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Turkey Announces the Regulation on Licensing of Medicinal Products for Human Use

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The Regulation on Licensing of Medicinal Products for Human Use ("**Regulation**") introduced by the Turkish Pharmaceuticals and Medical Devices Agency ("**Agency**") which aims to regulate the procedures and principles pertaining to licensing processes of medicinal products and practices regarding licensed medicinal products, was published in Official Gazette dated 11 December 2021 and numbered 31686.

The Regulation covers the medicinal products prepared industrially or manufactured with a method containing an industrial process as well as real and legal persons who are applying for or have been granted marketing authorizations for such products.

With the introduction of the Regulation, the Regulation on Licensing of Medicinal Products for Human Use published in Official Gazette dated 19 January 2005 and numbered 25705 and the Regulation on the Evaluation of Bioavailability and Bioequivalence of Pharmaceutical Drugs published in Official Gazette dated 27 May 1994 and numbered 21942 have been abrogated.

Certain important matters regarding changes introduced with the Regulation can be summarized as follows;

- When all characteristics are considered, in case of a reservation that a product may be qualified as medicinal product for human use and as a product within the scope of other related legislation, the provisions of the Regulation shall be applied.
- Regulations have been made regarding the application for marketing authorization, method of application as well as information and documents required to be submitted. As a principle, marketing authorization applications and all correspondences during the process shall be made electronically.
- With the Regulation, practices regarding application evaluation processes have been elaborated on and matters concerning the rejection of the application have been clarified. Additionally, detailed regulations have been made on the licensing process and duration.
- A special type of has been established for licensing of allergen products.
- Types of abridged application have been brought into conformity with European Union legislation, the definitions and requirements have been clarified.
- A conditional licensing (emergency use approval) procedure has been regulated in detail, with respect to medicinal products aimed at treatment, prevention or diagnosis of life-threatening diseases or diseases that create serious disabilities and/or medicinal products that will be used in emergencies against public health hazards that are recognized by the World Health Organization or the European Union or are accepted by the Ministry of Health, provided that certain conditions under the Regulation are met.
- With regards to marketing authorization applications made for co-marketed products, the Agency shall evaluate the Module 1 prepared in accordance with Annex 1 of the Regulation of the application dossier made with complete dossier. The marketing authorization application may also be made with the Module 1 prepared in accordance with Annex 1 of the Regulation. For co-marketed product marketing authorization applications made in this manner, other modules cannot be submitted during the licensing process or after licensing.
- With regards to co-marketed products, in case of revocation of the marketing authorization of the product the application of which has been made with a complete dossier, the marketing authorizations of the co-marketed products the application of which has been approved only with Module 1 prepared in accordance with Annex 1 of the Regulation shall also be revoked. A transition process has been envisaged for co-marketed products the application of which has already been made and the licensing process is on-going.

- An exception has been established regarding the approval of a transfer application that foregoes the court decision in the event that the concerning product is the sole diagnosis or treatment option for a disease in Turkey.
- Detailed regulations regarding the suspension of marketing authorizations have been provided under the Regulation. If at least one commercial batch of a licensed medicinal product is not found on domestic or international markets for 30 months continuously, the marketing authorization shall be suspended instead of revoked.
- In case the marketing authorization holder cannot release for any reason a product which already on the market, the marketing authorization holder shall notify the Agency at least 30 days in advance. Additionally, in the event of suspension or revocation of the marketing authorization or recall or collection from the market in other countries of medicinal products which are imported, exported or manufactured in Turkey under a license, the marketing authorization holder shall notify the Agency.
- In case the marketing authorization or the dossier is lost, the marketing authorization holder or the applicant may apply to the Agency. In this case, as applicable, a new marketing authorization document shall be issued, or the Agency shall provide a copy of the dossier to the applicant.
- Licensing process of products with import permits and registration documents for which a marketing authorization application has been made and interim products that qualify as medicinal product for human use shall be finalized within 1 year as of the entry into effect of the Regulation.

Sub-paragraphs (i) and (j) of paragraph 1 of article 22 of the Regulation regarding suspension of marketing authorizations shall enter into effect one year after publication, paragraph 1 of article 29 regarding market offering approval for blood products shall enter into effect on 1 January 2025 and other provisions of the Regulation shall enter into effect on the date of its publication.

Please see this link for the full text of the Regulation published in Official Gazette dated 11 December 2021 and numbered 31686 (only available in Turkish).

You may find the announcement of the Agency regarding the Regulation through this link (only available in Turkish).

Related Practices

- R&D, Licensing and Technology Transactions

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