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UNOFFICIAL TRANSLATION

Finnish Medicines Agency Administrative Regulation

LABELLING AND PACKAGE LEAFLETS FOR MEDICINAL PRODUCTS

Legal basis

Medicines Act (395/1987), section 25(3), 25b and 35(3) as they appear in section 25(3) and 35(3) amended by Act 773/2009 and section 25b in Act 330/2013

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 Administrative Regulation will enter into force on 9 February 2019 and will remain so until further notice.

Normative guideline repealed

Finnish Medicines Agency Administrative Regulation 3/2013

Community legislation to be implemented

Directive 2001/83/EC of the European Parliament and the Council (32001L0062, OJEC L 311, 28 November 2001, p. 67) as amended by Commission Directive 2003/63/EC (32003L0063, OJEC L 159, 27 June 2003, p. 46), Directive 2004/24/EC of the European Parliament and of the Council (32004L0024, OJEC L 136, 30 April 2004, p. 85), Directive 2004/27/EC of the European Parliament and of the Council (32004L0027, OJEC L 136, 30 April 2004, p. 34) and Directive 2010/84/EC of the European Parliament and of the Council (32010L0084, OJEC L 348, 31 December 2010, p. 74).
Directive 2001/82/EC of the European Parliament and of the Council (32001L0062, OJEC L 311, 28 November 2004, p. 1) as amended by Directive 2004/28/EC of the European Parliament and of the Council (32004L0028, OJEC L 136, 30 April 2004, p. 58) and the European Commission Directive 2009/9/EC (32009L0009, OJEC L 44, 14 February 2009, p. 10).

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1 GENERAL

By this Administrative Regulation, the Finnish Medicines Agency (hereinafter Fimea) implements the requirements concerning the labelling and package leaflets for medicinal products to comply with the following the European Community acts:

– Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use, as amended by Commission Directive 2003/63/EC, Directive 2004/24/EC of the European Parliament and of the Council, Directive 2004/27/EC of the European Parliament and of the Council, and Directive 2004/84/EC of the European Parliament and of the Council; and

– Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, as amended by Directive 2004/28/EC of the European Parliament and of the Council and the European Commission Directive 2009/9/EC, hereinafter the "Veterinary Medicinal Products Directive".

2 SCOPE OF THE ADMINISTRATIVE REGULATION

This Administrative Regulation sets forth the provisions for labelling and package leaflets relating to medicinal products for human use and veterinary medicinal products to be processed using the mutual recognition and decentralised procedures.

This Administrative Regulation does not apply to medicinal products subject to the EU centralised procedure.

3 DEFINITIONS

For the purposes of this regulation, the following terms shall have the following meanings:

dose-dispensing package means the package size for a medicinal product separately approved for dose-dispensing that is used for dispensing medicines as single doses to individual patients for specified treatment periods;

over-the-counter medicine means a medicinal product available without a prescription;

packaging of the blister-pack type means a preformed blister, tear or similar outer package;

medicinal product sample means the smallest package size of the medicinal product provided by a pharmaceutical manufacturer or wholesaler free of charge for the purpose of familiarisation with the product;

strength of the medicinal product means the quantity or concentration of the active substance(s) in the product;

labelling means the markings printed directly onto the label or package of the immediate or outer packaging;

package leaflet means the description of the medicinal product providing information to the user;

emergency package means a special package approved for the medicinal product intended for administration to patients without charge for the purpose of immediate commencement of treatment;

immediate packaging means packaging in immediate contact with the medicinal product;

shielding means the packaging into which a radiopharmaceutical preparation is placed.

safety features mean a unique identifier for the packaging that allows identification and authentication of a single medicinal product package and a device that identifies if the packaging has been tampered with;

outer packaging means the packaging into which the immediate packaging is placed;

manufacturer means the manufacturer responsible for batch release of the medicinal product in the EU/EEA;

generic name means the international non-proprietary name (INN) recommended by the World Health Organization or, if such does not exist, the usual generic name.

4 RELATIONSHIP TO OTHER REGULATIONS AND GUIDELINES

Fimea's regulation on applying for and maintaining a marketing authorisation and registration for a medicinal product sets forth provisions regarding the enclosure of labelling information and package leaflets with the application for a marketing authorisation and registration.

When labelling and package leaflets are prepared, due consideration should also be given to Fimea's Administrative Regulation 'Labelling and package leaflets for medicinal products' as well the following guidelines issued by the European Commission:

– A guideline on the excipients in the label and package leaflet of medicinal products for human use;

– A guideline on the readability of the label and package leaflet of medicinal products for human use;

– A guideline on summary of product characteristics;

– Guideline on preparation of Summary of Product Characteristics SPC – pharmaceuticals for veterinary medicinal products; and

– Guideline on preparation of Summary of Product Characteristics SPC /- Immunologicals for veterinary medicinal products.

The guidelines have been published on the Commission website at: http://ec.europa.eu/health/documents/eudralex/index_en.htm

Additionally, due consideration should be given to the guidelines and opinions issued by the European Medicines Agency (EMA), the Committee for Medicinal Products for Human Use (CHMP), the Committee for Medicinal Products for Veterinary Use and the Committee on Herbal Medicinal Products (HMPC), the latest versions of which are published on EMA's website (www.ema.europa.eu). Similarly, the template texts published by EMA's QRD (Quality Review of Documents) working group should be taken into account.

With regard to Braille conventions, the manufacturers are required to comply with the recommendations of the Braille Advisory Board of the Finnish Ministry of Education (Decree on the Library for the Visually Impaired. 639/1996) and patient associations (Finnish Federation of the Visually Impaired).

5 LABELLING

5.1 General

Labelling and texts must be easy to read and understand and printed indelibly on the packaging. According to Fimea's Administrative Regulation on applying for and maintaining a marketing authorisation and registration for a medicinal product, labelling must be at least in Finnish and Swedish. However, the composition of the medicinal product may be indicated only in Latin and labelling of certain low-demand products may be provided only in one of the official languages of the European Union.

The outer packaging may feature characters or visual symbols that are useful to patients and clarify the correct and safe use of the medicinal product. However, the size and design of such symbols may not affect the readability of the text, nor may they be used for marketing purposes.

Additionally, and with due consideration given to the provisions set out in the Commission Delegated Regulation (EU) 2016/161 concerning the safety features appearing on the packaging of medicinal products for human use, packaging may be provided with a bar code or other equivalent identifier.

5.2 Authorised human and veterinary medicinal products

In addition to the provisions set out in Commission Delegated Regulation (EU) 2016/161, the following information shall appear on the outer packaging of human and veterinary medicinal product or, if this does not exist, on the immediate packaging:

– name, strength and pharmaceutical form of the medicinal product (and the user group or target animal if necessary)

– active substance(s)

– package size

– composition (active substance[s] and, if necessary, excipients)

– method of administration and, if necessary, route of administration (parenteral products or if otherwise necessary)

– the necessary warnings

– expiry date (month / year)

– special storage conditions if necessary

– special precautions for the disposal of unused medicine or packaging (if necessary)

– name and address of the marketing authorisation holder (and the name of authorised representative if necessary)

– number of the marketing authorisation

– batch number

– Nordic product number (Vnr xx xx)

– dosage instructions for non-prescription medicines

- The outer packaging of non-prescription medicines intended for humans shall bear the marking “Itsehoitolääke/Receptfritt läkemedel”.

The additional requirements concerning veterinary, traditional herbal and authorised homeopathic and anthroposophic products are listed in sections 5.5.14–16.

The immediate packaging must have the same labelling as the outer packaging. An exception to this may be made if the immediate packaging is small, e.g. blister packs, inhalation products, small ampoules and injection bottles, and small tubes of semi-solid preparations with insufficient space for all the labelling.

At least the following information must be provided on small immediate packages:

– name, strength and pharmaceutical form of the medicinal product (and the user group or target animal if necessary) and the active substance(s)

– method and route of administration (parenteral products or if otherwise necessary) and/or method of administration

– expiry date

– batch number

– amount of contents

At least the following information must be provided on packaging of the blister-pack type:

– name, strength and pharmaceutical form of the medicinal product (and the user group or target animal if necessary) and the active substance(s)

– name of the marketing authorisation or registration holder

– expiry date

– batch number

5.3 Registered homeopathic and anthroposophic products

The following information must be provided on the outer packaging of homeopathic and anthroposophic medicinal products or, if this does not exist, on the immediate packaging:

– the scientific name of the stock or stocks followed by the degree of dilution making use of the symbols of the pharmacopoeia; if it is a combination product (composed of two or more stocks), an invented name may also be used in addition to the scientific names of the stocks;

– excipients

– the name and address of the registration holder (name of the manufacturer if necessary)

– the method of administration (route of administration if necessary)

– expiry date (month / year)

– pharmaceutical form

– package size

– special storage conditions if necessary

– the necessary warnings

– batch number

– registration number (in the format H xxx FI (if there are different dilutions in the same series, indicate this, for example, as follows: H xxx FI, D5 and H xxx FI, D6)

– “Ota yhteys lääkäriin, jos oireet jatkuvat / Kontakta läkare om symtomen fortsätter.”

– products intended for humans must display the text “HOMEOPAATTINEN VALMISTE – HOMEOPATISKT MEDEL” or “ANTROPOSOFINEN VALMISTE – ANTROPOSOFISKT MEDEL”

- products intended for animals must display the text “HOMEOPAATTINEN VALMISTE ELÄIMILLE – HOMEPATISKT MEDEL FÖR DJUR” or “ANTROPOSOFINEN VALMISTE ELÄIMILLE – ANTROPOSOFISKT MEDEL FÖR DJUR”

5.4 Radiopharmaceutical preparations

The following information must be provided on the protective package of radiopharmaceutical preparations:

– name of the medicinal product, strength and pharmaceutical form (the user group or target animal if necessary) and active substance(s)

– explanation of the code used

– amount of radioactivity per dose or bottle/ampoule at a given time (date and time)

– package size

The following information must be provided on the bottles and ampoules of radiopharmaceutical preparations:

– product name or code

– name or chemical symbol of the radionuclide

– batch number

– expiry date

– international symbol for radioactivity

– name and address of manufacturer

– amount of radioactivity

5.5 Detailed regulations concerning labelling

5.5.1 Name of the medicinal product

The trade name may be an invented name; a generic name combined with a trade mark; the name of the manufacturer, marketing authorisation holder or its representative; or a scientific name combined with a trademark, the name of the manufacturer, marketing authorisation holder or its representa-tive. The strength and the pharmaceutical form of the medicinal product is as-sociated with the name of the pharmaceutical product.

An invented name should not resemble the generic name to a misleading extent or otherwise exaggerate or mislead in a therapeutic or pharmaceuti-cal sense, for example. An invented name must not be the same or mis-leadingly similar to another medicinal product with marketing authorisation in Finland. A proposed name identical with or confusingly similar to the name of a medicinal product already on the Finnish market may also be re-jected. The applicant for a marketing authorisation or registration is respon-sible for the protection and registration of the trade name.

If a homeopathic or anthroposophic preparation derives from only one stock, the stock's scientific name and its degree of dilution should be given as the trade name. If two or more stocks have been used in the manufac-ture and the product is therefore a combination product, an invented trade name may also be used.

The name of a medicinal product (if necessary the strength) shall be indicated on the outer packaging in Braille of an approved standard. This requirement does not concern human medicinal products intended solely for hospital use or for dispensing by health care personnel or veterinary medicinal products.

5.5.2 Strength

The strength of the product must be indicated in connection with the trade name. The strength must be indicated in the same way as in the summary of product characteristics and package leaflet.

The strength must be indicated in connection with the trade name of herbal medicinal products when the compound or compound group achieving the therapeutic effect is known.

5.5.3 Pharmaceutical form

The names of pharmaceutical forms in Finnish and Swedish are indicated using the terminology of the List of Standard Terms of the European pharmacopoeia. Short terms may be used on small packages and if the full form of term has already been indicated in connection with the product.

5.5.4 Active substance

The names and quantities of active substances must always be declared on the labelling using the INN names of the World Health Organization. If no such names exist, names from the European pharmacopoeia or other common names may be used.

5.5.5 Method and route of administration

The method of administration, such as “Oral Use”, must be indicated on the packaging including the route of administration if necessary.

The name of the route of administration must be indicated using the terminology of the List of Standard Terms of the European pharmacopoeia.

5.5.6 Package size

The package size must be indicated as the weight or volume of contents or the number of doses or units.

5.5.7 Excipients

Excipients of medicinal products with known effects must be indicated in accordance with the European Commission guideline: “A guideline on the excipients in the label and package leaflet of medicinal products for human use”. The labelling of parenteral products, products used for the skin/locally, eye and inhalation products must identify all the excipients, i.e., the complete qualitative composition of the product.

5.5.8 Warnings

All packages must display the following warning to store the medicinal product out of reach or sight of children: “Ei lasten ulottuville eikä näkyville / Förvaras utom syn- och räckhåll för barn”. In addition, packages may also

display other warnings, for example to prevent injury, such as “Sytostaatti / Cytostatikum” or “Cytostatikum” on cytotoxics. Flammable products must be identified with the appropriate international symbol and the legend “Tulenarkaa / Brandfarlig”.

Over-the-counter medicines intended for children only by prescription must display the following warning “Ei alle X-vuotiaille lapsille ilman lääkärin määräystä / Ej för barn under X år utan läkarordination”. Over-the-counter medicines not approved for use in children must be marked "Ei lapsille / Ej för barn".

Packages of medicinal products that can have an adverse effect on driving performance must be marked with a red warning triangle. The red warning triangle need not be added to packages intended solely for hospital use.

5.5.9 Batch number and expiry date

The batch number and expiry date (month/year) must be indicated in a non-abbreviated form as follows: 09-2014, 09/2014 or 2014-09.

The shelf-life of the medicinal product once it has been opened, made ready for use or diluted for use should be indicated on the labelling if necessary.

5.5.10 Storage conditions

The instructions for storage based on the results of approved shelf-life analyses must be consistent with the storage conditions specified in the summary of product characteristics.

5.5.11 Nordic product number

The requirement to indicate the Nordic product number does not apply to radiopharmaceutical preparations, homeopathic products, medicinal products subject to a special permit or emergency packages.

When the outer packaging contains several packages, the Nordic product number shall not be marked on individual packages if the individual packages no not have a marketing authorisation.

5.5.12 Safety features

Safety features shall be incorporated in medicines defined in Commission Delegated Regulation (EU) 2016/161 as set out in the regulation concerned.

5.5.13 Over-the-counter medicines

The outer packaging of over-the-counter medicines intended for humans shall bear the marking “Itsehoitolääke / Receptfritt läkemedel”. The package of an over-the-counter medicine must show the therapeutic indication, the dosage and the necessary instructions for use. If the medicinal product is intended for children, the children’s dose must also be indicated.

5.5.14 Medicinal product samples and emergency packages

The outer packaging of a medicinal product sample must be identified with the text “Ilmainen lääkenäyte - ei myytäväksi / Gratis läkemedelsprov - inte till salu” or other text to a similar effect.

The outer packaging of an emergency package must clearly indicate the following text along with the other labelling: “Ilmainen päivystyspakkaus / Gratis jourförpackning”.

5.5.15 Additional regulations concerning veterinary medicinal products

In addition to the provision of section 5.2., the outer and immediate package of a product intended for veterinary use must display the text “Eläimille / För djur”. The outer package must also display the name of the animal species for which the veterinary medicinal product is intended. The outer package for a prescription medicinal product must display the following text: “Reseptivalmiste/Receptbelagt”.

The labelling of a veterinary medicinal product intended for food-producing animals must indicate the withdrawal period, i.e. the period during which foodstuffs made from animals treated with the medicine may not be supplied for consumption. In exceptional cases, the withdrawal period may be given in the package leaflet. If so, the package itself must indicate that the withdrawal period is indicated in the package leaflet. If there is no withdrawal period, this must also be stated.

Space must be provided on the package for entering the required dosage.

5.5.16 Additional regulations concerning traditional herbal medicinal products

In addition to the provisions of section 5.2, the labelling on traditional herbal medicinal products must display the following texts: “PERINTEINEN KASVIROHDOSVALMISTE – TRADITIONELLT VÄXTBASERAT LÄKEMEDEL” and “Ota yhteys lääkäriin, jos oireet jatkuvat tai jos hoidon aikana esiintyy haittavaikutuksia. / Kontakta läkare om symtomen fortsätter eller om det förekommer biverkningar under behandlingen”.

The registration number must be given in the format R xxx FI.

5.5.17 Additional regulations concerning homeopathic or anthroposophic products with marketing authorisation

In addition to the provisions of section 5.2, the labelling on homeopathic and anthroposophic products must display the following texts: “HOMEOPAATTINEN VALMISTE – HOMEOPATISKT MEDEL” or “ANTROPOSOFINEN VALMISTE - ANTROPOSOFISKT MEDEL”

Products intended for animals must display the text “HOMEOPAATTINEN VALMISTE ELÄIMILLE – HOMEPATISKT MEDEL FÖR DJUR” or “ANTROPOSOFINEN VALMISTE ELÄIMILLE – ANTROPOSOFISKT MEDEL FÖR DJUR”

The scientific name of the stock is entered as the active substance and the degree of dilution (for example D, DH, X (decimal) or C, CH (centesimal) is used for the strength.

The marketing authorisation number is of the format R xxx FI (if there are different dilutions in the same series, indicate this for example as follows: R xxx FI, D2 and R xxx FI, D3).

5.5.18 Special labelling

The labelling of vaccines intended for human use must display the following text: "… rokote / Vaccin mot … ".

Packages intended for dose dispensing must bear the text: "Vain annosjakeluun / Endast för dosdispensering".

6 PACKAGE LEAFLET

6.1 General

The information contained in the package leaflet must be based on the approved summary of product characteristics for the medicinal product involved. The package leaflet must be drafted in Finnish and Swedish using clear expressions understandable to the user.

No package leaflet is required if the same information is provided on the immediate or outer packaging.

No package leaflet is required for starter packs and packages intended for dose dispensing, nor for veterinary medicines prescribed or administered exclusively by a veterinarian.

6.2 Package leaflet for medicinal products intended for human use

The package leaflet of a medicinal product intended for human use must include the information required under article 59 of the Directive 2001/83/EC as amended by Directives 2004/27/EC, 2004/24/EC and 2010/84/EC. At the request of the patient association (Finnish Federation of the Visually Impaired), the holder of marketing authorisation or registration must provide the package leaflet in a format intended for the visually impaired (braille, large print, recording or accessible electronic format).

In the case of a medicinal product included in the list referred to in Article 23 of Regulation (EC) No 726/2004, the package leaflet must include the text "Tähän lääkkeeseen kohdistuu lisäseuranta" / "Detta läkemedel är föremål för utökad övervakning". The phrase is preceded by a black symbol and followed by a standard text explaining the matter.

6.3 Package leaflet for veterinary medicinal products

The package leaflet for veterinary medicinal products must include the information required under Article 61 of the Veterinary Medicinal Products Directive.

6.4 Package leaflet for traditional herbal medicinal products

The package leaflet for a traditional herbal medicinal product must display the following texts: "PERINTEINEN KASVIROHDOSVALMISTE – TRADITIONELLT VÄXTBASERAT LÄKEMEDEL" and "Ota yhteys lääkäriin, jos

oireet jatkuvat tai jos hoidon aikana esiintyy haittavaikutuksia. / Kontakta läkare om symtomen fortsätter eller om det förekommer biverkningar under behandlingen”.

7 EXEMPTIONS

7.1 Packages intended for dose dispensing

Fimea may grant exemptions regarding labelling of packages intended for dose dispensing.

7.2 Other exemptions

Under section 25b of the Medicines Act, Fimea may, where there are sufficient grounds for doing so, grant a derogation on the provisions concerning labelling and packaging information, and grant exemptions on the requirement to issue labels and packaging information in Finnish and Swedish, provided that the medicine is not intended to be dispensed directly to the patient, there is a severe shortage of supply and where such exemptions will not endanger human or animal health.

With multinational packaging of veterinary medicinal products, the labelling requirements can be derogated from in special cases to promote availability.

8 GUIDANCE AND ADVICE

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

9 ENTRY INTO FORCE

This Administrative Regulation enters into force on 9 February 2019.

Director General Eija Pelkonen

Head of Division Tarja Kankkunen

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

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