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

REQUEST FOR THE ESTABLISHMENT OF A PANEL BY THE EUROPEAN UNION

The following communication, dated 2 August 2019, from the delegation of the European Union to the Chairperson of the Dispute Settlement Body, is circulated pursuant to Article 6.2 of the DSU.

On 2 April 2019, the European Union requested 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 (SCM Agreement) with regard to various measures concerning the production, importation and marketing of pharmaceutical products.

The consultations took place on 9 and 10 May 2019 in Geneva with a view to reaching a satisfactory settlement of the matter. Unfortunately, they failed to settle the dispute. The European Union therefore requests that a panel be established pursuant to Articles 4 and 6 of the DSU, Article XXIII of GATT 1994, Article 8 of the TRIMs Agreement, and Article 4.4 of the SCM Agreement to examine the matter based on the standard terms of reference, as set out in Article 7.1 of the DSU.

The measures at issue are the localisation requirement, the import ban on localised products and the prioritization measure as explained below. They 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);¹
- "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

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, <http://www.resmigazete.gov.tr/eskiler/2013/07/20130706M1.htm>, <http://www.resmigazete.gov.tr/eskiler/2013/07/20130706M1-1.htm> and <http://www.resmigazete.gov.tr/eskiler/2013/07/20130706M1-1-1.doc>, last accessed on 7 March 2019, and in English http://www.sbb.gov.tr/wp-content/uploads/2018/11/The_Tenth_Development_Plan_2014-2018.pdf, last accessed on 7 March 2019.

While Devising New Health Schemes) of Component-3 (Improvement of Business and Entrepreneurial Ecosystems);²

- "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);³
- "The 65th 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

² <http://strateji.gtb.gov.tr/haberler/10kalkinma-plani-oncelikli-donusum-programlari-aciklandi>, <http://strateji.ticaret.gov.tr/data/54a2957ef29370219c5db800/1.%20grup%20eylem%20planlari.docx>, <http://strateji.ticaret.gov.tr/data/54a2957ef29370219c5db800/2.%20grup%20eylem%20planlari.docx>, <http://www.sbb.gov.tr/oncelikli-donusum-programlari-eylem-planlari/> and http://www.sbb.gov.tr/wp-content/uploads/2018/10/16Saglik_Endustrilerinde_Yapisal_Donusum_ProgramiBASKI.pdf, last accessed on 7 March 2019.

³ <http://bypass.teskilat.akparti.org.tr/Site/haberler/64.-hukümetin-eylem-plani/81171#1> and <https://www.tusev.org.tr/usfiles/files/64.HukumetEylemPlaniKitapcik.pdf>, last accessed on 7 March 2019.

⁴ http://reformlar.gov.tr/ui/pdf/65._hukumet_program.pdf, last accessed on 6 June 2018.

⁵ https://www.tcgb.gov.tr/assets/dosya/100_GUNLUK_ICRAAT_PROGRAMI.pdf, last accessed on 7 March 2019.

⁶ <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.

⁷ 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.

⁹ Published in the Official Gazette of 10 February 2016, 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.

¹⁰ 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.

¹¹ 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 Number 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

- "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;¹²
- "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 Related Agencies and Other Institutions and Agencies" of 15 July 2018;¹⁷
- "Regulation on the Registration of Medicinal Products for Human Use" of 19 January 2005;¹⁸
- "Notification/Communique on the Pricing of Medicinal Products for Human Use" of 29 September 2017;¹⁹

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/guncel_sut_01022019 and http://www.sgk.gov.tr/wps/wcm/connect/4cd197fc-aa36-45cb-9090-ee8c525b6c18/2019.02.01-De%20C4%9Fi%20C5%9Fiklik+Tebli%20C4%9Fi+%20C4%B0%20C5%9Flenmi%20C5%9F+G%20C3%BCncel+SUT.zip?MOD=AJPERES&CONVERT_TO=url&CACHEID=4cd197fc-aa36-45cb-9090-ee8c525b6c18, last accessed on 7 March 2019.

¹² 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&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.

¹⁴ 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.

¹⁵ 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.

¹⁶ 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.

¹⁷ 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 Published in the Official Gazette Number 25705 of 19 January 2005, <http://www.hukukturk.com/en/official-gazette-of-tr?Sayi=25705&Tarih=19%201%202005> and <http://www.resmigazete.gov.tr/eskiler/2005/01/20050119-7.htm>, last accessed on 18 July 2019, and in English <https://titck.gov.tr/storage/legislation/QEv7VEBH.pdf>, last accessed on 18 July 2019. For greater clarity, this Regulation 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.

¹⁹ Published in the Official Gazette Number 30195 of 29 September 2017, <http://www.hukukturk.com/en/official-gazette-of-tr?Sayi=30195&Tarih=29%209%202017> and <http://www.resmigazete.gov.tr/eskiler/2017/09/20170929-11.htm>, last accessed on 18 July 2019. For greater clarity, this Notification 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.

- "Protocol on the Procurement of Medicines from Pharmacies which are Members of the Turkish Pharmacists' Association by Persons Covered by the Social Security Institution" of 2016 and amendments;²⁰
- "Circular 2015/19" from the Prime Ministry of 23 December 2015 on the Health Industries Steering Committee;²¹
- Public announcements on localisation published on: (i) March 2016,²² April 2016,²³ 8 February 2017,²⁴ 16 February 2017,²⁵ April 2017,²⁶ January 2018²⁷ and May 2018²⁸ 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)".

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

²⁰ <https://www.teb.org.tr/content/74/TEBLIGER> and http://teb.org.tr/versions_latest/457/protokol2016, last accessed on 18 July 2019, and the 2017, 2018 and 2019 amendments, http://teb.org.tr/versions_latest/657/tebsqk-protokolu_20160401_ek-20170503, https://www.teb.org.tr/versions_latest/856/tebsqk-protokolu_20160401_ek-20180416_y_20180401 and https://www.teb.org.tr/versions_latest/1042/tebsqk-protokolu_20160401_ek-20190522_y_20190401, last accessed on 18 July 2019. For greater clarity, this Protocol and its amendments put in place and evidence the measures already identified and included in the request for consultations by the European Union in this dispute and explained below.

²¹ Published in the Official Gazette Number 29571 of 23 December 2015, <http://www.hukukturk.com/en/official-gazette-of-tr?Sayi=29571&Tarih=23%2f12%2f2015> and <http://www.resmigazete.gov.tr/eskiler/2015/12/20151223-9.pdf>, last accessed on 18 July 2019. For greater clarity, this Circular 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.

²² <https://www.titck.gov.tr/duyuru/2521>, <https://titck.gov.tr/storage/announcement/fzzD3Hwn.pdf> and <https://www.titck.gov.tr/PortalAdmin/Uploads/UnitPageAttachment/fzzD3Hwn.pdf>, last accessed on 7 March 2019.

²³ <https://www.titck.gov.tr/Duyurular/DuyuruGetir?id=2593>, last accessed on 23 July 2018.

²⁴ http://www.sgk.gov.tr/wps/portal/sgk/tr/kurumsal/merkez-teskilati/ana_hizmet_birimleri/gss_genel_mudurlugu/anasayfa_duyurular/duyuru_08022017_00 and www.sgk.gov.tr/wps/wcm/connect/8fa7cb90-6d4b-41ab-abe8-05a5a7c6db3e/duyuru_08022017_00.pdf?MOD=AJPERES&CONVERT_TO=url&CACHEID=8fa7cb90-6d4b-41ab-abe8-05a5a7c6db3e, last accessed on 7 March 2019.

²⁵ http://www.sgk.gov.tr/wps/portal/sgk/tr/kurumsal/merkez-teskilati/ana_hizmet_birimleri/gss_genel_mudurlugu/anasayfa_duyurular/duyuru_16022017, http://www.sgk.gov.tr/wps/wcm/connect/731a3892-8950-4d78-a75d-7cef4d3c6811/duyuru_16022017.pdf?MOD=AJPERES&CONVERT_TO=url&CACHEID=731a3892-8950-4d78-a75d-7cef4d3c6811 and http://www.sgk.gov.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.

²⁶ http://www.sgk.gov.tr/wps/portal/sgk/tr/kurumsal/merkez-teskilati/ana_hizmet_birimleri/gss_genel_mudurlugu/anasayfa_duyurular/duyuru_25042017 and http://www.sgk.gov.tr/wps/wcm/connect/22277d4b-1601-46a6-938e-a8fb97c092c6/duyuru_25042017.pdf?MOD=AJPERES&CONVERT_TO=url&CACHEID=22277d4b-1601-46a6-938e-a8fb97c092c6, last accessed on 7 March 2019.

²⁷ http://www.sgk.gov.tr/wps/portal/sgk/tr/kurumsal/merkez-teskilati/ana_hizmet_birimleri/gss_genel_mudurlugu/anasayfa_duyurular/duyuru_19012018_04, http://www.sgk.gov.tr/wps/wcm/connect/8c5a62b6-2029-4e04-b6fa-244b5a4edf2c/duyuru_19012018_04.pdf?MOD=AJPERES&CONVERT_TO=url&CACHEID=8c5a62b6-2029-4e04-b6fa-244b5a4edf2c and http://www.sgk.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.

²⁸ http://www.sgk.gov.tr/wps/portal/sgk/tr/kurumsal/merkez-teskilati/ana_hizmet_birimleri/gss_genel_mudurlugu/anasayfa_duyurular/duyuru_16052018_02, last accessed on 7 March 2019.

1. The localisation requirement

1.1. Identification of the specific measure at issue

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.

1.2. Summary of the legal basis of the complaint and reasons for this panel request

The European Union considers that the localisation requirement is inconsistent with Turkey's obligations under the following provisions of the covered agreements:

- Article III:4 of 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, through the localisation requirement Turkey 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 X:1 of GATT 1994, because Turkey has failed to publish certain elements, terms and conditions of general application of this measure promptly in such a manner as to enable governments and traders to become acquainted with them;
- Article 2.1 of the TRIMs Agreement, because the localisation requirement is an investment measure related to trade in goods inconsistent with Article III:4 of GATT 1994; and
- Article 3.1(b) of the SCM Agreement, 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 SCM Agreement. The localisation requirement makes the granting of that subsidy contingent upon the use of domestic over imported goods, thereby violating Article 3.1(b) of the SCM Agreement.

2. The import ban on localised products

2.1. Identification of the specific measure at issue

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 ban on localised products").

2.2. Summary of the legal basis of the complaint and reasons for this panel request

The European Union considers that 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, and 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 of other WTO Members.

3. The prioritization measure

3.1. Identification of the specific measure at issue

Lastly, even in certain cases where imported products are not excluded from the reimbursement scheme by virtue of the localisation requirement, Turkey gives priority to the review of applications for inclusion of domestic pharmaceutical products in the list of products covered by the reimbursement scheme, as well as with respect to any pricing and licensing policies and processes, over the review of the applications of like imported products (the "prioritization measure").

3.2. Summary of the legal basis of the complaint and reasons for this panel request

The European Union considers that the prioritization measure is inconsistent with Turkey's obligations under Article III:4 of 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, through the prioritization measure Turkey accords to imported pharmaceutical products treatment less favourable than that accorded to like products of national origin.

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.

Accordingly, the European Union respectfully requests that, pursuant to Articles 4 and 6 of the DSU, Article XXIII of GATT 1994, Article 8 of the TRIMs Agreement, and Article 4.4 of the SCM Agreement, the Dispute Settlement Body establish a panel to examine this matter, with the standard terms of reference as set out in Article 7.1 of the DSU.
