

SATURDAY, FEBRUARY 2, 2008

Official Gazette

Number : 26775

## REGULATION

Ministry of Health:

### DRAFT REGULATION ON THE AMENDMENTS TO THE REGULATION REGARDING THE PACKAGING AND LABELLING OF MEDICINAL PRODUCTS FOR HUMAN USE

**ARTICLE 1** – The following definitions have been added to Article 4 of the Regulation Regarding the Packaging and Labelling of Medicinal Products for Human Use, published on the Official Gazette dated 12/08/2005, with No. 25904.

“Manufacturer: Real person or legal entity to release the product so as to introduce it into the market,”

“Data Matrix: Two dimensional barcode in the form of Data Matrix,”

“Legible information: identifying content information written below or close to the identifier, with the purpose of demonstrating to the users the content of the barcode or data matrix”.

**ARTICLE 2** – Clauses (f), (i), (j), (m), (n), (ö), (r) and (s) in paragraph one of Article 5 in the Regulation have been modified as indicated below.

“f) The special warning, ‘Keep in its package, in places that cannot be seen and accessed by children.’ shall be included.

“i) In line with the Regulation Regarding the Control of Packages and Package Wastes published on the Official Gazette dated 24/06/2007, with No. 26562, the symbol of recyclable package as well as the number and abbreviation relating to the type of package shall be included. Except for the products mentioned under the heading of Radiopharmaceuticals in this regulation, the management of the immediate, outer and transport packaging wastes that are not classified as medical and hazardous waste shall be conducted within the scope of the referred regulation.”

“j) The name and address of the registration/permit holder shall be included on the package of the product. If desired, also the name of the company authorized to represent the registration/permit holder may be included.”

“m) The batch number shall be included into the secondary identifying information and the legible information of the data matrix.

n) The expiration date shall be written clearly in proportion with the pack, with the month in number or writing and the year only in number.”

“ö) “The warnings, ‘Do not purchase cut or opened packages’; ‘Read the package leaflet before using the drug’; ‘Consult your physician if any undesired effects appear’, as well as the other warnings designated by the Ministry shall be included.”

“r) A secondary identifier named data matrix as well as legible information adjacent to it relating to the content of the data matrix shall be included for the purpose of ensuring the traceability of the products. Registration/permit holders shall apply on the outer packages of their products legible information relating to the data matrix and its content, within the standards indicated in the barcode implementation guidance to be issued in relation with this regulation, so that they may be read by readers which are widely spread in the market and may read 2-dimensional barcodes. The data matrix shall be applied on the packages of promotional samples, hospital packaged products, prescription or non-prescription drugs, intermediate products subjected to reimbursement and formulas for medical purposes.”

s) The product’s barcode shall be included.”

**ARTICLE 3** – Paragraph 6 of the said Regulation has been amended as follows:

“**ARTICLE 6** – Except for cases identified in clauses (a) and (b) in this article and clauses (o), (ö), (p) and (s) in paragraph one of Article 5, immediate packages shall bear the characteristics and information specified in Article 5 of this Regulation.

Provided that compliance is achieved with paragraph of this article, the following shall be implemented in particular:

a) In immediate packages in blister form;

1) Name of the product as indicated in clause (a) of paragraph one in Article 5 of the Regulation,

2) Name or logo of the registration/permit holder,

3) Expiration date written clearly in proportion with the size and characteristic of the immediate package, with the

number in number or writing and the year only in number,

4) Batch number.

b) In small immediate packages where the characteristics and information indicated in terms of labelling in Article 5 of the Regulation, the following shall be included;

1) Where possible, the name or logo of the registration/permit holder,

2) Name of product and where necessary, dose and mode of administration,

3) Expiration date clearly written as month and year,

4) Batch number,

5) Its content in weight, volume or unit/amount,

6) Mode of administration.

Current packages of products with no outer package shall comply with Article 5 of the Regulation.

The batch number shall be included in immediate packages.”

**ARTICLE 4** – Clause (a) in paragraph one of Article 11 in the said Regulation has been amended as follows:

“a) It shall comply with the conditions designated by this Regulation. However, no barcode shall be included on the packages of these products, only the data matrix and the legible information relating to the content of the data matrix shall be included.”

**ARTICLE 5** – Paragraph four in Article 14 of the said Regulation has been amended as follows.

“The information relating to the outer, immediate packages and package leaflets shall be in Turkish for the market placement of the product. However, where necessary and desired, in addition to Turkish, one of the official languages or the EU member countries and one of the official languages of the other countries may be used in the outer packages, immediate packages and package leaflets.

**ARTICLE 6** – The following paragraphs have been added to Article 16 of the said Regulation.

“Registration/permit holders must use transport packages when delivering multiple products so as to ensure product safety. The transport packages may be in the form of palettes, parcels, boxes or bundles and be placed within one another. The amount contained inside the transport packages may be should be at reasonable levels so as to be transported until the final destination without opening during sales.

“The transportation packages shall always bear on them an identifier containing the information identifying the transport package or an identifier encompassing all of the data matrix information of the products contained within the transport package. The identifier to be placed on the transport package shall be applied as indicated in the barcode application guidance to be issued in relation with this regulation.”

**ARTICLE 7** – Article 19 of the said Regulation has been amended as follows:

“**ARTICLE 19** - The Ministry shall publish the general principles in the form of a guidance, where necessary, and in relation with the following cases in particular;

a) Formulation of warnings for some product categories,

b) Preparation of special information relating to the products to be used for self-medication purposes,

c) For the understandability of Package and Label information,

d) For product identification methods, identification content to be included on the outer packages and transport packages and their safety,

e) For the list of excipients to be included into the product label and the manner in which they should be indicated.

For cases not specified in this Regulation and where deemed necessary, the Ministry shall publish the additional guidance or notifications relating to the enforcement of the Regulation.”

**ARTICLE 8** – The enforcement date of Temporary Article 1 of the said Regulation has been extended to 01/07/2009 for original products and to 31/12/2009 for generic products.

**ARTICLE 9**- The following Temporary Articles have been added to the said Regulation.

“**TEMPORARY ARTICLE 2** – Data matrices shall be added on pharmaceutical packages until 01/01/2009 as of the publication date of the Regulation. It shall be mandatory to include data matrices, as of this date, for all products. The sale of products which have been manufactured without a data matrix before this date and are available in the market shall be permitted until the date 31/12/2009.

“**TEMPORARY ARTICLE 3** – In the application to be submitted by registration/permit holders regarding the registered products’ outer packages that need to be renewed after the enforcement of this Regulation, it will be regarded sufficient, until the date 01/01/2009, to notify the Ministry informing that only the price clippings are removed, the data matrix and the legible codes are included, and it will not be necessary to wait for the approval; the package updates within this scope shall not be evaluated as variations until 01/01/2009. However, for updates to be conducted as of this date, it shall be necessary to apply for a variation application. In case package updates encompass any variation other than the removal of the price clipping and the data matrix application, application shall be made for a variation.”

**ARTICLE 10 — In this Regulation;**

a) Article 8 of this Regulation shall be enforced on 31/12/2007

b) The other articles shall become effective on the publication date of the Regulation.

**ARTICLE 11** — The provisions of this Regulation shall be executed by the Minister of Health.