is of the view that restraint in the designation of BCI is not being exercised.
3. If a party, a third party, or the Panel, objects to the designation of information as BCI, the party designating the information shall provide reasons for the designation within seven (7) working days of the objection. After giving the other party an opportunity to comment on the justification provided within seven (7) working days, the Panel shall decide on the designation of the information. If the Panel disagrees with the designation of information as BCI, the submitting Party may either designate it as non-BCI or withdraw the information.
4. If a party or a third party considers that information submitted by the other party or a third party should have been designated as BCI and objects to its submission without designation, it shall provide reasons for its objection to the Panel, the other party, and where relevant the third parties within seven (7) working days of the submission of the information. After giving the submitting party or third party an opportunity to comment on whether the information should be designated as BCI within seven (7) working days, the Panel shall decide on the designation of the information. If the Panel agrees that the information should be designated as BCI, the submitting party will be asked to withdraw the earlier version and submit a new version properly labelled as BCI as set forth in these procedures.
5. As required by paragraph 2(1) of the Working Procedures of the Panel<sup>1</sup>, the deliberations of the Panel and the documents submitted to it shall be kept confidential. Further, pursuant to Article 18.2 of the DSU a party or third party having access to information designated as BCI submitted in these Panel proceedings shall treat it as confidential and shall not disclose that information other than to those persons authorized to receive it pursuant to these BCI Procedures. Each party, third party, and outside adviser having access to the BCI shall only use it for the purposes of this dispute. Each party and third party is responsible for ensuring that its employees, outside advisers, and experts comply with these BCI Procedures.
6. Panel Members and employees of the WTO Secretariat assigned to the dispute DS583, including translators and interpreters, shall have access to BCI submitted in these proceedings. Employees of the Governments of the European Union and Turkey, as well as of the third parties, shall have access to BCI submitted in these Panel proceedings to the extent necessary for their involvement in their official capacity in these proceedings. Outside advisers may be permitted access

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<sup>1</sup> Adopted on 15 April 2020.

to BCI. However, an outside adviser is not permitted access to BCI if that adviser is an officer or employee of an enterprise engaged in the production, marketing, export, or import of the products that are subject of this dispute or an officer or employee of an association of such enterprises.

7. Representatives of, and outside advisers to, each of the parties and representatives of, and outside advisers to, the third parties shall be notified to the Panel, other party, and third parties in a list containing the names, titles, and employers of persons legitimately requiring access to BCI. The list for each party is to be first submitted at the latest by one (1) week before the due date of the first written submission of the complainant. The list of each party or third party shall be subsequently amended and re-submitted if the names, titles, or employers are changed. Parties and third parties may give access to BCI only to outside advisers (including their clerical staff) providing assistance to the parties in these proceedings.

8. On the request of either party, the Panel will review whether specific confidential information it has submitted is so sensitive that it should not be provided to the third parties. In its review the Panel will take into consideration the need for the third party to have access to the particular information. If the Panel finds such information to be particularly sensitive, it will direct the party submitting the information to provide a non-confidential summary of the contents of the redacted information that will be made available to the third parties.

9. A party or third party submitting or referring to BCI in any written submission (including in any exhibits) shall mark the cover and the first page of the document containing any such information with the words "Contains Business Confidential Information" and listing the pages on which BCI appears. Any BCI that is submitted in binary-encoded form shall be clearly marked with the statement "Business Confidential Information" on a label on the storage medium, and clearly marked with the statement "Business Confidential Information" in the binary-encoded files. The specific information in question shall be enclosed in double brackets, as follows: [[\*\*\*]], and the notation "Contains Business Confidential Information" shall be marked at the top of each page containing the BCI. In the case of a statement containing BCI, the party or third party making such a statement shall inform the Panel before making it that the statement will contain BCI, and the Panel will ensure that only persons authorized to have access to BCI pursuant to these BCI Procedures are in the room to hear that statement. If a party submits a document containing BCI to the Panel, the other party or any third party referring to that BCI in its documents, including written submissions, written versions of oral statements and documents submitted in binary-encoded form, shall mark the document and any storage medium accordingly, and use double brackets, as set forth in these procedures.

10. The parties, third parties, the Panel, the WTO Secretariat, and any others permitted to have access to documents containing BCI under the terms of these BCI Procedures shall store all documents containing BCI in a manner so as to prevent unauthorized access to such information. Parties are invited to upload BCI into DORA rather than sending via email as the application is encrypted and has appropriate access controls. If a particular document is so sensitive that the party or third party does not wish to send it via email or upload it into DORA it should inform the Panel in advance of the submission so that arrangements can be made for off-line filing. Any party filing a document off-line must file a redacted version of the document with a non-confidential summary of the redacted information.

11. The Panel may include in its confidential Interim Report any information designated as BCI under these BCI Procedures. However, the Panel will not disclose in its Final Report any information designated as BCI under these BCI Procedures. The Panel may, however, make statements of conclusion based on such information. Before the Panel circulates the Final Report to Members, the Panel shall give each party or third party an opportunity to ensure that any information it has designated as BCI is not contained in the report.

12. At the conclusion of the dispute<sup>2</sup>, and within a period to be fixed by the Panel, each party and third party shall either return all documents (including electronic material) containing BCI, submitted during the Panel proceedings, to the party that submitted such documents or certify in writing to

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<sup>2</sup> Where this is defined as when (a) the Panel or Appellate Body report is adopted by the DSB, or the DSB decides by consensus not to adopt the Panel or the Appellate Body report; (b) the authority for the establishment of the Panel lapses under Article 12.12 of the DSU; or (c) a mutually satisfactory solution is notified to the DSB under Article 3.6 of the DSU.

the Panel and the other parties that all such documents have been destroyed, or otherwise protect the BCI against public disclosure, consistent with the party's obligations under its domestic laws. The WTO Secretariat shall have the right to retain the documents containing BCI for the archives of the WTO.

13. If a party formally notifies the DSB of its decision to appeal pursuant to Article 16.4 of the DSU, the Secretariat will take appropriate steps with respect to the preservation and transmission of the record in relation to the appeal. Following the completion or withdrawal of an appeal, the parties and third parties shall promptly return all such documents or certify to the parties that all such documents have been destroyed, taking account of any applicable procedures adopted during the appeal.

**ANNEX A-3****PRELIMINARY RULING OF THE PANEL****10 July 2020****1 INTRODUCTION**

1.1. Pursuant to the European Union's request for establishment of a panel (panel request)<sup>1</sup>, the Dispute Settlement Body (DSB) established the Panel on 30 September 2019.<sup>2</sup> The Panel was composed on 17 March 2020.<sup>3</sup> The Panel held a written exchange with the parties on organizational matters between 7 April 2020 and 9 April 2020. The Panel adopted its Working Procedures on 15 April 2020. On 15 May 2020, three days before the deadline for the European Union's first written submission, Turkey requested a preliminary ruling arguing that the European Union's panel request fails to identify the specific measures at issue and, with respect to certain claims, fails to provide a brief summary of the legal basis of the complaint sufficient to present the problem clearly.

1.2. After receiving comments from the parties<sup>4</sup> and third parties<sup>5</sup>, the Panel provides its preliminary ruling on Turkey's request below. This Ruling will become an integral part of the Panel's Final Report, subject to any changes that may be necessary in light of comments received from the parties at the interim review stage.

1.3. Turkey requests that the Panel issue a preliminary ruling, concluding that the measures and claims identified in its request for a preliminary ruling are not within the Panel's terms of reference. Turkey claims that the European Union has failed to comply with Article 6.2 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU) because its panel request did not identify the specific measures at issue.<sup>6</sup> In particular, Turkey argues that the panel request does not identify with sufficient precision: (i) the nature of the measures at issue as written or unwritten measures<sup>7</sup>; (ii) the content of the measures, including the products that are the subject of the measures and the requirement(s) concerned<sup>8</sup>; (iii) the legal instruments underpinning each of the measures at issue<sup>9</sup>; and (iv) the "as such" or "as applied" character of the prioritization measure.<sup>10</sup>

1.4. Turkey submits that, even if the Panel were to conclude that the European Union did identify the specific measures at issue, it should, nevertheless, conclude that any claims that the European Union makes with respect to "other instruments through which Turkey implements and administers the measures at issue" fall outside the Panel's terms of reference. This is because that reference is vague and does not allow the identification of the specific instruments or documents that the reference aims to cover.<sup>11</sup>

1.5. Lastly, Turkey submits that the European Union's panel request has failed to provide the legal basis of the complaint sufficient to present the problem clearly in connection with its claims under Article X:1 of the General Agreement on Tariffs and Trade 1994 (GATT 1994) and Article 3.1(b) of the Agreement on Subsidies and Countervailing Measures (SCM Agreement) with respect to the localisation requirement measure.<sup>12</sup>

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<sup>1</sup> WT/DS583/3.

<sup>2</sup> WT/DSB/M/434.

<sup>3</sup> WT/DS583/4.

<sup>4</sup> The European Union responded to Turkey's request on 5 June 2020. On 19 June 2020, Turkey commented on the European Union's comments. The European Union provided its comments on Turkey's comments on 26 June 2020.

<sup>5</sup> Canada, Ukraine, and the United States provided comments on 12 June 2020.

<sup>6</sup> Turkey's request for a preliminary ruling, paras. 16-48.

<sup>7</sup> Turkey's request for a preliminary ruling, paras. 22-25.

<sup>8</sup> Turkey's request for a preliminary ruling, paras. 26-33.

<sup>9</sup> Turkey's request for a preliminary ruling, paras. 34-44.

<sup>10</sup> Turkey's request for a preliminary ruling, paras. 45-46.

<sup>11</sup> Turkey's request for a preliminary ruling, paras. 49-50.

<sup>12</sup> Turkey's request for a preliminary ruling, para. 68.

1.6. The European Union asserts that Turkey's request is untimely and therefore inadmissible, and in any event, that its panel request fulfils all the requirements of Article 6.2 of the DSU.<sup>13</sup> The European Union asks the Panel to reject Turkey's request for a preliminary ruling.<sup>14</sup>

1.7. The Panel sets forth its decision below. A copy of this communication will be transmitted to the third parties for information.

## 2 THE LEGAL STANDARD UNDER ARTICLE 6.2 OF THE DSU

2.1. Article 6.2 of the DSU sets forth the requirements that a complaining party must fulfil when requesting the establishment of a panel. They are:

The request for the establishment of a panel shall be made in writing. It shall indicate whether consultations were held, identify the specific measures at issue and provide a brief summary of the legal basis of the complaint sufficient to present the problem clearly. In case the applicant requests the establishment of a panel with other than standard terms of reference, the written request shall include the proposed text of special terms of reference.

2.2. Article 7.1 of the DSU, explains that a panel's terms of reference are set by the provisions cited by the parties, most especially the "matter" referred to it in the request for establishment of a panel. Prior panels and the Appellate Body have clarified that the "matter" referred to in Article 7.1 is the measures and claims identified in the panel request.<sup>15</sup> Therefore, if a measure or claim is absent from the panel request or not clearly specified therein, it would be outside the panel's terms of reference.

2.3. The requirements for a panel request are also important for protecting the respondent's due process rights. Due process is "an essential feature of the WTO dispute settlement system" that helps ensure "the rights of parties to be afforded an adequate opportunity to pursue their claims and make out their defences".<sup>16</sup> The requirements in Article 6.2 are used to ensure that the respondent knows what case it has to answer and to protect its due process rights by enabling it to properly prepare a defence.<sup>17</sup>

2.4. When panels are called upon to examine a panel request for compliance with Article 6.2, they must carefully consider the panel request "to ensure compliance with both the letter and spirit of Article 6.2".<sup>18</sup> Although such compliance must be demonstrated on the face of the panel request<sup>19</sup>, panels are to examine the request as a whole and in light of the attendant circumstances.<sup>20</sup> Panels may have reference to the parties' written submissions to clarify or confirm the meaning of the phrases in the panel request, but the written submissions cannot be used to "cure" a deficiency in a panel request.<sup>21</sup>

2.5. The Panel recalls that Article 3.10 of the DSU requires both complaining and responding Members to comply with the requirements of the DSU in good faith. Thus, complaining Members must accord to responding Members the full measure of protection and opportunity to defend, contemplated by the letter and spirit of the procedural rules.<sup>22</sup> Likewise, responding Members must

<sup>13</sup> European Union's response to Turkey's request for a preliminary ruling, para. 2.

<sup>14</sup> European Union's response to Turkey's request for a preliminary ruling, para. 108.

<sup>15</sup> Appellate Body Report, *US – Carbon Steel*, para. 125.

<sup>16</sup> Panel Report, *India – Agricultural Products*, para. 7.82.

<sup>17</sup> Appellate Body Reports, *US – Carbon Steel*, para. 126; *Brazil – Desiccated Coconut*, para. 186, *EC – Bananas III*, para. 142; *US – Continued Zeroing*, para. 161.

<sup>18</sup> Appellate Body Report, *US – Carbon Steel*, paras. 126 and 127 (citing Appellate Body Report *EC – Bananas III*, para. 142).

<sup>19</sup> The Appellate Body has cautioned that a need to scrutinize a panel request on its face should not limit the examination of that request to the words appearing in the document as this would be "too formalistic an approach". See Appellate Body Report, *Argentina – Import Measures*, paras. 5.51-5.52.

<sup>20</sup> Panel Report, *US – FSC (Article 21.5 – EC II)*, para. 7.74. See also Appellate Body Reports, *Canada – Wheat Exports and Grain Imports*, para. 206 and *EC and certain member States – Large Civil Aircraft*, para. 787; Panel Report, *China – Publications and Audiovisual Products*, para. 7.104.

<sup>21</sup> Appellate Body Report, *Argentina – Import Measures*, para. 5.42 (citing Appellate Body Report, *US – Countervailing and Anti-Dumping Measures (China)*, para. 4.9).

<sup>22</sup> Appellate Body Report, *US – FSC*, para. 166.

seasonably and promptly bring claimed procedural deficiencies to the attention of the complaining Member, and to the DSB or the panel, so that corrections, if needed, can be made, so that differences or misunderstandings can be resolved.<sup>23</sup> As the Appellate Body has clarified, "the procedural rules of WTO dispute settlement are designed to promote, not the development of litigation techniques, but simply the fair, prompt and effective resolution of trade disputes."<sup>24</sup>

2.6. In light of the above, and after careful review of the parties' arguments and the third parties' comments, the Panel has reached the conclusions set forth below.

### 3 CONCLUSIONS ON TURKEY'S REQUESTS

#### 3.1 Timeliness of Turkey's request for a preliminary ruling

3.1. The European Union addressed a letter to the Panel on 26 May 2020 raising many of the arguments on the timeliness of Turkey's request for a preliminary ruling that it makes in its formal comments on the request. The Panel answered many of these issues in its letter to the parties of 29 May 2020 and sees no need to return to or repeat its reasoning here.

3.2. In its comments, the European Union expands on its arguments concerning the proper interpretation of paragraph 4(1)(a) of the Panel's Working Procedures. In particular, the European Union argues that paragraph 4(1)(a) of the Working Procedures sets two cumulative time limits: (i) a dynamic, yet objective, time limit to request a preliminary ruling "as soon as it is objectively possible for Turkey to do so"<sup>25</sup>, which is subject to review by the Panel<sup>26</sup>; and (ii) a fixed time limit linked to the filing of Turkey's first written submission, which addresses primarily situations where the request for a preliminary ruling relates to the lack of consistency between the panel request and the complainant's first written submission.<sup>27</sup> The European Union maintains that Turkey fails on the first requirement because Turkey could have filed its request immediately upon the composition of the Panel, or at the latest upon the adoption of the Working Procedures and Timetable.<sup>28</sup> The European Union considers that Turkey failed to explain how certain circumstances, including the COVID-19 pandemic, prevented it from filing its request at an earlier date.<sup>29</sup>

3.3. Turkey responds that its request for a preliminary ruling was filed "at the earliest possible opportunity" and well before the deadline of Turkey's first written submission<sup>30</sup> and thus complies with the Working Procedures. Turkey explains that it could not have filed its request before the date on which the Panel sent the parties the Working Procedures (i.e. 15 April 2020), because the procedure for filing such a request was outlined in the Working Procedures<sup>31</sup>, and that during the period 15 April 2020-15 May 2020 various factors, including the extraordinary situation created by the COVID-19 pandemic, influenced what may have been "the earliest possible opportunity".<sup>32</sup>

3.4. Although the Working Procedures are adopted pursuant to the Panel's authority under the DSU, they are not treaty text and do not need to be scrutinized according to customary rules of interpretation of public international law as codified in the Vienna Convention on the Law of Treaties. At the same time, the Panel finds nothing objectionable in applying its Working Procedures in good faith, relying on the ordinary meaning of the terms used in their context, bearing in mind their object

<sup>23</sup> Appellate Body Report, *US – FSC*, para. 166.

<sup>24</sup> Appellate Body Report, *US – FSC*, para. 160.

<sup>25</sup> European Union's response to Turkey's request for a preliminary ruling, para. 9.

<sup>26</sup> European Union's comments on Turkey's comments on the European Union's response to Turkey's request for a preliminary ruling, para. 8.

<sup>27</sup> European Union's comments on Turkey's comments on the European Union's response to Turkey's request for a preliminary ruling, para. 5.

<sup>28</sup> The European Union also notes that there was no need for Turkey to wait for the Panel to adopt its Working Procedures – see European Union's comments on Turkey's comments on the European Union's response to Turkey's request for a preliminary ruling, para. 10.

<sup>29</sup> European Union's comments on Turkey's comments on the European Union's response to Turkey's request for a preliminary ruling, para. 12.

<sup>30</sup> Turkey's comments on the European Union's response to Turkey's request for a preliminary ruling, para. 15.

<sup>31</sup> Turkey's comments on the European Union's response to Turkey's request for a preliminary ruling, para. 13.

<sup>32</sup> Turkey's comments on the European Union's response to Turkey's request for a preliminary ruling, para. 14.

and purpose. In that vein, the Panel recalls that the Working Procedures are adopted to set forth procedures for orderly panel proceedings while at the same time preserving the parties' due process rights, in the context of a dispute settlement mechanism where a panel's jurisdiction is limited pursuant to Article 7.1 of the DSU. As the Appellate Body has explained, because a panel's terms of reference define the scope of the dispute and serve to establish and delimit a panel's jurisdiction, "panels cannot simply ignore issues which go to the root of their jurisdiction – that is, to their authority to deal with and dispose of matters. Rather, panels must deal with such issues – if necessary, on their own motion – in order to satisfy themselves that they have authority to proceed."<sup>33</sup> The Panel, therefore, cannot adopt an overly legalistic reading of the Working Procedures that could lead to the Panel potentially exceeding its mandate.<sup>34</sup> The determination of what point in time constitutes a party's "earliest possible opportunity" to file a request for a preliminary ruling must take into account the specific circumstances of the case and the party concerned, as well as an understanding that parties must be given adequate time to prepare their submissions.

3.5. It is true that Turkey could have brought its request for a preliminary ruling at any time after the Panel was established or composed. However, Turkey could not have been bound to comply with paragraph 4(1)(a) of the Working Procedures until they were adopted, on 15 April 2020. Turkey filed its request for a preliminary ruling one month later. The Panel has already noted in its letter of 29 May 2020 that Turkey is a developing country and entitled to flexibility on the length of time necessary to prepare its submissions under the DSU. Coupled with the extraordinary situation created by the COVID-19 pandemic, one month to prepare a detailed legal submission is not unreasonable and is not inconsistent with making the request at the earliest possible opportunity. Moreover, the Panel recalls its finding in its letter of 29 May 2020 that in any event, the fact that Turkey's request for a preliminary ruling was filed before its first written submission meant that the request was made within the time allowed in paragraph 4(1)(a).

3.6. In light of the above, the Panel finds that Turkey's request for a preliminary ruling is not untimely.

### **3.2 Whether the European Union's panel request identified the specific measures at issue**

3.7. The Panel recalls that it should determine whether a specific measure at issue has been sufficiently identified in a panel request based not only on the text of a request, but also upon a respondent's ability to defend itself given the description of a measure in a panel request.<sup>35</sup> Measures can be identified either by reference to a specific legislative instrument or by their substance.<sup>36</sup> The identification of the specific measures at issue is different from a demonstration of the existence of such measures and the applicable provisions of the covered agreements.<sup>37</sup> An examination of a panel request's specificity does not entail substantive consideration of the existence and precise content of a measure or whether that measure is susceptible to challenge in WTO dispute settlement. Such consideration may need to be explored by a panel and the parties during the panel proceedings but is not a prerequisite for setting the jurisdictional boundaries of a panel.<sup>38</sup>

3.8. The European Union referred in the introductory paragraphs of its panel request to three different measures – a localisation requirement, an alleged import ban on localised products, and a prioritization measure. The European Union also provided a list of 28 different legal instruments or other types of documents with the preface that the three measures "are put in place and evidenced by, and are implemented and administered through, *inter alia*, the following legal and other instruments, considered alone and in any combination". The panel request is then divided into three sections, each one devoted to one of the measures. Each section has a subheading for "identification

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<sup>33</sup> Appellate Body Report, *Mexico – Corn Syrup (Article 21.5 – US)*, para. 36. See also *Ibid.*, para. 53; Appellate Body Report, *EC and certain member States – Large Civil Aircraft*, para. 791; Panel Reports, *US – Clove Cigarettes*, para. 7.134, *EU – Energy Package*, paras. 7.200, 7.215 and 7.221, and *Morocco – Hot-Rolled Steel (Turkey)*, paras. 7.54-7.57.

<sup>34</sup> In that regard, the Panel recalls that paragraph 4 of the Working Procedures provides that the deadlines in paragraph 4 can be waived by the Panel for "good cause".

<sup>35</sup> Appellate Body Report, *EC – Computer Equipment*, para. 45. See also Panel Report, *Canada – Wheat Exports and Grain Imports*, para. 6.10, sub-paras. 17 and 20.

<sup>36</sup> Panel Report, *Argentina – Footwear (EC)*, para. 8.40.

<sup>37</sup> Appellate Body Report, *US – Continued Zeroing*, paras. 168-169.

<sup>38</sup> Appellate Body Report, *US – Continued Zeroing*, para. 169.

of the specific measure at issue", which is then accompanied by a narrative description of the challenged measure.

### 3.2.1 The nature, content, and legal instruments underpinning the measures at issue

3.9. As noted above, Turkey argues that the European Union failed to identify all three of the measures at issue consistently with the obligation in Article 6.2 of the DSU.

3.10. Turkey has relied on the findings of the panel in *Russia – Traffic in Transit*<sup>39</sup> to support its position that the European Union was required to specify individually and cumulatively (i) the nature of the measures at issue as written or unwritten<sup>40</sup>; (ii) the content of the measures, including the products that are the subject of the measures and the requirement(s) concerned<sup>41</sup>; and (iii) the legal instruments underpinning each of the measures at issue<sup>42</sup> in its panel request to comply with the obligation in Article 6.2 to identify the specific measure at issue.<sup>43</sup> The Panel notes that the panel in *Russia – Traffic in Transit* was dealing with the specifics of that case in light of the measures at issue, the way that panel request was drafted, the attendant circumstances surrounding that dispute and the relationship between the two parties. This Panel is not of the view that the panel report in *Russia – Traffic in Transit* established a new standard for compliance with Article 6.2 of the DSU. We agree with the panel in *India – Export Related Measures*, that a determination of whether a measure has been sufficiently identified may depend on "the particular context in which those measures exist and operate", and "involves, by necessity, a case-by-case analysis since it may require examining the extent to which those measures are capable of being precisely identified".<sup>44</sup> The Panel, therefore, does not believe that it can simply adopt wholesale the same factors that the panel in *Russia – Traffic in Transit* adopted in its evaluation of the panel request in that case. The Panel will instead examine the European Union's panel request as a whole and in light of the attendant circumstances<sup>45</sup> to determine whether it complies with both the letter and spirit of Article 6.2.<sup>46</sup>

3.11. The Panel has examined not only the listing of legal instruments and other documents in the introductory section of the panel request, but also the narrative descriptions of each measure in the relevant sections of the panel request. The Panel has also examined the attendant circumstances, which in its view include discussions in WTO bodies on the matter as well as bilateral discussions between the parties on the matter.<sup>47</sup> These attendant circumstances cannot be discounted in reaching a conclusion on whether the language in the panel request adequately identified the challenged measures to *Turkey* as opposed to a person with no prior understanding of the dispute.

3.12. First, the Panel recalls that a broad range of measures may be challenged under the WTO dispute settlement system and that they need not fit within neat categories to be susceptible to challenge. In principle, any act or omission attributable to a Member can be brought before the DSB.<sup>48</sup> The Panel does not believe that a measure must fall discretely into the category of either

<sup>39</sup> Turkey's request for a preliminary ruling, paras. 13-14, and 44.

<sup>40</sup> Turkey's request for a preliminary ruling, para. 25.

<sup>41</sup> Turkey's request for a preliminary ruling, para. 26.

<sup>42</sup> Turkey's request for a preliminary ruling, para. 40. In its comments on the European Union's comments on its request for a preliminary ruling, Turkey raises the issue that in its first written submission, the European Union referred to new legal instruments and documents that were not identified in its panel request with respect to its claims under each of the challenged measures. See Turkey's comments on European Union's response to Turkey's request for a preliminary ruling, paras. 66–73. Turkey argues that this inclusion of new legal instruments supports its contention that the European Union did not properly identify the measures in its panel request.

<sup>43</sup> Turkey's request for a preliminary ruling, para. 21. See also Turkey's request for a preliminary ruling, para. 14 (citing Panel Report, *Russia – Traffic in Transit*, para. 7.301).

<sup>44</sup> Panel Report, *India – Export Related Measures*, Annex D-2, para. 2.8.

<sup>45</sup> Panel Report, *US – FSC (Article 21.5 – EC II)*, para. 7.74. See also Appellate Body Reports, *Canada – Wheat Exports and Grain Imports*, para. 206 and *EC and certain member States – Large Civil Aircraft*, para. 787; Panel Report, *China – Publications and Audiovisual Products*, para. 7.104.

<sup>46</sup> Appellate Body Report, *US – Carbon Steel*, paras. 126 and 127 (citing Appellate Body Report *EC – Bananas III*, para. 142).

<sup>47</sup> The Panel notes in this regard that it is not referring to discussions that took place in the context of consultations under Article 4 of the DSU as these are confidential, but rather other publicly available information that the European Union referred to in its submissions.

<sup>48</sup> Appellate Body Reports, *US – Anti-Dumping Methodologies (China)*, para. 5.122 (referring to Appellate Body Report, *US – Corrosion-Resistant Steel Sunset Review*, para. 81); *Argentina – Import Measures*, para. 5.100; *US – Supercalendered Paper*, para. 5.17.

written or unwritten to be properly identified in a panel request. What matters is whether the responding Member can discern from the language which of its acts or omissions<sup>49</sup> are being challenged. The European Union noted in its panel request that the identified measures were "put in place and evidenced by, and are implemented and administered through, *inter alia*, the following legal and other instruments, considered alone and in any combination." The European Union, thus, indicated that there were written components of the challenged measures. The fact that the European Union raised a claim under Article X:1 of the GATT 1994 indicates that it believes that there are also unwritten or at least *unpublished* aspects of the localisation requirement.

3.13. Second, the Panel finds that the European Union adequately identified the content of the measures in terms of the requirements it was challenging in the narrative descriptions of the measures in the panel request. Furthermore, nothing in Article 6.2 requires complainants to identify with specificity the *products* covered by the challenged measures. As the Appellate Body has noted such knowledge will usually flow from the identification of the measures.<sup>50</sup> In this case, the European Union identified the challenged measures as relating to the production, importation, and approval of pharmaceutical products in particular as it relates to their inclusion in the Turkish scheme for reimbursing pharmacies for the purchase of such products by Turkey's citizens. Moreover, nothing in the DSU requires Members to restrict the scope of their disputes to limited or discrete sets of products.<sup>51</sup>

3.14. Finally, with respect to the legal instruments underpinning the measures, the Panel recognizes that the easiest way to identify a "specific measure at issue" would be by a reference to the name, number, date or place of promulgation of a particular law or regulation.<sup>52</sup> A panel request that does not specify the relevant law, regulation, or other legal instrument to which a claim relates, however, is not necessarily inconsistent with Article 6.2 of the DSU so long as it contains "sufficient information that effectively identifies the precise measures at issue".<sup>53</sup> As the Appellate Body has explained, a complainant need only frame the measure "with sufficient particularity so as to indicate the nature of the measure and the gist of what is at issue".<sup>54</sup> The Panel also recalls that there is no requirement that, in order to establish a panel's jurisdiction, a panel request must answer questions concerning the existence and content of the measures at issue and the consistency of such measures with the covered agreements. Rather, arguments and evidence on these questions will be developed progressively during the proceeding in the parties' written submissions and oral pleadings.<sup>55</sup> A complainant need not, therefore, list all the evidence it will use to support its arguments about the existence of the measure and how it operates in its panel request. The Panel, therefore, concludes that the narrative descriptions of the measures in the European Union's panel request are sufficient for purposes of compliance with Article 6.2 of the DSU, particularly in light of the fact that the European Union provided an illustrative list of relevant legal instruments that it contends put in place, evidence, implement, and administer the challenged measures.

### 3.2.2 The "as such" or "as applied" character of the prioritization measure

3.15. Turkey raises a separate issue with respect to the prioritization measure, arguing that the European Union did not specify whether it was challenging the measure "as such" or "as applied". Turkey considers that it is unclear from the European Union's narrative description of the prioritization measure, which refers to "certain cases where imported products are not excluded from the reimbursement scheme", whether the European Union challenges that measure "as such" or "as applied in certain cases" (i.e. individual instances of application).<sup>56</sup>

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<sup>49</sup> Appellate Body Reports, *US – Anti-Dumping Methodologies (China)*, para. 5.122 (referring to Appellate Body Report, *US – Corrosion-Resistant Steel Sunset Review*, para. 81); *Argentina – Import Measures*, para. 5.100; *US – Supercalendered Paper*, para. 5.17.

<sup>50</sup> Appellate Body Report, *EC – Chicken Cuts*, para. 165.

<sup>51</sup> For example, the dispute in *US – FSC* related to revenue foregone with respect to "foreign sales corporations" in the United States. The measure at issue applied to any sales of any products by qualifying companies.

<sup>52</sup> Appellate Body Report, *US – Continued Zeroing*, para. 168.

<sup>53</sup> Panel Report, *Canada – Wheat Exports and Grain Imports*, para. 6.10.

<sup>54</sup> Appellate Body Report, *US – Continued Zeroing*, para. 169.

<sup>55</sup> Appellate Body Report, *US – Continued Zeroing*, para. 169.

<sup>56</sup> Turkey's request for a preliminary ruling, paras. 45-46.

3.16. The European Union argues that the wording "as such" need not be used, so long as it is clear that an "as such" challenge is intended.<sup>57</sup> According to the European Union, the wording in the panel request describing the prioritization measure as giving "priority to the review of applications ... over the review of the applications of like imported products" "unambiguously" shows that the European Union is challenging a measure of "general and prospective application" (an "as such" challenge) not "specific instances" of application.<sup>58</sup> The European Union responds that Turkey's reading of the wording "certain cases" does not take account of the full wording of that sentence, which specifies that imported products that still benefit from the reimbursement scheme are discriminated against when compared with like domestic products. According to the European Union, that wording describes a challenge that is broader than addressing specific instances of application.<sup>59</sup>

3.17. The Panel agrees with the Appellate Body that the distinction between measures challenged "as such" and "as applied" does not govern the definition of a measure for purposes of WTO dispute settlement, nor does it exhaustively define the types of measures susceptible to challenge. These categories serve as analytical tools to facilitate the understanding of challenged measures; the measures need not fit squarely within these categories in order to be susceptible to WTO dispute settlement.<sup>60</sup> The Panel, therefore, is not of the view that there is an absolute requirement that a challenge to a particular measure be specified either "as such" or "as applied" in a panel request to satisfy the obligation in Article 6.2 to identify the specific measure at issue. Rather, such identification can aid in understanding the legal basis for the complaint and *how* the measure is alleged to be inconsistent with the relevant provisions of the covered agreements.

3.18. In the instant case, the Panel understands that the reference to "certain cases" in the panel request covers all instances where imported products are still eligible under the reimbursement scheme. This is confirmed by reading the panel request as a whole which includes the entire narrative on the prioritization measure as well as its relationship to the localisation requirement measure and the narrative description of that measure. This understanding is confirmed by the European Union's first written submission. The Panel, therefore, finds that Turkey has not established that the European Union's panel request is inconsistent with Article 6.2 on the basis that it did not specify the "as such" or "as applied" nature of its challenge to the prioritization measure.

### **3.2.3 Other instruments through which Turkey implements and administers the measures at issue**

3.19. Turkey argues that the terms "other instruments through which Turkey implements and administers the measures at issue", "implementing measures" and "other related measures" as used in the panel request are too vague and do not allow the specific instruments to be identified.<sup>61</sup> Turkey considers that the European Union should have identified any other sources or evidence of the measures "precisely".<sup>62</sup>

3.20. The European Union notes in its comments on Turkey's request for a preliminary ruling that the Panel can only decide on whether claims are within its terms of reference once those claims have been made, such that Turkey's "jurisdictional objection" to any "hypothetical claims" the European Union may or may not make should be rejected.<sup>63</sup> The European Union rejects the notion that certain terms may not be used in a panel request; rather, the terms of a panel request would need to be assessed reading the panel request as a whole in light of attendant circumstances.<sup>64</sup>

3.21. As noted above, the easiest way to identify a "specific measure at issue" would be a reference to the name, number, date or place of promulgation of a particular law or regulation.<sup>65</sup> Such a level of specificity is not required and sometimes may not be possible. Parties often use language similar

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<sup>57</sup> European Union's response to Turkey's request for a preliminary ruling, para. 70 (referring to Panel Report, *EC — Selected Customs Matters*, para. 7.62).

<sup>58</sup> European Union's response to Turkey's request for a preliminary ruling, para. 71.

<sup>59</sup> European Union's response to Turkey's request for a preliminary ruling, para. 73.

<sup>60</sup> Appellate Body Reports, *US — Anti-Dumping Methodologies (China)*, paras. 5.124-5.125; *US — Continued Zeroing*, para. 179; *Argentina — Import Measures*, para. 5.102; *US — Supercalendered Paper*, fn 64 to para. 5.17.

<sup>61</sup> Turkey's request for a preliminary ruling, paras. 50-53.

<sup>62</sup> Turkey's request for a preliminary ruling, para. 51.

<sup>63</sup> European Union's response to Turkey's request for a preliminary ruling, para. 75.

<sup>64</sup> European Union's response to Turkey's request for a preliminary ruling, para. 76.

<sup>65</sup> Appellate Body Report, *US — Continued Zeroing*, para. 168.

to that used by the European Union in its panel request to include unnamed measures within a panel's terms of reference. Panels have cautioned that the "mere incantation" of such phrases will not permit Members "to bring in measures that were clearly not contemplated in the Panel request".<sup>66</sup> At the same time, the use of such terms in a panel request is not necessarily so vague as to *exclude* all other instruments from falling within the scope of a panel's mandate. In this respect, panels have examined measures not yet in force or concluded on the date of the panel request, measures that the complainants were not yet aware of, such as government procedures not yet published that have the same essential effect as the measures that were specifically identified, and others.<sup>67</sup>

3.22. At this point in time, the Panel finds Turkey's arguments to be premature. The Panel can only determine whether the language is sufficient if and when such measures are actually raised before the Panel. The Panel will, of course, make any such determination by reading the panel request as a whole and in light of the attendant circumstances once such measures are actually raised before it. The Panel will not make a finding that the European Union's panel request fails to identify the specific measures at issue simply because of the use of this language.

### **3.3 Whether the European Union's panel request provided the legal basis of the complaint sufficient to present the problem clearly**

3.23. In addition to requiring that the specific measures at issue be identified, Article 6.2 of the DSU obliges complaining Members to present a brief summary of the legal basis of the complaint sufficient to present the problem clearly. Members comply with this obligation by plainly connecting the challenged measures with the provisions of the covered agreements claimed to have been infringed. In this way the responding party is aware of the legal basis for the alleged nullification or impairment of the complaining party's benefits and thereby knows the case it has to answer and can begin to prepare its defence.<sup>68</sup>

3.24. The "legal basis" of the complaint is commonly understood to mean "the claims".<sup>69</sup> A "claim" in the WTO context has been described as "a claim that the respondent party has violated, or nullified or impaired the benefits arising from, an identified provision of a particular agreement".<sup>70</sup> This requirement in Article 6.2 may not be satisfied by a "mere listing of the articles of an agreement alleged to have been breached", especially if a particular article contains more than one obligation.<sup>71</sup> At the same time, complying with the requirement to present the problem clearly does not require a complainant to set out its legal case in full in a panel request. Rather, "Article 6.2 demands only a summary – and it may be a brief one – of the legal basis of the complaint".<sup>72</sup> Moreover, the Appellate Body has repeatedly stated that "Article 6.2 of the DSU requires that the claims, but not the arguments, must all be specified sufficiently in the request for the establishment of a panel".<sup>73</sup> This distinction is important. Arguments are contained in the parties' written submissions and in their oral presentations during substantive meetings with a panel and, unlike the claims, need not be presented in a panel request.

#### **3.3.1 Article X:1 of the GATT 1994**

3.25. Turkey submits that the European Union's reference to non-publication of "certain elements, terms and conditions of general application" in its panel request is too vague and does not explain how or why the localisation requirement (or parts of it) is inconsistent with Article X:1. Turkey argues that because the panel request fails to plainly connect the localisation requirement with Article X:1, it is "impossible" for Turkey to know the case it has to answer and prepare its defence.<sup>74</sup>

<sup>66</sup> Panel Report, *EC – IT Products*, para. 7.140.

<sup>67</sup> Panel Report, *EC – IT Products*, para. 7.140. See also Appellate Body Reports, *Chile – Price Band System*, paras. 139 and 144; *US – Zeroing (21.5 - Japan)*, para. 116.

<sup>68</sup> Appellate Body Report, *US – Oil Country Tubular Goods Sunset Reviews*, para. 162.

<sup>69</sup> Appellate Body Report, *Guatemala – Cement I*, para. 72.

<sup>70</sup> Appellate Body Report, *Korea – Dairy*, para. 139.

<sup>71</sup> Appellate Body Report, *Korea – Dairy*, para. 123.

<sup>72</sup> Appellate Body Report, *Korea – Dairy*, para. 120.

<sup>73</sup> Appellate Body Report, *EC – Bananas III*, para. 143. For recent iterations, see Communication from the Panel, *India – Agricultural Products*, para. 3.80; Appellate Body Report, *US – Countervailing Measures (China)*, para. 4.8.

<sup>74</sup> Turkey's request for a preliminary ruling, para. 60.

3.26. The European Union recalls that the requirement to present the problem clearly does not require a complainant to provide arguments in support of its claims, which are to follow progressively in later submissions and panel meetings. It considers that to require a description of the "precise and specific manner in which certain elements, terms and conditions of the localization requirement... are inconsistent with Article X:1" would amount to requiring arguments in a panel request.<sup>75</sup>

3.27. The Panel recalls that what is sufficient to "plainly connect" the measure with the provision of the covered agreements claimed to have been infringed depends on the circumstances of each case, including such factors as the nature of the measure at issue, the manner in which it is described in the panel request, and the nature of the provision of the covered agreements alleged to have been breached.<sup>76</sup>

3.28. The Panel notes, in particular, the nature of Article X:1 of the GATT 1994 which requires the publication of measures of general application so that traders can become familiar with their contents and that the European Union's claim pertains to the *non*-publication of certain elements, terms and conditions of general application of the localisation requirement measure. Although, the reference to "certain elements, terms and conditions of general application" in the European Union's panel request is general, the Panel is cognizant that in the context of a claim of non-publication it can be difficult for a complainant to cite a particular instrument or parts thereof. The Panel recalls that the European Union has described the localisation requirement measure in narrative form in its panel request and listed certain *published* instruments as well. The combination of these two elements in the request provides adequate notice to Turkey what elements, terms and conditions of general application could be covered by the European Union's allegation that they were *not published*. Moreover, the Panel recalls that in providing the legal basis of the complaint, a panel request need not set out "arguments"<sup>77</sup>, i.e. statements made in order "to demonstrate that the responding party's measure does indeed infringe upon the identified treaty provision".<sup>78</sup>

3.29. In light of the above, the Panel considers that, although the reference to "certain elements, terms and conditions of general application" in the panel request is general, it provided adequate notice to Turkey regarding the legal basis of the European Union's claim sufficient to present the problem clearly.

### 3.3.2 Article 3.1(b) of the SCM Agreement

3.30. Turkey argues that merely referring to Articles 1.1 and 3.1(b) of the SCM Agreement is not sufficient to present the problem clearly under Article 6.2, given the circumstances of this dispute and the nature of the provisions alleged to have been breached.<sup>79</sup> In particular, Turkey asserts that the panel request does not explain how or why the reimbursement scheme under the "Turkish social security system" "involves" the granting of a subsidy, and that it fails to identify the beneficiaries of the subsidy, or what constitutes the subsidy.<sup>80</sup> Turkey argues that the panel request should have specified the type of financial contribution, from the list provided in Article 1.1, it is alleged to have offered. Turkey maintains that without this level of specificity it is "left in the dark" as to the measure it has to defend.<sup>81</sup>

3.31. The European Union responds that its panel request refers to and describes the reimbursement scheme, localisation requirement and how they interact in sufficient detail. The European Union considers that it is clear from the panel request and understood by Turkey, that it

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<sup>75</sup> European Union's response to Turkey's request for a preliminary ruling, paras. 87, and 90-95. See also European Union's comments on Turkey's comments on European Union's response to Turkey's request for a preliminary ruling, para. 53.

<sup>76</sup> See Appellate Body Reports, *US – Countervailing Measures (China)*, para. 4.9; *Korea – Pneumatic Valves (Japan)*, para. 5.6.

<sup>77</sup> Appellate Body Reports, *China – HP-SSST (Japan) / China – HP-SSST (EU)*, para. 5.14. See also Appellate Body Report, *US – Countervailing Measures (China)*, para. 4.9.

<sup>78</sup> Appellate Body Reports, *China – HP-SSST (Japan) / China – HP-SSST (EU)*, para. 5.14 (quoting Appellate Body Report, *Korea – Dairy*, para. 139); *Korea – Pneumatic Valves (Japan)*, para. 5.6. See also Panel Reports, *US – Large Civil Aircraft (2<sup>nd</sup> complaint) (Article 21.5 – EU)*, para. 7.318, *India – Export Related Measures*, para. 2.15.

<sup>79</sup> Turkey's request for a preliminary ruling, para. 66 (quoting Appellate Body Reports, *Korea – Pneumatic Valves (Japan)*, para. 5.9 and *Russia – Railway Equipment*, para. 5.28).

<sup>80</sup> Turkey's request for a preliminary ruling, paras. 6.

<sup>81</sup> Turkey's request for a preliminary ruling, para. 66.

does not challenge the reimbursement scheme *per se*, but that the reimbursement scheme confers a subsidy that is prohibited by virtue of the localisation requirement. Moreover, as the localisation requirement is the "element" that violates Article 3.1(b) of the SCM Agreement, the European Union submits it would have been "inaccurate and misleading" to identify the reimbursement scheme as a distinct measure challenged.<sup>82</sup>

3.32. The Panel first notes that the narrative description of the localisation requirement measure explains that it requires companies to produce pharmaceuticals locally in Turkey to qualify for inclusion in the reimbursement scheme under Turkey's social security system. The description of the legal basis for the complaint notes that the reimbursement scheme includes the granting of a subsidy and that the localisation requirement measure would, according to the European Union, make that subsidy contingent upon the use of domestic over imported products. The Panel also recalls that in Annex A to its consultations request, pursuant to Article 4.2 of the SCM Agreement, the European Union provided a statement of available evidence with respect to the existence and nature of the subsidy. That statement lists 17 legal instruments and two broader categories of other evidence, namely (i) a series of seven public announcements informing that certain imported medicines would no longer be reimbursed, and (ii) a broader reference to other instruments through which Turkey implements and administers the alleged measures at issue. This list overlaps with 19 out of the 23 "legal and other instruments" listed in the panel request.<sup>83</sup> We note that at least seven of these legal instruments refer broadly to the underlying reimbursement scheme (through references to "reimbursement policies", "reimbursement system", "reimbursement procedures", "reimbursement principles" etc.). We consider this an important "attendant circumstance" in terms of whether Turkey was given adequate notice of the subsidy that is relevant to the European Union's claim.

3.33. The Panel is of the view that the European Union is not required to identify the subsidy as a challenged measure if it is not challenging the subsidy *per se*, but rather one particular element of the broader reimbursement scheme. The Panel sees nothing in the European Union's panel request to indicate that the European Union is arguing that the reimbursement scheme *writ large* is inconsistent with any element of the SCM Agreement. Rather, its claim is narrowly focused on alleged limits on the eligibility for that subsidy based on whether the product is produced domestically or imported. The Panel also recalls that a panel request need not address the arguments and evidence in respect of whether a particular covered agreement is applicable and whether the measure at issue is inconsistent with a provision of that agreement. The Panel, therefore, does not consider that the European Union is required to demonstrate in the panel request how the reimbursement scheme falls within the definition of a subsidy in Article 1.1 of the SCM Agreement. The Panel finds the explanation of the legal basis for the complaint under Article 3.1(b) of the SCM Agreement presents the problem clearly within the meaning of Article 6.2 of the DSU.

## 4 CONCLUSION

4.1. In sum, the Panel finds that:

- a. Turkey's request for a preliminary ruling was not untimely;
- b. the localisation requirement measure, alleged import ban, and prioritization measure were identified with sufficient specificity to comply with Article 6.2 of the DSU when reading the panel request on its face, as a whole, and in light of the attendant circumstances; and
- c. the European Union 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

<sup>82</sup> European Union's response to Turkey's request for a preliminary ruling, para. 98. See also European Union's comments on Turkey's comments on European Union's response to Turkey's request for a preliminary ruling, paras. 57-60.

<sup>83</sup> Compared to the list in Annex A to the consultations request, the panel request refers to four additional legal instruments. The panel request specifies that "[f]or greater clarity", each of these instruments "puts in place and evidences the measures already identified and included in the request for consultations by the European Union in this dispute and explained below" (European Union's panel request, footnotes 18, 19, 20, and 21).

GATT 1994 and Article 3.1(b) of the SCM Agreement. Both claims, therefore, are properly within the Panel's terms of reference.

4.2. The Panel reminds the parties that a conclusion that a measure or claim is within its terms of reference does not equate to a finding that the European Union has sufficiently established the existence and nature of the measure, the applicability of the relevant provisions of the covered agreements, or the inconsistency of Turkey's measures with those agreements. The Panel agrees with the panel in *Thailand – H Beams*, that a finding that a panel request complies with the requirements in Article 6.2 "does not relate directly to the sufficiency" of the parties' subsequent written and oral arguments "nor does it determine whether the complaining party will manage to establish a *prima facie* case of violation during panel proceedings".<sup>84</sup> The Panel will carefully scrutinize the arguments and evidence adduced by the parties during the proceedings before reaching any conclusions on the substance of the matter before it.

4.3. Finally, we recall that the standard of Article 6.2 of the DSU is not perfection. A panel request will satisfy the requirement in Article 6.2 to identify the specific measures at issue if such measures are discernible from the panel request.<sup>85</sup> The European Union's panel request in this case satisfies this standard. At the same time, "[p]arties to disputes must not leave it to panels to divine the identity of measures at issue"<sup>86</sup> or the legal basis of their claims. The Panel notes that the drafting of consultations and panel requests are entirely within the power of the complaining Member and there are no time limits that would require a rushed process.<sup>87</sup> Although the Panel finds that the panel request in this case has met the minimum requirements of Article 6.2, procedures such as this one can be avoided if complaining Members are more precise in the drafting of their requests. Such increased precision would be consistent with the principle that Members should participate in dispute settlement in good faith and aid in the prompt and orderly resolution of disputes while ensuring the protection of all parties' due process rights.

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<sup>84</sup> Panel Report, *Thailand – H-Beams*, para. 7.43. See also Panel Report, *US – Gambling*, Annex B, para. 39.

<sup>85</sup> Appellate Body Report, *US – Continued Zeroing*, para. 170.

<sup>86</sup> Appellate Body Report, *Ukraine – Ammonium Nitrate (Russia)*, para. 6.37.

<sup>87</sup> See Panel Report, *China – Publications and Audiovisual Products*, para. 7.58.

**ANNEX B**

## COMMUNICATIONS REGARDING THE IMPACT OF THE COVID-19 PANDEMIC ON THE PROCEEDINGS

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**ANNEX B-1**

## COMMUNICATION FROM THE PANEL

**12 August 2020**

Dear representatives of the parties,

At the time that it adopted the Working Procedures for this dispute, the Panel indicated that if any change to the proceedings were to become necessary because of the COVID-19 pandemic, the Panel would amend the Working Procedures following consultation with the parties. In a 10 July 2020 communication to the parties, the Panel noted that the travel restrictions in place at that time would restrict travel to Geneva by some participants in the proceedings. The Panel stated that it would continue to monitor developments with respect to travel restrictions with a view to confirming or consulting further with the parties, by the middle of August, on the timing of the first substantive meeting currently scheduled for 22-24 September 2020. The Panel invited the parties to provide their views on how the Panel should proceed if the current restrictions were to remain in place, and they did so on 17 July 2020.

As the parties are aware, there has been an upsurge in COVID-19 cases across many countries. Entry into Switzerland is still not permitted from most countries outside of the EU/Schengen area. Under the current Swiss travel restrictions, two of the three panelists would be prevented from travelling to Geneva, and key members of the parties' delegations may also be impacted. Furthermore, travel restrictions taken by countries of departure/return in the light of the upsurge in COVID-19 cases could further impact on the participants' ability to travel to Switzerland. While the situation is fluid, there have been no recent additions to the small list of non-EU/Schengen countries exempted from the Swiss travel restrictions. The Secretariat has received no indication that any significant change to the Swiss travel restrictions is to be expected in the near future.

**Accordingly, the Panel concludes that, based on the information available at this time, it will not be possible to hold an in-person first substantive meeting on 22-24 September 2020.**

In their letters of 17 July 2020, both parties proposed that if an in-person meeting is impossible in September, the first substantive meeting should be postponed to a later date. In this connection, Turkey indicated that "[h]earings conducted in person and in the presence of all three Panelists, of the delegations of both parties to the dispute, and of the Secretariat team, are an invaluable part of a WTO dispute settlement process."

At the same time, both parties agreed that the Panel should conduct the proceedings in a manner that avoids undue delay. More specifically, the European Union proposed that the Panel should amend its Working Procedures to have just one substantive meeting with the parties in person, and have the parties file their second written submissions prior to that meeting. The meeting could possibly be preceded by an exchange of written questions and answers. The European Union suggested that the postponed first substantive meeting could be held on the dates for which the second substantive meeting with the parties had already been scheduled, i.e. 12-13 January 2021.

The Panel agrees with the parties that the postponement of an in-person first substantive meeting should not delay the conduct of the proceeding. The Panel is also mindful that having an exchange of the parties' first and second written submissions prior to the substantive meeting is the well-established procedure in the context of compliance panel proceedings under Article 21.5 of the DSU. In the circumstances of this dispute, the Panel sees no legal impediment under the DSU to amending its Working Procedures and Timetable to provide for the parties to exchange their first and second written submissions prior to the first substantive meeting. At the same time, the Panel does not wish to foreclose the possibility of holding a second substantive meeting with the parties and considers that the exchange of second written submissions prior to the first substantive meeting should be without prejudice to that question.

Accordingly, the Panel proposes to modify its Working Procedures to provide that the parties will file their second written submissions prior to the rescheduled first substantive meeting (change to

para. 3(2) of the Working Procedures), and to provide that the Panel may hold a second substantive meeting with the parties if so requested by either party (see para. 15). The modifications to the Working Procedures include a clarification that the third parties would receive the parties' rebuttal submissions (see para. 30(e)).

The Panel also proposes to suspend all dates in the current Timetable, and adopt a new partial timetable to provide that:

- the European Union shall file its second written submission on Monday, 21 September 2020;
- Turkey shall file its second written submission on Monday, 16 November 2020;
- the first substantive meeting with the parties will be scheduled for 12-13 January 2021, with the third-party session scheduled for the morning of 13 January, on the understanding that the Panel will consult with the parties at the end of November 2020 on the dates and modalities for the conduct of the first substantive meeting, and determine at least one month prior to the hearing whether, in the light of the circumstances prevailing then, it is possible to proceed with an in-person meeting on those dates;
- the Panel will fix the dates for any written questions or answers prior to the first substantive meeting in conjunction with consulting with the parties by the end of November on the dates and modalities for the conduct of the first substantive meeting;
- all remaining dates in the timetable, including the dates for any second substantive meeting with the parties, are left "To Be Determined" pending further consultation with the parties at or following the first substantive meeting.

Revised versions of the Working Procedures and the Timetable, reflecting the suggested modifications, are attached to this communication.

**The Panel requests that the parties provide any comments on these modifications to the Working Procedures and Timetable by 5 p.m. on Friday, 14 August 2020, with a view to enabling the Panel to finalize its amended Working Procedures and Timetable and transmit them to the parties and the third parties.**

Best regards,

Gudmundur Helgason  
*Chairman of the Panel*

**ANNEX B-2**

## COMMUNICATION FROM THE PANEL

**25 August 2020**

Dear representatives of the parties and third parties,

At the time that it adopted the Working Procedures for this dispute, the Panel indicated that if any change to the proceedings were to become necessary because of the COVID-19 pandemic, the Panel would amend the Working Procedures following consultation with the parties. In a 10 July 2020 communication to the parties, the Panel noted that the travel restrictions in place at that time would restrict travel to Geneva by some participants in the proceedings. The Panel stated that it would continue to monitor developments with respect to travel restrictions with a view to confirming or consulting further with the parties, by the middle of August, on the timing of the first substantive meeting currently scheduled for 22-24 September 2020. The Panel invited the parties to provide their views on how the Panel should proceed if the current restrictions were to remain in place, and they did so on 17 July 2020.

As the parties and third parties are aware, there has been an upsurge in COVID-19 cases across many countries. Entry into Switzerland is still not permitted from most countries outside of the EU/Schengen area. Under the current Swiss travel restrictions, two of the three panelists would be prevented from travelling to Geneva, and key members of the parties' delegations may also be impacted. Furthermore, travel restrictions taken by countries of departure/return in the light of the upsurge in COVID-19 cases could further impact on the participants' ability to travel to Switzerland. While the situation is fluid, there have been no recent additions to the small list of non-EU/Schengen countries exempted from the Swiss travel restrictions. The Secretariat has received no indication that any significant change to the Swiss travel restrictions is to be expected in the near future.

**Accordingly, the Panel concludes that, based on the information available at this time, it will not be possible to hold an in-person first substantive meeting on 22-24 September 2020.**

In their letters of 17 July 2020, both parties proposed that if an in-person meeting is impossible in September, the first substantive meeting should be postponed to a later date. In this connection, Turkey indicated that "[h]earings conducted in person and in the presence of all three Panelists, of the delegations of both parties to the dispute, and of the Secretariat team, are an invaluable part of a WTO dispute settlement process."

At the same time, both parties agreed that the Panel should conduct the proceedings in a manner that avoids undue delay. More specifically, the European Union proposed that the Panel should amend its Working Procedures to have just one substantive meeting with the parties in person, and have the parties file their second written submissions prior to that meeting. The meeting could possibly be preceded by an exchange of written questions and answers. The European Union suggested that the postponed first substantive meeting could be held on the dates for which the second substantive meeting with the parties had already been scheduled, i.e. 12-13 January 2021.

The Panel agrees with the parties that the postponement of an in-person first substantive meeting should not delay the conduct of the proceeding. The Panel is also mindful that having an exchange of the parties' first and second written submissions prior to the substantive meeting is the well-established procedure in the context of compliance panel proceedings under Article 21.5 of the DSU. In the circumstances of this dispute, the Panel sees no legal impediment under the DSU to amending its Working Procedures and Timetable to provide for the parties to exchange their first and second written submissions prior to the first substantive meeting. At the same time, the Panel does not wish to foreclose the possibility of holding a second substantive meeting with the parties and considers that the exchange of second written submissions prior to the first substantive meeting should be without prejudice to that question.

Accordingly, in a communication to the parties on 12 August 2020, the Panel proposed to modify its Working Procedures to provide that the parties will file their second written submissions prior to the

rescheduled first substantive meeting (change to para. 3(2) of the Working Procedures), and to provide that the Panel may hold a second substantive meeting with the parties if so requested by either party (see para. 15). The modifications to the Working Procedures include a clarification that the third parties would receive the parties' rebuttal submissions (see para. 30(e)).

The Panel also proposed to suspend all dates in the current Timetable, and adopt a new partial timetable setting out the dates for the parties' rebuttal submissions and a provisional date of 12-13 January 2021 for the first substantive meeting.

In their comments, neither party objected to the proposed procedure. However, the European Union requested that the Panel extend the proposed deadline for filing its second written submission, from 21 September 2020 to 30 October 2020. In its comments, Turkey indicated that if the proposed deadline for the European Union's second written submission were to be extended, then the deadline for Turkey's second written submission would also have to be extended accordingly.

The Panel has decided to grant the European Union's request to extend the deadline for its second written submission, from 21 September 2020 to **30 October 2020**. The Panel accordingly extends the deadline for Turkey's second written submission from 16 November 2020 to **29 January 2021**.

Revised versions of the Working Procedures and the Timetable, reflecting the modifications adopted by the Panel on today's date, are attached to this communication.

Best regards,

Gudmundur Helgason  
*Chairman of the Panel*

**ANNEX B-3**

**COMMUNICATION FROM THE PANEL**

**3 February 2021**

Dear representatives of the parties,

In a communication to the parties on 10 July 2020 regarding the timing of the first substantive meeting, the Panel noted that the travel restrictions in place at that time would restrict travel to Geneva by some participants and invited the parties to provide their views on how the Panel should proceed if the restrictions were to remain in place. In their letters of 17 July 2020, both parties proposed that, if it would be impossible to hold an in-person first substantive meeting as initially scheduled on 22-24 September 2020, the first substantive meeting should be postponed to a later date. The parties also agreed that the Panel should conduct the proceedings in a manner that avoids undue delay.

In a communication to the parties and third parties on 25 August 2020, the Panel confirmed that it would not be possible to hold an in-person first substantive meeting on 22-24 September 2020 because of the travel restrictions that remained in place. The Panel agreed with the parties that the postponement of an in-person first substantive meeting should not delay the conduct of the proceedings. After consultation with the parties, the Panel adopted a new partial Timetable setting out the dates for the parties' rebuttal submissions and a provisional window for the timing of the first substantive meeting.

The partial Timetable, as revised on 25 August 2020, states that the provisional window for the timing of the rescheduled first substantive meeting is March/April 2021, "pending further developments in terms of the pandemic and ongoing travel restrictions". The revised partial Timetable also states that the Panel expects to consult with the parties on the dates/modalities for the conduct of the first substantive meeting after receiving the parties' second written submissions.

As the parties are aware, there has been a recent upsurge in COVID-19 cases across many countries, including Switzerland. Entry into Switzerland is currently restricted and a number of countries imposes travel restrictions upon return. In addition, meetings of more than five people, such as an in-person substantive meeting of the Panel with the parties and third parties, are currently prohibited in Switzerland until at least the end of February 2021. The Secretariat has to date received no indication of whether or how these restrictions may then be extended or amended.

Based on the information available at this time, the Panel thus considers that it will not be possible for the participants in these proceedings to plan to hold an in-person first substantive meeting (including the third-party session) within the March/April 2021 provisional window for the timing of the rescheduled first substantive meeting.

Accordingly, and in keeping with the parties' agreement that the Panel should conduct the proceedings in a manner that avoids undue delay, the Panel proposes to hold a first substantive meeting with the parties (including third party session) in the form of a virtual meeting. The Panel is informed by the Secretariat that virtual meetings have of late been conducted in numerous other panel proceedings. The Panel proposes to hold this virtual first substantive meeting during the period **12-16 April 2021** or, alternatively, **19-23 April 2021**.

**The Panel requests that the parties provide any comments they may have on the possibility of holding a virtual first substantive meeting and the feasibility of these suggested dates, by no later than 5 p.m. on 10 February 2021.**

Best regards,

Gudmundur Helgason  
*Chairman of the Panel*

**ANNEX B-4**

COMMUNICATION FROM THE PANEL

**17 February 2021**

The Panel thanks the parties for their comments on the possibility of holding the first substantive meeting in virtual format in April, as suggested by the Panel in its communication of 3 February 2021.

The Panel has given due regard to Turkey's suggestion to delay the first substantive meeting until June or July, so that it could be conducted in-person. However, the Panel considers that it is highly uncertain whether conditions for an in-person meeting in Geneva will prevail by June or July 2021. The infection rate in Europe remains high and the vaccination process is still at an early stage.

Accordingly, the Panel has decided to proceed by holding a first substantive meeting with the parties (including a third-party session) in virtual format, during the week of 19-23 April 2021.

As suggested by both parties, the Panel will provide for an exchange of written questions and answers in advance of the first substantive meeting.

The Panel will consult with the parties in due course on issues regarding the organization of the first substantive meeting, including logistical issues and the conduct of any question and answer sessions. The Panel will endeavour to adopt procedures enabling the effective participation of the parties in an interactive exchange, taking into account the comments already received from the parties.

As indicated in the partial revised timetable adopted by the Panel on 25 August 2020, the Panel will consult with the parties on subsequent steps in the timetable, including any second substantive meeting, at or following the first substantive meeting.

Best regards,

Gudmundur Helgason  
*Chairman of the Panel*

## **ANNEX B-5**

### COMMUNICATION FROM THE PANEL

#### **25 February 2021**

Dear representatives of the parties,

In its 17 February 2021 communication to the parties, the Panel indicated that it would provide for an exchange of written questions and answers in advance of the first substantive meeting, and consult with the parties in due course on issues regarding the organization of the first substantive meeting, including logistical issues and the conduct of any question and answer sessions.

The Panel recognizes that a virtual hearing imposes limitations on the ability of the parties, as well as the Panel itself, to respond in real-time to any issues requiring internal coordination and consultation. This consideration informed the Panel's decision to provide for an exchange of written questions and answers in advance of the first meeting, which may be expected to limit the number of oral questions from the Panel at the meeting.

The Panel considers that the effective participation of the parties and other participants in the meeting can also be served by:

- scheduling the meeting spread out over several days, between the hours of 15h00-18h00 (Geneva time), to shorten the duration of the daily exchanges and thereby allow the parties and third parties sufficient time for internal coordination and consultation outside of those hours;
- making the interactive/Q&A session primarily an opportunity for the parties to comment on the other's opening statement and to comment on the other's written responses to the pre-meeting written questions from the Panel;
- ensuring that the parties and third parties have sufficient time to prepare their written responses and also that the responses are received sufficiently in advance of the meeting to enable the parties and third parties to provide meaningful comments;
- ensuring that any oral questions which the Panel or the parties intend to pose are transmitted to the parties and third parties, as appropriate, in writing sufficiently well in advance of the interactive/Q&A session;
- scheduling the third-party session to take place in between the delivery of the opening statements and the interactive/Q&A session with the parties so as to afford the parties more time to prepare comments on one another's oral statements; and
- allocating to the parties for their closing statements more time (45 minutes) than is typically the case in a panel meeting, thereby allowing either party to use its closing statement as an opportunity to deliver prepared comments on the other party's opening statement, third-party oral statements, or the other party's oral comments during the interactive/Q&A session.

The Panel's proposed approach for conducting the first substantive meeting is reflected in the attached procedures and timetable which include:

- Proposed revisions to the Working Procedures to modify the provisions governing the conduct of the first substantive meeting with the parties and the third-party session;
- Protocol for logistical aspects of the virtual hearing; and
- Proposed revisions to the partial timetable, including dates for the written exchange prior to the meeting, and a proposed schedule for the sessions during the week of 19-23 April 2021.

The Panel trusts that most of the proposed revisions to the Working Procedures, as reflected in track changes, are largely self-explanatory. For greater clarity:

- The Panel notes that there are limitations on the possibility for providing interpretation through a virtual meeting platform. Moreover, neither of the parties requested interpretation at the organizational phase, and no third party made any request for interpretation after receiving the working procedures, as envisaged by paragraphs 14 and 20 of the Working Procedures adopted by the Panel. The attached Working Procedures are adjusted accordingly.
- The Panel proposes allocating each party 75 minutes for its opening statement. If either party considers that it requires more (or substantially less) time for its opening statement, it is invited to so indicate in the context of providing its comments on these proposed Working Procedures (rather than at the later date typically provided for in paragraph 15(b) of the Working Procedures).

The Protocol for logistical aspects of the virtual hearing is similar to the procedures adopted in other panel proceedings. Paragraph 17 makes explicit that the Panel may pause a session at any time, at its own initiative or upon request by a party, to enable any necessary internal coordination and consultation within a party's delegation and/or among the panelists.

As regards the proposed timetable:

- Given the time differences affecting the panelists and the representatives of the parties (the week of 19-23 April 2021 will span the nine-hour time difference of GVA – 7 hrs to GVA + 2 hrs), the timetable proposes sessions between the hours of 3 pm – 6 pm (Geneva time).
- In its 17 February 2021 communication, the Panel indicated that at or following the first substantive meeting, it would consult with the parties on the steps in the timetable subsequent to the first substantive meeting, including any second substantive meeting. The proposed revisions to the partial timetable include proposed dates for the Panel and the parties to send written questions following the meeting, and for the parties and third parties to provide their written responses (with corresponding dates in the revised Working Procedures). The Panel is proposing such dates at this juncture on the understanding that it may assist the parties and third parties with their planning, and that fixing dates for these steps would not prejudice whether to hold a second substantive meeting. However, should either party prefer to not include the dates for these steps in the current revision of the timetable and Working Procedures at this time, it may so indicate in its comments on the attached timetable and Working Procedures and the Panel will leave them "TBD" until it consults with the parties on the timetable at the first substantive meeting.

As reflected in the attached procedures and timetable, the Panel proposes to send its advance written questions to the parties and third parties on 8 March 2021. Accordingly, with a view to finalizing arrangements for the conduct of the first substantive meeting and the timetable for the written exchange of questions and answers, which are to some extent interlinked, the Panel hereby invites the parties to provide, **no later than 3 March 2021**, any comments they may have on the Panel's proposed approach as reflected in these proposed procedures and timetable.

Best regards,

Gudmundur Helgason  
*Chairman of the Panel*

**ANNEX B-6**

## COMMUNICATION FROM THE PANEL

**5 March 2021**

Dear representatives of the parties,

The Panel thanks the parties for their comments on the proposed revisions to the partial Timetable, revisions to the Working Procedures, and Protocol for logistical aspects of the virtual meeting. The Panel does not consider it necessary to make the changes suggested by the parties for the following reasons:

- With respect to Turkey's request to change the schedule of the daily meeting sessions, between 3pm – 6pm (Geneva time) to 2pm – 5pm (Geneva time), Turkey's request appears to be premised on the current +2 hour time difference between Geneva and Ankara. However, while Geneva is currently 2 hours ahead of Ankara, the Secretariat advises that, by the week of 19-23 April, the time difference between Geneva and Ankara will only be +1 hour. If this is correct, then it is not necessary to make any change to the proposed meeting hours in order to accommodate Turkey's concern. The Panel notes that the meeting hours being between 3pm – 6pm are in any event an indicative time, and the actual duration of each daily session will be a function of the length of the parties' opening statements (Tuesday), the number of third party statements (Wednesday), the length of the parties' comments/responses to questions (Thursday), and the length of their closing statements (Friday).
- With respect to Turkey's request to provide for the possibility for interpretation, the Panel notes that the relevant provision of the Working Procedures is only directed to situations involving the simultaneous interpretation offered by the WTO Secretariat into one or more of the other official WTO languages. As there has been no request for interpretation into French or Spanish in this case, the relevant sentence in paragraph 15(a) can be deleted (it concerns providing paper copies of opening statements to WTO interpreters to facilitate live interpretation, into one or both of the other official WTO languages, for other parties or third parties participating in the session). The Panel notes that the Secretariat does not provide interpretation of a panel meeting into any language that is not one of the three official WTO languages. Insofar as Turkey wishes for its delegation to include its own interpreter, so that it can conduct simultaneous interpretation for certain members of its delegation, it is free to do so. The Secretariat will liaise with Turkey on any associated technical limitations with Webex in the context of assisting the parties on technical and logistical aspects of the virtual meeting.
- Paragraph 15(e) of the revised Working Procedures provides that "The parties and the Panel shall transmit any questions they expect to pose orally by no later than 16 April 2021. If the parties' opening statements raise any additional issues that the Panel wishes to address through oral questions, the Panel will transmit those questions in writing sufficiently well in advance of the interactive/Q&A session with the parties." As indicated in the Communication to the parties of 25 February 2021, the Working Procedures have the objective of "ensuring that any oral questions which the Panel or the parties intend to pose are transmitted to the parties and third parties, as appropriate, in writing sufficiently well in advance of the interactive/Q&A session" – which, as the Panel recalls, is scheduled for Thursday, 22 April 2021.
  - In its comments, Turkey requests that the oral questions be sent no later than Wednesday, 14 April 2021, otherwise it "leaves the parties with little time to prepare" because the meeting itself starts on Monday, 19 April 2021. The Panel does not agree that sending questions that the Panel expects to pose orally six days in advance of the interactive/Q&A session, scheduled for Thursday, 22 April 2021, leaves little time for the parties to prepare, especially taking into account that the Panel only expects to meet with the parties for up to one hour on Monday, and for sessions that should not last more than 3 hours each on the Tuesday and

Wednesday. Furthermore, as already indicated in the Panel's Communication of 25 February 2021, its "decision to provide for an exchange of written questions and answers in advance of the first meeting ... may be expected to limit the number of oral questions from the Panel at the meeting."

- In its comments, the European Union stresses that the working procedures "should not preclude either the Panel or the parties from asking questions that were not sent out in advance". Bearing in mind the virtual nature of the meeting and any ensuing physical constraints on internal coordination and consultation within each party's delegation, the Panel considers it appropriate to transmit questions to the parties in advance of the interactive Q&A session with the parties. Further, as drafted, the revised Working Procedures allow the parties to comment on one another's opening statements, including any issues that were not covered by any questions sent out in advance. Thus, the Panel does not see the need to add the words "endeavour to" in the places suggested by the European Union. For the same reasons, the Panel does not consider that the reference to "follow-up" questions in paragraph 9 unduly circumscribes the Panel's discretion in the manner that might be implied by the European Union's suggested drafting change.

However, to avoid any misunderstanding, the Panel has made a small revision to fully align the wording of item 18 of the partial Timetable to paragraph 15(e) of the Working Procedures, so that item 18, regarding questions sent by Friday, 16 April, indicates: "Panel and parties to transmit **any** questions that will be posed orally during the first substantive meeting (including third-party session)". The Panel has also made a small revision of item 17 of the partial Timetable, setting the deadline for the third parties' written responses to the Panel's written questions to 29 March 2021, in alignment with the deadline for the parties' written responses to the Panel's written questions.

Turkey points out that the Protocol for logistical aspects of the virtual hearing indicates 5 April instead of 6 April (the date indicated in the revised Working Procedures) as the deadline for the parties and third parties to transmit their delegation lists and for any third party to indicate whether it intends to make an oral statement at the meeting. The correct date is 6 April, and the necessary change has been made to the Protocol.

The revised partial Timetable and revised Working Procedures, as well as the Protocol, are hereby adopted.

As indicated in the partial Timetable, the Panel will transmit its advance written questions to the parties and third parties on Monday, 8 March 2021.

A separate communication will be sent to the third parties.

Best regards,

Gudmundur Helgason  
*Chairman of the Panel*

**ANNEX B-7**

## COMMUNICATION FROM THE PANEL

**3 May 2021**

The Panel recalls that it adopted the most recent version of its revised partial Timetable on 5 March 2021. This partial Timetable provided that the Panel would send a second set of written questions following the first substantive meeting scheduled for 20-23 April 2021 and set the deadline of 28 May 2021 for the parties' written responses to these questions. This partial Timetable left all remaining steps, including the date of any second meeting, to be determined following further consultation with the parties.

The Panel recalls that Paragraph 15 of its Working Procedures provides that it "shall hold at least one substantive meeting with the parties. Upon request by either party, the Panel may hold a second substantive meeting with the parties." At the substantive meeting held in April, the Panel invited the parties to present their views on the necessity of holding a second substantive meeting, on the timing of such a meeting, on the format of such a meeting (i.e. in-person or virtual again), and on any alternatives to holding a second meeting.

At the meeting, the European Union argued that a second substantive meeting is not a legal requirement under the DSU, is unnecessary in the circumstances of this case, and would cause undue delay. In the European Union's view, it would suffice for the Panel to provide the parties with an opportunity to submit written comments on one another's responses to the second set of questions. Turkey recognized that there is no legal requirement to hold a second meeting, but argued that the Panel should follow the usual practice and do so because of the inherent limitations of the substantive meeting being held in virtual format, and because of the fact-intensive nature of the case. In Turkey's view, such a meeting could be a one-day meeting and be held in virtual format.

Having considered the views of the parties, the Panel considers that an additional substantive meeting is not warranted.

If the purpose of an additional substantive meeting were simply to afford the parties an opportunity to deliver oral statements that comment on one another's written responses to the second set of questions, then the same result can be achieved simply by inviting the parties to provide such comments in writing. To be justified, an additional substantive meeting at this stage of the proceedings would necessitate the submission, either prior to or following the meeting, of either additional written submissions from the parties, or responses to a third set of questions from the Panel, or both.

The parties' first and second written submissions already present the parties' detailed arguments on the factual and legal issues in dispute, and the Panel is not persuaded that there is any special circumstance in this case that would justify the extraordinary step of inviting the parties to make a third written submission. The Panel considers that a third set of written questions from the Panel to the parties would also be unwarranted, taking into account that the Panel has endeavoured to be comprehensive in the two sets of written questions already sent to the parties. Accordingly, the Panel considers that any further submissions required to justify holding an additional substantive meeting at this stage of the proceedings would result in undue delay.

The Panel may elaborate on the reasons for its decision in the Report.

Instead of holding an additional substantive meeting, the Panel invites the parties to provide written comments on one another's responses to the second set of questions by 18 June 2021. While the original Timetable adopted by the Panel in April 2020 provided that the parties would have two weeks to provide written comments on one another's responses to the second set of questions, the Panel is of the view that a longer period of three weeks is more appropriate in the current circumstances. The Panel considers that this additional time will ensure that the due process rights of the parties are respected, taking into account the views presented by both parties at the substantive meeting.

The Panel will accord the parties the same amount of time for each of the remaining steps in the revised final Timetable as in the original Timetable, adopted by the Panel in April 2020, as regards: (i) the submission of the integrated executive summaries of the parties (ii) the parties' comments on the draft descriptive part of the Report (iii) the parties' comments on the Interim Report (iv) the parties' comments on one another's comments on the Interim Report.

Given that these time periods were set in the original Timetable following consultation with the parties, and the Panel is not altering any of them, the Panel does not consider it necessary to invite the parties to provide further comments on the revised final Timetable.

Accordingly, the attached revised final Timetable is hereby adopted.

Best regards,

Gudmundur Helgason  
*Chairman of the Panel*

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**ANNEX C**

ARGUMENTS OF THE PARTIES

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## ANNEX C-1

### INTEGRATED EXECUTIVE SUMMARY OF THE ARGUMENTS OF THE EUROPEAN UNION

#### **1. INTRODUCTION**

1. Turkish authorities have adopted plans to achieve progressively the localisation in Turkey of the production of a substantial part of the pharmaceutical products consumed in Turkey. In order to achieve that objective, Turkey requires foreign producers to commit to localise in Turkey their production of certain pharmaceutical products. If such commitments are not given, are not accepted by Turkish authorities, or are not fulfilled, the pharmaceutical products concerned are excluded from the scheme for the reimbursement of the pharmaceutical products sold by pharmacies to patients operated by Turkey's social security system (the "reimbursement system").

2. The above described localisation requirement (the "Localisation Requirement"), is designed to apply on an ongoing basis, or at least until the localisation objectives established by the Turkish government are achieved. The Localisation Requirement is periodically adapted, modified, updated or extended with respect to, *inter alia*, the products it applies to and/or the extent of localisation sought.

3. The specific commitments to be implemented in order to comply with the Localisation Requirement are established for each foreign producer in a non-transparent manner and may differ from producer to producer.

#### **2. THE LOCALISATION REQUIREMENT**

##### **2.1. FACTUAL BACKGROUND**

4. Turkey's Universal Health Insurance (Genel Sağlık Sigortası) system provides all insured and uninsured individuals in Turkey "with a comprehensive, fair and equitable access to healthcare services, regardless of their economic status." The large majority of the population is covered by universal health insurance. The system is mainly funded by social security premiums based on employer and employee contributions, and any deficit is covered from public funds.

5. The major actor in the Universal Health Insurance system is the Social Security Institution ("SSI"), affiliated to the Ministry of Labour and Social Security. The SSI administers the Universal Health Insurance system. Its duties are, among others, to implement the social security policies by taking into consideration the national development strategies and policies. The SSI is responsible for reimbursing all healthcare goods and services covered by that system, including pharmaceutical products. Thus, it provides the major part of the funding for healthcare in Turkey.

6. The Turkish Medicines and Medical Devices Agency ("TMMDA"), an institution affiliated to the Ministry of Health, is the Turkish regulatory authority on human medicinal products, medical devices and cosmetics. It is responsible for the regulation, evaluation and monitoring of these products.

7. The distribution of pharmaceutical products in Turkey is organised differently in the in-patient sector (patients treated in hospitals) and the out-patient sector (ambulatory care including patients purchasing medicines from private pharmacies).

8. The distribution of pharmaceuticals in the in-patient sector is based on the principle that persons registered with the SSI can receive medical treatment free of charge in hospitals contracted to the SSI. In the in-patient sector, the only major source of funding is the SSI. Pharmaceutical products are distributed to in-patients by hospital pharmacies. These pharmacies can be public or private, but they are always parts of hospitals, and not separate entities. They only serve in-patients and cannot sell medicines to out-patients or to the public. There are no co-payments for in-patient pharmaceuticals. Any prescriptions for in-patient use are specifically marked as "in-patient", unlike those for out-patients.

9. Hospitals can purchase pharmaceuticals either from wholesalers or directly from producers. However, they are required to purchase pharmaceuticals through a tendering process.

10. Pharmaceutical products are distributed to out-patients by pharmacies, which are private entities. Pharmacies purchase pharmaceuticals from warehouses, which are supplied by pharmaceutical companies. Pharmaceutical products are delivered on the basis of reimbursement of costs. Pharmaceuticals are not purchased by hospitals, or by Turkish government agencies, but by patients or consumers, from private pharmacies. In the out-patient sector, the two major sources of funding for pharmaceutical products are the SSI and out-of-pocket payments. Patients purchase their prescription pharmaceuticals from private pharmacies. The SSI reimburses the pharmacies based on the invoices submitted by the pharmacies. Unlike in-patient pharmaceuticals which are fully reimbursed, there are co-payments or contributions for out-patient pharmaceuticals. In the majority of cases, these include a payment of 10% or 20%, for pensioners and employed persons respectively, as well as an additional fixed amount per pack. These contributions are collected by pharmacies.

11. The reimbursement of the costs of pharmaceuticals purchased by persons covered by the universal health care system is governed by the Protocol on the procurement of medicines from pharmacies concluded between the Turkish Pharmacists' Association (TEB) and the SSI. Pharmacies covered by the reimbursement system periodically send the invoices for all their sales of pharmaceutical products to out-patients to the SSI, which reviews them and, assuming that it accepts them, reimburses the balance of the invoices within a certain period.

12. In the out-patient sector, the pharmaceuticals that could benefit from reimbursement are determined by the Drug Reimbursement Committee (DRC) and the Alternative Drug Reimbursement Committee (ARC), which are both affiliated to the SSI.

13. The reimbursement system is based on a positive list of goods and services (Reimbursement List). Pharmaceutical products are included into the Reimbursement List on the basis of applications by pharmaceutical companies. In order to be reimbursed, products must be not only included, but also listed as "active". After a product has been included in the Reimbursement List, it can either be excluded entirely ("delisted"), or kept on the list but "deactivated" (or, variously, made "passive", "passivated" or "passivized"). While neither delisted nor deactivated products are reimbursed, the consequences of delisting and deactivation differ. Deactivated products can be reactivated relatively easily, for example upon submission of the distribution certificate to the SSI subject to certain conditions or upon request. On the other hand, relisting a delisted products is more difficult and requires an application.

## **2.2. THE LOCALISATION REQUIREMENT**

14. On 2 July 2013, the Turkish Parliament approved the Government's Tenth Development Plan for 2014-2018.

15. With respect to healthcare in particular, the Plan includes a "Healthcare Industries Structural Transformation Program" which aims to relieve the pressure on social security spending and Turkey's current account deficit created by the increased demand for pharmaceuticals and medical devices. The Program also aims to ensure that Turkish production could meet a higher proportion of domestic demand of pharmaceuticals and medical devices, especially for high-value added products. The Program sets the target of meeting 60 percent of domestic pharmaceutical demand by value through domestic production. Among the performance indicators to assess compliance with that target is the "ratio of exports to imports in pharmaceuticals.

16. This localisation objective has been confirmed and further refined in various legal instruments or statements by or on behalf of the Turkish government, such as the Structural Transformation Program for Healthcare Industries Action Plan of 7 November 2014, the "2016 Action Plan of the 64<sup>th</sup> Government" of 10 December 2015 or the 11<sup>th</sup> Development Plan for the period 2019-2023.

17. Between 7 and 9 December 2017, representatives of the TMMDA gave a presentation in which they explained that, in order to meet the objectives of the 10<sup>th</sup> Development Plan and the 64<sup>th</sup> Governmental Action Plan (addressing pressure on social security expenditure and the trade deficit by meeting 60% of the need for medicines through domestic production), it is necessary to rely on localisation.

18. Despite the diversity of instruments used, and despite the fact that much of the detailed implementation of the Localisation Requirement takes place in bilateral communications between Turkish authorities and individual pharmaceutical companies, there is no doubt that all of these steps are taken within the framework of a single Localisation Requirement, in order to achieve the objectives described above. Indeed, many of the relevant legal instruments and documents expressly refer, for example, to the Tenth Development Plan or to the Action Plan of the 64<sup>th</sup> Government. Turkish authorities have repeatedly emphasized that the Localisation Requirement is a single, cohesive measure, and that individual steps such as the announcements on the removal of certain products from the Reimbursement List are taken within the framework of that measure.

19. The localisation policy has been designed and implemented in five phases, depending on (a) the existing market share of domestic producers; (b) the number of locally produced generic products and local producers in the equivalent group; (c) the existence of an equivalent group. Each phase progressively targets products with less existing domestic production, and more sophisticated products. Thus, these so-called "phases" are not temporal in nature, but refer essentially to product categories. The implementation of the phases is a dynamic process. Multiple phases have been put in practice in parallel, and products have been shifted between different phases. Thus, all of them should be understood as ongoing.

20. The **first phase** covers imported products for which the overall market share of domestic manufacturing in the equivalent group is between 50% and 100% and for which three or more local generic products, produced by three or more producers, exist.

21. The **second phase** covers imported products for which the overall market share of domestic manufacturing in the equivalent group is more than 10%, and for which two or more local generic products, produced by two or more producers, exist.

22. The **third phase** covers imported products for which the overall market share of domestic manufacturing in the equivalent group is less than 10%, or for which there is only one local producer in the equivalent group.

23. The **fourth phase** covers imported products for which there is an equivalent group, but in which there is no domestic production.

24. Finally, the **fifth phase** covers imported products for which there is no equivalent group or domestic production, and would cover patented products.

25. The conditions on the basis of which a product may fall within one of these phases can change over time.

26. While the localisation measure has foreseen all five phases from the outset (and continues to do so), the summary set out above indicates that not all of them have been put in practice yet. The evidence shows that, so far, products have been deactivated within the framework of the first and second phase.

27. When the Localisation Requirement is applied to certain products, under any of the phases, companies may typically be informed that the covered products would be delisted or deactivated from the Reimbursement List unless companies offer commitments. In particular, the Turkish authorities have periodically published "announcements on the localisation process", which state that certain products in the annexed list ("Annex-4/A") would be deactivated from the Reimbursement List within a certain period, unless companies commit to localise the production of pharmaceuticals in Turkey. In other, individual communications addressed to one or more companies, companies are *inter alia* informed that their products are to be included in the localisation process, invited to make commitments, notified of the authorities' decision to accept the commitments, refuse them, delist or deactivate their products (as the case may be), and instructed on the various steps to be followed (including follow up, possible updates or alternative commitments, variation applications etc.).

28. Evidence, such as announcements and communications shows that the Localisation Requirement has been implemented. Turkish authorities informed companies of a number of products included in the Localisation Requirement. Moreover, a number of pharmaceutical products

covered by the first and second phases, for which no commitments were given or the commitments were not accepted, have been deactivated as of 8 February 2018 and 31 July 2018.

29. Much of the communication related to the implementation of the Localisation Requirement takes place bilaterally between Turkish authorities and the companies concerned. TMMDA has invited companies to meetings in order to discuss the "evaluation" of products, requested companies to submit localisation commitments, provided instructions on the process, notified companies of the outcome of the assessment and of the next steps or required companies with accepted localisation commitments to submit progress reports at regular intervals. At times, Turkish authorities have made it clear to companies that their products will be deactivated.

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

30. The European Union explained first, that the domestic and imported pharmaceutical products at issue are like and, second, that the Localisation Requirement is a law, regulation, or requirement affecting the internal sale, offering for sale, purchase, transportation, distribution, or use of products.

31. The Localisation Requirement accords less favourable treatment in violation of Article III:4 of the GATT 1994. It expressly reserves a major advantage – reimbursement, which covers approximately 90% of the entire Turkish pharmaceuticals market – to domestic like products to the exclusion of imported like products. While imported products caught by the Localisation Requirement can still be imported and sold, their exclusion from reimbursement creates a clear disincentive on their sales in Turkey. Consumers are unlikely to choose a non-reimbursed product over a like reimbursed product. This modifies the conditions of competition between domestic and imported like products in a way that is highly detrimental to imports. It takes away the ability of imported products to compete on the basis of an "effective equality of opportunities".

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

32. The jurisprudence held that WTO respondents invoking provisions which, like Article III:8(a), set out measures to which a more general provision "does not apply", bear the burden of proof.

#### **2.4.1. The Localisation Requirement is not a "law, regulation or requirement governing procurement"**

33. The European Union considers that this condition for the application of Article III:8(a) is not fulfilled because no procurement is involved, which means that Turkey's measures (neither the reimbursement scheme for out-patient pharmaceuticals, nor the Localisation Requirement itself) do not constitute a process pursuant to which Turkey acquires products, and do not "govern" procurement.

34. It is impossible for a measure to "govern" procurement if no procurement is involved. There can be no procurement where there is no "acquisition" of products, i.e. where the government does not obtain any products. Furthermore, as is clear from the jurisprudence, Article III:8(a) does not apply unless the measure governs "the process pursuant to which a government acquires products". The Appellate Body has tied the concept of "procurement" to the concept of "acquisition" or "obtainment" of products.

35. The European Union rejects Turkey's argument that the SSI acquires the medicines because it pays for their cost, and is therefore the "ultimate buyer" of those products, the pharmacies being just an "agent for the SSI" and the "distribution network of the SSI".

36. First, this interpretation would expand the scope of Article III:8(a) far beyond what was intended by the drafters. Article III:8(a) is a government procurement exception, not a government financing exception. Second, the act of payment does not on its own constitute an "acquisition", much less a "purchase" of anything, generally or even in Turkish law. Third, the fact that Turkey's Public Procurement Law exempts the SSI from tendering procedures which apply to government procurement also tends to suggest that no procurement is involved, and certainly that no "process pursuant to which the government acquires products" is involved. Fourth, the Protocol concluded between pharmacists and the SSI similarly does not support Turkey's position. To the extent the Protocol discusses "procurement", it concerns procurement by patients, i.e. the persons acquiring

or obtaining the medicines from pharmacies. Fifth, the SSI does not procure, purchase, obtain or acquire anything under the reimbursement scheme for out-patient pharmaceuticals, the Localisation Requirement itself (which is, as Turkey points out, the measure challenged by the EU) is not a law, regulation or requirement that governs procurement.

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

37. The Appellate Body has explained that the word "purchased" in Article III:8(a) refers to "the type of transaction used to put into effect" the procurement that is at issue. The term "procurement", as interpreted by the Appellate Body, already contains the concept of "obtaining" products. Since the "purchase" requirement is additional, it must mean something more. Therefore, simply put, if there is no acquisition of property, there is no "purchase" and Article III:8(a) does not apply.

38. The EU considers that in the context of the reimbursement system and the Localisation Requirement, the SSI engages in neither procurement nor the purchase of any products.

39. The "purchase" requirement is additional to the "procurement" requirement, and, with respect to out-patients, no Turkish governmental agency ever acquires pharmaceutical products, whether through purchase or otherwise. Retail pharmacies cannot be regarded as agents of the SSI, even when one looks at their relationship with patients purchasing prescription medicines.

40. The "approval" in the Medula system, which takes place at the time of the transaction between the pharmacy and the out-patient, is merely to confirm that the out-patient is under SSI coverage and that the medicines contained in the prescription are within the Reimbursement List. It does not, however, guarantee that the SSI will reimburse the price of that product. The risk of non-reimbursement by the SSI, even where a transaction is approved in Medula, is significant and is borne by the pharmacies. This risk is not compatible with the pharmacies acting as agents of the SSI in the provision of medicines by the SSI to the population. A significant number of retail pharmacies in Turkey are not in any relationship with the SSI. Moreover, it is the retail pharmacies that place orders for medicines with wholesale pharmacies in the desired quantities. Upon delivery, it is of course the retail pharmacy that holds the title to the medicines, and does so until they are sold to an outpatient (which could in turn be covered by the SSI, a private insurer, or not at all, something that the pharmacy does not know until the moment of provision). Retail pharmacies also do not know how long it will take them to sell the products. Thus, they bear the risk that the medicines' expiry date will pass before they are sold, in which case they can no longer sell them or be reimbursed for them, and have to dispose of them.

**2.4.3. The Localisation Requirement does not involve any procurement or purchase "for governmental purposes"**

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

42. Turkey disagrees and explains, at length, the reasons why healthcare is an important governmental objective. However, while reimbursing medicines is obviously linked to the protection of human health, the Localisation Requirement is not.

43. The relevant question under this part of the Article III:8(a) test is not simply whether the measure is linked to a governmental objective. It must also be shown that products are "purchased for the use of government, consumed by government, or provided by government to recipients in the discharge of its public functions". Retail pharmacies cannot be regarded as agents of the SSI. However one characterises the different payments involved, it is clear that no Turkish governmental agency *provides* the pharmaceutical products to anyone – pharmacies do. Even if it was somehow considered that the government procures and purchases those products, consumers use them, and not the government.

**2.4.4. Even if procurement and purchase by governmental agencies for governmental purposes was involved, it would be "with a view to commercial resale"**

44. If the Panel were to reach this stage of the analysis, it would have accepted, before reaching that question, that the Localisation Requirement governs the procurement and purchase of pharmaceutical products by governmental agencies for governmental purposes. This would mean that the government procures and purchases pharmaceutical products when it reimburses a part of their cost to the pharmacies which ultimately sell them to consumers. Accepting this logic would mean also accepting that the procurement and purchase are undertaken with a view to commercial resale.

**2.4.5. If the reimbursement system were covered by Article III:8(a), the Localisation Requirement would still be inconsistent with Article III:4 of the GATT 1994**

45. A Member that can avail itself of Article III:8(a), is not free to discriminate in any way, as long as there is some connection to the products being procured and purchased.

46. Article III:8(a) must be read narrowly, as permitting only measures that discriminate on the basis of the origin of the products being purchased and procured. It does not permit, for example, measures that discriminate on the basis of the origin of some other products (for example, inputs into the products being purchased and procured), as has already been recognized in *Canada – Renewable Energy* and *India – Solar Cells*. Nor does it permit measures that discriminate on the basis of whether certain investment or production commitments pertaining to the product being (allegedly) purchased have been considered acceptable by Turkish authorities.

47. Thus, it would be entirely coherent to say that the Localisation Requirement, which requires the localisation of production in general, accords less favourable treatment under Article III:4 of the GATT 1994, even if the reimbursement system was found to be covered by Article III:8(a) because it governs the purchase and procurement of pharmaceutical products by Turkey.

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

48. The Localisation Requirement is imposed through a number of legal instruments resulting from governmental action, and setting out rules with which compliance is necessary to obtain an advantage from a government. These various legal instruments, including presentations and private communications, fall under the category of either "law", "regulation" or "administrative rulings". At the same time, given the fact that the Localisation Requirement is to a significant extent "embodied" through "specific laws or decrees" or "formal legal instruments", it should, as a whole, also be described as a "law or regulation".

49. The Localisation Requirement is a measure of general application. First, as to its subject matter, it is a measure directed to imports of the covered pharmaceutical products in Turkey generally. Second, although the detailed implementation of the Localisation Requirement takes place in bilateral communications between Turkish authorities and individual pharmaceutical companies, all of these steps are taken within the framework of a single Localisation Requirement. The presentations and private communications are also "of general application" as they convey rules affecting an unidentified number of economic operators not limited to those specific companies.

50. The Localisation Requirement as a single and cohesive measure has been "made effective". There is no doubt that this measure has been brought into effect by Turkish authorities, both generally and through application in individual cases.

51. The Localisation Requirement pertains to "requirements on imports, or affecting the sale of imports". Since the measure at issue is a localisation requirement on the covered imports, as a condition for them to benefit from reimbursement, it directly affects the internal sale of pharmaceutical products.

52. A number of key elements of the Localisation Requirement were not published promptly in such a manner as to enable governments and traders to become acquainted with them.

53. Overall, only the instruments containing the broad outlines of the Localisation Requirement have been appropriately and promptly published: the Tenth Development Plan, the Structural Transformation Program for Healthcare Industries Action Plan of 7 November 2014, and the 2016 Action Plan of the 64<sup>th</sup> Government, the 2015 HISC Circular.

54. Its substantive content has, for the most part, been put in place in an entirely non-transparent manner, through a series of announcements, presentations and communications, none of which have been adequately and promptly published. Specifically, certain terms and conditions of the Localisation Requirement that are also its key elements have not been adequately published: the process and various steps that must be taken as part of localisation; the phases of localisation, and the product categories to which those phases relate; the requirements about commitments and alternative localisation commitments; criteria for accepting or refusing commitments; the criteria, phases and deadlines for delisting or deactivate their products; instructions on the various steps to be followed (including follow up, possible updates or alternative commitments, variation applications); instructions for submitting progress reports.

55. Although the Turkish authorities published the various announcements on localisation, they did not elaborate on the details of the localisation policy of pharmaceuticals. Moreover, even those announcements were not published in an adequate way, but were simply placed on the websites of Turkish government authorities. Also, the HSPC Decision was made accessible only to companies making products included in the first two phases of the localisation measure but not "generally made available" to governments and traders.

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

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

56. The Localisation Requirement is not designed to achieve the public health objective alleged by Turkey. Rather, it has been designed to promote the economic development and industrial policy objectives pursued by Turkey in the pharmaceutical sector. Those objectives are reflected in various policy documents of the Turkish Government. Those documents evidence a preoccupation with the large size of Turkey's trade deficit in the pharmaceutical sector, together with a desire to promote the domestic production of higher value-added pharmaceutical products with a view to becoming competitive in global markets, thereby contributing to the development of Turkey's economy. These are legitimate economic development and industrial policy industrial objectives. But Turkey can and ought to pursue them in a manner consistent with its obligations under the WTO Agreement.

57. The structure and design of the Localisation Requirement cannot be reconciled with the public policy alleged by Turkey in this dispute. If Turkey's objective were to ensure access to medicines, it would facilitate imports of pharmaceutical products, rather than restrict those imports. Far from being necessary to ensure access to medicines, the Localisation Requirement could undermine that objective by causing a shortage of supply of medicines.

58. Turkey has recognized that that the Turkish authorities assessed, before the implementation of Phase 1 and Phase 2, that there was no significant risk of shortage of supply of the pharmaceutical products covered by those phases. Yet, in the absence of such risk of shortage of supply, the Localisation Requirement cannot possibly be considered "necessary" in order to ensure access to the pharmaceutical products covered by those two phases. At the same time, Turkey's explanations have the implication that the Turkish authorities consider that the Localisation Requirement cannot be applied with regard to other products where local production is not sufficient yet (the products covered by Phases 3 to 5) because restricting imports of those products could, by Turkey's own admission, entail the "risk of a sudden shortage of supply".

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

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

59. In order to prove that the Localisation Requirement is justified under Article XX(b), Turkey is required to prove that there is a risk of shortage of supply of the pharmaceutical products within the scope of the Localisation Requirement. In accordance with the guidance provided by the Appellate Body in *India- Solar Cells*, Turkey has the burden of demonstrating that there is a risk that "the quantity of available supply from both domestic and international sources in the relevant geographical market may be insufficient to meet demand", having regard to all relevant factors affecting supply and demand, including those identified in the above quoted passage.

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

61. Turkey has failed to meet that burden of proof. Indeed, Turkey has provided no relevant evidence of the existence of a risk of shortage of supply. Quite to the contrary, Turkey has stressed that there is no risk of shortage of supply as regards the products covered by the First and Second phases.

62. Turkey has been able to identify just five instances of alleged disruption of supply since 2012. The anecdotal evidence concerning those alleged five instances is hardly probative of a genuine risk of shortage of supply affecting each and every pharmaceutical product actually or potentially covered by the Localisation Requirement, which could render necessary the adoption of that measure. Rather, it suggests that disruptions of supply are infrequent, limited in time and, more often than not, attributable to factors other than a disruption of imports, including the Turkish administration's own inefficiencies.

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

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

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

65. Turkey concedes implicitly that there is no evidence of such contribution, but seeks to justify the lack of evidence by arguing that "at this stage it is difficult to isolate the contribution". The implementation of Phases 1 and 2 started in 2016 and 2017, respectively. If the Localisation Requirement were capable of making a contribution to the stated objective, some effects should be noticeable by now.

**2.6.3. The Localisation Requirement is very trade-restrictive**

66. The Localisation Requirement is extremely trade-restrictive because, in practice, it has the effect of excluding imports from a very large part of the Turkish market.

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

67. The shortage of medicines can occur for many different reasons. Given their multifaceted causes, there is no single response to the shortages of medicines. As mentioned above, local production of pharmaceutical products is not a panacea for improving access to medicines. In specific contexts, and subject to certain conditions, local production may be a useful tool for improving access to medicines. But there are other tools available. Such other tools include the creation of contingency reserves of medicines at risk of shortage, and in particular of those previously identified as essential, the diversification of sources of supply, the simplification of supply chains, the facilitation of imports, the improvement of pricing mechanisms and procurement procedures, the harmonization and simplification of regulatory requirements and increased international cooperation. The World Health Organization has recommended "to develop strategies that may be used to forecast, avert or reduce shortages/stockouts". Those strategies do not include any measure resembling the Localisation Requirement.

68. Furthermore, in those cases where local production can be an effective tool, it can be more effectively supported by resorting to alternative measures which, unlike the Localisation Requirement, do not restrict trade in a manner inconsistent with the WTO Agreement. The World Health Organization has developed a comprehensive "Policy Framework for Government support for local production and access". Again, that framework does not include any measure resembling the Localisation Requirement.

#### **2.6.5. The Localisation Requirement is not applied in accordance with the chapeau of Article XX**

69. The application of the Localisation Requirement is not calibrated to reflect the difference in health risks that may arise in relation with different pharmaceutical products. In principle, the Localisation Requirement applies to all pharmaceutical products covered by the Reimbursement Scheme, regardless of how essential they are, and regardless of the degree of risk of shortage of supply of each group of equivalent products. To the extent that Turkey modulates the application of the Localisation Requirement, by dividing its implementation into five phases, such modulation is at odds with the public health objective allegedly pursued by Turkey. Indeed, as explained above, Phase 1 and Phase 2, the only ones implemented so far by Turkey, cover pharmaceutical products where, by Turkey's own admission, there is no risk of shortage of supply and, hence, no health risk.

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

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

70. Turkey has identified just two provisions included in Article 405 of Presidential Decree No. 4, of 2018, as "laws or regulations" requiring Turkey to ensure the financial sustainability of the SSI. Having regard to the characteristics identified as relevant by the Appellate Body in previous cases, those two provisions cannot be considered as "laws" or "regulations" within the meaning of Article XX(d) of the GATT 1994. As indicated by the title of Article 405 and by its own terms, Article 405(1) of Presidential No 4 is but an aspirational provision, whose only function is to set out the "main purpose" that should guide the functioning of the SSI. As such, Article 405(1) lacks the requisite degree of specificity and normativity to qualify as a "law" or "regulation" within the meaning of Article XX(d). Furthermore, Turkey has not shown that Article 405(1) is legally enforceable as such, let alone that its breach may result in any sanctions or penalties. In turn, paragraph 2 a) of Article 405 limits itself to describe one of the SSI's "tasks" in very general terms. The "national development strategies and policies and annual implementation programs" mentioned in that provision are policy documents, which do not qualify by themselves as "laws" and "regulations" within the meaning of Article XX(d). Furthermore, pursuant to paragraph 2 a), the SSI is merely instructed to "take into account" those policy documents and "work on their development". Again, this provision lacks the requisite degree of specificity and normativity to qualify as a "law" or "regulation" within the meaning of Article XX(d). In addition, Turkey has not shown that Article 405(2) a) of Presidential Decree No 4 is legally enforceable, let alone that its breach may result in any sanctions or penalties.

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

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

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

###### 2.7.2.2 The Localisation Requirement is very trade-restrictive

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

2.7.2.3 There are adequate less trade-restrictive alternatives in order to achieve the objective alleged by Turkey the alleged objective of ensuring "financially sustainable healthcare"

73. There are many alternatives to ensure the financial sustainability of Turkey's health system without breaching Turkey's obligations under the WTO Agreement. For example, Turkey could implement one or more of the following alternatives: improving the functioning of Turkey's SSI, with a view to making it more efficient and reducing unnecessary expenditure; increasing the co-payments of patients; increasing the overall tax revenue by raising tax rates or ensuring a more efficient collection; transferring funds from other budgetary lines to the financing of the SSI, etc.

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

74. There is no "rational connection" between that objective and the manner in which the Localisation Requirement is applied. Indeed, the Localisation Requirement applies equally to all imported products, regardless of their price. Even if an imported product is less costly to the SSI than its domestic counterpart, it will still be excluded from reimbursement. As a result, the Localisation Requirement may well have the effect of increasing the reimbursement costs for the SSI, thereby defeating the objective invoked by Turkey.

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

75. The Localisation Requirement is an investment measure related to trade in goods that is inconsistent with Article III:4 of the GATT. For those reasons, the Localisation Requirement is incompatible with Article 2.1 of the TRIMS Agreement. Turkey does not contest that the Localisation Requirement is an "investment measure" within the scope of the TRIMS Agreement. As explained above, the Localisation Requirement is not excluded from the scope of Article III:4 by virtue of Article III:8(a). Therefore, the Localisation Requirement is inconsistent with Article 2.1 of the TRIMS Agreement.

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

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

**2.9.1. Financial contribution**

2.9.1.1 Direct transfer of funds

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

2.9.1.2 Entrustment or direction of the provision of goods

78. As explained above, the European Union considers that the Reimbursement Scheme does not involve a "procurement" or "purchase" of pharmaceutical products "for governmental purposes" within the meaning of Article III: 8(a) of the GATT 1994. However, if the Panel agreed with Turkey that the SSI does "procure" and "purchase" pharmaceutical products "for governmental purposes", the European Union submits that the subsequent provision of those goods by the pharmacies to the out-patients would constitute, by itself, a "financial contribution" within the scope of Article 1.1(a)(1)(iv) of the SCM Agreement.

### **2.9.2. Benefit**

79. The financial contributions identified in the previous section confer a direct "benefit", within the meaning of Article 1.1(b) of the SCM Agreement, upon the out-patients who are beneficiaries of the Turkish Social Security System. It is beyond question that the out-patients are "better off" as a result those financial contributions. As acknowledged by Turkey, "the payments made by the SSI to retail pharmacies cover the costs of pharmaceutical products and essentially replace the payments that would have been otherwise required from patients". By conferring a direct benefit to the out-patients, the Reimbursement Scheme also confers an indirect benefit to the Turkish producers of the pharmaceutical products covered by the Reimbursement Scheme.

80. Previous panels have cautioned against extrapolating the case-law on the pass through of input subsidies invoked by Turkey to different situations. It is far more relevant to consider the guidance provided by the panels *Brazil – Aircraft (Article 21.5 – Canada II)* and *Canada – Aircraft Credits and Guarantees*, which have examined specifically the situation where, as in the present case, a subsidy is granted to a purchaser of goods on condition that she purchases goods from certain producers. The decision of the Arbitrator in *US-Upland Cotton* does not involve a departure from the approach followed by the above-mentioned panels.

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

82. Turkey further contends that "the choice of the pharmaceutical product is not left to the patient". However, this is contradicted by Turkey's own description of the Reimbursement Scheme, which evidences that patients do have certain choices. In particular, where a product is a "generic" or belongs to a group of "equivalent products" (which is the case for the majority of the products, including all the products covered by phase 1 and phase 2 of the localisation measure, the only ones implemented so far), the out-patient is allowed to purchase the product of his choice among the generic or equivalent products.

### **2.9.3. Contingency upon the use of domestic over imported goods**

83. The subsidy identified in the preceding sections is contingent upon the use of domestic over imported goods by the out-patients. Both the financial contributions and the benefits thereby conferred are conditional upon the out-patients being provided pharmaceutical products included in the Reimbursement List, for their personal use. In turn, the inclusion of a product in the Reimbursement List is conditional upon the product being produced in Turkey.

## **3. THE IMPORT BAN ON LOCALISED PRODUCTS**

### ***3.1. THE EUROPEAN UNION ESTABLISHED THE EXISTENCE AND CONTENT OF THE IMPORT BAN ON LOCALISED PRODUCTS***

84. By this measure, when the production of a pharmaceutical product has been localised in Turkey in accordance with the Localisation Requirement, applied in conjunction with the Turkish rules for approving the importation and marketing of pharmaceutical products, that pharmaceutical product can no longer be imported in Turkey.

85. According to the Regulation on Marketing Authorisation, a pharmaceutical product can either be granted a local marketing authorisation or an import marketing authorisation. The same product cannot hold two marketing authorisations, one "local" and one "import". Therefore, to the extent that a pharmaceutical product has been localised in Turkey in accordance with the Localisation Requirement, it can no longer be imported. According to the Announcement on import applications, in the absence of the required import marketing authorisation, a pharmaceutical company cannot obtain the inspection certificate necessary for importation.

86. When companies commit to localise their production of a pharmaceutical product (that was previously imported under an import marketing authorisation) in Turkey, as required by the Regulation on Variations, they have to apply for a variation of their marketing authorisation, from import to local status.

87. Several documents confirm that companies are required to change their marketing authorisation from import to local within the Localisation Requirement: TMMDA's presentation of 7-9 October 2016 on localisation; TMMDA's presentation "Project Transition from importing to manufacturing" of 6 March 2017, TMMDA's communication of 10 October 2017, entitled "Preparing a progress report for your products in localization process", several letters sent by TMMDA to companies whose localisation commitments have been accepted, the HSPC Decision regarding the Localisation Process, a press article dated 14 March 2017, TMMDA's communication of 31 January 2018, entitled "Localization Process".

88. Turkey does not deny the existence of an import ban for the localized pharmaceutical product with respect to the marketing authorisation already granted (product with the same formulation and pharmaceutical form, already authorized by the Ministry, to the same real person or legal entity).

89. The European Union disagrees with Turkey's claims that additional marketing authorizations can be issued for: (i) applications made by sister companies for pharmaceutical products with the same composition and pharmaceutical form and (ii) for different therapeutical indications.

90. First, according to the Regulation on Marketing Authorisation, only one company is authorized to import, register and sell a pharmaceutical product, except for co-marketing.

91. Second, a different marketing authorisation is not granted for a different indication. Marketing authorizations may cover several indications. Additional therapeutic indications are submitted via variation applications to the same marketing authorisation already granted. Moreover, the Localisation Requirement applies to pharmaceutical products irrespective of their indications and, if companies do not comply with the Localisation requirement, pharmaceutical products are deactivated from the Reimbursement List for all their indications.

92. In any event, a legal ban on certain goods or any goods, even with exceptions, remains a prohibition within the meaning of Article XI:1 of the GATT 1994.

### **3.2. THE IMPORT BAN IS INCONSISTENT WITH ARTICLE XI:1 OF THE GATT 1994**

93. The Import Ban on localised products is inconsistent with Turkey's obligations under Article XI:1 of GATT 1994, because, once a foreign producer has localised production of a certain pharmaceutical product pursuant to the Localisation Requirement, applied in conjunction with the Turkish rules for approving the importation and marketing of pharmaceutical products, that product can no longer be imported. Therefore, Turkey institutes and maintains a prohibition or restriction, other than duties, taxes or other charges, on the importation of pharmaceutical products of the territory from other WTO Members.

94. The Import Ban is not an internal measure that is merely "enforced at the time of importation". The absence of an import marketing authorisation makes impossible the granting of this certificate and therefore importation itself becomes impossible. Therefore, the Import Ban directly relates to the importation of pharmaceutical products.

95. The Import Ban prohibits the importation of pharmaceutical products with the same formulation and pharmaceutical form as those localised in Turkey in accordance with the Localisation Requirement. Since the products prohibited from importation are not products *imported* into Turkey's territory, this measure falls outside Article III:4.

96. The Import Ban does not cover domestic products as such (which are already on Turkey's territory) and foreign products that are not (yet) localized and can still be imported. The mere fact that the marketing authorization rules also apply to domestic products does not mean that the Import Ban is a "law, regulation or requirement of the kind referred to in paragraph 1 which applies to an imported product and to the like domestic product" within the meaning of the Ad Note to Article III.

### **3.3. THE IMPORT BAN ON LOCALISED PRODUCTS CANNOT BE JUSTIFIED UNDER ARTICLE XX(D) OF THE GATT 1994**

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

97. The Import Ban is not a mean "to enforce obligations" under the Localisation Requirement to manufacture domestically as it does not oblige foreign producers to actually manufacture in Turkey. It merely seeks to prevent alleged circumvention related to reimbursement. Turkey ensures compliance with the Localisation Requirement through the exclusion of pharmaceutical products from the reimbursement scheme.

98. Although the Import Ban might have the incidental consequence of ensuring that the commitments of the foreign producers to produce domestically are not abused, and, therefore, the Import Ban "may share the same policy objective" with the Localisation Requirement, that alone is insufficient to establish that the Import Ban was meant to "secure compliance" with the Localisation Requirement.

#### **3.3.2. The Import Ban is also not "necessary" within the meaning of Article XX(d).**

99. First, as regards the importance of interests or value, the Import Ban allegedly secures compliance with the Localisation Requirement. The latter is designed to promote the economic development which are essentially commercial in nature and, thus, not as important as, for instance, the protection of human life and health against a life threatening health risk.

100. Second, the contribution of the Import Ban to fight circumvention of the Localisation Requirement is limited, if at all. Once production is localised (after a process including progress reports), the circumvention of reimbursement rules is a separate issue that does not ensure compliance with the already finalised localisation process.

101. Third, the trade restrictiveness of the Import Ban is very high since it prohibits importation of localised products.

102. Fourth, regarding alternative measures, Turkey could reasonably be expected to employ a labelling requirement. Products are imported following a detailed procedure that includes an inspection certificate for importation. Therefore, Turkey already has detailed information as to the imported products compared to those manufactured domestically. Such alternative measure would preserve Turkey's right to achieve its desired level of compliance with the Localisation Requirement as pharmacies could easily distinguish between an imported and a domestically manufactured product to reimburse only the latter. Moreover, this alternative measure is significantly less trade-restrictive than the Import Ban since it would allow the importation of localised products.

## **4. THE PRIORITIZATION MEASURE**

### **4.1. THE EUROPEAN UNION ESTABLISHED THE EXISTENCE AND NATURE OF THE PRIORITIZATION MEASURE**

103. By this measure, Turkey gives priority to the review of applications for inclusion of domestic pharmaceutical products in the list of products covered by the reimbursement system, as well as with respect to some licensing policies and processes, over the review of the applications of like imported products.

104. The panel request shows that the European Union challenged the Prioritization Measure as such and not as an ongoing practice as Turkey alleges.

105. The following action plans and programmes confirm the existence and content of an overarching Prioritization Measure with respect to locally manufactured pharmaceutical products :

- i. The Structural Transformation Program for Healthcare Industries Action Plan of 7 November 2014 whose "Action 2" has "the objective of prioritizing medicines and medical devices produced in Turkey in the reimbursement and pricing policies and licensing processes.";

- ii. The 2016 Action Plan of the 64th Government 10 December 2015 that lists as Action No 46 "[T]o improve the reimbursement, pricing and licensing processes for medical devices and strategic and domestic medicines";
- iii. The 65th Government Programme of 24 May 2016 providing that : "When it comes to reimbursement and pricing policies and licensing procedures, we will give priority to domestically produced medicines and medical devices".

106. The SSI Regulation on Drug Reimbursement of 10 February 2016 implements the abovementioned actions and programmes with respect to the inclusion on the Reimbursement List. For example, Articles 5 (g), 6(ç) and 9 (c) provide that various bodies are responsible for: a fast track review of pharmaceutical products manufactured in Turkey for the purpose of being placed on the Reimbursement List; assessments about locally manufactured products and decisions to be taken at an extraordinary meeting of the Drug Reimbursement Committee in relation to those products; prioritizing the review of locally manufactured pharmaceutical products.

107. Locally manufactured pharmaceutical products are also given priority with respect to the applications for good manufacturing practices ("GMP") and marketing authorisations.

108. The Priority Assessment Guideline enables giving priority, inter alia, to applications regarding pharmaceutical products whose production is transferred to Turkey applications for locally manufactured products for exportation purposes and applications relating to products which have strategic importance for Turkey's policies.

109. Some of the relevant provisions of the Priority Assessment Guideline are the following:

- i. Article 10 e) provides that "applications relating to products which have strategic importance in terms of country policies are assessed by the Commission independently of the scoring criteria in the guideline.";
- ii. Article 10 f) provides that "the applications relating to locally manufactured products having export relation among marketing authorisation applications are assessed by the Commission according to the criteria of planned exportation time, planned exporting countries, planned exportation size and the starting date of exportation."
- iii. Article 10 ğ) provides that "the priority matter of locally manufactured product applications relating to the transferring of production of imported medicines to our country is assessed by the Commission."

110. In addition, Annex 3 of the Priority Assessment Guideline attributes certain coefficients to applications concerning Local production, applications concerning a Local active substance and applications involving the performance of bioequivalence studies in Turkey.

111. Finally, TMMDA representatives also confirmed in a press article of 24 February 2018 that local manufacturing is among the criteria governing the assessment of the prioritisation process of pharmaceutical products.

#### **4.2. THE PRIORITIZATION MEASURE IS INCONSISTENT WITH ARTICLE III:4 OF THE GATT 1994**

112. The Prioritization Measure accords "less favourable" treatment to imported pharmaceutical products than that accorded to like domestic products. This measure consists in granting priority to the review of applications regarding pharmaceutical products of national origin for inclusion in the reimbursement scheme, and the review of GMP and marketing authorisation applications. The fact that the products of domestic origin are granted priority review whereas the imported products are not distorts the conditions of competition to the detriment of imported products.

113. Turkish legislation mandates giving priority to locally manufactured products:

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

- ii. the Priority Assessment Guideline enables giving priority, inter alia, to applications regarding pharmaceutical products manufactured in Turkey;
- iii. Turkey's actions plans and programmes confirm that it grants priority to domestically produced pharmaceutical products for reimbursement, pricing policies and licensing procedures.

114. Even if eventually Turkish authorities do not grant priority to each application involving locally manufactured products, local manufacturing represents nonetheless a mandatory priority criteria during the application review. It is clear from the terms, design, structure, and expected operation of the Prioritization Measure that it is a *de jure* discriminatory measure, and that, by its very nature, it accords less favourable treatment to imports. This suffices to find that the Prioritization Measure mandates action inconsistent with Article III:4 of the GATT 1994. It is not necessary to analyse the actual market impact, what proportion of applications are granted priority eventually or other consequences of the measure further. In any event, Turkey's actions plans and programme show that Turkey effectively grants priority to domestically produced pharmaceutical products for reimbursement, pricing policies and licensing procedures.

## **5. CONCLUSIONS**

115. For the reasons set out in this submission, the European Union requests the Panel to find that:
- 1) The Localisation Requirement is inconsistent with Turkey's obligations under Article III:4 of GATT 1994, Article X:1 of GATT 1994 and Article 2.1 of the TRIMs Agreement;
  - 2) To the extent that the Panel found that the Localisation Requirement is not inconsistent with Article III:4 of the GATT 1994, that such measure is inconsistent with Article 3.1(b) of the SCM Agreement;
  - 3) The Import Ban on localised products is inconsistent with Turkey's obligations under Article XI:1 of GATT 1994; and
  - 4) The Prioritization Measure is inconsistent with Turkey's obligations under Article III:4 of GATT 1994.

**ANNEX C-2****INTEGRATED EXECUTIVE SUMMARY OF THE ARGUMENTS OF TURKEY****I. INTRODUCTION**

1. The present dispute concerns certain measures taken in the framework of Turkey's social security system. These measures are aimed at ensuring a fair and uninterrupted access to medicines for all patients in Turkey while maintaining the financial stability of the system. This dispute thus raises important systemic issues about the freedom of a WTO developing country Member to organise and manage its healthcare system in a manner that ensures an optimal balance between, on the one hand, a wide scope and coverage and, on the other hand, the financial viability of the system. In the midst of the COVID-19 pandemic, it has become more obvious than ever before that Governments must play a central role in protecting the health of their population and guaranteeing access to medical products, including medicines, vaccines and medical devices.

2. The Turkish healthcare system is unique in terms of its generosity and coverage. It guarantees the provision of medicines to almost the entire Turkish population at minimal cost. In order to make this possible, the Turkish authorities control strictly the conditions for placing medicines on the Turkish market, their prices and the manner of their distribution to patients. Medicines that are placed on the Turkish market for supply to outpatients are purchased by the Turkish Social Security Institution ("SSI") and dispensed to patients via retail pharmacies.

3. The claims brought by the European Union against measures taken by Turkey with respect to medicines ignore the public health objectives behind those measures and are based on a fundamental misunderstanding of the Turkish social security and healthcare systems. The European Union treats the supply of medicines to patients as individual commercial transactions between economic operators aiming at profit maximisation. Such erroneous interpretation ignores that medicines are dispensed to patients by retail pharmacies under contract with the Turkish Government on the basis of prescriptions by medical doctors at prices set by the Turkish Government. The measures challenged by the European Union form an integral part of the Turkish social security system and help to ensure the procurement of medicines under optimal conditions. They cannot be seen in isolation from the Turkish social security system as a whole. Interfering in the design and the functioning of the statutory social security schemes of the Members goes beyond the aims of the WTO covered agreements and was clearly not the intention of the Contracting Parties while negotiating and signing those agreements.

**II. FACTUAL BACKGROUND**

4. The two key actors in the system of provision of medicines to patients in Turkey are the Turkish Medicines and Medical Devices Agency ("TMMDA"), operating under the Ministry of Health, and the SSI, operating under the Ministry of Family, Labour and Social Services.<sup>1</sup> TMMDA is the authority that determines the conditions for placing the medicines on the market, fixes the retail prices of the medicines and ensures their safety and availability on the market. The SSI is the single public authority purchaser of healthcare services, including medicines, from the healthcare service providers for both outpatients and inpatients.

*1. The placing of medicines on the Turkish market*

5. In order to be placed on the Turkish market, medicine must obtain (i) a Good Manufacturing Practices ("GMP") certification, (ii) a marketing authorization, (iii) a fixed price and (iv) a sales permit. These authorizations are delivered by the TMMDA.

6. The vast majority of medicines that are actively sold and prescribed in Turkey are covered by the social security system. However, medicines can be placed on the Turkish market even if they are not covered by the social security system, if they meet all quality, safety and efficacy

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<sup>1</sup> This Ministry has been recently renamed as Ministry of Labour and Social Security and there is a separate Ministry of Family and Social Services.

requirements and receive the relevant authorizations. In that sense, any measure taken with respect to the functioning of the social security system, including its scope, has no impact on the access of medicines to the Turkish market.

### *2. The purchasing of medicines for the patients*

7. Medicines placed on the Turkish market and covered by the Universal Health Insurance Scheme are purchased by the SSI and provided to patients either directly by hospitals for inpatient treatment, or through retail pharmacies for outpatient treatment. In both cases, the costs of medicines necessary for a patient's treatment are covered by the State.

8. The rules relating to the provision and payment for healthcare services, including medicines are set out in the SSI's Drug Reimbursement Regulation, and in the Health Implementation Communiqué ("SUT"). Notably, the list of medicines for which the costs are covered by the SSI is included in Annex 4/A to the SUT entitled "list of medicines to be paid for" which is revised regularly to reflect both inclusion and exclusion of medicines in and from the list. Pharmaceutical companies must apply to the SSI to request the inclusion of their products in Annex 4/A.

9. The inclusion of a medicine in Annex 4/A is not permanent as the status of that medicine might change over time. Medicine listed in Annex 4/A may be "passivized", meaning that the payment for that medicine by the SSI is temporarily suspended, in certain circumstances foreseen by law. Medicines that have been "passivized" may be re-activated upon request of the pharmaceutical company if the conditions for setting the product's status to "passive" are no longer valid or removed from Annex 4/A if their re-activation is not requested within ten months from the date of their passivation.

10. Imported medicines may be "passivized" if they do not comply with the localisation measure. Medicines which are "passivized" as a result of the localisation measure are not excluded from Annex 4/A after ten months from the moment of their passivation but instead retain the "passivized" status.

11. The retail prices of all medicines sold in Turkey are regulated. The public price of a medicine included in Annex 4/A paid by the SSI is different from the retail price of that product and results from the application of public discounts, the amounts of which are set out in the SUT for each type of medicine.

12. The medicines listed in Annex 4/A are grouped in pharmaceutical equivalent groups based on price comparisons between products with similar dosage, having the same active substance(s) and for the same indication. If a medicine does not have an equivalent group, the SSI pays 100% of its price. However, if a product has an equivalent group, the price paid by the SSI is determined according to the "internal reference pricing mechanism" which relies on a single reimbursement price per each equivalent group. This price is determined on the basis of the price of the product having the cheapest unit price and at least 1% market share. For pharmaceutical products with an equivalent group, the maximum price paid by the SSI is the lowest price in the equivalent group increased by 10%. If a patient prefers a more expensive product from the same equivalent group, he or she must pay the difference between the price of that product and the price paid by SSI.

13. Finally, pharmacy discounts apply to the prices paid by the SSI for all medicines included in Annex 4/A and dispensed by retail pharmacies to patients. The pharmacy discount rates are calculated based on the annual income of a retail pharmacy and are listed in the Protocol signed between the SSI and the Turkish Pharmacists Association.

14. This system ensures that the prices paid by the SSI for medicines are as low as possible in order to maintain financial sustainability of the healthcare system in Turkey.

### *3. The provision of medicines to the patients*

15. Medicines listed in Annex 4/A and prescribed by medical doctors are dispensed to outpatients by the retail pharmacies on behalf of the SSI.

16. This is in line with the Turkish legislation which provides that healthcare services, including provision of medicines, are provided based on contracts concluded between the SSI and domestic and/or foreign healthcare service providers.

17. Under Turkish law, a pharmacy is considered as a primary healthcare service provider and is defined as "a healthcare organization that provides health services, opened according to the law under the ownership and responsibility of a pharmacist". In line with Law No. 5510, the provision of medicines to outpatients in Turkey is carried out by retail pharmacies contracted with the SSI.

18. All retail pharmacists in Turkey are members of the Turkish Pharmacists' Association ("TPA"), which is authorized to conclude protocols on behalf of the retail pharmacies. The SSI and the TPA have concluded a "Protocol on the Provision of Medicines to the Persons Covered by the Social Security Institution by the Pharmacies which are Members of the Turkish Pharmacists' Association" ("the Protocol").

19. The Protocol sets out the rules and procedures regarding the direct payments made by the SSI to retail pharmacies for medicines listed in Annex 4/A and dispensed by the pharmacies to patients. The Protocol includes an annex with a standard contract between the SSI and retail pharmacies, which is signed by individual retail pharmacies and the SSI and renewed on an annual basis.

20. The SSI approves the provision of the medicines to be dispensed to patients through the electronic information system, Medula, and pays the invoice it receives for those medicines from the pharmacies contracted with the SSI. This means that, patients do not pay for those medicines as their costs are covered by the SSI. Patients pay, however, a prescription fee and a contribution fee to the social security system. Both of these fees aim at preventing abuses of the healthcare system, including overconsumption of medicines, as well as ensuring its financial sustainability. These fees are not economically significant and many patients, such as those with chronic diseases, are in fact exempted from the contribution fee.

21. Out of the 26.600 retail pharmacies in Turkey, 25.300 are under contract with the SSI. Retail pharmacies which do not have individual contract with the SSI do not have access to and do not use the SSI's Medula system. Although these retail pharmacies may *sell* medicines included in Annex 4/A, they cannot invoice those medicines to the SSI. These are mostly retail pharmacies located in touristic areas and pharmacies that focus their offer on cosmetic products rather than medicines.

### **III. THE MEASURES AT ISSUE**

22. The European Union challenges three measures. First, the European Union challenges the localisation measure whereby "Turkey requires foreign producers to commit to localise in Turkey their production of certain pharmaceutical products". Second, the European Union challenges the alleged import ban on localised products. Third, the European Union challenges the prioritization measure whereby "Turkey gives priority to the review of applications for inclusion of domestic pharmaceutical products in the list of products covered by the reimbursement system, as well as with respect to some licensing policies and processes, over the review of the applications of like imported products". The European Union's claims with respect to all three measures must be rejected.

### **IV. THE LOCALISATION MEASURE**

23. Good health is impossible without access to medicines. Guaranteeing sufficient domestic production is an important step for ensuring access to medicines. Indeed, local production of medicines, especially in developing countries, is widely recognized as an important way to increase access to medicines and improve public health.

24. The localisation measure aims at ensuring an uninterrupted access to safe, effective and affordable medicines in Turkey by guaranteeing domestic supply of medicines and financial sustainability of the social security system.

25. For a developing country having such a generous social security system as Turkey, the prices of medicines must be set at the lowest possible rate so as to ensure the financial sustainability of the system without compromising patients' access to medicines. In that context, local production of medicines prevents the risk of a shortage of supply, if pharmaceutical companies decide to supply other countries where they can receive a higher price for their products.

26. "Localisation" under the localisation measure does not mean that the entire production process needs to take place in Turkey. Rather, "localisation" requires that the bulk production, i.e. the

establishment of a finished pharmaceutical form (granular, tablet, solution) from raw materials (active substances) and excipients (inactive substances), takes place in Turkey. The localisation measure does not impose any restrictions on pharmaceutical companies' ability to import the active substance(s) or excipients into Turkey and does not require the use of domestic inputs of any kind.

27. The selection of pharmaceutical products subject to localisation was carried out by the TMMDA on the basis of two main criteria, namely: (i) whether a medicine holds a valid marketing authorization and sales permit in Turkey, and (ii) whether that medicine is included in Annex 4/A. All medicines that fulfil these two criteria are initially considered within the scope of localisation. While determining the scope of the localisation measure, no distinction was made based on whether companies producing the medicines concerned have domestic or foreign capital.

28. The localisation measure was designed to be implemented through five phases. So far, only Phase 1 and Phase 2 have been implemented by Turkey. The classification of a medicine into one of the phases was based on two criteria: (i) the market share of the domestic production, and (ii) the existence of substitute medicine on the Turkish market. The two criteria have been selected to ensure the effectiveness of the localisation measure in the long term, while minimizing the risk that in the short term it could lead to a temporary shortage of supply. Indeed, the fact that Phase 1 and Phase 2 cover medicines which are already available on the market is justified by the need to guarantee that if companies are not willing to comply with the localisation measure, patients in Turkey will continue to have access to medicines included in these phases.

**A. The European Union has failed to establish the existence and precise content of the localisation measure**

29. While a complaining party may challenge any act or omission, it must establish the existence and precise content of the measure it challenges. The constituent elements that must be substantiated to prove the existence of a challenged measure depend on how the measure is described or characterized by the complainant.<sup>2</sup> If the complainant challenges a single measure composed of several different instruments, it must provide evidence of "how the different components operate together as part of a single measure and how a single measure exists as distinct from its components".<sup>3</sup>

30. Turkey takes issue with the fact that the European Union referred to the localisation measure as a "single and cohesive measure" which is based on a number of plans, instruments or tools but that the European Union failed to identify those instruments and tools precisely.

31. By failing to identify them precisely, the challenged measure becomes a moving target. This is particularly relevant in the context of the European Union's claim under Article X:1 of the GATT 1994 where the European Union has submitted that not all legal instruments that form part or give effect to the localisation measure have been published promptly. The European Union should have identified the specific instruments and tools which form part or give effect to the localisation measure. By failing to do so, the European Union did not to identify the precise content and scope of the measure it challenges.

32. Establishing the existence and precise content of the challenged measure is a threshold issue. Therefore, to the extent that the European Union is found not to have established the existence and/or precise content of what it describes as the "localisation requirement", the Panel should not proceed with examining the European Union's claims against that measure.

**B. The localisation measure is covered by Article III:8(a) of the GATT 1994**

33. Article III:8(a) of the GATT 1994 establishes a derogation from the national treatment obligation of Article III for government procurement activities falling within its scope. Thus, measures satisfying the requirements of Article III:8(a) are not subject to the national treatment obligation set out in Article III:4.

34. The localisation measure meets the requirements of Article III:8(a) and thus is not subject to the national treatment obligation of Article III:4. Furthermore, given that the localisation measure

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<sup>2</sup> Appellate Body Report, *Argentina – Import Measures*, para. 5.108.

<sup>3</sup> Appellate Body Report, *Argentina – Import Measures*, para. 5.108.

falls outside the scope of Article III, by virtue of Article III:8(a), that measure cannot be found to be inconsistent with Article 2.1 of the TRIMs Agreement.<sup>4</sup>

35. Turkey notes that for the purpose of interpreting and applying Article III:8(a) in this case, it is important for the Panel to look at the system of the provision of medicines included in Annex 4/A as a whole rather than at the individual transactions between different entities. The European Union's approach to Article III:8(a) is very formalistic, fails to take into account the specificities of Turkey's healthcare system and, if followed, would prevent WTO Members from organising their healthcare systems in the most cost-effective manner. It also goes against the approach taken in the European Union's legal system whereby contracts through which a statutory insurance fund pays part of the costs of medical equipment provided by a private company directly to patients appear to fall within the scope of "public supply contracts" and thereby public procurement.

1. *The localisation measure is a "law, regulation, or requirement governing procurement"*

36. Article III:8(a) of the GATT 1994 applies to measure constituting "laws, regulations or requirements governing procurement". This means that there must be "an articulated connection between the laws, regulations, or requirements and the procurement, in the sense that the act of procurement is undertaken within a binding structure of laws, regulations, or requirements".<sup>5</sup>

37. The localisation measure constitutes a "requirement" because compliance with the localisation measure determines whether or not a medicine will be covered by the "reimbursement scheme", i.e. whether that medicine will continue to be paid for by the SSI for the benefit of the Turkish population. The European Union appears to agree that the localisation measure constitutes a "requirement".

38. Furthermore, the localisation measure "governs" the procurement of medicines included in Annex 4/A because the compliance with the localisation measure determines whether a medicine will remain included and keep the active status in Annex 4/A. Only medicines with an active status in Annex 4/A are subject to the SSI procurement. It follows that there is an articulated connection between the localisation measure and the procurement.

39. Contrary to what the European Union argues, the Turkish healthcare and social security system involves the *procurement* by the SSI of medicines included in Annex 4/A and dispensed to patients.

40. The term "procurement" refers to "the process pursuant to which a government acquires products".<sup>6</sup> In the present case, the existence of procurement, i.e. the process pursuant to which the SSI acquires medicines included in Annex 4/A, is demonstrated by the fact that the SSI controls the entire process of obtaining and dispensing those medicines to patients. More specifically, (i) the SSI decides which medicines are listed in Annex 4/A; (ii) the SSI, together with the TMMDA, sets the prices of those medicines at all stages of the supply chain including the public price charged to the SSI, which is lower than the retail price charged for those medicines to a private party as a result of the application of statutory public discounts; (iii) the SSI signs contracts with retail pharmacies pursuant to which the latter dispense medicines included in Annex 4/A to patients in Turkey, (iv) the SSI approves the provision of medicines to be dispensed to patients through the Medula system and thereby purchases those medicines for the patients, and (v) finally, the SSI pays the public price for those medicines based on consolidated invoices it receives from the retail pharmacies.

41. It follows that, contrary to what the European Union argues, the role of the SSI is not limited to a mere financing of medicines included in Annex 4/A but is much broader and involves *procurement* of those medicines. The retail pharmacies play an important role in that process by acting on behalf of the SSI on the basis of the Protocol and the contracts signed between individual pharmacies and the SSI.

<sup>4</sup> Panel Reports, *Canada – Renewable Energy / Canada – Feed-in Tariff*, para. 7.118. (footnotes omitted).

<sup>5</sup> Appellate Body Reports, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 5.58.

<sup>6</sup> Appellate Body Reports, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 5.59.

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2. *The procurement is done "by governmental agency"*

42. The term "governmental agency" in Article III:8(a) of the GATT 1994 has been interpreted as referring to "an entity acting for or on behalf of government and performing governmental functions within the competences conferred on it".<sup>7</sup>

43. The SSI constitutes a governmental agency within the meaning of Article III:8(a) of the GATT 1994 because it is a public institution established by law, which acts on behalf of the Turkish government and performs governmental function namely the provision of social security and healthcare, including pharmaceutical products, to the Turkish population.

44. The European Union agrees with Turkey that the SSI is a "governmental agency" within the meaning of Article III:8(a) but argues that the SSI does not purchase medicines included in Annex 4/A. In essence, the European Union argues that "purchase" refers to a specific contractual arrangement which requires the governmental agency to acquire property over a product and to have a physical possession over that product. This is wrong.

45. Although Article III:8(a) does not define the concept of "purchase", the ordinary meaning of that term suggests that it involves a payment in exchange for a good. The specific features of a purchase, including whether the governmental agency obtains the physical possession or property rights over the product, will vary depending on factors such as the nature of the purchased product. Turkey considers that nothing in the ordinary meaning of the word "purchase" or in the text of Article III:8(a) suggests that a purchase must, in each and every case, involve acquiring property rights over a product.

46. The SSI purchases the medicines included in Annex 4/A from the retail pharmacies and instructs them to dispense those medicines directly to patients. In particular, a specific purchase transaction occurs when a patient presents a prescription for a medicine included in Annex 4/A in a retail pharmacy and the provision of that medicine to the patient is approved through the Medula system. At that moment, the SSI acquires the right to dispose of that medicine by dispensing it – through the pharmacy – to the patient. Contrary to what the European Union argues that approval does not merely confirm that the patient is under SSI coverage and that the medicine contained in the prescription is included in Annex 4/A. Importantly, that approval also means that the medicine may be invoiced by the pharmacy to the SSI at the previously set public price, which thereby purchases that medicine for the patient.

47. Article III:8(a) applies in the present case also because the purchase of medicines included in Annex 4/A by the retail pharmacies from the wholesalers is made on behalf of the SSI. In order to provide the services pursuant to the Protocol and the individual contracts between retail pharmacies and the SSI, retail pharmacies must first obtain pharmaceutical products included in Annex 4/A from the wholesalers in order to then dispense them to patients. 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. In the present case, the retail pharmacies are classified as primary healthcare service providers and as such perform certain duties on behalf of the SSI. It follows that to the extent the retail pharmacies perform certain duties for the SSI, based on the provisions of the Protocol and the individual contracts with the SSI, they act as governmental agencies.

48. Contrary to what the European Union argues, patients do not purchase medicines listed in Annex 4/A. Rather they are the receivers of the prescribed medicines that are purchased for them by the SSI. The existence of a purchase transaction requires mutual rights and obligations between the parties. There are no mutual rights and obligations between the patients and the pharmacies. The mutual rights and obligations, based on the Protocol and the individual contracts, arise only between the pharmacies and the SSI.

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<sup>7</sup> Appellate Body Reports, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 5.61.

3. *The localisation measure involves procurement of products purchased for "governmental purposes"*

49. The term "products purchased for governmental purposes" in Article III:8(a) refers to "products purchased for the use of government, consumed by government, or provided by government to recipients in the discharge of its public functions".<sup>8</sup>

50. Medicines included in Annex 4/A are purchased for governmental purposes within the meaning of Article III:8(a) because they are provided by the SSI, through the retail pharmacies, to patients in the discharge of its public function, namely the provision of healthcare services to the Turkish population. The European Union appears to agree that the provision of healthcare services constitutes a public function but takes issue with the fact that it is the retail pharmacies that dispense medicines listed in Annex 4/A to patients.

51. Turkey explained that for practical reasons, in order to improve the efficiency of the system and to reduce its costs, medicines purchased by the SSI are dispensed to patients by the retail pharmacies which act on behalf of the SSI. The fact that retail pharmacies act on behalf of the SSI is demonstrated by the provisions of the Turkish legislation, the terms of the Protocol and the individual contracts signed between the SSI and the retail pharmacies. It is also confirmed by the fact that retail pharmacies receive a service fee from the SSI for the service they provide on its behalf, that is the provision of medicines included in Annex 4/A to patients as well as the fact that retail pharmacies collect the contribution fee from the patients for the SSI.

52. Turkey also explained that in the past, the SSI itself obtained the medicines from the wholesalers and dispensed them to patients through pharmacies run by the SSI. Since that system was not efficient, it has been changed, with the introduction of the Transformation in Health Program in 2003, to a system whereby medicines are dispensed through retail pharmacies. The essence of the system after the reform remains unchanged, the only difference being that part of the tasks previously carried out by the SSI has now been delegated to the retail pharmacies.

53. Interestingly, the European Union appears to agree that pharmacies act on behalf of the SSI when they dispense medicines to patients in the context of its claim under Article 3.1(b) of the SCM Agreement where it argues that the SSI "entrusts" or "directs" the pharmacies to perform the function of "providing goods" to outpatients and that such function is one "normally vested in the government".

4. *The procurement is not done with a view to commercial resale or with a view to production of goods for commercial sale*

54. Article III:8(a) of the GATT 1994 does not apply to procurement "with a view to commercial resale or with a view to production of goods for commercial sale". A "commercial resale" is a "resale of a product at arm's length between a willing seller and a willing buyer".<sup>9</sup>

55. The procurement of medicines by the SSI is not done with a view to commercial resale since medicines are not resold on the commercial market but are dispensed by retail pharmacies – on behalf of the SSI – to patients. They are provided to patients upon presentation of a relevant prescription and are, at that moment, purchased for the patients by the SSI.

56. The fact that the patient may need to pay a contribution fee or the difference between the price of the received medicine and the price paid by the SSI in case the patient opts for a more expensive medicine within the equivalent group does not mean that there is a commercial resale transaction between that patient and the pharmacy. The payment made by the patient is not economically significant compared to the cost of the medicine.

57. When dispensing medicines included in Annex 4/A to patients, retail pharmacies provide a service on behalf of the SSI and receive a fixed service fee for that service. This further confirms

<sup>8</sup> Appellate Body Reports, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 5.74.

<sup>9</sup> Appellate Body Reports, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 5.70.

that the provision of medicines included in Annex 4/A to patients does not constitute "commercial resale".

58. Similarly, the SSI does not procure the medicines with a view to using them in the production of goods for commercial sale. Medicines listed in Annex 4/A are procured by the SSI with a view to ensure the access to medicines and, more generally, to provide adequate healthcare to the Turkish population. Those medicines are dispensed to patients to address their specific health needs.

**C. The localisation measure is not inconsistent with Article X:1 of the GATT 1994**

59. The Panel must reject the European Union's claim under Article X:1 of the GATT 1994 for the following reasons.

60. First, the European Union keeps changing the scope of its claim. Indeed, in its Panel Request and its written submissions, the European Union has taken issue with the non- or inappropriate publication of certain elements, terms and conditions of the localisation measure, the localisation measure as a single measure or some specific legal instruments or documents.

61. Second, to the extent that what the European Union challenges is the "Localisation Requirement" as a single measure, the European Union fails to show that that measure falls within the scope of Article X:1 of the GATT 1994. In particular, the European Union fails to show that the localisation measure is a "law, regulation, judicial decision or administrative ruling of general application" which has been made effective by Turkey. It also fails to demonstrate that that measure has not been published promptly in such a manner as to enable governments and traders to become acquainted with it.

62. Third, to the extent that what the European Union challenges is the lack of adequate and prompt publication of some specific legal instruments or documents, if those legal instruments and documents have not been identified in the Panel Request, they are outside the Panel's terms of reference. This applies in particular to the Roadmap and the HSPC Decision regarding the Localisation Process. Regarding the other legal instruments and documents, such as the localisation announcements, private communications and presentations, the European Union has failed to show that they fall within the scope of Article X:1 of the GATT and that they have not been published promptly and adequately as required by Article X:1.

63. Announcements which are published on a publicly accessible government website in their final version are published "in a manner as to enable governments and traders to become acquainted with them". Private communications sent and presentations delivered by government officials do not have a general scope of application, nor have been "made effective" and therefore fall outside the scope of Article X:1.

**D. The localisation measure is justified under Article XX(b) of the GATT 1994**

64. Should the Panel find that the localisation measure does not fall within the scope of Article III:8(a) of the GATT 1994 and is inconsistent with Article III:4 of the GATT 1994 and Article 2.1 of the TRIMs Agreement – *quod non* – any such inconsistency is justified under Article XX(b) of the GATT 1994.

65. Article XX(b) justifies GATT-inconsistent measures that are "necessary to protect human, animal or plant life or health". The responding party must show that the measure is provisionally justified under paragraph (b) of Article XX and meets the requirements of the chapeau.

*1. The localisation measure is provisionally justified under Article XX(b) of the GATT 1994*

66. To be provisionally justified under Article XX(b), the policy objective pursued by the measure must be the protection of human, animal or plant life or health; and the measure must be necessary to fulfil that policy objective. The determination whether the challenged measure is necessary to fulfil that policy objective is based on a weighing and balancing of the importance of the interests or values at stake, the extent of the contribution to the achievement of the measure's objective, and its trade restrictiveness.<sup>10</sup> If the Panel finds that the challenged measure is necessary, it may confirm this finding by comparing the measure at issue with alternative measures that are less-trade

<sup>10</sup> Appellate Body Report, *Brazil – Retreaded Tyres*, para. 178.

restrictive while providing an equivalent contribution to the achievement of the measure's objective. The burden to identify such alternative measures rests of the European Union.

a. The localisation measure is designed to protect human life and health

67. The localisation measure is designed to ensure an uninterrupted access to safe, effective and affordable medicines for all patients in Turkey which falls within the range of policies to protect human life and health within the meaning of Article XX(b) of the GATT 1994.

68. Local production is recognised by the WHO and other international organisations as an effective tool for improving access to medicines. By requiring that certain medicines be produced domestically in order to be included in Annex 4/A, the localisation measure seeks to ensure that those medicines are available to patients in Turkey.

69. Contrary to what the European Union argues, the localisation measure is not a tool to remedy any potential short-term shortage of supply but serves the long-term objective of ensuring stable access to safe, effective and affordable medicines in Turkey.

70. This requires addressing long-term pressures exerted on the Turkish healthcare and social security system, including a growing and aging population, in addition to any acute risks to the supply of medicines that may arise from global pandemics or other emergencies. Access to medicines requires both their availability and affordability. Turkey considers that local production of medicines in Turkey is necessary to preserve and improve the long-term availability of safe and effective medicines which the healthcare system can continue to provide in a financially sustainable manner.

71. The fact that the localisation measure is designed to protect human life and health by ensuring adequate access to medicines in Turkey is confirmed by the design and structure of that measure, as well as the authorities responsible for its implementation. It is also recognised in a number of official documents.

72. Furthermore, the fact that the localisation measure may be seen as pursuing an industrial policy objective, in addition to the public health objective, does not preclude the measure from being justified under Article XX(b) of the GATT 1994. A measure may pursue multiple objectives which will often be intertwined and may be advanced in a mutually supportive manner.<sup>11</sup> The fact that policies supporting local production of medicines may be seen as pursuing both public health and industrial objectives and that these two objectives are complementary has been recognized by the WHO and the European Union itself in its recent Pharmaceutical Strategy for Europe.

b. The localisation measure is necessary to protect human life and health

73. The localisation measure is "necessary" because it pursues an extremely vital objective, is apt to materially contribute to that objective and is not trade restrictive.

74. First, it is well established that the more vital or important the interests or values pursued by a measure, the easier it is to accept that measure as necessary<sup>12</sup> and that the preservation of human life and health is "both vital and important to the highest degree".<sup>13</sup> The European Union agrees that the "objective to ensure adequate access to medicines falls within the scope of Article XX(b) of the GATT 1994 and is 'extremely vital and important'".

75. Second, the localisation measure is apt to make a material contribution to the objective of ensuring stable access to medicines in Turkey. This is supported by a number of documents and statements from the WHO and other international organisations such as UNCTAD, UNIDO or the OHCHR which endorse local production as a way to improve access to medicines and thereby improve public health.

76. Whereas local production of medicines may have different effects in different countries, the factors which may jeopardize the successful implementation of a localisation policy, such as a weak regulatory environment, a lack of availability of quality-assured materials or a skilled workforce, are

<sup>11</sup> Appellate Body Reports, *US – Clove Cigarettes*, paras. 113, 115, *US – Tuna II (Mexico)*, para. 302.

<sup>12</sup> Appellate Body Report, *Korea – Various Measures on Beef*, para. 162.

<sup>13</sup> Appellate Body Report, *EC – Asbestos*, para. 172.

not present in Turkey. Furthermore, the available studies suggest that localisation policies materially contribute to ensuring access to medicines, especially for rural populations.

77. Finally, contrary to what the European Union argues Turkey is not required to present quantifiable effects of the localisation measure. In fact, since the implementation of the localisation measure is still ongoing, given that only two of its five phases have been implemented so far, it is too early to accurately evaluate and quantify the effects of the measure. In that regard, the Appellate Body has recognized that "certain complex public health [...] problems may be tackled only with a comprehensive policy comprising a multiplicity of interacting measures" and thus, in short term, it might be "difficult to isolate the contribution to public health [...] objectives of one specific measure from those attributable to the other measures that are part of the same comprehensive policy".<sup>14</sup>

78. Third, the localisation measure is not trade restrictive. The localisation measure does not restrict the importation of medicines to Turkey but relates to the status of certain medicines in Annex 4/A, which provides the list of medicines paid for by the SSI.

79. Medicines which do not comply with the localisation measure may continue to be imported and placed on the Turkish market without any restrictions. While the SSI will not procure such medicines, as acknowledged by the European Union, other entities such as private insurance companies may still purchase those medicines. The localisation measure is also implemented in a flexible manner whereby pharmaceutical companies are granted a transition period and may propose localisation of alternative products. These features of the localisation measure ensure that its trade restrictiveness is limited as much as possible. In any event, any trade-restrictive effects of the localisation measure are outweighed by a material contribution which that measure makes to the achievement of its public health objective.

80. There are also no less trade restrictive alternative measures which are reasonably available and would achieve the objective of ensuring access to medicines in Turkey to the same degree as the localisation measure. In fact, the European Union has failed to satisfy its burden of proof because it merely enumerated general categories of measures which may be "useful for improving access to medicines" but failed to explain how any of these measures would contribute to ensuring uninterrupted access to safe, effective, and affordable medicines in Turkey.

81. In any case, the alternative measures put forward by the European Union do not constitute viable "alternative measures". First, since the localisation measure serves the long-term objective of ensuring uninterrupted access to safe, effective and affordable medicines, any measure that may remedy an *ad hoc* short-term shortage of supply is not an alternative to the localisation measure. Second, measures which are already in place in Turkey do not constitute alternative measures, so that they cannot be taken into account. Finally, measures which rely on investment promotion, such as the facilitation of joint ventures with foreign pharmaceutical manufacturers are not capable of ensuring reliable access in times of increased worldwide demand for medicines, as demonstrated by the COVID-19 pandemic.

2. *The localisation measure is applied in accordance with the chapeau of Article XX of the GATT 1994*

82. Measures which are provisionally justified under one of the paragraphs of Article XX cannot, pursuant to the chapeau of Article XX, be applied in a manner that constitutes arbitrary or unjustifiable discrimination between countries where the same conditions prevail or that constitutes a disguised restriction on international trade.

83. The localisation measure applies indistinctly to pharmaceutical products falling within the scope of localisation irrespective of the country of origin of the products. While based on objective criteria, it provides necessary flexibility for taking into account the circumstances of specific pharmaceutical companies. Pharmaceutical companies whose products are subject to localisation are able to request exemption by proposing to localise an alternative product or request additional time to complete localisation.

84. Furthermore, the implementation of the localisation measure through five phases follows a discernible logic and has a clear rational connection with its public health objective. Turkey sought to minimize the risk of a short-term shortage of supply due to the implementation of the measure

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<sup>14</sup> Appellate Body Report, *Brazil – Retreaded Tyres*, para. 151.

by including in the first and second phases only medicines that, to a certain extent, are already produced in Turkey. This approach balances long-term supply security with avoiding short-term shortages and does not give rise to a contradiction, contrary to what the European Union suggests.

85. It follows that the localisation measure is applied in conformity with the chapeau and is therefore justified under Article XX(b).

**E. The localisation measure is justified under Article XX(d) of the GATT 1994**

86. In the alternative, the localisation measure is justified under Article XX(d) of the GATT 1994 because it is necessary to secure compliance with the laws and regulations requiring Turkey to ensure accessible, effective and financially sustainable healthcare.

87. To justify a measure that is inconsistent with the GATT 1994 under Article XX(d), the responding party must identify (i) "laws or regulations" that are consistent with the provisions of the GATT 1994. The challenged measure must be (ii) "necessary" to "secure compliance" with the "laws or regulations" that the responding party identifies. In addition, the measure must meet the requirements of the chapeau of Article XX.

*1. Laws and regulations requiring Turkey to ensure accessible, effective and financially sustainable healthcare system*

88. The term "laws and regulations" in Article XX(d) covers "rules of conduct and principles governing behaviour or practice that form part of the domestic legal system of a Member".<sup>15</sup> Such rules or principles may be laid down in specific provisions of a specific instrument, or several elements or parts of one or more instruments under a Member's domestic legal system.<sup>16</sup> Rules of international law "may have direct effect within the domestic legal systems of some Members without specific domestic action to implement such rules".<sup>17</sup>

89. Articles 2, 56 and 60 of the Turkish Constitution, Law No. 5510 and Article 405 of Presidential Decree No. 4, as well as several international human rights treaties to which Turkey is a party, in particular Articles 9 and 12 of the International Covenant on Economic, Social and Cultural Rights ("ICESCR") and Articles 11(1) and 12 of the European Social Charter ("ESC"), together impose a rule that Turkey must provide accessible, effective and financially sustainable healthcare. The ICESCR and ESC are international agreements that contain fundamental rights and freedoms and therefore apply directly in the Turkish domestic legal order by virtue of Article 90 of the Turkish Constitution. These domestic and international instruments are themselves not GATT inconsistent. As a result, the obligation to ensure accessible, effective and financially sustainable healthcare falls within the scope of Article XX(d) of the GATT 1994.

*2. The localisation measure is necessary to secure compliance with such "laws or regulations"*

90. A measure is necessary to secure compliance with GATT-consistent laws and regulations if two conditions are met.

91. First, the measure is designed 'to secure compliance' with specific rules, obligations, or requirements under the relevant provisions of such 'laws and regulations', meaning that it must not be "incapable" of securing compliance with the identified rules or regulations.<sup>18</sup>

92. The localisation measure, by encouraging domestic production of medicines in Turkey, with a focus on local production of common medicines which are most essential for healthcare needs, is not "incapable" of ensuring that the provision of those medicines by the SSI remains financially viable in the future, so as to ensure accessible and effective healthcare.

93. Second, the assessment of the "necessity" of the challenged measures involves the "weighing and balancing" of (i) the importance of securing compliance with the laws or regulations at issue; (ii) the contribution of the measure to securing compliance with the laws or regulations at issue;

<sup>15</sup> Appellate Body Report, *India – Solar Cells*, para. 5.106.

<sup>16</sup> Appellate Body Report, *India – Solar Cells*, para. 5.111.

<sup>17</sup> Appellate Body Report, *India – Solar Cells*, para. 5.140.

<sup>18</sup> Appellate Body Reports, *India – Solar Cells*, para. 5.58; *Colombia – Textiles*, para. 5.135; Panel Report, *Indonesia – Chicken*, para. 7.248.

and (iii) the trade-restrictiveness of the measure.<sup>19</sup> If this assessment renders the preliminary conclusion that the measure is necessary, the burden shifts to the complainant to show that the invoked objective could be achieved with less trade-restrictive alternative measures.

94. The right to health and social security are of central importance in guaranteeing human dignity. Ensuring the long-term sustainability of the Turkish social security system as well as the stable supply of medicines are interrelated objectives that ultimately serve a vital and important health interest.<sup>20</sup> The European Union appears to agree that ensuring accessible, effective and financially sustainable healthcare is of vital importance.

95. The localisation measure contributes to securing compliance with the obligation to ensure accessible, effective, and financially sustainable healthcare by encouraging the domestic production of medicines listed in Annex 4/A. Turkey submits that for the financial sustainability, the healthcare system should rely more on domestic products, since the medicines which are domestically produced are less costly over the years and they are more easily supplied.

96. As explained above in the context of Article XX(b), the localisation measure is not trade restrictive and, in any event, the degree of restrictiveness is offset by the measure's contribution to its objective.

97. Finally, there are no less trade restrictive alternative measures which are available to Turkey and would achieve its objective to the same degree as the localisation measure. By providing an open-ended list of vaguely described policies, the European Union has failed to identify "alternative measures" for the purpose of Article XX(d) of the GATT 1994. In any case, the general measures put forward by the European Union would not preserve Turkey's chosen level of protection. In particular, the suggestion that Turkey cuts spending and raises taxes and patients' co-payments would negatively impact the accessibility of the healthcare system and risk further impoverishing already disadvantaged populations.

3. *The localisation measure is applied in accordance with the chapeau of Article XX*

98. The localisation measure serves the long-term objective of ensuring uninterrupted access to medicines in Turkey while preserving the financial sustainability of the Turkish healthcare system. The measure thus covers all pharmaceutical products included in Annex 4/A, i.e. products that are purchased by the SSI and provided to patients. The fact that the measure does not differentiate on the basis of the price of the pharmaceutical products cannot lead to a conclusion that its application amounts to arbitrary or unjustifiable discrimination. Indeed, access and sustainability must be ensured with regard to all medicines included in Annex 4/A.

99. Accordingly, the manner in which the localisation measure is implemented has a clear rational connection to its aim and therefore the localisation measure meets the requirements of the chapeau of Article XX of the GATT 1994.

**F. The localisation measure is not inconsistent with Article 3.1(b) of the SCM Agreement**

100. The European Union's alternative claim under Article 3.1(b) of the SCM Agreement must be rejected because the system of the provision of medicines included in Annex 4/A to patients does not involve the granting of a subsidy and, in any case, any alleged subsidy is not contingent upon the use of domestic over imported products.

1. *No financial contribution*

101. For a subsidy to exist there must be a financial contribution that confers a benefit. The evaluation of the existence of a "financial contribution" involves examining the nature of the transaction through which something of economic value is transferred by a government to economic operators as opposed to its effects.<sup>21</sup> Article 1.1 (a)(1) of the SCM Agreement outlines various

<sup>19</sup> Appellate Body Report, *India – Solar Cells*, para. 5.59.

<sup>20</sup> Appellate Body Report, *EC – Asbestos*, para. 172.

<sup>21</sup> Appellate Body Report, *US – Softwood Lumber IV*, para. 52.

transactions deemed to be forms of financial contributions under the SCM Agreement. In the present case, the European Union has failed to establish the existence of a financial contribution.

102. First, contrary to what the European Union argues there is no financial contribution in the form of direct transfer of funds. This is because the payments made by the SSI to retail pharmacies for medicines that are dispensed to outpatients constitute normal payments for goods purchased by the SSI from the pharmacies. Adopting the European Union's view would turn virtually any government payment for purchased goods into a "transfer of funds". This view does not align with the Appellate Body's finding that the bracketed examples in Article 1.1 (a)(1)(i) are illustrative of the conduct captured by the sub-paragraph (i).<sup>22</sup> The specific examples (grants, loans, and equity infusion) indicate that Article 1.1 (a)(1)(i) is concerned with various forms of government capital or debt financing to an economic operator to the exclusion of normal payments for goods supplied on behalf of a government entity. This is confirmed by the Appellate Body's findings in *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, where the Appellate Body rejected Japan's argument that the government payments for electricity constituted direct transfers of funds.<sup>23</sup>

103. Second, the fact that retail pharmacies can be seen as being "entrusted" or "directed" by the SSI to dispense medicines to outpatients, does not mean that the system of the provision of medicines listed in Annex 4/A amounts to a "subsidy" within the meaning of the SCM Agreement. This is because the provision of medicines included in Annex 4/A to outpatients does not confer any indirect benefit on the pharmaceutical companies and the direct benefit conferred on outpatients falls outside the scope of the SCM Agreement. Thus, a holistic analysis of the measure at issue shows that it does not qualify as a subsidy, understood as a financial contribution which confers a benefit, within the meaning of the SCM Agreement.

## 2. *No benefit*

104. The European Union argues that the two types of financial contributions it has identified confer a *direct benefit* upon outpatients because the latter are "better-off" compared to a situation where they would be required to pay to the retail pharmacies the full price of the medicine included in Annex 4/A. The European Union further argues that because of the direct benefit conferred upon the outpatients, there is an *indirect benefit* on producers of medicines included in Annex 4/A as the financial contributions lower the cost of those medicines to the outpatients making them more attractive relative to imported like products not included in Annex 4/A. These arguments must be rejected.

105. First, the *direct benefit* to outpatients falls outside the scope of the SCM Agreement.

106. Indeed, the scope of the SCM Agreement is limited to economic entities that receive a "benefit". This is confirmed by the text of several provisions of the SCM Agreement, including Articles 2.1, 6(1)(b), 11.2(ii) and 19.3, which refer to "enterprise", "industry", "firm" or "producer". These textual references and emphasis on the notion of industry or enterprise support the interpretation that the SCM Agreement does not contemplate an individual citizen (consumer), in the present case a patient, as the recipient of a "benefit". This is confirmed by the object and purpose of the SCM Agreement which is to impose "multilateral disciplines" on subsidies which "distort international trade".<sup>24</sup> Subsidies which assist citizens by ensuring their access to medicines are not subsidies which distort international trade. Thus, patients are not the "recipient" of a benefit within the meaning of the SCM Agreement. In that sense any "benefit" conferred on the patients falls outside the scope of the SCM Agreement.

107. Second, there is no *indirect benefit* to producers of pharmaceutical products included in Annex 4/A.

108. The European Union bears the burden to show how the "benefit" flows from the direct subsidy recipient (i.e. outpatient) to the indirect subsidy recipient (i.e. pharmaceutical companies). This cannot be simply presumed. The European Union, however, has failed to meet this burden.

<sup>22</sup> Appellate Body Report, *US – Large Civil Aircraft (2nd Complaint)*, para. 615.

<sup>23</sup> Appellate Body Reports, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 5.131.

<sup>24</sup> Panel Report, *Canada – Aircraft*, para. 9.119.

109. The direct benefit provided to patients is not transmitted or passed through to the producers of pharmaceutical products because there is no relationship – contractual or of any other kind – between the patients and the producers. Thus, the situation in the present case is very different from the situation in *Brazil – Aircraft (Article 21.5 – Canada II)*, referred to by the European Union.

110. Medicines included in Annex 4/A are prescribed by medical doctors on the basis of specific health needs of a given patient and are paid for by the SSI. Patients do not know whether the medicine prescribed to them by a medical doctor is domestic or imported. Patients do not go to a retail pharmacy and choose the medicine of their liking. They are not the "purchasers" of medicines included in Annex 4/A. Rather, patients come to a retail pharmacy with a prescription issued by a medical doctor and are provided with the medicine that was prescribed to them in a specific dose and for a specific period of time.

### 3. *No contingency upon the use of domestic over imported products*

111. To be prohibited by Article 3.1(b) of the SCM Agreement, a subsidy must be "contingent upon the use of domestic over imported goods". The European Union argues that this requirement is met because the alleged subsidy is contingent upon the use of domestic over imported medicines by patients. This argument must be rejected.

112. The localisation measure is addressed only to producers of pharmaceutical products and not to patients. It therefore does not impose any condition or requirement for the patients to use domestic over imported medicines. Furthermore, the use of medicines by patients does not lead to contingency within the meaning of Article 3.1(b) of the SCM Agreement. The term "use" refers to "consuming a good in the process of manufacturing" or "incorporating a component into a separate good, or serving as a tool in the production of a good".<sup>25</sup> This interpretation of the term "use" in Article 3.1(b) of the SCM Agreement is consistent with the fact that the "recipient" of a "benefit" as contemplated by the SCM Agreement is a producer, an enterprise, an industry or a firm and not individual citizen or consumer. Thus, the personal medical use of pharmaceutical products by patients in Turkey does not constitute "use" within the meaning of Article 3.1(b) of the SCM Agreement. This position is supported by Canada.

113. In any case, the contingency requirement must be satisfied at the level of the entity which has received the subsidy falling within the scope of the SCM Agreement, namely the economic operators. Indeed, any contingency relating to a "subsidy" which is outside the scope of the SCM Agreement logically cannot be inconsistent with Article 3.1(b). This means that any alleged contingency on the "use" of domestic over imported medicines *by patients* is inapposite for the purpose of the European Union's claim under Article 3.1(b) of the SCM Agreement.

114. Furthermore, to the extent that the European Union takes issue with the fact that the localisation measure requires the production of medicines in Turkey in order for those medicines to be included in Annex 4/A, there can be no violation of Article 3.1(b) of the SCM Agreement as it does not prohibit the subsidization of the domestic "production" *per se*. The localisation measure sets a local production requirement for the procurement of certain group of medicines by the SSI. It does not require the use of any domestic inputs in the production process. It follows that the alleged subsidy to pharmaceutical companies, if anything, is conditional upon the domestic production of medicines and not upon the use of domestic over imported goods. A measure which requires the siting of certain manufacturing activities in a WTO Member does not make a subsidy contingent upon the use of domestic over imported products.<sup>26</sup>

## V. THE IMPORT BAN

115. For placing a medicine on the Turkish market, that medicine must *inter alia* have received a valid marketing authorization. The purpose of this authorization is for the Ministry of Health to ensure that medicines placed on the market are effective in their designated use, are safe and feature the appropriate pharmaceutical properties.

116. Once a real person or a legal entity obtains a marketing authorization for a medicine, they cannot obtain a second marketing authorization for a product *which is identical in all respects*, having

<sup>25</sup> Appellate Body Report, *US – Tax Incentives*, para. 5.8. See also Appellate Body Report, *Brazil – Taxation*, para. 5.242.

<sup>26</sup> Appellate Body Report, *US – Tax Incentives*, paras. 5.41, 5.75-5.76.

the same composition and the same pharmaceutical form and commercial name. This rule, set out in Article 20(2) of the Marketing Authorisation Regulation, applies to all medicines regardless of whether they are imported or produced domestically.

117. The European Union argues that the localisation measure in conjunction with the single authorisation rule results in an "import ban" on localised medicines inconsistent with Article XI:1 of the GATT 1994. This claim must be rejected.

**A. The European Union has failed to establish the existence and precise content of the import ban**

118. To the extent that the European Union describes the measure as the "import ban on localised products", it must demonstrate the existence of a formal prohibition on the importation of localised medicines. There is, however, no such prohibition on the importation of medicines in Turkey.

119. First, the same medicine can receive a different marketing authorization if it is presented in a different form or has a different dosage. Second, a "special import authorization" may be requested in specific circumstances for exactly the same medicine. Third, a single marketing authorization may indicate multiple production sites in Turkey or abroad. Finally, contrary to what the European Union argues sister companies, with separate legal entities, may obtain different marketing authorizations for the same product and products with the same active ingredient may have different marketing authorizations when intended for different therapeutic indications.

120. Since the European Union has failed to establish the existence of a measure formally prohibiting the importation of localised pharmaceutical products, i.e. the import ban, the Panel should not proceed with examining the claim of inconsistency with Article XI:1 of the GATT 1994.

**B. There is no violation of Article XI:1 of the GATT 1994**

121. The European Union's claim must be rejected as Article XI:1 of the GATT 1994 is not applicable given that the measure causing the alleged restriction is an internal measure which falls within the scope of Article III of the GATT 1994 and not of Article XI:1.

122. Indeed, the measure causing the alleged restriction, if any, is not the "import ban" which constitutes the effect, but Article 20(2) of the Marketing Authorization Regulation. This rule is an internal measure which falls within the scope of Article III of the GATT 1994.

123. Article 20(2) of the Marketing Authorization Regulation which is part of the marketing authorization rules constitutes a law, regulation or requirement which affect the internal sale and offering for sale of pharmaceutical products, within the meaning of Article III:4 and it therefore falls within the scope of that provision. This rule applies to all products, regardless of where they are manufactured, namely in Turkey or abroad. It follows that the restriction, if any, is a restriction of not getting a second marketing authorization and is thus not a restriction "on the importation", that is a restriction "with regard to" or "in connection" with the importation of pharmaceutical products. The mere fact that such a rule is enforced with respect to imports at the time of importation, because it is easier or more efficient to do so, does not render the rule a restriction "on importation" that is prohibited under Article XI. Otherwise, it would mean that all domestic regulations, as they apply to imports, would become border measures and would consequently be prohibited pursuant to Article XI:1 of the GATT 1994.

124. Furthermore, even if Article XI:1 of the GATT is found to be applicable, *quod non*, there is no "prohibition" on the importation of localised medicines as explained above. In particular, where a producer can obtain an import marketing authorization for the same medicine, whether in another form or in a different dosage, there is no prohibition.

**C. The import ban is justified under Article XX(d) of the GATT 1994**

125. If the Panel were to conclude that there is an import ban and that this import ban is inconsistent with Article XI:1 of the GATT 1994, Turkey submits that this import ban is in any case justified under Article XX(d) of the GATT 1994 as necessary to secure compliance with the localisation measure. The latter is covered by the derogation under Article III:8(a) of the GATT 1994 and thus is not WTO-inconsistent.

1. *The effect of the measure at issue is to ensure the effectiveness of the localisation measure*

126. The measure the European Union refers to as the import ban on localised products is the outcome of the rules on marketing authorization when applied to localised products. This measure is necessary in order to secure compliance with the localisation measure.

127. The measure prevents pharmaceuticals manufacturers from circumventing the localisation measure by localizing a negligible part of production of a given product and supplying the remaining part by importation. Without this measure, Turkey will not be able to achieve the health and development objectives pursued by the localisation measure.

2. *The measure at issue is necessary to secure compliance with the localisation measure*

128. The determination of whether a challenged measure is necessary to secure compliance with a GATT-consistent law or regulation under Article XX(d) of the GATT 1994 involves a process of weighing and balancing a series of factors, including the importance of the common interests or values protected by that law or regulation, the contribution made by the compliance measure to the enforcement of the law or regulation at issue, and the accompanying impact of the law or regulation on imports or exports.

129. The import ban contributes to the objective of the localisation policy, which is to protect human life and health by ensuring an uninterrupted access to safe, effective and affordable medicines for all patients in Turkey. As emphasized by the Appellate Body in *EC – Asbestos* and as acknowledged by the European Union, the preservation of human life and health is "both vital and important in the highest degree".<sup>27</sup> The Panel should give appropriate weight to that.

130. The import ban on the localised products ensures that pharmaceutical products subject to localisation are produced in Turkey. Indeed, without the import ban pharmaceutical companies could easily circumvent the localisation measure by localizing only small part of the production while continuing to rely on imports. It follows that the measure substantially contributes to securing compliance with the localisation measure.

131. Furthermore, the trade-restrictiveness of the measure remains limited. Indeed, although localised pharmaceutical products cannot be imported into Turkey, the same pharmaceutical product may have two marketing authorizations if it is sold in a different form or if it has a different composition (e.g. different salts of the active substance or excipients or different dosage). Additionally, the measure is limited to one manufacturer meaning that two sister pharmaceutical companies registered as different legal entities may request two marketing authorizations for the same pharmaceutical product. Similarly, when the same pharmaceutical product has different indications, that pharmaceutical product may be granted two different marketing authorizations.

132. Turkey submits that any trade-restrictiveness of that measure is in any event outweighed by the fact that the measure makes a material contribution to the achievement of its objective, i.e. ensuring compliance with the localisation measure.

133. Finally, there are no less trade-restrictive alternative measures which would ensure compliance with the localisation measure to the same degree and a labelling requirement suggested by the European Union does not constitute a viable alternative measure. More specifically, a labelling requirement would not be less trade-restrictive, since medicines would still only be paid for by the SSI if they were produced domestically and not if they were imported. Moreover, the labelling requirement would not ensure the enforcement of the localisation measure to an equivalent degree and would impose an undue burden on the Turkish authorities.

3. *The measure is applied in accordance with the chapeau of Article XX*

134. Finally, the measure meets the requirements of the chapeau of Article XX of the GATT. Indeed, the alleged import ban does not discriminate arbitrarily since it stands in clear connection to the objective of enforcing the Turkish marketing authorization rules with respect to localised products. The measure also does not discriminate unjustifiably since there is a clear anti-circumvention rationale behind the measure. Finally, the alleged import ban applies equally with respect to all

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<sup>27</sup> Appellate Body Report, *EC – Asbestos*, para. 172.

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localised pharmaceutical products regardless of origin and therefore does not discriminate between countries where the prevailing conditions are the same.

135. Turkey understands that the European Union agrees that the measure is applied consistently with the chapeau since it has not presented any arguments with respect to the chapeau of Article XX.

## **VI. THE PRIORITIZATION MEASURE**

136. Turkey provides the possibility to apply for priority assessment of certain applications and requirements relating to pharmaceutical products in specific cases and based on objective criteria. In each case, priority assessment can be requested for domestically manufactured products as well as imported products.

137. For GMP and marketing authorization applications, the Guideline for Working Principles and Procedures of Human Medicinal Products Priority Assessment Commission ("Prioritization Guideline") sets out the criteria for priority treatment, as well as the procedure that must be followed to obtain priority. Imported medicines in the scope of the Prioritization Guideline may apply for prioritization in the same way as domestic products. The Prioritization Guideline requires applicants to submit a prioritization request, which is then considered by the TMMDA. For applications for inclusion in Annex 4/A, the Drug Reimbursement Regulation provides that the Medicine Reimbursement Commission evaluates and decides on applications for inclusion in the list.

### **A. The European Union has failed to establish the existence and precise content of the prioritization measure**

138. If the complaining party challenges a single measure composed of several different instruments, it must provide evidence of "how the different components operate together as part of a single measure and how a single measure exists as distinct from its components".<sup>28</sup> Likewise, challenging an ongoing conduct requires "evidence of its repeated application, and of the likelihood that such conduct will continue".<sup>29</sup>

139. Based on the description of the measure in the European Union's first written submission, Turkey understood that the European Union challenges the prioritization measure as a measure of general application consisting of a practice or an ongoing conduct whereby Turkey gives priority to the review of applications of domestic medicines over the review of the applications of like imported products. The European Union did not initially dispute Turkey's description of the prioritization measure as an ongoing conduct or practice of general application.

140. The European Union, however, has failed to provide any evidence that Turkey effectively gives priority to domestic pharmaceutical products over imported products, thereby failing to establish the existence of the prioritization measure.

141. Whereas Turkish law provides authorities with a possibility to give priority in certain administrative procedures relating to pharmaceutical products, this alone does not suffice to establish a general practice favouring domestic products to the detriment of imports.

142. First, the possibility of the Chair of Medical and Economic Assessment Committee, which reviews applications for medicines to be included in Annex 4/A, to hold an extraordinary meeting to examine applications for domestically manufactured products, does not prove the uniform practice which the European Union challenge, i.e. that this discretion is in fact exercised in a manner that prioritises locally produced medicines.

143. Second, the fact that certain applications for priority review are scored pursuant to the Prioritization Guideline based on criteria which include whether a medicine is locally produced does not imply that granting priority is mandatory in such cases.

144. To the extent that the European Union later argued that it challenges as such the various legal instruments supporting the prioritization measure, this does not correspond to the description of the

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<sup>28</sup> Appellate Body Report, *Argentina – Import Measures*, para. 5.108.

<sup>29</sup> Appellate Body Report, *Argentina – Import Measures*, para. 5.108 referring to Appellate Body Report, *US – Continued Zeroing*, para. 191.

measure included in the Panel Request and the European Union's earlier submissions and would change the scope of the measure. Turkey further notes that it remains unclear which specific legal instruments are allegedly challenged as such. While the European Union specifically refers to the SSI Regulation and the Prioritization Guideline, it also refers to "various action plans, programmes and legal instruments underpinning the Prioritization Measure". In any case, the European Union has failed to establish the WTO-inconsistency of those legal instruments because it has not established that certain laws or regulations will necessarily be inconsistent with Turkey's obligations. Indeed, the mere possibility that priority might be granted is not enough to establish an "as such" inconsistency with WTO Agreements.

**B. There is no violation of Article III:4 of the GATT 1994**

145. Even if it were to be concluded that the European Union has demonstrated the existence and precise content of the prioritization measure, *quod non*, Turkey submits that there is no violation of Article III:4 of the GATT 1994.

146. First, the European Union does not show that the "prioritization measure" as a single measure constitutes a law, regulation or requirement. To the extent that the European Union argues that the prioritization measure constitutes a "requirement" because it lays down a condition to obtain an advantage, i.e. priority, this is incorrect. Indeed, even if the product fulfils the condition, namely it is domestically produced, it is not necessarily so that priority will be granted. In other words, the discretion left to the authorities prevents from qualifying the measure as a "requirement".

147. Second, no less favourable treatment is accorded to imported medicines over domestic medicines. Indeed, given that the authorities have discretion to assess the application for prioritization submitted by an applicant, there is no competitive advantage being granted to domestic over imported medicines. In other words, the status of a medicine as "domestic product" does not guarantee that such medicine will be treated with priority.

148. Finally, the data submitted by Turkey support the conclusion that the European Union fails to make a *prima facie* case that imported medicines are treated less favourably than domestically manufactured medicines.

**VII. CONCLUSION**

149. For the reasons outlined above, Turkey respectfully requests that the Panel reject the European Union's claims and confirm that Turkey's measures are not inconsistent with its WTO obligations.

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**ANNEX D**

## ARGUMENTS OF THE THIRD PARTIES

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**ANNEX D-1**

## INTEGRATED EXECUTIVE SUMMARY OF THE ARGUMENTS OF CANADA

**I. CLAIMS UNDER THE SCM AGREEMENT**

1. Canada provides its views on three issues related to the Parties' claims under the Agreement of Subsidies and Countervailing Measures (SCM Agreement). First, when a complainant alleges that the benefit is conferred on an entity other than the entity receiving the financial contribution, it is for the complainant to demonstrate that the benefit is in fact "passed through". Second, the benefit analysis under Article 1.1(b) should focus on the terms of the financial contribution, and not its trade effects. Third, the consumption of a pharmaceutical product by an individual patient does not amount to "use" for the purposes of Article 3.1(b).

2. The Appellate Body in *Canada – Aircraft* found that "a 'benefit' does not exist in the abstract, but must be received and enjoyed by a beneficiary or a recipient."<sup>1</sup> Moreover, the Appellate Body considered that while Article 14 of the SCM Agreement applies only for the purposes of Part V, it nevertheless constitutes relevant context for the interpretation of "benefit" in Article 1.1(b) and supports the view that the benefit in Article 1.1(b) is concerned with the benefit to the recipient.<sup>2</sup>

3. Although the definition of a subsidy in Article 1.1 does not contain the term "recipient", the Appellate Body has used this term to interpret the meaning of "direct transfer of funds". The Appellate Body defined "a government practice {involving} a direct transfer of funds" as "action involving the conveyance of funds from the government to the recipient"<sup>3</sup> and "conduct on the part of the government by which money, financial resources, and/or financial claims are made available to a recipient".<sup>4</sup>

4. Therefore, when the financial contribution is a "direct transfer of funds", the recipient of the direct transfer of funds and the recipient of the benefit will usually be the same entity. In the case of a loan, for example, Article 14(b) provides that the benefit to the recipient is the difference between "the amount that the firm receiving the loan pays on the government loan and the amount the firm would pay on a comparable commercial loan which the firm could actually obtain on the market." This provision indicates that the benefit is bestowed on the "firm receiving the loan", *i.e.* the recipient of the "direct transfer of funds".

5. However, the recipient of a financial contribution and the recipient of a benefit may not always be the same entity. This is the case when a financial contribution confers an indirect benefit because it is "passed through" from one entity to another. The Appellate Body emphasized that the pass through of benefit must be established on the basis of positive evidence, and cannot simply be presumed.<sup>5</sup> Canada's view is that when the recipient of the direct transfer of funds and the recipient of the benefit are not the same entity, the complainant must establish how the benefit conferred to the recipient of the direct transfer of funds is in fact "passed through" to the producer.

6. The benefit analysis under Article 1.1(b) entails determining whether the financial contribution was provided on terms that are more advantageous than those that would have been available to the recipient on the market.<sup>6</sup> Therefore, the benefit analysis focuses on the terms of the financial contribution, and not its trade effects.

7. Canada invites the Panel to take these considerations into account when addressing the European Union's claim that the Reimbursement Scheme confers an "indirect benefit" to the producers of pharmaceutical products included in the Reimbursement List, because the lower cost

<sup>1</sup> Appellate Body Report, *Canada – Aircraft*, para. 154.

<sup>2</sup> *Ibid.* para. 155.

<sup>3</sup> Appellate Body Report, *US – Large Civil Aircraft (2<sup>nd</sup> complaint)*, para. 614. (emphasis added)

<sup>4</sup> *Ibid.* (emphasis added)

<sup>5</sup> Appellate Body Report, *US – Softwood Lumber IV*, paras. 142 and 143.

<sup>6</sup> Appellate Body Report, *Canada – Aircraft*, para. 149. (citing the Panel Report, *Canada – Aircraft*, para. 9.112)

of the reimbursed products makes them more attractive relative to non-reimbursed imported like products.<sup>7</sup>

8. In *US – Tax Incentives*, the Appellate Body has interpreted the term "use" in Article 3.1(b) as referring to the actions of "consuming a good in the process of manufacturing", "incorporating a component into a separate good, or serving as a tool in the production of a good."<sup>8</sup> All these actions imply that the consumption or employment of a good within the meaning of Article 3.1(b) must occur in the context of manufacturing or production activities. "Use" of pharmaceutical products by individual out-patients does not occur as part of a production or manufacturing process. Therefore, it does not amount to "use" for the purposes of Article 3.1(b).

## II. CLAIMS UNDER THE GATT 1994 – INTERPRETATION OF ARTICLE III:8(A)

9. Canada provides its views on how the Panel should interpret GATT Article III:8(a) in the context of the present dispute. GATT Article III:8(a) creates a derogation from the national treatment obligation for "certain measures that contain rules regarding the process by which governmental agencies purchase products."<sup>9</sup>

10. First, Canada recalls that in the context of Article III:8(a), the word "procurement" has been interpreted as referring to "the process of obtaining products, rather than [...] an acquisition itself."<sup>10</sup> Therefore, in order for a measure to govern "procurement" within the meaning of Article III:8(a), the measure must establish rules regarding the process by which governmental agencies "obtain" products.

11. Secondly, even though the Appellate Body has found that the concepts of "procurement" and "purchase" in Article III:8(a) are legally distinct,<sup>11</sup> it remains that a product must somehow be purchased by the governmental agency.<sup>12</sup> In this regard, the Appellate Body has explained that "[t]he word "purchased" is used to describe the type of transaction used to put into effect [the] procurement."<sup>13</sup> In Canada's view, while the concept of "purchase" under Article III:8(a) does not require the governmental agency to physically take possession of the product, the governmental agency must still obtain some form of property rights over the product.

12. Third, in order for a measure to be protected by Article III:8(a), the procurement must be done by a "governmental agency", *i.e.* "an entity acting for or on behalf of government and performing governmental functions within the competences conferred on it."<sup>14</sup> If the action of obtaining the product is carried out by a private entity, the procurement cannot be said to be done by a "governmental agency".

13. Fourth, the product must be purchased "for governmental purposes."<sup>15</sup> In *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, the Appellate Body found that the phrase "products purchased for governmental purposes" in Article III:8(a) refers to "products purchased for the use of government, consumed by government or provided by governments to recipients in the discharge of its public functions."<sup>16</sup> In Canada's view, this suggests that in order for a WTO Member to avail itself of Article III:8(a) with respect to a product that is not used or consumed by government, the procured product must be provided by a governmental agency to recipients on non-commercial terms within the context of that agency's public functions.

<sup>7</sup> European Union's first written submission, para. 292.

<sup>8</sup> Appellate Body Reports, *US – Tax Incentives*, para. 5.8 and *EU and certain Member States – Large Civil Aircraft (Article 21.5 – US)*, para. 5.57.

<sup>9</sup> Appellate Body Report, *India – Solar Cells*, para. 5.18.

<sup>10</sup> Appellate Body Reports, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 5.59 (emphasis added).

<sup>11</sup> *Ibid.*

<sup>12</sup> Appellate Body Report, *India – Solar Cells*, para. 5.18, "The measures within the scope of Article III:8(a) are "laws, regulations or requirements governing ... procurement", and the entity purchasing products needs to be a "governmental agency". (emphasis added)

<sup>13</sup> Appellate Body Reports, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 5.59.

<sup>14</sup> *Ibid.* para. 5.61.

<sup>15</sup> *Ibid.* para. 5.64.

<sup>16</sup> *Ibid.* para. 5.74.

14. Based on the above, Canada submits that so long as the product is first "purchased" and "obtained" by a "governmental agency", and then provided by a "governmental agency" to recipients on non-commercial terms within the context of that agency's public functions, the Member can validly rely on GATT Article III:8(a) in order to derogate from its national treatment obligation. By contrast, if the product is "purchased" and "obtained" by a private entity, or if the product is provided to recipients by a private entity acting on commercial terms, then the WTO Member would not be able to avail itself of GATT Article III:8(a).

15. In the case of Turkey's pharmaceutical reimbursement system, the pharmaceutical products are neither "purchased" nor "obtained" by a "governmental agency". Instead, the pharmaceutical products are "purchased" and "obtained" by private entities (*i.e.*, retail pharmacies), who receive reimbursement from the Social Security Institution (SSI) after the pharmaceutical products have been sold to eligible recipients. At no point does the SSI conclude any transaction to "obtain" the pharmaceutical products, nor does the SSI obtain any form of "property rights" over the pharmaceutical products. Furthermore, the pharmaceutical products are not provided to recipients within the context of a governmental agency's public functions – rather, the pharmaceutical products are distributed to eligible recipients by private entities (*i.e.*, the retail pharmacies) acting in pursuit of their own commercial interests.

16. If the Panel were to find that this type of pharmaceutical reimbursement system falls within the scope of Article III:8(a), it would effectively mean that whenever a governmental agency "reimburses" or "finances" a certain product, that governmental agency is engaging in "government procurement." This would not only stretch the term "procurement" in Article III:8(a) far beyond its natural and ordinary meaning, it would also constitute a significant expansion of the limited derogation established by Article III:8(a).

### III. CLAIMS UNDER THE GATT 1994 - ARTICLE XX

17. Canada provides its views on several elements in relation to GATT 1994 Article XX: the availability of more than one paragraph of Article XX to potentially justify a measure; the need to identify a risk to human life or health under Article XX(b); the examination of trade restrictiveness under the necessity test applicable to Articles XX(b) and (d); and the nature of the requirements under the chapeau to GATT Article XX.

18. A Member can seek to justify, under Article XX, a measure otherwise inconsistent with the GATT 1994, provided that the measure falls within the scope of one of the paragraphs of Article XX and meets the required elements of both the specific paragraph and the chapeau to Article XX.<sup>17</sup>

19. In Canada's view, it is open to a responding Member to seek to justify a measure under more than one of the enumerated paragraphs in Article XX. However, the Member is still required to establish that the measure meets the requirements of the particular paragraph.

20. In this dispute, Turkey has invoked Article XX(b) – measures necessary to protect human, animal or plant life or health – as a defence if the panel finds a violation under the GATT 1994.

21. In order to fall within the scope of Article XX(b), first, there must exist a specific risk to human, animal or plant life or health that the policy objective seeks to address.<sup>18</sup> Canada agrees, as a general principle, that lack of access to medicines poses a serious threat to human life or health. Canada is also of the view that WTO members have the right to take action to develop domestic capacity in the production of medicines in a manner consistent with their obligations under the WTO. However, this does not relieve a Member seeking to rely on the exceptions under Article XX from establishing that the requirements under Article XX are met.

22. To the extent the objective of Turkey's localization measure is to ensure access to medicines by preventing "the risk of a shortage of supply" of medicines in the Turkish market, Canada's view is that the risk being identified is the risk to human life or health from a shortage of supply of medicines and therefore, it is incumbent on Turkey to provide evidence of this risk. In Canada's view, this requires establishing two elements: (1) that there is a risk of a shortage of supply of the

<sup>17</sup> Appellate Body Report, *Indonesia – Import Licensing Regimes*, para. 5.94.

<sup>18</sup> Panel Reports, *Brazil – Taxation*, para 7.859.

medicines; and (2) that a lack of sufficient supply of the medicines would be a risk to human life or health. With respect to the risk of a shortage of supply, Canada would caution against mechanically importing the nature and standard of required evidence from Article XX(j).

23. Second, the measure must be designed to achieve the policy objective, which involves examining the structure and operation of the measure in order to assess the relationship between the measure at issue and the policy objective.<sup>19</sup> In making this assessment, the Panel should take into account the Members' characterization of the objective, but it is not bound by this, and may form its own characterization of the objective based on all the evidence put forward.<sup>20</sup>

24. Third, if the risk to human life or health from a shortage is established, then the Panel must determine whether the localisation requirement is "necessary" within the meaning of Article XX(b). This means that there must be a genuine relationship of ends and means between the measure and the objective.<sup>21</sup> The necessity test also involves a weighing and balancing of relevant factors including the contribution the measure makes to the objective, the importance of the objective and the relative trade restrictiveness of the measure.<sup>22</sup>

25. In assessing the trade restrictiveness of a measure, a panel may find that a measure restricts trade on the basis of an actual restrictive effect illustrated by trade data<sup>23</sup> or on a qualitative basis.<sup>24</sup> Further, Canada notes that incentivizing the purchasing of domestic over imported goods has been found to be trade restrictive in the necessity analysis under Article XX.<sup>25</sup>

26. Finally, an assessment of trade restrictiveness also includes an assessment of whether there is a less trade restrictive alternative measure that is reasonably available and that would make an equivalent contribution to the objective.

27. If a measure is provisionally justified under one of the paragraphs of Article XX, it must also be applied in a manner that does not constitute "arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade" consistent with the chapeau to Article XX.

28. The Appellate Body has emphasized that the language of the chapeau, as supported by the negotiating history of Article XX, confirms that the exceptions in paragraphs (a) to (j) of Article XX are limited and conditional exceptions from the obligations of the substantive provisions of the GATT 1994 and subject to compliance with the requirements of the chapeau.<sup>26</sup>

29. The task of interpreting and applying the chapeau is "essentially the delicate one of locating and marking out a line of equilibrium between the right of a Member to invoke an exception under Article XX and the rights of other Members under varying substantive provisions" while also noting that the "location of the line of equilibrium, as expressed in the chapeau, is not fixed and unchanging; the line moves as the kind and shape of the measures at stake vary and as the facts making up a specific case differ."<sup>27</sup>

30. In Canada's view, if the Panel finds that Turkey's Localization Measure is necessary, the Panel must seek to strike an appropriate balance between the right of Turkey to take measures to respond to risks or threats to human life or health and the right of other Members to not be subject to arbitrary or unjustifiable discrimination with respect to their exports of pharmaceutical products.

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<sup>19</sup> Appellate Body Reports, *EC – Seal Products*, para. 5.144.

<sup>20</sup> *Ibid.* para. 5.144.

<sup>21</sup> Appellate Body Report, *Brazil – Retreaded Tyres*, para. 145

<sup>22</sup> *Ibid.* paras. 142, 143 and 210.

<sup>23</sup> Panel Report, *Colombia – Ports of Entry*, para. 7.597.

<sup>24</sup> Appellate Body Report, *Colombia – Textiles*, para. 5.72.

<sup>25</sup> Panel Reports, *Brazil – Taxation*, para. 7.927.

<sup>26</sup> Appellate Body Report, *US – Shrimp*, para. 157.

<sup>27</sup> Appellate Body Report, *US – Shrimp*, paras. 158 and 159.

**ANNEX D-2****INTEGRATED EXECUTIVE SUMMARY OF THE ARGUMENTS OF JAPAN****I. INTRODUCTION**

1. Japan has a systemic interest in ensuring the coherent interpretation of the covered WTO agreements. Japan addresses three issues regarding (i) the government procurement under Article III:8(a) of the GATT 1994; (ii) the relationship between Article XI:2(a), Article XX(b) and Article XX(j) of the GATT 1994; and (iii) an invocation of Article XX(b) of the GATT 1994.

**II. GOVERNMENT PROCUREMENT UNDER ARTICLE III:8(A) OF THE GATT 1994**

2. On the issue of Article III:8(a) of the GATT 1994, in Japan's view, for a measure to fall within its scope, as articulated by the Appellate Body in *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, it must satisfy four requirements.

3. First, the measure must constitute "laws, regulations or requirements governing the procurement". Second, the procurement governed by the measure must be "by governmental agencies" of "products purchased". Third, such procurement must be "for governmental purposes". Finally, the procurement must not be "with a view to commercial resale or with a view to use in the production of goods for commercial sale".

4. Japan herein expresses its views on the second requirement regarding the scope of Article III:8(a).

5. Japan recalls that, as articulated by the Appellate Body in *India – Solar Cells*, a governmental agency must purchase such products. Japan also notes that the Appellate Body in *Canada – Renewable Energy / Canada – Feed-in Tariff Program* explained that "[t]he word 'purchased' is used to describe the type of transaction used to put into effect [the] procurement" at issue.

6. In the present dispute, Japan observes that there are divergent views as to the meaning of "products purchased" under Article III:8(a) of the GATT 1994 as well as an identification of the purchaser of the products in question.

7. The European Union argues that "purchase" under Article III:8(a) of the GATT 1994 requires an acquisition of property over the products, and there is no "purchase" by the SSI because the SSI never acquires title over the pharmaceutical products. Turkey argues that "purchase" under Article III:8(a) does not necessarily require acquiring an "entitlement" to or obtaining property rights over the products, but in any case, the SSI acquires the title to the pharmaceutical products from the retail pharmacies, and therefore, the SSI "purchases" the pharmaceutical products.

8. Japan raises that it is not clear what "right", deriving from an "entitlement" or "property rights", if any, the SSI holds over the pharmaceutical products in question. Turkey insists that the SSI acquires the title to the pharmaceutical products at the moment the provision of the medicine by the pharmacy is registered and approved in the Medula system. However, when the retail pharmacies purchase the pharmaceutical products from the manufacturer, they have the authority to store, ship, or sell the products. Retail pharmacies also control the timing and quantity of the sale, manage their inventories, and bear the risks associated with storage of the pharmaceutical products. These elements lead to a conclusion that the retail pharmacies obtain an entitlement to the pharmaceutical products. By contrast, such characteristics are not found in the SSI over the pharmaceutical products.

9. Therefore, the Panel must ascertain whether, as Turkey argues, the SSI does obtain an "entitlement" or "property right" of the pharmaceutical products in question from the retail pharmacies, by looking at the relevant transactions of the pharmaceutical products including through the Medula system.

10. If the Panel determines that the retail pharmacies purchase the pharmaceutical products, it must still determine whether the retail pharmacies could be considered "governmental agencies" within the meaning of Article III:8(a).

11. In this regard, Japan notes the views of Canada in its third-party submission that retail pharmacies may be considered "governmental agencies" under certain circumstances, in accordance with the view expressed by the Appellate Body in *Canada – Renewable Energy / Canada – Feed-in Tariff Program*. Specifically, when examining the nature of retail pharmacies, the Panel should consider whether such retail pharmacies have (i) an authority to act for or on behalf of government, and (ii) specific competences to discharge governmental functions.

### **III. RELATIONSHIP BETWEEN ARTICLE XI:2(A), ARTICLE XX(B) AND ARTICLE XX(J) OF THE GATT 1994**

12. Japan provides a general observation on a relationship between Article XI:2(a), Article XX(b) and Article XX(j) of the GATT 1994.

13. Article XI:2(a) of the GATT 1994 provides that the general elimination of quantitative restrictions under Article XI:1 shall not extend to export restrictions applied to prevent or relieve critical shortages of foodstuffs or other essential products. Articles XX(b) and XX(j), meanwhile, provide for general exceptions for certain measures necessary to protect human, animal or plant life or health and measures essential to the acquisition or distribution of products in general or local short supply, respectively.

14. With regard to Article XI, the Appellate Body in *China – Raw Materials* has held that, "where the requirements of Article XI:2(a) are met, there would be no scope for the application of Article XX, because no obligation exists." The Appellate Body explained that Article XI:2(a) limits the obligation under Article XI:1 only. In other words, if the quantitative restrictions are permissible because the measure falls within the scope of Article XI:2(a), there is no GATT inconsistency to be justified by general exceptions under Article XX of the GATT 1994.

15. With regard to Article XX, Articles XX(b) and XX(j) are distinct exceptions with separate requirements. As Article XX(b) permits measures "necessary to protect human, animal or plant life or health", a measure that is "necessary" under Article XX(b) may address "health risks". On the other hand, Article XX(j) permits measures "essential to the acquisition or distribution of products in general or local short supply". In *India – Solar Cells*, the Appellate Body explained that the phrase "products in general or local short supply" requires the party invoking the exception to demonstrate shortages at the time the measure was enacted. The shortages "may continue over time, but are nonetheless expected not to last indefinitely".

16. Japan also observes that, as noted by the panel in *China – Rare Earths* in the context of Article XX(g), "the special circumstances that Article XX(j) was drafted to handle (severe shortages caused by war and other emergencies) counsel against the provision's direct use in the interpretation" of other exceptions under Article XX.

### **IV. INVOCATION OF ARTICLE XX(B) OF THE GATT 1994**

17. On the issue of an invocation of Article XX(b) of the GATT 1994, Japan notes that it is undisputed that the Member invoking an exception under Article XX of the GATT 1994 bears the burden of proof in demonstrating that the challenged measures come within the scope of that exception.

18. As articulated by the Appellate Body in *US – Gambling*, "it is for a responding party to make a *prima facie* case that its measure is 'necessary' by putting forward evidence and arguments that enable a panel to assess the challenged measure". By contrast, the burden of proof to show that there are reasonably available alternative measures remains with the complainant.

19. In the context of Article XX(b) of the GATT 1994, as articulated by the Appellate Body in *EC – Seal Products* referring to the panel report in *EC – Asbestos*, under the term "to protect" in Article XX(b), "the notion of 'protection' ... impl[ies] the existence of a health risk". The panel in *Brazil – Taxation* observed that "in the specific case of subparagraph (b) of Article XX, ... past panels and the Appellate Body have explained that the existence of a risk to human, animal or plant life or health must be determined in the first place. ...Once that risk is found to exist, the second step is to examine whether the policy underlying the measure aims to reduce such risk."

20. Therefore, the Panel must first determine whether there is a risk to human life or health. As a bearer of the burden of proof under Article XX(b) of the GATT 1994, it is Turkey's responsibility to demonstrate, with sufficient evidence, that there is a risk to human life or health by the shortage of supply.

21. Japan also reiterates that it is a risk to human life or health, not a risk to shortage of supply, that the Panel must find to meet the first step under Article XX(b) of the GATT 1994.

22. Once a measure is found to be designed to protect human life or health, the Panel must assess whether the measure is "necessary" to achieve that objective. Determination of "necessity" requires "a process of 'weighing and balancing' a series of factors, including the importance of the objective, the contribution of the measure to that objective, and the trade-restrictiveness of the measure." A responding Member has the right to determine the level of protection it considers appropriate with respect to the objective pursued, but there must be no reasonably available less trade-restrictive alternative to achieve its desired level of protection.

**ANNEX D-3****INTEGRATED EXECUTIVE SUMMARY OF THE ARGUMENTS OF SWITZERLAND****I. THE REQUIREMENTS OF ARTICLE III:8(a) OF THE GATT 1994**

1. As stated by the Appellate Body, the word "procurement" refers to the process of acquiring or obtaining products<sup>1</sup>. In turn, the word "purchased" describes the type of transaction used to put into effect that procurement<sup>2</sup>. The Appellate Body further indicated that the entity purchasing products needs to be a "governmental agency"<sup>3</sup>. The Appellate Body also recalled that Article III:8 (a) of the GATT 1994 should be interpreted holistically. This requires in particular consideration of the linkages between the different terms used in the provision<sup>4</sup>.

2. Switzerland considers that in order to determine whether the requirements of Article III:8(a) are fulfilled, the Panel should examine not only the relationship between the SSI and the retail pharmacies, but also the relationship and transactions taking place between retail pharmacies and wholesalers. Switzerland notes in particular that Turkey indicates that under the localisation measure, it is the retail pharmacies that *obtain* the pharmaceutical products included in Annex 4/A from the wholesalers<sup>5</sup>.

3. In Switzerland's view, in determining the existence of a process of acquiring or obtaining products, or of a transaction putting into effect such procurement, the question of who is "covering the costs" of, or ultimately "paying for", certain products is only one factor among others to be analysed by the Panel. Switzerland considers that such factors need to be assessed in light of the particular circumstances of the case.

4. In Switzerland's view, other factors to be considered by a panel when assessing whether the measure is a law, regulation or requirement governing procurement by governmental agencies include whether the government may choose how to dispose of the products procured, for instance by reallocating them to another use<sup>6</sup>; does the government control the process of obtaining the product, for instance does it have a right to cancel contracts between retail pharmacies and wholesalers; whether the government carries the risk associated with maintaining inventories; and whether tendering processes could be organized in order to acquire or obtain the products concerned.

5. Other factors to be considered in particular when assessing whether a purchase by a governmental agency is involved include who obtains entitlement (with or without physical possession) over the products concerned through the transaction; who carries the commercial risk in the transaction with the seller; and whether the purchasing entity is perceived as a governmental agency by the seller in the transaction.

6. It would be difficult to consider that there is *procurement by governmental agencies* or a *purchase of* products within the meaning of Article III:8(a) where private entities have ownership of the products, control their disposition, have the right to cancel contracts with wholesalers, bear the risks of unsold inventories and other commercial risks, do not go through tendering processes to acquire the products, or are not perceived to be government agencies by wholesalers. In Switzerland's view, none of these factors are individually dispositive, but each would weigh against a finding that there is procurement or a purchase of a product under Article III:8(a).

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<sup>1</sup> Appellate Body Report, *Canada – Renewable Energy / Feed-In Tariff Program*, para. 5.59.

<sup>2</sup> Appellate Body Report, *Canada – Renewable Energy / Feed-In Tariff Program*, para. 5.59.

<sup>3</sup> Appellate Body Report, *India – Solar Cells*, para. 5.18.

<sup>4</sup> Appellate Body Report, *Canada – Renewable Energy / Feed-In Tariff Program*, para. 5.57.

<sup>5</sup> First Written Submission of Turkey, para. 192; Second Written Submission of Turkey, para. 50.

<sup>6</sup> See GATT Panel Report, *US – Sonar Mapping*, paras. 4.5-4.13.

## II. THE JUSTIFICATION OF THE LOCALISATION MEASURE UNDER ARTICLE XX OF THE GATT 1994

### a) Requirements under Article XX (b)

7. Switzerland recalls that it is for a party invoking an exception or affirmative defense such as Article XX of the GATT 1994 to prove that the conditions contained therein are fulfilled<sup>7</sup>. To meet its burden of proof, Turkey must put forward *evidence* and arguments supporting its assertion that the challenged measure satisfies the requirements of the defence<sup>8</sup>. As underlined by the panel in *Brazil – Taxation*, "in the specific case of subparagraph (b) of Article XX, which deals with the protection of human, animal and plant life or health, past panels and the Appellate Body have explained that the existence of a risk to human, animal or plant life or health must be determined in the first place"<sup>9</sup> and "[o]nce that risk is found to exist, the second step is to examine whether the policy underlying the measure aims at reducing such risk"<sup>10</sup>. Turkey should therefore demonstrate that a risk to human life or health exists and that the policy underlying the measure aims at reducing such risk.

8. Further, as confirmed by the Appellate Body, "in order to determine whether a measure is 'necessary' within the meaning of Article XX(b) of the GATT 1994, a panel must assess all the relevant factors, particularly the extent of the contribution to the achievement of a measure's objective and its trade restrictiveness, in the light of the importance of the interests or values at stake"<sup>11</sup>.

9. Regarding the extent of the contribution to the achievement of a measure's objective, in order to be characterized as necessary, the measure's contribution to the achievement of the objective must be material, not merely marginal or insignificant<sup>12</sup>.

10. The demonstration that a measure brings about a material contribution to the achievement of its objective can be made by resorting to evidence or data, pertaining to the past or the present. A panel might also conclude that a measure is necessary on the basis of a demonstration that it is apt to produce a material contribution to the achievement of its objective. Such demonstration could consist in quantitative projections in the future, or qualitative reasoning based on a set of hypotheses that are tested and supported by sufficient evidence<sup>13</sup>.

11. Switzerland recalls that "the aspects of a measure to be justified under the subparagraphs of Article XX are those that give rise to the finding of inconsistency under the GATT 1994"<sup>14</sup>. In case of a finding of less favourable treatment under Article III:4 GATT 1994, the analysis of the defense under Article XX should thus focus on the "differences in the regulation of imports and of like domestic products", which is the aspect of the measure giving rise to that finding<sup>15</sup>. Moreover, a respondent may not justify the inconsistency of a measure by basing its defence on aspects of that measure different from those that were found by the panel to be inconsistent<sup>16</sup>.

12. Whereas the risk of shortage of supply of the products subject to the measure is certainly an important factor when assessing the contribution of the measure to the objective of ensuring access to medicines, it is not determinative. In any event, it is for Turkey to demonstrate specifically that the difference in treatment of imports and like domestic products has led, will lead or is apt to lead to a more adequate access to medicines and thus contributes to the realization of the stated public health objective.

<sup>7</sup> Panel Report, *Turkey – Textiles*, para. 9.57.

<sup>8</sup> Appellate Body Report, *US – Gambling*, para. 282.

<sup>9</sup> Panel Report, *Brazil – Taxation*, para. 7.859.

<sup>10</sup> Panel Report, *Brazil – Taxation*, para. 7.873.

<sup>11</sup> Appellate Body Report, *Brazil – Retreaded Tyres*, para. 157.

<sup>12</sup> Appellate Body Report, *Brazil – Retreaded Tyres*, para. 210.

<sup>13</sup> Appellate Body Report, *Brazil – Retreaded Tyres*, para. 151.

<sup>14</sup> Appellate Body Report, *EC – Seal Products*, para. 5.185. See also Panel Report, *Brazil – Taxation*, para. 7.886.

<sup>15</sup> Appellate Body Report, *Thailand – Cigarettes (Philippines)*, para. 177.

<sup>16</sup> Appellate Body Report, *Argentina – Financial Services*, para. 6.169. See also Panel Report, *Brazil – Taxation*, para. 7.886, Fn 1238, in which the Panel indicated that it could see no reason not to apply this statement by the Appellate Body in the context of Article XVI of the GATS, in the context of Article XX of the GATT.

13. Finally, Switzerland considers that the fact that a measure may "overshoot" its intended objective for certain categories of products subject to it is also to be considered by a panel in its assessment of the contribution of the measure to its stated objective<sup>17</sup>. A panel should also consider whether the discriminatory aspects actually detract from the attainment of the objective of ensuring adequate access to medicines, instead of contributing to that objective<sup>18</sup>.

#### **b) Requirements under Article XX (d)**

14. In its assessment of whether a responding party has identified a rule that falls within the scope of "laws or regulations" under Article XX(d), a panel should evaluate and give due consideration to *all the characteristics* of the relevant instrument(s) and the assessment must be carried out on a case-by-case basis<sup>19</sup>. Relevant characteristics are in particular the degree of normativity of the instrument, the degree of specificity of the relevant rule, its legal enforceability, the competence of the adopting authority, the form and title of the instrument containing the rule, and the penalties or sanctions that may accompany it<sup>20</sup>.

15. Switzerland recalls that even where a particular international instrument can be said to form part of the domestic legal system of a Member – for instance by way of incorporation or of direct effect of the relevant rules – this does not in itself demonstrate the existence of a "law or regulation" under Article XX(d)<sup>21</sup>. Rather, as stated by the Appellate Body, "an assessment of whether an instrument operates with a sufficient degree of normativity and specificity under the domestic legal system of a Member so as to set out a rule of conduct or course of action, and thereby qualify as a 'law or regulation', must be carried out on a case-by-case basis, taking into account all the other relevant factors relating to the instrument and the domestic legal system of the Member"<sup>22</sup>.

16. The terms "secure compliance" with laws or regulations imply that the design of the measure reveals that it secures compliance with specific rules, obligations, or requirements under such laws or regulations<sup>23</sup>. It is in this regard important to distinguish between the *specific rules* with respect to which a measure seeks to secure compliance and the *objectives* of the relevant "laws or regulations"<sup>24</sup>.

17. Therefore, Switzerland considers that, in order to assess whether Turkey has demonstrated the existence of a rule falling within the scope of laws or regulations, the Panel should carefully examine the degree of normativity of the relevant provisions, and the degree of specificity with which the relevant instruments lay down a particular rule of conduct or course of action within Turkey's domestic legal system, as opposed to simply providing a legal basis for action that may be consistent with certain objectives<sup>25</sup>.

18. In particular, hortatory, aspirational, declaratory or solely descriptive language would not set out a "rule" because it would lack sufficient normativity and specificity<sup>26</sup>.

#### **c) Relationship between Articles XI:2(a), XX (b) and XX (j)**

19. Article XI:2 (a) of the GATT 1994 does not function as an exception, but limits the scope of the obligation not to impose quantitative restrictions provided for in Article XI:1. Therefore, where the requirements of Article XI:2(a) are met, no obligation exists<sup>27</sup>, whereas Members can resort to Article XX of the GATT 1994 as an exception to justify measures that would otherwise be inconsistent with their GATT obligations. Accordingly, if a measure does not meet the requirements provided for

<sup>17</sup> See Panel Report, *Indonesia – Chicken*, para. 7.228.

<sup>18</sup> See Panel Report, *Brazil – Taxation*, para. 7.920.

<sup>19</sup> Appellate Body Report, *India – Solar Cells*, para. 6.6.

<sup>20</sup> Appellate Body Report, *India – Solar Cells*, para. 5.113.

<sup>21</sup> Appellate Body Report, *India – Solar Cells*, para. 5.141.

<sup>22</sup> Appellate Body Report, *India – Solar Cells*, para. 5.141.

<sup>23</sup> Appellate Body Report, *Argentina – Financial Services*, para. 6.203.

<sup>24</sup> Appellate Body Report, *Argentina – Financial Services*, fn 495 to para. 6.203; Appellate Body Report, *India – Solar Cells*, para. 5.110.

<sup>25</sup> Appellate Body Report, *India – Solar Cells*, para. 5.110.

<sup>26</sup> Appellate Body Report, *India – Solar Cells*, para. 5.133.

<sup>27</sup> Appellate Body Reports, *China – Raw Materials*, para. 334.

in Article XI:2(a) and is found to be in violation of Article XI:1, it may nevertheless be justified under Article XX.

20. The different paragraphs of Article XX provide for distinct requirements and the fact that a measure fails to fulfill the requirements of one paragraph does not imply that it cannot be justified under another paragraph of Article XX.

21. Whereas the different paragraphs of Article XX establish distinct requirements, it cannot be excluded that the same considerations can be relevant for the analysis under paragraph (b) and paragraph (j). In *India – Solar Cells*, the Appellate Body recalled that the term "essential", provided for in paragraph (j) is at least as close to the "indispensable" end of the continuum as the word "necessary", provided for in paragraph (d), and considered that the same process of weighing and balancing is relevant in assessing whether a measure is necessary under Article XX (d) or "essential" within the meaning of Article XX(j)<sup>28</sup>.

### III. APPLICABILITY OF ARTICLE XI:1 OF THE GATT 1994 TO THE IMPORT BAN MEASURE

22. The fact that the rules concerning marketing authorization apply to all pharmaceutical products, regardless of where they are produced, does not *per se* exclude the measure from the scope of Article XI:1.

23. As indicated by the panel in *Colombia – Ports of Entry* "a number of GATT and WTO panels have recognized the applicability of Article XI:1 to measures which create uncertainties and affect investment plans, restrict market access for imports or make importation prohibitively costly, all of which have implications on the competitive situation of an importer"<sup>29</sup>.

24. Further, as stated by the panel in *India – Autos*, "it is the nature of the measure as a restriction in relation to importation which is the key factor to consider in determining whether a measure may properly fall within the scope of Article XI:1"<sup>30</sup>. Accordingly, as confirmed by that panel, even if a measure cannot necessarily be considered to relate to the actual "process" of importation, or to constitute a "border" measure, this would not be a sufficient reason to conclude that it cannot come within the scope of Article XI:1<sup>31</sup>.

25. The Appellate Body recalled in *China – Raw Materials* that Article XI of the GATT 1994 covers prohibitions and restrictions that have a limiting *effect* on the quantity or amount of a product being imported or exported<sup>32</sup>. Moreover, the scope of Article XI:1 covers measures through which a prohibition or restriction *is produced* or *becomes operative*<sup>33</sup>. Further, the disciplines of Article XI:1 extend to restrictions of a *de facto* nature<sup>34</sup>. In our view, this confirms that a measure cannot be excluded from the scope of Article XI:1 solely because the regulation it rests on applies to both domestically manufactured and imported products.

26. Moreover, the fact that the marketing authorization rules do not *specifically* deal with the importation of pharmaceutical products, or the fact that those rules have not been *specifically* instituted or maintained in connection with the importation of pharmaceutical products, does not imply that the measure cannot fall within the scope of Article XI:1 of the GATT 1994. In this regard, Switzerland notes that the EU alleges that an import marketing authorisation is To the extent that an import marketing authorization represents a prerequisite for the importation of a product, the marketing authorization rules may constitute a restriction "on the importation". In our view, these are relevant elements for the Panel's analysis of whether the measure, based on its design and operation, falls within the scope of Article XI:1 of the GATT 1994.

<sup>28</sup> Appellate Body, *India – Solar Cells*, para. 5.62-5.63.

<sup>29</sup> Panel Report, *Colombia – Ports of Entry*, para. 7.240.

<sup>30</sup> Panel Report, *India – Autos*, para. 7.261.

<sup>31</sup> Panel Report, *India – Autos*, para. 7.262.

<sup>32</sup> Appellate Body Reports, *China – Raw Materials*, para. 320.

<sup>33</sup> Appellate Body Reports, *Argentina – Import Measures*, para. 5.218.

<sup>34</sup> Panel Report *India – Autos*, para. 7.275, quoting Panel Report on *Argentina – Hides and Leather*, WT/DS155/R, adopted on 16 February 2001, para. 11.17

**ANNEX D-4****INTEGRATED EXECUTIVE SUMMARY OF THE ARGUMENTS OF UKRAINE**

1. In its written submission Ukraine provided comments on certain aspects of understanding and meaning of Article X:1 of the GATT 1994 with respect to the introduced by Turkey measures on localization of the pharmaceutical products.

2. The text of Article X:1 of the GATT 1994 reads as follows:

"Laws, regulations, judicial decisions and administrative rulings of general application, made effective by any contracting party, pertaining to the classification or the valuation of products for customs purposes, or to rates of duty, taxes or other charges, or to requirements, restrictions or prohibitions on imports or exports or on the transfer of payments therefor, or affecting their sale, distribution, transportation, insurance, warehousing inspection, exhibition, processing, mixing or other use, shall be published promptly in such a manner as to enable governments and traders to become acquainted with them. Agreements affecting international trade policy which are in force between the government or a governmental agency of any contracting party and the government or governmental agency of any other contracting party shall also be published. The provisions of this paragraph shall not require any contracting party to disclose confidential information which would impede law enforcement or otherwise be contrary to the public interest or would prejudice the legitimate commercial interests of particular enterprises, public or private."

3. Ukraine considers that in order to understand whether there is a violation of the provisions of Article X:1 of the GATT 1994 a measure under consideration should be examined in a whole with regard to if this measure:

(1) falls within the concept of "laws, regulations, judicial decisions and administrative rulings of general application";

(2) pertains "to the classification or the valuation of products for customs purposes, or to rates of duty, taxes or other charges, or to requirements, restrictions or prohibitions on imports or exports or on the transfer of payments therefor, or affecting their sale, distribution, transportation, insurance, warehousing inspection, exhibition, processing, mixing or other use";

(3) is "of general application";

(4) is "published promptly in such a manner as to enable governments and traders to become acquainted with them".

4. So, in order to find out is there any violation of the provisions of Article X:1 of the GATT 1994 in the present case it is necessary to determine whether Turkey's normative acts, introducing the localisation requirement, fall within the concept of "laws, regulations, judicial decisions and administrative rulings of general application".

5. The terms 'laws, regulations, judicial decisions and administrative rulings' in the meaning of Article X:1 of the GATT 1994 have been already interpreted by several Panels.

6. Thus, in *EC – IT Products*, the Panel examined a claim under Article X:1 of the GATT 1994: "Substantively, and when read as a whole within the context of Article X:1, the phrase 'laws, regulations, judicial decisions and administrative rulings' reflects an intention on the part of the drafters to include a wide range of measures that have the potential to affect trade and traders.<sup>1</sup> A narrow interpretation of the terms 'laws, regulations, judicial decisions and administrative rulings' would not be consistent with this intention, and would also undermine the due process objectives of Article X [...] Based on the foregoing, we observe that the ordinary meanings of the terms 'laws, regulations, judicial decisions and administrative rulings' indicates that the instruments covered by

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<sup>1</sup> (footnote original) In *US – Corrosion-Resistant Steel Sunset Review*, the Appellate Body similarly found that the expression "laws, regulations and administrative procedures" in Article 18.4 of the Anti-Dumping Agreement seemed to encompass the entire body of generally applicable rules, norms and standards adopted by Members in connection with the conduct of anti-dumping proceedings. (Appellate Body Report on *US – Corrosion Resistant Steel Sunset Review*, para. 87).

Article X:1 range from imperative rules of conduct to the exercise of influence or an authoritative pronouncement by certain authoritative bodies. Accordingly, we consider that the coverage of Article X:1 extends to instruments with a degree of authoritativeness issued by certain legislative, administrative or judicial bodies. This does not mean, however, that they have to be 'binding' under domestic law. [...] However, whether a particular measure has a degree of authoritativeness such that it would be properly characterised as 'laws, regulations, administration rulings or judicial decisions' requires a case-by-case assessment of the particular factual features of the measure at issue".<sup>2</sup>

7. Ukraine believes that in order to understand whether Article X:1 of the GATT 1994 can be applied the Panel has to ensure that the measure under consideration pertains to "the classification or the valuation of products for customs purposes, or to rates of duty, taxes or other charges, or to requirements, restrictions or prohibitions on imports or exports or on the transfer of payments therefor, or affecting their sale, distribution, transportation, insurance, warehousing inspection, exhibition, processing, mixing or other use", as these are subjects of the Article.

8. Likewise when examining measures under consideration whether they are in line with Article X:1 of the GATT 1994 the measures should be examined with regard to their general application.

9. In *US – Underwear*, the Panel interpreted the term "of general application": "We note that Article X:1 of GATT 1994, which also uses the language 'of general application', includes 'administrative rulings' in its scope. The mere fact that the restraint at issue was an administrative order does not prevent us from concluding that the restraint was a measure of general application. Nor does the fact that it was a country-specific measure exclude the possibility of it being a measure of general application. If, for instance, the restraint was addressed to a specific company or applied to a specific shipment, it would not have qualified as a measure of general application. However, to the extent that the restraint affects an unidentified number of economic operators, including domestic and foreign producers, we find it to be a measure of general application."<sup>3</sup>

10. In *EC – IT Products*, examining the measure, the Panel found that "the CNEN amendments at issue in this dispute are of 'general application' within the meaning of Article X:1 of the GATT 1994. This is so because the application of a CNEN is not limited to a single import or a single importer. Rather, the objective of the CNEN is to ensure the uniform application of the Common Customs Tariff to all products falling under a specific CN code upon importation into the European Communities."<sup>4</sup>

11. The European Union claims that in the present case not all of the legal instruments that form part of, or give effect to, the localisation requirement were published in such a manner as to enable governments and traders to become acquainted with them.<sup>5</sup>

12. According to the European Union only the broad outlines of the localisation requirement have been appropriately and promptly published. Its substantive content has, for the most part, been put in place in an entirely non-transparent manner, through a series of announcements, presentations and communications, none of which have been adequately and promptly published<sup>6</sup>.

13. In its turn Turkey submits that "in the present case, the standard of adequate publication is met." Turkey states that it "published the final version of the localisation announcements on the [...] websites, which were easily acceptable to traders and governments. Therefore, the publication was done "in such a manner as to enable governments and traders to become acquainted with the published measure", as required by Article X:1 of the GATT 1994."<sup>7</sup>

14. Ukraine believes, that publication in line with Article X:1 of the GATT 1994 of legal instruments, which form part of, or give effect to measures, that have an impact on imports or exports, is of a great importance for market players. A number of Panels and the Appellate Body have already examined this aspect.

15. In *EC – IT Products*, the Panel considered the aspect of publication in line with Article X:1 of the GATT 1994 and found generally: "Article X:1 addresses the due process notion of notice by

<sup>2</sup> Panel Report, *EC – IT Products*, paras. 7.1026-7.1027.

<sup>3</sup> Panel Report, *US – Underwear*, para. 7.65.

<sup>4</sup> Panel Report, *EC – IT Products*, para. 7.1034.

<sup>5</sup> First Written Submission by the European Union, *Turkey – Pharmaceutical Products* WT/DS583, para. 249.

<sup>6</sup> First Written Submission by the European Union, *Turkey – Pharmaceutical Products* WT/DS583, para. 6.

<sup>7</sup> First Written Submission by Turkey, *Turkey – Pharmaceutical Products* WT/DS583, para. 314.

requiring publication that is prompt and that ensures those who need to be aware of certain laws, regulations, judicial decisions and administrative rulings of general application can become acquainted with them." [...] "...if measures are to be published 'in such a manner as to enable governments and traders to become acquainted with them', it follows that they must be generally available through an appropriate medium rather than simply making them publicly available."<sup>8</sup>

16. Likewise, the Panel in *Thailand – Cigarettes (Philippines)* examined claims regarding failure to sufficiently publish the general rules relating to the right to the release of guarantees deposited by importers for excise and other internal taxes. The Panel found that Thailand does not clearly indicate a definite right to the release of guarantees mentioned above. "In such circumstances, importers will not be able to become acquainted with the exact nature of the right they have in respect of the release of guarantees for the internal taxes within the meaning of Article X:1".<sup>9</sup>

17. With this respect Ukraine believes that determining whether Turkey's application of the measure under consideration falls in line with concepts, mentioned in para 3 of this Executive Summary, will help to determine if there is any violation of the provisions of Article X:1 of the GATT 1994.

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<sup>8</sup> Panel Report, *EC – IT Products*, para. 7.1015. In footnote 1312 to this paragraph, the Panel referred to the Appellate Body Report in *US – Underwear* (DSR 1997:I, p. 29) and stated that "We consider that this statement, although addressing Article X:2, is equally applicable to Article X:1."

<sup>9</sup> Panel Report, *Thailand – Cigarettes (Philippines)*, para. 7.860.

**ANNEX D-5****INTEGRATED EXECUTIVE SUMMARY OF THE ARGUMENTS OF THE UNITED STATES****EXECUTIVE SUMMARY OF THE U.S. THIRD PARTY ORAL STATEMENT**

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

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

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

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

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

6. The text of Article XX(b) does not make justification of a measure contingent on meeting other obligations of the covered agreements, including other exceptions listed in Article XX. The text of Article XX(d) similarly does not rely on meeting other obligations. The chapeau to Article XX makes clear that "nothing in this Agreement shall be construed to prevent the adoption of or enforcement by any contracting party of measures" that meet one of the exceptions in Article XX.

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

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

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

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

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

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

13. Further, if a panel "may form its own characterization of the objective based on all the evidence put forward," then a responding Member arguably would not need to assert *any* general exception under Article XX. That is, even with silence by a responding Member, a panel could examine the measure to determine whether it has the objective of one of the subparagraphs of Article XX. If the panel were to so conclude, the panel would need to ensure that the relevant subparagraph could not be established "based on all the evidence put forward." If the panel failed to make that assessment, the panel would not have ensured that (in the terms of Article XX) nothing in the Agreement had been construed to prevent the application of a measure satisfying Article XX.

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

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

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

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

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

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

19. The European Union identified certain measures of Turkey in its panel request, identifying for each measure the covered agreement or agreements for which the measures are inconsistent. The Panel was established with the standard terms of reference as specified by Article 7.1 of the DSU. Subsequently, Turkey filed a request for preliminary findings by the Panel regarding the panel request of the European Union, and the Panel received submissions from the parties and third parties concerning Turkey's request. The Panel made findings regarding Turkey's "preliminary ruling" request on 10 July 2020, concluding that the measures of concern to Turkey fell within the terms of reference.

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

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

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

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

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

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

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

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

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