

# WT/DS583/1, G/L/1305 G/TRIMS/D/44, IP/D/41 G/SCM/D126/1

10 April 2019

(19-2299) Page: 1/8

Original: English

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

# REQUEST FOR CONSULTATIONS BY THE EUROPEAN UNION

The following communication, dated 2 April 2019, from the delegation of the European Union to the delegation of Turkey, is circulated to the Dispute Settlement Body in accordance with Article 4.4 of the DSU.

My authorities have instructed me to request consultations with the government of the Republic of Turkey (Turkey) pursuant to Articles 1 and 4 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU), Article XXII:1 of the General Agreement on Tariffs and Trade 1994 (GATT 1994), Article 8 of the Agreement on Trade Related Investment Measures (TRIMs Agreement), Article 64 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), and Article 4.1 of the Agreement on Subsidies and Countervailing Measures (ASCM) with regard to various measures concerning the production, importation and marketing of pharmaceutical products.

### 1. The Measures at issue

# a. The localisation requirement

The 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 scheme"). That scheme covers the vast majority of sales of pharmaceutical products by pharmacies to patients. Consequently, if an imported pharmaceutical product is excluded from the reimbursement scheme, its competitive opportunities in the Turkish market are significantly impaired, as compared with domestically produced like products.

In order to comply with the above described localisation requirement (the "localisation requirement"), certain producers of pharmaceutical products commit to localise their production of certain pharmaceutical products in Turkey. In those cases where foreign producers do not give the required commitments to localise (or where their offered commitments are rejected, or are considered not to be fulfilled, by the Turkish authorities), the pharmaceutical products concerned are no longer reimbursed. 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.

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.

### b. The technology transfer requirement

As part of the localisation requirement, or closely connected to it, foreign producers may be required, in particular, to transfer technology, including patent rights, to a producer established in Turkey (the "technology transfer requirement"). This requirement does not apply to Turkish producers of pharmaceutical products. The type of technology transfer may also differ from producer to producer.

### c. The import ban on localised products

It appears that where the production of a pharmaceutical product has been localised in Turkey in accordance with the localisation requirement, applied in conjunction with the Turkish rules for approving the importation and marketing of pharmaceutical products, the importation of that pharmaceutical product is no longer permitted ("the import prohibition").

#### d. The prioritization measure

Lastly, it appears that, even in certain cases where imported products are not excluded from the reimbursement scheme by virtue of the localisation requirement, the Turkish authorities give priority to the review of applications for inclusion of domestic pharmaceutical products in the list of products covered by the reimbursement scheme, as well as with respect to any pricing and licensing policies and processes, over the review of the applications of imported products (the "prioritization" measure). This measure is also administered in a non-transparent manner.

#### 2. The legal and other instruments relevant to the measures at issue

The various measures at issue described above 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 Tenth Development Plan 2014-2018" of 2 July 2013, in particular 1.2 (Program for Reducing Import Dependency) and 1.16 (Healthcare Related Industries Structural Transformation Program) under Chapter 3.1 (Priority Transformation Programs);<sup>1</sup>
- "The Structural Transformation Program for Healthcare Industries Action Plan" of 6 November 2014, coordinated by the Ministry of Health and the Ministry of Development, in particular Actions 2 and 3 under Policy No 5 (Strengthening the capacity of the procurement bodies (public institutions) to steer and regulate the sector) of Component-1 (Strengthening Public Sector's Steering Capacity) and Actions 1 and 2 under Policy No 1 (Developing Cooperation Models with the domestic Medicines/ Medical Devices Industry While Devising New Health Schemes) of Component-3 (Improvement of Business and Entrepreneurial Ecosystems);<sup>2</sup>
- "The 2016 Action Plan of the 64th Government (Implementation and Reforms)" of 10
   December 2015, in particular Action 46 (The reimbursement, pricing and licensing processes of medical devices and strategic and domestic medicines shall be improved);<sup>3</sup>

¹ Decision No. 1041 of the Grand National Assembly of Turkey of 2 July 2013 on the approval of the Tenth Development Plan (2014-2018), in accordance with the Law No. 3067, dated 30 October 1984, <a href="http://www.resmigazete.gov.tr/eskiler/2013/07/20130706M1.htm">http://www.resmigazete.gov.tr/eskiler/2013/07/20130706M1.htm</a>, <a href="http://www.resmigazete.gov.tr/eskiler/2013/07/20130706M1-1.htm">http://www.resmigazete.gov.tr/eskiler/2013/07/20130706M1-1.htm</a> and <a href="http://www.resmigazete.gov.tr/eskiler/2013/07/20130706M1-1-1.doc">http://www.resmigazete.gov.tr/eskiler/2013/07/20130706M1-1-1.doc</a>, last accessed on 7 March 2019, and in

English <a href="http://www.sbb.gov.tr/wp-content/uploads/2018/11/The Tenth Development Plan 2014-2018.pdf">http://www.sbb.gov.tr/wp-content/uploads/2018/11/The Tenth Development Plan 2014-2018.pdf</a>, last accessed on 7 March 2019.

<sup>&</sup>lt;sup>2</sup> http://strateji.qtb.qov.tr/haberler/10kalkinma-plani-oncelikli-donusum-programlari-aciklandi, http://strateji.ticaret.qov.tr/data/54a2957ef29370219c5db800/1.%20qrup%20eylem%20planları.docx, http://strateji.ticaret.qov.tr/data/54a2957ef29370219c5db800/2.%20qrup%20eylem%20planları.docx,

http://www.sbb.gov.tr/oncelikli-donusum-programlari-eylem-planlari/ and http://www.sbb.gov.tr/wp-content/uploads/2018/10/16Saglik Endustrilerinda Yapisal Donusum ProgramiBASKI.pdf, last accessed on 7 March 2019.

<sup>&</sup>lt;sup>3</sup> http://bypass.teskilat.akparti.org.tr/Site/haberler/64.-hukumetin-eylem-plani/81171#1

- "The 65<sup>th</sup> Government Programme" of 24 May 2016, in particular Part 3 (Human Development) and Part 4 (Strong Economy);4
- "The Performance Program for 100 Days" announced on 3 August 2018 by Turkish President Erdogan for the first 100 days of his Presidency, in particular points 9 and 10 of the actions falling under the responsibility of the Ministry of Health;5
- "Presidency Decision No. 108 on the New Economy Program for the period 2019-2021" of 20 September 2018, in particular Part 4 (Current Account Deficit) and 7 (Programs and Projects - Health);6
- "The SSI Regulation on Drug Reimbursement" of 10 February 2016;7
- "The SSI Regulation on Alternative Reimbursement for Universal Health Insurance" of 10 February 2016;8
- "Regulation amending the Regulation on the Working Procedures and Principles of the Social Security Institution Healthcare Services Pricing Commission" of 10 February 2016;9
- "Circular 2018/1" from the Prime Ministry of 24 January 2018 on the Localisation Board; 10
- "The Health Implementation Notification/Communique", in particular "Annex-4/A"; 11
- "The Social Security Institution Law Number 5502" of 16 May 2006, as amended by Article 88 of "Decree Law 703 Amending Certain Laws and Decree Laws for the Purposes of Compliance with the Amendments to the Constitution" of 2 July 2018;<sup>12</sup>

and https://www.tusev.org.tr/usrfiles/files/64.HukumetEylemPlaniKitapcik.pdf, last accessed on 7 March 2019.

<sup>4</sup> http://reformlar.gov.tr/ui/pdf/65. hukumet\_program.pdf, last accessed on 6 June 2018.

5 https://www.tccb.gov.tr/assets/dosya/100 GUNLUK ICRAAT PROGRAMI.pdf, last accessed on 7 March 2019.

<sup>6</sup> http://www.resmigazete.gov.tr/eskiler/2018/09/20180920M2.htm,

http://www.resmigazete.gov.tr/eskiler/2018/09/20180920M2-1.pdf and

http://www.bumko.gov.tr/Eklenti/11246,yeni-ekonomi-programipdf.pdf?0, last accessed on 7 March 2019, and in English https://ms.hmb.gov.tr/uploads/sites/2/2019/01/Turkey-NEP-2019-21.pdf, last accessed on 7 March 2019.

<sup>7</sup> Published in the Official Gazette of 10 February 2016, page 23,

http://www.resmigazete.gov.tr/eskiler/2016/02/20160210.htm

and http://www.resmigazete.gov.tr/eskiler/2016/02/20160210-7.htm, last accessed on 7 March 2019.

8 Published in the Official Gazette of 10 February 2016, page 16,

http://www.resmigazete.gov.tr/eskiler/2016/02/20160210.htm and

http://www.resmigazete.gov.tr/eskiler/2016/02/20160210-6.htm, last accessed on 7 March 2019.

<sup>9</sup> Published in the Official Gazette of 10 February 2016, at page 37,

http://www.resmigazete.gov.tr/eskiler/2016/02/20160210.htm and

http://www.resmigazete.gov.tr/eskiler/2016/02/20160210-8.htm, last accessed on 7 March 2019.

<sup>10</sup> Published in the Official Gazette of 24 January 2018, page 8,

http://www.resmigazete.gov.tr/eskiler/2018/01/20180124-5.pdf, last accessed on 7 March 2019.

<sup>11</sup> In Turkish the "Sağlık Uygulama Tebliği" (SUT), published in the Official Gazette Number 28597 of 24 March 2013,

http://www.mevzuat.gov.tr/Metin.Aspx?MevzuatKod=9.5.17229&MevzuatIliski=0&sourceXmlSearch and its annexes http://www.mevzuat.gov.tr/MevzuatMetin/yonetmelik/9.5.17229-EKK.zip, last accessed on 7 March 2019. Latest amendments published in the Official Gazette of 28 December 2018 No 30639,

http://www.resmigazete.gov.tr/eskiler/2018/12/20181228M1.htm and http://www.resmigazete.gov.tr/eskiler/2018/12/20181228M1-1.pdf, last accessed on 7 March 2019; published on the Social Security Website on 11 February 2019,

http://www.sgk.gov.tr/wps/portal/sgk/tr/kurumsal/merkez-

teskilati/ana hizmet birimleri/gss genel mudurlugu/anasayfa duyurular/quncel sut 01022019 and http://www.sqk.gov.tr/wps/wcm/connect/4cd197fc-aa36-45cb-9090-ee8c525b6c18/2019.02.01-

+De%C4%9Fi%C5%9Fiklik+Tebli%C4%9Fi+%C4%B0%C5%9Flenmi%C5%9F+G%C3%BCncel+SUT.zip?MOD =AJPERES&CONVERT\_TO=url&CACHEID=4cd197fc-aa36-45cb-9090-ee8c525b6c18, last accessed on 7 March 2019.

<sup>12</sup> Published in the Official Gazette Number 26173 of 20 May 2006,

http://www.resmigazete.gov.tr/eskiler/2006/05/20060520.htm and

http://www.resmigazete.gov.tr/eskiler/2006/05/20060520-2.htm, last accessed on 7 March 2019, including its amendment by Article 88 of Decree Law 703 of 2 July 2018, "Law on Certain Amendments to the Social Security Institution Law".

http://www.mevzuat.gov.tr/Metin1.Aspx?MevzuatKod=1.5.5502&MevzuatIliski=0&sourceXmlSearch=&Tur=1&

- "The Social Insurance and Universal Health Insurance Law Number 5510" of 31 May 2006;13
- "Decree Law No. 663 on Organization and Duties of Ministry of Health and its Affiliated Agencies" of 11 October 2011;14
- "Presidential Decree Number 1 on Organization of Presidency" of 10 July 2018; 15
- "Decree Law 703 Amending Certain Laws and Decree Laws for the Purposes of Compliance with the Amendments to the Constitution" of 2 July 2018;16
- "Presidential Decree Number 4 on Organization of the Ministries, Affiliated, Linked and
- including presentations made by Government officials and letters or other documents making

Related Agencies and Other Institutions and Agencies" of 15 July 2018;<sup>17</sup> Public announcements on localisation published on: (i) March 2016,18 April 2016,19 8 February 2017,<sup>20</sup> 16 February 2017,<sup>21</sup> April 2017,<sup>22</sup> January 2018<sup>23</sup> and May 2018<sup>24</sup> informing that the imported medicines listed in the annex(es) to the announcement would no longer be reimbursed; Other instruments through which Turkey implements and administers the measures at issue, Tertip=5&No=5502 and http://www.mevzuat.gov.tr/MevzuatMetin/1.5.5502.pdf, last accessed on 7 March 2019.  $^{13}$  Published in the Official Gazette Number 26200 of 16 June 2006, http://www.resmigazete.gov.tr/eskiler/2006/06/20060616.htm and http://www.resmigazete.gov.tr/eskiler/2006/06/20060616-1.htm, last accessed on 7 March 2019. <sup>14</sup> Published in the Official Gazette Number 28103(bis) of 2 November 2011, http://www.resmigazete.gov.tr/eskiler/2011/11/20111102M1.htm and http://www.resmigazete.gov.tr/eskiler/2011/11/20111102M1-3.htm, last accessed on 7 March 2019. <sup>15</sup> Published in the Official Gazette Number 30474 of 10 July 2018, http://www.resmigazete.gov.tr/eskiler/2018/07/20180710.htm and http://www.resmigazete.gov.tr/eskiler/2018/07/20180710-1.pdf, last accessed on 7 March 2019. <sup>16</sup> Published in the Official Gazette Number 30473 of 9 July 2018, http://www.resmigazete.gov.tr/eskiler/2018/07/20180709M3.htm and http://www.resmigazete.gov.tr/eskiler/2018/07/20180709M3-1.pdf, last accessed on 7 March 2019. <sup>17</sup> Published in the Official Gazette Number 30479 of 15 July 2018, http://www.resmigazete.gov.tr/eskiler/2018/07/20180715.htm and http://www.resmigazete.gov.tr/eskiler/2018/07/20180715-1.pdf, last accessed on 7 March 2019.  ${}^{18} \ \underline{\text{https://www.titck.gov.tr/duyuru/2521}}, \ \underline{\text{https://titck.gov.tr/storage/announcement/fzzD3Hwn.pdf}} \ \text{and}$ https://www.titck.gov.tr/PortalAdmin/Uploads/UnitPageAttachment/fzzD3Hwn.pdf, last accessed on 7 March 2019. <sup>19</sup> https://www.titck.gov.tr/Duyurular/DuyuruGetir?id=2593, last accessed on 23 July 2018. 20 http://www.sgk.gov.tr/wps/portal/sgk/tr/kurumsal/merkezteskilati/ana hizmet birimleri/gss genel mudurlugu/anasayfa duyurular/duyuru 08022017 00 and www.sqk.gov.tr/wps/wcm/connect/8fa7cb90-6d4b-41ab-abe8-05a5a7c6db3e/duyuru 08022017 00.pdf?MOD=AJPERES&CONVERT TO=url&CACHEID=8fa7cb90-6d4b-41ababe8-05a5a7c6db3e, last accessed on 7 March 2019. 21 http://www.sqk.gov.tr/wps/portal/sqk/tr/kurumsal/merkezteskilati/ana hizmet birimleri/gss genel mudurlugu/anasayfa duyurular/duyuru 16022017, http://www.sqk.gov.tr/wps/wcm/connect/731a3892-8950-4d78-a75d-7cef4d3c6811/duyuru 16022017.pdf?MOD=AJPERES&CONVERT TO=url&CACHEID=731a3892-8950-4d78a75d-7cef4d3c6811 and http://www.sqk.qov.tr/wps/wcm/connect/e4fdaff9-e53c-4a6f-babf-457c16249f49/ek 25042017.xlsx?MOD=AJPERES&CONVERT TO=url&CACHEID=e4fdaff9-e53c-4a6f-babf-457c16249f49, last accessed on 7 March 2019. 22 http://www.sqk.gov.tr/wps/portal/sqk/tr/kurumsal/merkez-

teskilati/ana hizmet birimleri/gss genel mudurlugu/anasayfa duyurular/duyuru 25042017 and http://www.sgk.gov.tr/wps/wcm/connect/22277d4b-1601-46a6-938ea8fb97c092c6/duyuru 25042017.pdf?MOD=AJPERES&CONVERT TO=url&CACHEID=22277d4b-1601-46a6-

938e-a8fb97c092c6, last accessed on 7 March 2019. <sup>23</sup> http://www.sgk.gov.tr/wps/portal/sgk/tr/kurumsal/merkezteskilati/ana hizmet birimleri/gss genel mudurlugu/anasayfa duyurular/duyuru 19012018 04, http://www.sqk.gov.tr/wps/wcm/connect/8c5a62b6-2029-4e04-b6fa-244b5a4edf2c/duyuru 19012018 04.pdf?MOD=AJPERES&CONVERT TO=url&CACHEID=8c5a62b6-2029-4e04b6fa-244b5a4edf2c and http://www.sqk.gov.tr/wps/wcm/connect/3f6b1970-6b26-4fdf-b31e-6efa89fb4dd8/ek 19012018 04.xlsx?MOD=AJPERES&CONVERT TO=url&CACHEID=3f6b1970-6b26-4fdf-b31e-6efa89fb4dd8, last accessed on 7 March 2019.

24 <a href="http://www.sgk.gov.tr/wps/portal/sgk/tr/kurumsal/merkez-">http://www.sgk.gov.tr/wps/portal/sgk/tr/kurumsal/merkez-</a> teskilati/ana hizmet birimleri/gss genel mudurlugu/anasayfa duyurular/duyuru 16052018 02, last accessed on 7 March 2019.

requests, communicating decisions or imparting instructions addressed by the Turkish authorities to individual companies exporting pharmaceutical products to Turkey (or importing pharmaceutical products in Turkey)";

This request also covers any annexes or schedules thereto, amendments, supplements, replacements, renewals, extensions, implementing measures or any other related measures.

#### 3. Legal basis for the complaint

The various measures at issue described above appear to be inconsistent with Turkey's obligations under the covered agreements, in particular:

- Article III:4 of the GATT 1994, because, by excluding imported pharmaceutical products for which localisation commitments have not been given, have not been accepted or have not been fulfilled from the reimbursement scheme, the localisation requirement accords to imported pharmaceutical products treatment less favourable than that accorded to like products of national origin covered by that scheme in respect of laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use;
- Article III:4 of the GATT 1994, because, by according priority to the review of applications for inclusion in the reimbursement scheme, as well as with respect to any other pricing and licensing policies and processes, of pharmaceutical products of national origin the prioritization measure accords more favourable treatment to those products than to like imported products;
- Article X:1 of the GATT 1994, because Turkey has failed to publish all measures of general application relating to the localisation requirement, the technology transfer requirement and the prioritization measure promptly, and in such a manner as to enable governments and traders to become acquainted with them;
- Article X:2 of the GATT 1994, because, through the measures at issue, Turkey applies a new or more burdensome requirement, restriction or prohibition on imports which is enforced before being officially published;
- Article X:3(a) of the GATT 1994, because Turkey has failed to administer its laws, regulations, decisions and rulings in relation to the localisation requirement, the technology transfer requirement and the prioritization measure in a uniform, impartial and reasonable manner;
- Article XI:1 of the 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, and therefore Turkey institutes and maintains a prohibition or restriction, other than duties, taxes or other charges, on the importation of products of other contracting parties;<sup>25</sup>
- Article 2.1 of the TRIMs Agreement, because the localisation requirement is an investment measure inconsistent with Article III:4 of the GATT 1994;
- Article 3.1 of the TRIPS Agreement, because the technology transfer requirement does not apply to domestic producers of pharmaceutical products, and therefore it accords to the producers of other Members treatment less favourable than that accorded to domestic producers with regard to the protection of intellectual property;

<sup>&</sup>lt;sup>25</sup> In addition, under Article 5 of "Decision No 1/95 of the EC-Turkey Association Council of 22 December 1995 on implementing the final phase of the Customs Union (96/142/EC)", Turkey committed to the obligation that quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between the Parties. Turkey has not fulfilled that obligation.

- Article 27.1 of the TRIPS Agreement, because the technology transfer requirement may cover patent rights and does not apply to domestic producers of pharmaceutical products, and thus patents are not available and patent rights are not enjoyable without discrimination as to whether products are imported or locally produced;
- Article 28.2 of the TRIPs Agreement, because the technology transfer requirement may cover patent rights and because it restricts or infringes on the right of patent owners to assign, or transfer by succession, the patent and to conclude licensing contracts;
- Articles 39.1 and 39.2 of the TRIPS Agreement, because the technology transfer requirement may require foreign producers of pharmaceutical products to transfer undisclosed information protected by those provisions to a Turkish producer; and
- Article 3.1 b) of the ASCM, because the reimbursement scheme operated by the Turkish social security system involves the granting of a subsidy within the meaning of Article 1.1 of the ASCM. The localisation requirement makes the granting of that subsidy contingent upon the use of domestic goods over imported goods, thereby violating Article 3.1 b) of the ASCM. A statement of available evidence with regard to the existence and nature of that subsidy is annexed to this request.

The various measures relating to pharmaceutical products identified in this request appear to nullify or impair the benefits accruing to the European Union directly or indirectly under the covered agreements.

The European Union reserves the right to address additional measures and claims under other provisions of the covered agreements regarding the above matters during the course of the consultations.

#### **ANNEX**

#### STATEMENT OF AVAILABLE EVIDENCE

For purposes of Article 4.2 of the ASCM, the European Union sets out below evidence available to it at this time regarding the existence and nature of the subsidies subject to this request for consultations. The European Union reserves the right to supplement or alter this list in the future, as required:

- "The Tenth Development Plan 2014-2018" of 2 July 2013, in particular 1.2 (Program for Reducing Import Dependency) and 1.16 (Healthcare Related Industries Structural Transformation Program) under Chapter 3.1 (Priority Transformation Programs);
- "The Structural Transformation Program for Healthcare Industries Action Plan" of 6 November 2014, coordinated by the Ministry of Health and the Ministry of Development, in particular Actions 2 and 3 under Policy No 5 (Strengthening the capacity of the procurement bodies (public institutions) to steer and regulate the sector) of Component-1 (Strengthening Public Sector's Steering Capacity) and Actions 1 and 2 under Policy No 1 (Developing Cooperation Models with the domestic Medicines/ Medical Devices Industry While Devising New Health Schemes) of Component-3 (Improvement of Business and Entrepreneurial Ecosystems);
- "The 2016 Action Plan of the 64th Government (Implementation and Reforms)" of 10
   December 2015, in particular Action 46 (The reimbursement, pricing and licensing processes of medical devices and strategic and domestic medicines shall be improved);
- "The 65<sup>th</sup> Government Programme" of 24 May 2016, in particular Part 3 (Human Development) and Part 4 (Strong Economy);
- "The Performance Program for 100 Days" announced on 3 August 2018 by Turkish President Erdogan for the first 100 days of his Presidency, in particular points 9 and 10 of the actions falling under the responsibility of the Ministry of Health;
- "Presidency Decision No. 108 on the New Economy Program for the period 2019-2021" of 20 September 2018, in particular Part 4 (Current Account Deficit) and 7 (Programs and Projects – Health);
- "The SSI Regulation on Drug Reimbursement" of 10 February 2016;
- "The SSI Regulation on Alternative Reimbursement for Universal Health Insurance" of 10 February 2016;
- "Regulation amending the Regulation on the Working Procedures and Principles of the Social Security Institution Healthcare Services Pricing Commission" of 10 February 2016;
- "Circular 2018/1" from the Prime Ministry of 24 January 2018 on the Localisation Board;
- "The Health Implementation Notification/Communique", in particular "Annex-4/A";
- "The Social Security Institution Law Number 5502" of 16 May 2006, as amended by Article 88 of "Decree Law 703 Amending Certain Laws and Decree Laws for the Purposes of Compliance with the Amendments to the Constitution" of 2 July 2018;
- "The Social Insurance and Universal Health Insurance Law Number 5510" of 31 May 2006;
- "Decree Law No. 663 on Organization and Duties of Ministry of Health and its Affiliated Agencies" of 11 October 2011;

- "Presidential Decree Number 1 on Organization of Presidency" of 10 July 2018;
- "Decree Law 703 Amending Certain Laws and Decree Laws for the Purposes of Compliance with the Amendments to the Constitution" of 2 July 2018;
- "Presidential Decree Number 4 on Organization of the Ministries, Affiliated, Linked and Related Agencies and Other Institutions and Agencies" of 15 July 2018;
- Public announcements on localisation published on: (i) March 2016, April 2016, 8 February 2017, 16 February 2017, April 2017, January 2018 and May 2018 informing that the imported medicines listed in the annex(es) to the announcement would no longer be reimbursed;
- Other instruments through which Turkey implements and administers the measures at issue, including presentations made by Government officials and letters or other documents making requests, communicating decisions or imparting instructions addressed by the Turkish authorities to individual companies exporting pharmaceutical products to Turkey (or importing pharmaceutical products in Turkey)".