Normative guideline 28.05.2013
000091/00.01.02/2013

1/2013

UNOFFICIAL TRANSLATION

Finnish Medicines Agency normative guideline

LABELLING AND PACKAGE LEAFLETS FOR MEDICINAL PRODUCTS

Target groups

Medicinal product manufacturers
Medicinal product wholesalers
Persons responsible for placing medicinal products on the market
National Institute for Health and Welfare
Finnish Red Cross, Blood Transfusion Service

Entry into force

This guideline will enter into force on the 3rd of June 2013 and shall be valid until further notice.

Normative guideline repealed

Finnish Medicines Agency normative guideline 1/2010

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1 GENERAL

The purpose of this guideline is to supplement the Finnish Medicines Agency Fimea's Administrative Regulation 3/2013 entitled "Labelling and package leaflets for medicinal products" presenting regulatory requirements for the labelling and package leaflets of medicinal products. The guideline should be read side by side with the Administrative Regulation.

Product-specific deviation from this guideline is allowed if well justified. In situations in which the space on the packaging is limited, the holder of the marketing authorization and registration is encouraged to seek alternative solutions to ensure that information vital to the patient or user is included in the medicinal product packaging.

If the marketing authorisation application concerns a multinational package, the applicant is advised to indicate this in the cover letter accompanying the application.

Draft-like proposals (Mock-ups) for labelling should be dated (DD-MM-YYYY) to facilitate document management. The actual dimensions of the label or packaging as well as font size should be stated.

2 DEFINITIONS

This guideline is governed by the definitions specified in Fimea's Administrative Regulation 3/2013.

In addition, the following term will have the following meaning in this guideline:

Blue-Box text means additional national requirements concerning package instructions and labelling.

3 LABELLING

3.1 Text

In order to ensure the proper delivery and use of medicinal products, vital information about the individual products must be written in a clear font with a large type size on prime spaces on the packaging. This applies in particular to the name, strength, pharmaceutical form, active substance, and instructions for use of the product, and to any storage conditions or warnings. Other information such as the composition of the product and the marketing authorization and registration holder can be indicated using a smaller font. Medicinal packaging must also leave enough space for the pharmacy's prescription label.

Less information is allowed on smaller immediate packages with a maximum volume of 10 millilitres. In special cases such as the Inter-Nordic

package, less text can be allowed on even larger immediate packaging. Special attention should be paid to the readability of the text.

The text font used in the packages should be plain, simple and sans serif. The minimum font size is 7 points (i.e. the smallest x should be at least 1.4 mm high.) It is advisable to use bold or switch to a larger size font if there is a need to highlight any parts of the text. Italics, spacing out of words or characters, and underlining should be avoided. Clear contrast with the background also improves the clarity of the text. It is advisable to use black, dark green or dark blue text on a white or light background.

The label must be attached to the medicinal product permanently to make it possible to verify its origin. Partial correct of the label, whether by printing or through the use of a sticker, is not acceptable.

If the price, use, or other feature of the medicinal product creates the risk of medicine counterfeiting, the packaging of these products should incorporate identifiers that impede forgery and confirm the true origin of the product. Such identifiers should be designed so as not to interfere with or impede inspection of the medicinal product or make it difficult to read the instructions.

3.2 Images and colours

An image of the medicinal product can be included on the packaging for identification purposes. Such an image should correctly depict the medicinal product in the package in terms of size, shape, colour and printing and the description provided in the summary of product characteristics.

The primary purpose of the use of colours and designs on the medicinal product packaging is to clarify or highlight important information on the package. Colour and design can also make the pharmaceutical packaging easier to recognize or more difficult to counterfeit.

Images included in the medicinal product packaging should be practical, appropriate, and related to the clinical use of the medicinal product. Images and pictograms may not be used to replace the compulsory information required on product packaging. Legends explaining the pictograms must be provided on the packaging or in the package leaflet (if there is a lack of space).

The colours, shape and images of the pharmaceutical packaging should not encourage misuse of the medicinal product or make the package more attractive, particularly for children. Pharmaceutical packaging should be clearly distinguishable from food and sweets packages in particular.

When marketing authorization and registration holders use a uniform corporate design in their medicine packages, the specific medicinal products and strengths should be easy to distinguish from one another. This can be accomplished with different colours of the backgrounds and texts, text layout, use of boxed text, and graphic images.

Specific strengths of the same medicinal product should be distinguished by colour or by using bars of different colours. Strong colours signal a stronger medicinal product, while lighter colours suggest lower strengths.

When new medicinal products are introduced to a product family, they should be packaged so as to ensure that they can be told apart from the existing medicinal products. To do so, it may be necessary to redesign the packaging for the entire product family.

3.3 Trade names of medicinal products

The name of the medicinal product is supposed to make it easy to identify the product and distinguish it from the other medicinal products on the market. The name of the medicinal product can be an invented name, but it should be distinct enough to be easily recognizable in speech (on the phone) and in writing (when handwritten). As a rule, there should be a difference of at least three letters from other invented names. When evaluating distinctiveness, the strength and pharmaceutical form of the medicinal product may also be taken into account When the name of a medicinal product is a 'generic name', distinctiveness should be secured with respect to the name of the manufacturer or marketing authorization holder associated with the generic name in the manner stated above.

With medicinal products intended for animals, it is advisable to add the abbreviation 'Vet' to the name.

An invented name of a medicinal product should not convey any promotional message or be misleading. Invented names should not arouse misleading connotations as to the intended use or efficacy of the medicinal product. The invented name should be clearly different from the internationally approved INN name. If there is reason to believe that the name of the medicinal product may cause confusion, the distinctiveness of the name and the connotations associated with it should be evaluated in user tests with health care staff and patients.

Where possible, the name and strength of the medicinal product should be printed in the same font on at least three sides of the outer packaging (on one of the two opening end panels as well). The front panel of the package should clearly indicate the name, strength and pharmaceutical form of the medicinal product.

3.4 Strength of the medicinal product

If the medicinal product contains several active substances, the strengths can be indicated in connection with the name, e.g. as follows: 25 mg / 10 mg / 5 mg. The active substances should be indicated under the name in the same order.

The quantity of active substance is normally expressed in milligrams (mg). If the quantity of the active substance is one gram or more, it is expressed in grams (g). If the quantity is less than 0.1 mg, it is expressed in micrograms (microg). However, the strengths of all medicinal products of the same product family must be expressed using the same unit of measurement. If necessary, other internationally approved units of measurement for the quantity of the active substance can be used, such as the millimole (mmol) and the international unit (IU).

The radioactivity of a radiopharmaceutical preparation is expressed in Becquerels (kBq, MBq or GBq).

The strength of a medicinal product pre-divided into doses is expressed per dose. This also applies to medicinal products that include a fixed dispenser as an integral part of the package.

The strength of medicinal product in liquid form not pre-divided into doses is expressed as the quantity of active substance per millilitre (ml). The strength of solid or semi-solid forms not pre-divided into doses is expressed per gram.

The strength of a medicinal product administered parenterally is indicated as the nominal quantity of active substance per package if the product is intended to be administered all at once in a single dose. With liquid products, the packaging must also indicate the concentration of the active substance per millilitre as well as total volume of the product or the quantity of active substance per total volume.

For a liquid medicinal product intended for oral administration as drops, the quantity of active substance is expressed per drop and as the number of drops per millilitre.

3.5 Pharmaceutical form

A list of the terms of pharmaceutical forms in English, Finnish and Swedish is available on the Fimea website (www.fimea.fi). The List of Standard Terms can be ordered from: Council of Europe, European Directorate for the Quality of Medicines, Publications, BP 907, F-67029 Strasbourg Cedex 1, France; fax +33 3 88 41 27 71; E-mail: Publications@pheur.org.

Approved abbreviations of pharmaceutical form (e.g. tabl., kaps.) can be used together with package size. Abbreviations may also be used in packages of the blister pack type.

3.6 Active substance

The name of the active substance should be printed on the packaging under the name, strength and pharmaceutical form of the medicinal product using a smaller font beginning with a lower-case character to distinguish it from the name of the medicinal product. The name of the active substance should be consistent with the strength of the medicinal product. If the strength corresponds to the free base of the active substance, the active substance is expressed as base. If the strength corresponds to the salt form, the active substance is expressed as salt.

Where possible, colours should be used to make a distinction between the name of the medicinal product and active substance. If the name of the active substance is included in the name of the medicinal products, it is not necessary to repeat it.

3.7 Route and method of administration

To save space, approved abbreviations for routes of administration may be used in the immediate packages of parenteral preparations: i.m. (muscle); i.v. (intravenous), s.c. (subcutaneous).

The method of administration indicates the correct use of the product, such as"Ravistettava ennen käyttöä / Skakas före användning" or "Niellään kokonaisena / Sväljes hela".

3.8 Package size

The package size of a liquid medicinal product is expressed in millilitres, of solid and semi-solid medicinal products in grams, and of medicinal products pre-packed in doses in the number of doses (e.g. number of tablets).

The overage used in ampoules and injection bottles is not indicated.

3.9 Excipients

The approved E codes can be used for colourings and preservatives. Excipients that the medicinal product does not contain are not specified on the package.

3.10 Batch number and expiry date

The terms "Erä / Sats" are recommended for indicating the batch number. Alternatively, the international terms "Lot" or "Batch" may be used. The abbreviations "Käyt. viim. / Utg.dat." ("Anv. Senast") are recommended for indicating the expiry date of the medicinal product. Alternatively, the equivalent international abbreviation "EXP" may be used.

The batch number and expiry date of a medicinal product should be placed near each other and on the outer package preferably on the opening end panel. The batch number and expiry date should be indicated clearly; a marking made in ink is preferable to embossed text. The batch numbers on the immediate and outer package of a medicinal product should be the same or based as a rule on the same series of numbers or letters.

Any restrictions on the use of an opened package should be positioned next to the instructions concerning storage conditions. If a medicinal product is to be prepared for use at a pharmacy and this involves restrictions on use, it should be clearly indicated on the package.

3.11 Storage conditions

The instructions for storage are based on the results of approved stability studies. Detailed instructions for storage are provided in the guideline (Note for Guidance on Declaration of Storage Conditions) issued by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA). Appendix III related to the QRD templates approved by the CHMP and posted on EMA's website provides instructions for storage in all the languages of the Member States.

3.12 Other information necessary for the correct use of the medicinal product

Packages containing medicinal products that affect driving capacity must carry a red warning triangle on a white background with the red point of the triangle pointing up. The sides of the triangle are 10 mm long and the

frames 2 mm wide. The warning triangle can be complemented with the following text: “Voi haitata suorituskykyä liikenteessä / Kan nedsätta reaktionsförmågan i trafik”. Detailed instructions are provided on the CMDh website.

3.13 Nordic product number, bar code and other equivalent identifiers

The Nordic product number (Vnr xx xx xx) is placed in a clearly visible place on the same side of the package as the name of the product and the package size. A suitable location is the top corner of the front panel of the package.

The bar code or other such identifier may be used for ensuring delivery of the correct medicinal product by pharmacies and for stock monitoring purposes. The bar code or other such identifier should be placed in such a location that it will not be covered by the prescription label.

3.14 Reference to the package leaflet

The outer package must include a reference to the package leaflet contained in the package: ”Lue pakkausseloste ennen käyttöä / Läs bipacksedeln före andvändning” or, alternatively, a reference to any special information contained in the package leaflet: ” Lue lisätietoja pakkausselosteesta / Se bipacksedeln för ytterligare information”.

3.15 Space for the prescription label

Medicinal packaging must leave enough space for the pharmacy's prescription label. Essential information related to the medicine package should not be placed in the space reserved for the label. The space for the label should be marked clearly with lines or indicated with text (for example “Apteekin ohjelipulle / För apoteksetiketten”).

If a medicinal product is intended for storage in its outer package (for example blister packs), there should be adequate space for the prescription label on the outer package. For bottles of tablets or small packages (for example eye drops), it is recommended that space be reserved in the immediate package for the prescription label (or at least its adhesive surface).

3.16 Child-safe packages

All medicinal products are intended for storage out of the reach and sight of children.

Child-safe packages are recommended for use with products that are fatal for pre-school-age children in small dosages. Additionally, the product package or package leaflet must provide instructions for opening the safety lock.

3.17 Blister packs

Where possible, the name and strength of the medicinal product should be indicated over each blister. However, the package must be designed so as to ensure that the information on the package is readable even after the package has been opened and used. This can be achieved by printing the name of the medicinal product in a recurring pattern across the entire blis-

ter. If the blister pack is of the unit-dose type, all the information should be provided on each unit dose presentation.

Medicinal products involving the risk of misuse should use packaging types and materials that enable monitoring of product use and hence reduce unintended overuse. The use of tablet bottles and other multi-dose packages should be avoided for such medicinal products.

4 PACKAGE LEAFLET

The package leaflet must be prepared in accordance with “A Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use” issued by the European Commission. The guidance on the typographical presentation must also be observed (particularly with regard to minimum font size).

When entering the information regarding excipients, due consideration is to be given to “A Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use” issued by the European Commission. With regard to warnings to marked on the package concerning excipients, reference is made to EMA’s publications (www.ema.europa.eu).

With regard to instructions for storage conditions, due consideration should be given to ”Note for Guidance on Declaration of Storage Conditions” issued by the CHMP and Appendix III related to the GRD templates approved by the CHMP (see section 3.11 above).

4.1 Package leaflet for medicinal products intended for human use

Preferably, the package leaflet should be prepared using the template approved by the Committee for Medical Products for Human Use (CHMP). The latest version of the template is posted on EMA’s website (www.ema.europa.eu).

The package leaflet may include symbols and images to clarify the information provided for the patient or user. However, they may not be used for promotional purposes. The readability of the package leaflets of medicinal products intended for human use must be ascertained by means of user tests.

The relevant Finnish ‘blue box’ texts should also be included in the package leaflet. The texts and instructions concerning the texts are posted on Fimea's website (www.fimea.fi).

The package leaflet of products subject to additional monitoring under the pharmacovigilance provisions should be marked with a black symbol. The relevant guidance and standard phrases are available on the EMA website (www.ema.europa.eu). EMA maintains a list of preparations subject to additional monitoring.

4.2 Package leaflet for veterinary medicinal products

Preferably, the package leaflet should be prepared using the template approved by the Committee for Medical Products for Veterinary Use (CVMP).

The latest version of the template is posted on EMA's website (www.ema.europa.eu).

5 GUIDANCE AND INFORMATION

Fimea will provide on request guidance and advice on the application of this normative guideline.

6 ENTRY INTO FORCE

This normative guideline enters into force on 3/6/13.

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DISTRIBUTION

Medicinal product manufacturers

Medicinal product wholesalers

Persons responsible for placing medicinal products on the market

National Institute for Health and Welfare

Finnish Red Cross, Blood Transfusion Service

FOR INFORMATION

Ministry of Social Affairs and Health

Ministry of the Economy and Employment

Ministry of Agriculture and Forestry

The Social Insurance Institution of Finland

National Supervisory Authority for Welfare and Health (Valvira)

The Finnish Consumer Agency

Pharma Industry Finland

Finnish Generic Pharmaceutical Industry

Eläinlääketeollisuus ry

Finnish Food Safety Authority

Apteekkitavaratukkukauppiaat

Luontaistuotealan Keskusliitto ry

Health Product Wholesalers' and Manufacturers' Association

Suomen Terveystuotekauppiaiden Liitto ry

The Finnish Grocery Trade Association

Finnish Association of Homeopaths

Antroposofisen Lääketieteen Yhdistys ry

University of Helsinki, Faculty of Veterinary Medicine

University of Helsinki, Faculty of Pharmacy

University of Helsinki, Faculty of Medicine

University of Eastern Finland, Faculty of Health Sciences

University of Oulu, Faculty of Medicine

University of Tampere, Faculty of Medicine

University of Turku, Faculty of Medicine

Åbo Akademi University, Department of Biosciences

The Association of Finnish Pharmacies

The Finnish Veterinary Association

The Finnish Pharmacists' Association

Finnish Dental Association

The Finnish Medical Association

Suomen Proviisoriyhdistys

Finnish Association of Municipalities and Regional Authorities

Helsinki University Pharmacy

University of Eastern Finland Pharmacy

The Finnish Federation of the Visually Impaired