Turkey Introduces a New Regulation on Packaging, Inserts and Tracking of Pharmaceuticals, in line with EU Directives

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I - Introduction

On April 25th, 2017, the Ministry of Health ("Ministry") has published the Regulation on Packaging Information, Inserts and Tracking of Medicinal Products for Human Use ("Regulation") on the Official Gazette.

Upon publication of the Regulation, the Regulation on Packaging and Labeling of Human Medicinal Products published on August 12th, 2005 ("Abolished Regulation"), has been abrogated.

The Regulation has been prepared within the scope of "legislative harmonization", in consideration of the Directive 2001/83/EC on the Community code relating to medicinal products for human use and Directive 2011/62/EU, as regards the prevention of the entry into the legal supply chain of falsified medicinal products.

In a nutshell, the Regulation governs principles as to the notifications to be made by sellers/importers for tracking of the distribution chain and includes information required on the packaging and inserts of medicinal products for human use.

II - Interior, Exterior Packaging and Directions for Use

- Articles 5 and 6 of the Regulation list the information required to be added to exterior and interior packaging of human medicinal products.

- As per Article 5 of the Regulation, in case a Turkish version of the exterior packaging cannot be prepared, manufacturers will be allowed to attach a label on the exterior packaging which specifies the required information listed in Article 5.

- Manufacturers/importers are obliged to include the name of pharmaceutical in Braille format, as per Article 13. Packaging of pharmaceuticals should be made complaint with this requirement until 31.12.2018[1].

- Inserts (directions for use) will have to be prepared as per Article 8 of the Regulation, listing the information indicated thereunder and in line with the summary of product characteristics and the relevant guidelines of the Ministry.

[1] Provisional Article 2 of the Regulation

- Article 18 lays out the principles on the packaging of radiopharmaceuticals and the additional information for their directions for use, such as special precautions, the parts which are not to be used and the duly disposal of their packages.

III - Marketing Samples

- Principles on the marketing samples of medicinal products for human use are set forth under Article 10 of the Regulation.

- Products to be used for marketing purposes as per the Regulation on Promotional Activities of Human Medicinal Products, should also fulfill the requirements determined by the Regulation.

- Turkish Pharmaceuticals and Medical Devices Institution ("Institution") will determine the products to be excluded from Data Matrix practice applied to marketing products.

- Data Matrix inserted to the marketing samples should indicate that the product is for marketing purposes and not for sale.

IV - Tracking of Human Medicinal Products

- The Regulation, contrary to the Abolished Regulation, brings an in-depth roundup on the Product Tracking System ("System") of the Institution. Mechanism of the System is described as the following:

"*The System operates based on the principle of recording of the notifications required to be made by partners who are identified with a Global Location Number in accordance with their identified type, to the central data system and the tracking of these. Data Matrix of human medicinal products is notified to the System by the license/permit holders. System, upon controlling the uniqueness, standards and content of the notified Data Matrix records the Data Matrix to data base or rejects those that are not qualified.*"[2]

- The Term "partner" used in the foregoing expression has been described in Article 4 of the Regulation as "*Real/legal persons, institutions or organizations that can, limited to their field of authorization, conduct any operation under human medicinal products' supply chain such as manufacturing, import, purchasing, sale, usage, consuming, exportation, assignment, loss, refund.*"

- Article 15 of the Regulation lists the incidents that should be notified to the System by partners as well as pharmaceutical warehouses, such as deactivation process, activities on the registered pharmaceutical and the cancellation of those.

- Principles on recording and protection of the data gathered in the System are regulated under Articles 16 and 17 of the Regulation. Regarding the distribution of human medicinal products,

[2] Article 15 of the Regulation

partners will have to comply with rules set forth under Article 17, which in general underlines the transport packaging requirements.

V - Transition Process

The Ministry has granted the following transitional periods for fulfilling the requirements under the Regulation:

(1) Medicinal products for human use that are licensed or permitted or subject to license/permit application before the enforcement of the Regulation will have to be made compliant with packaging and insert requirements of the Regulation until September 30th, 2017.

(2) Medicinal products for human use manufactured before December 31st, 2017 can be preserved with their current packaging until the expiration of their shelf life.

(3) For medicinal products for human use manufactured after December 30, 2017, packaging and direction requirements of the Regulation should be fulfilled.

(4) Foods for special medical purposes that are not reimbursed but brought under the scope of the Data Matrix practice as per Article 5 of the Regulation should participate to the Data Matrix practice latest by December 31st, 2018.

(5) Bulky parenteral, radiopharmaceuticals and individualized human medicinal products should participate to the Data Matrix practice (under the scope of guidelines specified in Article 20) latest by December 31st, 2018.

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