

Recent Developments and Legal Landscape on Procurement of Medicines from Abroad

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I - Introduction and Recent News on the Assignment of the Duties to Social Security Institution

In Turkey, import and sale of medicines are subject to licensing requirements of the Ministry of Health (“Ministry”). The principle is that medicines which are not licensed in Turkey cannot be put on the Turkish market. “Procurement of medicines from abroad” mechanism, on the other hand, brings an exception to this rule.

With the “Procurement of medicines from abroad” process which is regulated under the Guidelines for Procurement of Medicines from Abroad (“Guidelines”), as published on the Ministry’s website, the Ministry paves the way for a distinct mechanism allowing the procurement of medicines that are licensed but not accessible in Turkey for various reasons (e.g. stock-out) or medicines which are not duly licensed in Turkey, on prescription basis or in emergent cases, collectively.

The Ministry’s current list of approved suppliers, as attached to Annex 8 of the Guidelines¹, points out the Turkish Pharmacy Association (“TEB”) as the sole supplier authorized to procure medicines from abroad. Although TEB recaptured its role as the sole supplier following a public feud with the Ministry², there are news³ appeared this year on the media alleging that Social Security Institution (“SSI”) will take over TEB’s authority to procure medicines from abroad. Apart from this current media coverage, the legislation in force stands the same and TEB reserves its title as the sole authorized supplier.

II - Overview of the Ministry of Health’s Guidelines

The Ministry’s process of “Procurement of Medicines from Abroad” is regulated under the Guidelines⁴. The Guidelines, while setting forth the criteria for procurement, outlines the rules to be fulfilled both by patients and the supplier approved for the procurement.

In light of the Guidelines, medicines which are not licensed in Turkey and/or cannot be found in market (though being licensed), can be procured from abroad on prescription basis or, in emergent cases, collectively. Lists of medicines that can be procured from abroad as well as the approved suppliers authorized to procure such medicines are published on the Ministry’s website. All of the substances listed under the list can only be imported by those approved suppliers. This said, currently TEB, being the sole entity under the list, holds the title of the sole supplier authorized for the procurement.

According to the Guidelines, during the import of these medicines, a Control Certificate should also be prepared by the Ministry for importation of the medicines containing the active substances listed under the Ministry’s “Active Substance List”⁵. Doctor prescription and patient information form are also

¹ See at http://www.titck.gov.tr/PortalAdmin/Uploads/UnitPages/tedarikci_depolar_listesi_%2029.01.2016.pdf (latest access on December 6th, 2016)

² See Subtitle IV below.

³ See at <http://www.haberturk.com/saglik/haber/1267805-yurtdisindan-ilaci-artik-sgk-getirecek> (latest access on December 6th, 2016) and <http://www.dunya.com/ekonomi/sgk-yurtdisindan-ilac-getirme-isini-buyuk-oranda-ustlenecek-haberi-320214> (latest access on December 6th, 2016)

⁴ See at <http://www.titck.gov.tr/Mevzuat/MevzuatGetir?id=2649> (latest access on December 6th, 2016)

⁵ Article 7 (3) of the Guidelines for Procurement of Medicines from Abroad.

sought during the procurement process each time. Also, procurement consent for the substances is individual for each patient.⁶ A consent obtained for a specific patient does not set an example for other patients with same diagnoses yet with different clinical courses, as accepted by the Ministry.

III - Criteria for Procurement

In light of the Guidelines, TEB can procure the medicines from abroad which are not licensed in Turkey or cannot be found in Turkey despite being licensed, in exceptional cases where all treatment options in Turkey have been exhausted or where such options cannot be exhausted in certain patients, for the diagnoses and the treatment of diseases. These medicines can only be procured by TEB by complying with the following order:

(i) Medicines approved and marketed by FDA/EMA or manufactured, licensed and marketed in countries which are member to Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme, should be procured.

(ii) In case the medicine cannot be found in or procured from the countries under (i), the names of the medicines manufactured and used in countries other than the ones listed under (i) can be added to the list of “Medicines to be Procured from Abroad”, with the approval of the Chairman of the Turkish Medicine and Medical Device Institution (“Institution”)⁷, by collecting the opinion of the relevant scientific commission.

(iii) During the application to be made by TEB to the Institution for the inclusion of the medicines not licensed by FDA/EMA to the “Medicines to be Procured from Abroad” list, the following documentation should be submitted:

a) Certificate of Pharmaceutical Product for the medicine

b) Medicine information (including safety information) and letter or corporate e-mail from the manufacturing company which includes the country information where the medicine is used.

c) In cases where the documentation set forth in (a) and (b) cannot be procured and attested by TEB, letter of corporate e-mail regarding medicine information (including safety information) from the foreign supplier warehouse.

To that end, TEB would be the responsible authority for the duly procurement and supply of the foreign medicines and should comply with the foregoing criteria, in respective order, for procurement. While the principle is to procure the product on a prescription basis (with the request of the doctor), TEB can stock the medicines listed under Medicines to be Procured from Abroad, as per the Guidelines.

IV - Discussion of Authorization for Procurement

Back in 2013, the Ministry gave the authority to procure medicines from abroad to a number of pharmaceutical warehouses by way of including them to the authorized suppliers list, which triggered controversy between TEB and the Ministry.

⁶ Article 6 (10) of the Guidelines for Procurement of Medicines from Abroad.

⁷ Turkish Medicine and Medical Device Institution is a division of the Ministry of Health.

Following certain public announcements criticizing the Institution's approach⁸ and failed negotiations with the Institution, TEB has initiated a lawsuit against the Institution before the Council of State alleging that the amendment made in the legislation which paves the way for other suppliers to enter into protocols with the Institution for the procurement process is unlawful and breaches the protocol provisions between TEB and the Institution. As a result, the Council of State has granted a motion for stay of execution for the Institution's amendment in the legislation⁹.

In light of the foregoing, the Institution re-amended the Guidelines and published the revised authorized suppliers list in its website with the following note;

“As per 15th Department of Council of State's motion for stay of execution, procurement activities of pharmaceutical warehouses previously authorized by our Institution for procurement medicines from abroad, have been ceased as of 30.04.2016.”

V - List of Medicines That Can Be Procured From Abroad

The active substance sought for the medicines to be procured from abroad are listed on an excel sheet announced weekly on the Institutions website¹⁰. As per Article 5 of the Guidelines, except for the active substances marked as the “Medicines that can only be imported with the Ministry's consent”, the Ministry does not seek an import permit for the active substances listed on the first tab of the excel sheet.

For the active substances that are not included in the Lists of medicines that can be procured from abroad, an application can be made to the Institution with the documents listed in Article 5 (4) of the Guidelines.

VI - Reimbursement of Procured Medicines

In Turkey, SSI deals with the reimbursement front of the medicines procured from abroad. In other words, the Ministry is the authority for the import of the medicine, whereas the SSI is the relevant authority for the reimbursement thereof. The Ministry's current list of approved suppliers, points out the TEB as the sole supplier which has arrangements with the SSI for reimbursement. There is a protocol in place between SSI and TEB for reimbursement since 2007¹¹.

VII - Conclusion

“Procurement of medicines from abroad” process without doubt holds great importance for the health sector and patients seeking medicines that are short in the Turkish market. Regardless of the

⁸ See at <http://213.153.183.41/news/6325/T%C3%BCrkiyede-Ruhsat%C4%B1-Olmayan-veya-Piyasada-Bulunmayan-%C4%B0la%C3%A7-Temininde-Tart%C4%B1%C5%9Fma-Tekelle%C5%9Fme-De%C4%9Fil-Hasta-Yarar%C4%B1-%C3%9Czerinden-Olmal%C4%B1d%C4%B1r> (latest access on December 6th, 2016) and <http://teb.org.tr/news/6684/%C4%B0thal-%C4%B0la%C3%A7-Temini-Konusunda-SGK-ile-Anla%C5%9Fmas%C4%B1-Olan-Tek-Tedarik%C3%A7i-TEB%EF%BF%BD%EF%BF%BDdir> (latest access on December 6th, 2016)

⁹ TEB's announcement as to Department of Council's verdict can be found at <http://www.teb.org.tr/news/6901/Yurtd%C4%B1%C5%9F%C4%B1ndan-%C4%B0la%C3%A7-Temini-Yetkisi-Verilen-Tedarik%C3%A7iler-Konusunda-T%C4%B0TCKya-A%C3%A7t%C4%B1%C4%9F%C4%B1m%C4%B1z-Dava-Sonu%C3%A7land%C4%B1> (latest access on December 6th, 2016)

¹⁰ As of the publication date of this article, the most recent list is published on December 2nd 2016. See the current list at <http://www.titck.gov.tr/Yurtd%C4%B1%C5%9F%C4%B1%C4%B0la%C3%A7> (latest access on December 6th, 2016)

¹¹ See signed copy of the protocol in Turkish at http://www.istanbuleczaciodasi.org.tr/upload/pdf/20120203_protokol.pdf (latest access on December 6th, 2016)

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controversies as to suppliers of these medicines, the Ministry continues to lay the way open for the exporters willing to contribute in procurement of medicines in to the Turkish market.

The content of this article is intended to provide a general guide to the subject matter. Specialist advice should be sought about your specific circumstances.

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(First published in Mondaq on December 7, 2016)