MOROĞLU ARSEVEN

Update on the Guide for Import Applications and Market Placement Permits

20 Jul 2024

The "Guide for Import Applications and Market Placement Permits" ("**Guide**") was updated on May 27, 2024, by the Turkish Medicines and Medical Devices Agency ("**TİTCK**") and published on the TİTCK website. These updates include various regulations concerning import applications and market placement permits.

The Guide aims to establish the conditions for import applications of non-controlled human medicinal products, blood products or human medicinal products containing blood products, immunological human medicinal products, traditional herbal medicinal products, intermediate products classified as traditional herbal medicinal products, registered radiopharmaceuticals, allergenic products, and non-controlled raw materials. It also outlines the requirements for market placement permits for blood products or human medicinal products containing blood products, immunological human medicinal products, and allergenic products, as well as the procedures and principles to be followed in these applications.

- The Guide covers:
- "Control Certificate" and "Invoice Annotation" approval,
- "Import Approval for Promotional Samples",
- "Customs Exemption Certificate" application,
- "Sample Import Permit for Blood Products or Human Medicinal Products Containing Blood Products",
- "Invoice and/or Loading Site Notifications for Imported Products",
- "Authority Notification for Raw Material Importer Firms for Licensed Products",
- "Import Feedback Information Form",
- "Notification of Drug Raw Material Production" for non-controlled human medicinal products, blood products or human medicinal products containing blood products, immunological human medicinal products, traditional herbal medicinal products, intermediate products classified as traditional herbal medicinal products, allergenic products, registered radiopharmaceuticals, and raw materials.

However, the Guide does not cover:

(a) The import of clinical research and early access products,

(b) The import procedures for substances and products subject to the Current Ministry of Health's Special Permit and the Import Inspection Communiqué (Product Safety and Inspection).

The provisions of the Guide will come into effect as follows:

a) Subparagraph (l) of the first paragraph of Article 6, subparagraph (d) of the second paragraph of Article 6, subparagraph (j) of the fourth paragraph of Article 7, subparagraph (g) of the second paragraph of Article 8, subparagraph (f) of the sixth paragraph of Article 8, subparagraph (e) of the first paragraph of Article 10, subparagraph (ç) of the second paragraph of Article 10, effective from January 1, 2025,

b) Subparagraphs (g) and (ğ) of the third paragraph of Article 6, subparagraphs (e) and (f) of the third paragraph of Article 11, subparagraphs (e) and (f) of the fourth paragraph of Article 11, effective from July 1, 2024,

c) Other provisions, effective from May 27, 2024.

For more detailed information, you can visit the official website of the Turkish Medicines and Medical Devices Agency from this link (the Guide is only available in Turkish).

Related Attorneys

- A. BAŞAK ACAR, LL.M.
- MERVE ALTINAY