Guideline on Procurement and Use of Medicines from Abroad has been Amended

24 Dec 2021

Guideline on Procurement and Use of Medicines from Abroad ("**Guideline**") was amended by the Turkish Medicines and Medical Devices Agency ("**Agency**") and published on 23 October 2021. Accordingly, "foreign suppliers" authorized to supply drugs from abroad have been defined. In addition, annex-5 of the Guideline updated the requirements and supply conditions to be complied by foreign suppliers during the procurement of the medicinal product for human use containing the active substances indicated in the Foreign Drug List listed in annex-1.

The competent authorities in terms of licensing and supply requirements within the scope of the Guideline have been updated as the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), the Medicines and Healthcare Products Regulatory Agency of United Kingdom (MHRA) and the Therapeutic Goods Administration of Australia (TGA). Prior to the updated Guideline, competent authorities were determined as American Food and Drug Administration (FDA), European Medicines Agency (EMA), and Pharmaceutical Inspection Co-operation Scheme (PIC/S).

"Foreign Suppliers" has been regulated in article 4 of the Guideline under "Definitions" title. Accordingly, foreign suppliers have been defined as public institutions/organizations deemed suitable for supply of drugs from abroad by Uluslararas? Sa?l?k Hizmetleri A.?. (USHA?), Turkish Pharmacists Association Economic Enterprise (TEB), Social Security Institution (SGK) and Agency.

Pursuant to subparagraph (a) of paragraph 3 of article 5 of the Guideline, drugs to be procured from abroad must be licensed and placed on the market by MHRA, TGA or the competent authorities of the founding or permanent member of ICH and a certificate of conformity must be obtained for these drugs by carrying out a Good Manufacturing Practices (GMP) audit.

It has been envisaged that products not in conformity with these conditions will be excluded from the list as of the publication date of the Guideline. For products that have been excluded from the list, re-application can be made to the Agency within 30 days in order to be added to the Foreign Drug List.

Agency may decide that for a product based GMP inspection in case that a product produced in a production facility in a country except countries indicated above is requested to be included in the Foreign Drugs List.

In line with the import data transmitted by the foreign suppliers, the products that have not been supplied for the last one year will be removed from the Suppliable Medicines List following the necessary order/stock controls by Agency.

In accordance with annex-5 of the Guideline titled Rules to be followed by Foreign Suppliers During the Supply of Medicines documents as Certificate of Origin, Certificate of Analysis and Batch of Release Certificate documents can be requested from foreign suppliers when deemed necessary by the Foreign Drug Evaluation Commission.

As per the Guideline, medicinal products for human use containing active substances, which are allowed to be supplied by the Agency for the first time shall be shipped by foreign suppliers within thirty days at latest and within fifteen working days at latest for the products that are allowed to be supplied earlier in accordance with Good Distribution Practices.

The Guideline regulates that foreign suppliers are allowed to keep in their stocks the medicinal products for human use included in the Suppliable Medicines list in annex-1.

In case the products present in stock, or their equal substitute are intended to be placed on Turkish market, the date of supply to the market will be officially notified to the Agency and foreign drug suppliers by the relevant company. It will be ensured that these products can be returned to the foreign pharmaceutical warehouse/manufacturer with whom the supply contract was made.

The products that are in stock will be able to be delivered to the patients for a maximum of one month. At the end of this period, in cases where the product is out of stock or the stock is depleted earlier than one month, the active substance of the relevant human medicinal product and the drugs containing the active substance will be removed from the Active Substances and Suppliable Medicines lists in Annex-1.

A protocol may be signed with public or private reimbursement institutions by foreign suppliers, covering tax and other legal obligations and operating costs, regarding the collection of human medicinal product costs. However, any protocol to be made within this scope must be submitted to the Agency within five business days. The cost to the public of the products to be procured within the scope of the protocols made with public institutions and organizations should not be higher than the cost to private reimbursement institutions.

You can access the full text of the Guideline and Annex-5 through this link.

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