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*UNOFFICIAL TRANSLATION*

## **Finnish Medicines Agency Normative Guideline**

# **LABELLING AND PACKAGE LEAFLETS FOR MEDICINAL PRODUCTS**

### **Target groups**

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

### **Period of validity**

This guideline will enter into force on 9 February 2019 and will remain so until further notice.

### **Normative guideline repealed**

Finnish Medicines Agency normative guideline 1/2013

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# 1 GENERAL

The purpose of this guideline is to supplement the Finnish Medicines Agency Fimea's Administrative Regulation 3/2019 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 said 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 authorisation 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 packaging, 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 version management. The actual dimensions of the label or packaging as well as font size should be indicated in the proposals.

# 2 DEFINITIONS

This guideline is governed by the definitions specified in Fimea's Administrative Regulation 3/2019.

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 authorisation 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

packaging, 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 repair of the label, whether by printing or through the use of a sticker, is not acceptable.

Safety features must be incorporated in the packaging of medicinal products that involve a risk of falsification. The safety features of a medicine package consist of a unique identifier and an anti-tampering device. Detailed requirements and a list of medicinal products the safety features pertain to are provided in European Commission Delegated Regulation 2016/161. The same requirements also apply to medicinal product samples and emergency packages.

## 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 and score line 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 medicinal product packaging easier to recognise or more difficult to falsify.

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. A legend explaining the pictogram must be provided in connection with the pictogram 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 market authorisation 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 background and text, 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 Name of the medicinal product

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 recognisable 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 authorisation 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 trade name 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 trade 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 or KY/IE).

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**

The pharmaceutical form, route of administration and packaging must be stated using the officially approved standard terms. A list of standard terms complete with definitions and translations has been published in the Standard Terms database maintained by the EDQM (<https://standardterms.edqm.eu/>). The database requires a registration, but is open and free for all users. The registration takes place on the EQDM website (<https://www.edqm.eu/register/>).

The short terms of pharmaceutical form (e.g. tabl., kaps.) presented in the list can be used in labelling. Short terms 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 alkaline form of the active substance, the active substance is expressed as an alkaline. If the strength corresponds to the acidic form, the active substance is expressed as an acid.

Where possible, colours should be used to make a distinction between the name of the active substance and that of the medicinal product. If the name of the active substance is included in the name of the medicinal product, 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" ('Shake before use') or "Niellään kokonaisena / Sväljes hela" ('Swallow whole').

### 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. It is not necessary to specify on the package excipients that the medicinal product does not contain.

### 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 shelf-life analyses. 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 GRD 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.

In exceptional cases, the red warning triangle can be added to Inter-Nordic packaging if the requirements differ between the Nordic countries.

### 3.13 Safety features, Nordic product number, bar code and other equivalent identifiers

The safety features shall be incorporated on the outer packaging or, in the absence of it, on the immediate packaging in accordance with the guidelines published by the European Commission. The legibility of labelling must be ensured when the safety features are located on the packaging. The unique identifier and its human readable format must be printed indelibly on the packaging. The unique identifier and its human readable format include the product code (PC) and serial number (SN). In Finland, the unique identifier does not contain a national number (NN). The human readable format of the unique identifier (PC, SN) must be placed next to the 2D code whenever the size of the package so permits.

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 EAN bar code or other equivalent identifier may be used for ensuring the provision of the correct medicinal product by pharmacies and for stock monitoring purposes. The EAN bar code or other equivalent identifier may not be used for identifying an individual medicine package. The EAN bar code or other equivalent identifier should be placed in such a way as to ensure that the labelling remains legible.

### 3.14 Reference to the package leaflet

The outer package must include a reference to the package leaflet contained in the package: “Lue pakkauseloste ennen käyttöä / Läs bipacksedeln före användning” or, alternatively, a reference to any special information contained in the package leaflet: “Lue lisätietoja pakkauselosteesta / 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 apoteketiketten”).

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 in each individual blister. The package must be so designed 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 package. If the blister pack is of the unit-dose type as defined in the marketing authorisation, all the information should be provided next to each dose (including the expiry date and batch number).

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. Attention should also be paid on the sections of the guideline concerning typography (especially the 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 be marked on the package concerning excipients, reference is made to EMA’s publications ([www.ema.europa.eu](http://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 QRD 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](http://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](http://www.fimea.fi)).

The package leaflet of products subject to additional monitoring under the pharmacovigilance provisions shall be marked with a black symbol. The relevant guidance and standard phrases are available on the EMA website ([www.ema.europa.eu](http://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](http://www.ema.europa.eu)).

## **5 GUIDANCE AND ADVICE**

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 9 February 2019.

Director General

Eija Pelkonen

Head of Division

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## **DISTRIBUTION**

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

## **FOR INFORMATION**

The Ministry of Social Affairs and Health  
Ministry of Employment and the Economy  
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 Association  
Finnish Veterinary Pharma Association  
Finnish Food Safety Authority  
Finnish Association of Pharmaceutical Distributors  
Central Organisation of Health and Food Trade in Finland  
Health Product Wholesalers' and Manufacturers' Association  
Finnish Health Product Retailers' Association  
The Finnish Grocery Trade Association  
Finnish Homeopaths' Association  
The Finnish Association for Anthroposophic Medicine  
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  
The Finnish Pharmacists' Society  
The Association of Finnish Local and Regional Authorities  
University of Helsinki Pharmacy  
University of Eastern Finland Pharmacy  
The Finnish Federation of the Visually Impaired

