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The Medical Products Agency's Code of Statutes

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Person responsible for publication: Christina Åkerman, Director-General

The Medical Products Agency's provisions on labelling and package leaflets for medicinal products[1];

Adopted on 10 October 2005.

Pursuant to chapter 10 section 5 of the Medicinal Products Ordinance (2006:272), the Medical Products Agency issues the following provisions on the labelling of and package leaflets for medicinal products[2].

Definitions and area of application

Section 1
The regulations shall not apply to medicinal products manufactured in pharmacies. The expressions and terms used in the Medicinal Products Act (1992:859) have the same meaning in the present provisions. The following definitions are used in the present provisions for:

package leaflet – a leaflet containing information for the user which accompanies the medicinal product

common name – the international non-proprietary name recommended by the World Health Organisation or, if none exists, the usual common name

withdrawal period – the period of time which must elapse, under normal usage conditions, between the last administration of a veterinary medicinal product to animals and the production of food from those animals

immediate packaging – the container or other form of packaging immediately in contact with the medicinal product

pharmaceutical form – the form of preparation approved by the Medical Products Agency, which shall be included in the labelling

name of the medicinal product – may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trade mark or the name of the marketing authorisation holder *(LVFS 2009:23, the change does not effect the English version).*

strength of the medicinal product – the content of the active substance in the product, expressed quantitatively per dosage unit, per unit of volume or weight according to the dosage form

labelling – all text and pictograms on both the immediate and the outer packaging

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[1] Amended by LVFS 2009:23.

[2] Cf. Council directive 2001/83/EG of 6 November 2001 on the Community code relating to medicinal products for human use (OJ no. L 311, 28.11.2201, p.67, Celex 32001L0083), most recently amended by Council directive 2004/27/EG of 31 March 2004 (OJ no. L 136, 30.04.2004, p.34, Celex 32004L0027). Also cf. Council directive 2001/82/EG of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ no. L 311, 28.11.2001, p.1, Celex 32001L0082), most recently amended by Council directive 2004/28/EG of 31 March 2004 (OJ no. L 136, 30.04.2004, p.58, Celex 32004L0028).

local representative – the company appointed to represent the holder of the marketing authorisation in Sweden *(LVFS 2009:23)*

manufacturer – the company on whose behalf the qualified person decides to release the medicinal product

outer packaging – the packaging that contains the immediate packaging.

Section 1 a

If the marketing authorisation holder does not have a permanent establishment in Sweden the name of the medicinal product, besides what is regulated in section 1, may be a common or scientific name accompanied by a trade mark or the name of the local representative. *(LVFS 2009:23)*

Labelling of medicinal products for human use

Information on the outer packaging and on the immediate packaging

Section 2

The following particulars shall appear on the outer packaging of the medicinal product or, where there is no outer packaging, on the immediate packaging.

1. The name of the medicinal product, followed by its strength and pharmaceutical form. If appropriate, the text should also state whether the medicinal product is intended for infants, children or adults. If the medicinal product contains up to three active substances, the international non-proprietary name (INN) shall be given or, if one does not exists, the common name.
2. A statement of the active substances, expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight, using their common names.
3. The pharmaceutical form and the contents by weight, by volume or by number of doses of the product.
4. A list of those excipients known to have a recognized action or effect and included in the guidelines published by the European Commission[3]. However, if the product is injectable, or a topical or eye preparation, all excipients must be stated.
5. The method and, if necessary, the route of administration.
6. A special warning that the medicinal product must be stored out of the reach and sight of children.
7. A separate instruction to read the package leaflet, if such exists for the medicinal product in question.
8. A special warning, if this is necessary for the medicinal product.
9. The expiry date (month/year).
10. Special storage precautions, if any.

[3] See guidelines issued by the European Commission in July 2003: Guidelines for Medicinal products for human use, Safety, environment and information, Excipients in the label and package leaflet of medicinal products for human use (Notice to applicants, Volume 3B).

11. If required, information about special precautions for disposal of unused medicinal products or waste materials from medicinal products, and if necessary, references to appropriate collection system in place.
12. The name and address of the marketing authorisation holder, and where applicable, the name of the local representative. *(LVFS 2009:23)*
13. The number of authorisation for placing the medicinal product on the market.
14. The manufacturer's batch number.
15. The Nordic Product Number (Vnr.).
16. A blank space for the pharmacy label.
17. Non-prescription medicinal products shall also have information about therapeutic indications, normal dosage, warnings and other necessary information for the medicinal product in question.
18. Natural remedies shall be labelled "Natural remedy". In other respects the same requirements apply as for non-prescription medicinal products, see 17.

Exemptions from the requirements in section 2 for information on immediate packagings in the form of blister packs and other small immediate packagings

Section 3
The following particulars shall at least appear on immediate packagings which take the form of *blister packs* placed in outer packaging which meets the requirements of section 2:
- the name of the medicinal product as laid down in section 2.1,
- the name of the holder of the authorisation for placing the product on the market,
- the expiry date,
- the batch number.

Section 4
At a minimum, the following particulars shall appear on small immediate packagings units on which the particulars laid down in section 2.1 cannot be displayed:
- the name of the medicinal product as laid down in section 2.1 and, if necessary, the route of administration
- the method of administration
- the expiry date,
- the batch number,
- the contents by weight, by volume, or by unit.

Section 5
(LVFS 2009:23, section 5 has abolished with effect from 14 December 2009).

Braille

Section 6
The name of the medicinal product shall appear in Braille on the outer packaging. If the medicinal product exists in several strengths, the strength shall also appear in Braille.
(LVFS 2009:23, the change of section 6 does not effect the English version).

General requirements for labelling

Section 7
The labelling on the outer packaging and the immediate packaging shall be in Swedish. Other languages may also feature, on condition that the information given is the same in all the languages.

The labelling of the outer packaging and the immediate packaging shall be easily legible, clearly comprehensible, and indelible. Some of the information shall be given a prominent position and an especially clear design. This applies to particulars such as the medicinal product's name as specified in 2.1, directions for storage and use, and warnings, all of which are essential to the user's correct use of the medicinal product. It is important that the labelling be designed in such a way that the medicinal product can be handled within the health care system and be dispensed from pharmacies without the risk of mix-ups.

The marketing authorisation holder shall ensure that the labelling is kept up to date with the current scientific knowledge, including the conclusions of the assessment and recommendations made public by means of the European medicines web-portal established in accordance with Article 26 of Regulation (EC) No 726/2004 of the European Parlament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[4]. *(LVFS 2012:17)*

Exemptions relating to labeling obligations

Section 7 a
Where the medicinal product is not intended to be delivered directly to the patient, or where there are severe problems in respect of the availability of the medicinal product, and it is necessary to protect human health, the medicinal product may be granted an exemption to the obligation in section 2 that certain particulars should appear on the labelling. The medicinal product may also be granted an exemption to the obligation in section 7 that the labeling should be written in Swedish.

Application for exemption from the obligations under the first paragraph shall be made to the Medical Products Agency. *(LVFS 2012:17)*

Radioactive medicinal products

Section 8
The outer carton and the container of medicinal products containing radio nuclides shall be labelled in accordance with the regulations for the safe transport of radioactive materials laid down by the International Atomic Energy Agency[3].

The labelling on the protective shield shall comply with the provisions listed in section 2. In addition, the labelling on the shielding shall include a complete explanation of the

[4] EUT L 136, 30.4.2004, s. 1, (Celex 32004R0726).
[3] International Atomic Energy Agency safety standards series No. TS-R-1, Regulations for the safe transport of radioactive material, 1996 edition (amended in 2003).

codes used on the vial. If necessary, the amount of radioactivity per dose or per vial and the number of capsules, or for liquids, the number of millilitres in the container, shall also be stated, with the time and date.

For radioactive medicinal products, the injection vial/ampoule shall be labelled with the name and the code for the medicinal product, including the name or chemical symbol for the radionuclide in question, the batch identification, expiry date, the international symbol for radioactivity, the name and address of the manufacturer, and the amount of radioactivity.

Dose-dispensed medicinal products

Section 9
Packages provided for dose dispensing by pharmacies and which are used solely in this context do not need to have the same complete labelling as is required for other medicinal products under the present provisions.

Section 9 a
The stipulations of the Medical Products Agency's provisions (LVFS 2010:9) on mechanical dose dispensing shall be applied when labelling dose-dispensed medicinal products. *(LVFS 2012:17)*

Medicinal products for clinical trials

Section 10
The stipulations of the Medical Products Agency's provisions (LVFS 2011:19) on clinical trials of medicinal products for human use shall be applied when labelling medicinal products for clinical trials. *(LVFS 2012:17)*

Homeopathic medicinal products

Section 11
The stipulations of the Medical Products Agency's provisions and guidelines (LVFS 1997:9)[4] on the registration of certain homeopathic products shall be applied when labelling homeopathic medicinal products.

Parallel imported medicinal products

Section 12
Further to the stipulations of the present provisions, the Medical Products Agency's provisions (LVFS 2012:19) on parallel imported medicinal products shall be applied when labelling medicinal products obtained through parallel importation. *(LVFS 2012:17)*

[4] Amended and reprinted by LVFS 2003:2.

Section 12 a
Further to the stipulations of the present provisions, the Medical Products Agency's provisions (LVFS 2006:3) for traditional herbal medicinal products for human use shall be applied when labelling traditional herbal medicinal products. *(LVFS 2009:23)*

Package leaflets for medicinal products for human use

Contents of the package leaflet

Section 13
The package shall contain user information in the form of a package leaflet, or if there is space, as text on the outer packaging or on the immediate packaging. In the latter case, however, the text must not limit the legibility of the other information required on the package.

The package leaflet shall be drawn up in accordance with the summary of product characteristics; it shall include, in the following order:

1. For the identification of the medicinal product:
    a) The name of the medicinal product, followed by its strength and pharmaceutical form and, where applicable, a statement as to whether the medicinal product is intended for infants, children or adults. The common name shall be stated if the medicinal product contains only one active substance and if its name is an invented one.
    b) The pharmaco-therapeutic group or type of activity in terms easily comprehensible for the patient.

1 a. For medicinal products included in the list referred to in Article 23 of Regulation (EC) No 726/2004, the following additional statement shall be included 'This medicinal product is subject to additional monitoring'. This statement shall be preceded by the black symbol referred to in Article 23 of Regulation (EC) No 726/2004 and followed by an appropriate standardised explanatory sentence. *(LVFS 2012:17)*

2. Therapeutic indications.
3. A list of the information needed before the medicinal product can be taken, as follows:
    a) contra-indications;
    b) appropriate precautions for use;
    c) forms of interactions with other medicinal products, and other forms of interactions (e.g. with alcohol, tobacco and foodstuffs) which may affect the medicinal product's effect;
    d) special warnings

The list must
    i) take into account the particular condition of certain categories of users (e.g. children, pregnant or breastfeeding women, the elderly, persons with specific pathological conditions),

ii) state whether or not the ability to drive vehicles or operate machinery is affected;

iii) state those excipients which are important to know for safe and effective use of the medicinal product and which are included in the detailed guidance published by the European Commission[6].

4. The customary instructions required for correct use, in particular:
   a. the dosage;
   b. the method and, if necessary, route of administration;
   c. how often the medicinal product is to be administered, if necessary with a statement about the suitable time in which the medicinal product can or must be administered; and, when appropriate due to the nature of the medicinal product:
   d. the length of time of the treatment, if this should be limited;
   e. the action to be taken in the case of an overdose (e.g. symptoms, emergency procedures);
   f. what should be done if one or several doses have not been taken;
   g. indication, if necessary, of the risk of withdrawal effects
   h. a special recommendation to consult a doctor or a pharmacist to get more detailed information, if needed, about how the product is to be used.

5. A description of any suspected adverse reaction that may occur under normal use of the medicinal product, and if necessary, the action to be taken in such cases. The patient should be told to communicate any suspected adverse reaction to healthcare professionals or directly to the Medicinal Products Agency. It must also state that it is possible to submit the report electronically or by mail. (*LVFS 2012:17)*

6. A reference to the expiry date that appears on the label, and
   d. a warning against using the product after that date;
   e. special storage precautions;
   f. if necessary, a warning concerning certain visible signs of deterioration;
   g. a full qualitative composition (in active substances and excipients) and the quantitative composition in active substances, using common names for each presentation of the medicinal product,
   h. for each presentation of the product, the pharmaceutical form and content in weight, volume or units of dosages,
   i. the name and address of the marketing authorisation holder and, where appropriate, the local representative; *(LVFS 2009:23)*
   j. the name and address of the manufacturer.
7. If the medicinal product has been authorised for sale through the mutual recognition or decentralised procedure under different names in the concerned member states, a listing detailing the authorised name in each of the member states shall be included.
8. The date of the most recent version of the package leaflet.

[6] See guidelines issued by the European Commission in July 2003: Guidelines for Medicinal products for human use, Safety, environment and information, Excipients in the label and package leaflet of medicinal products for human use (Notice to applicants, Volume 3B).

Package leaflets for the blind and partially sighted

Section 14
The marketing authorisation holder shall be responsible for making the package leaflet available in formats adapted for the blind and partially sighted, should patients' organisations request it.

General requirements for the package leaflet

Section 15
The package leaflet shall be written in Swedish. It may, however, be printed in several languages, on condition that the same information is given in all these languages and that it is grouped by language.

The text in the package leaflet shall be written in a clear and easily understandable terms, and shall reflect the results of patient consultations. The package leaflet shall be designed in such a way that the user is able to handle and use the medicinal product in the intended way, if necessary with the help of health care personnel.

The marketing authorisation holder shall ensure that the package leaflet is kept up to date with the current scientific knowledge, including the conclusions of the assessment and recommendations made public by means of the European medicines web-portal established in accordance with Article 26 of Regulation (EC) No 726/2004. *(LVFS 2012:17)*

Exemptions relating to package leaflet obligations

Section 15 a
Where the medicinal product is not intended to be delivered directly to the patient, or where there are severe problems in respect of the availability of the medicinal product, and it is necessary to protect human health, the medicinal product may be granted an exemption to the obligation in section 13 that certain particulars should appear in the package leaflet. The medicinal product may also be granted an exemption to the obligation in section 15 that the package leaflet should be written in Swedish.

Application for exemption from the obligations under the first paragraph shall be made to the Medical Products Agency. *(LVFS 2012:17)*

Information leaflet for radioactive medicinal products

Section 16
In packages containing radiopharmaceuticals, radionuclide generators, radionuclide kits or radionuclide precursors, a detailed information leaflet shall also be included. The text in this leaflet shall be written in accordance with the requirements of section 13. Additionally, the information leaflet shall state which precautions, if any, shall be observed by the user and patient when preparing and administering the medicinal product, and which special precautions apply to the disposal of the container and its unused contents.

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Labelling of veterinary medicinal products

Information on the outer packaging and the immediate packaging

Section 17
The following information shall appear on the outer packaging and the immediate packaging or, when no outer packaging exists, on the immediate packaging:

1. The name of the veterinary medicinal product, followed by its strength and pharmaceutical form. The common name shall appear if the medicinal product contains only one active substance and if its name is an invented one.
2. A statement of the active substances, expressed a qualitatively and quantitatively per unit or according to the form of administration for a particular volume or weight using the common names.
3. A listing of excipients included in the summary of product characteristics.
4. The manufacturer's batch number.
5. The marketing authorisation number.
6. The Nordic Product Number (Vnr.).
7. The name and address of the marketing authorisation holder and local representative, if any. *(LVFS 2009:23)*
8. The species of animal for which the veterinary medicinal product is intended, the method and, if necessary, the route of administration.
9. The withdrawal period for veterinary medicinal products to be administrated to food-producing species, for all the species concerned and for the various foodstuffs concerned (meat and slaughter by-products, eggs, milk, honey), including those for which the withdrawal period is zero;
10. Expiry date (month/year).
11. Special storage precautions, if any.
12. If required, information about special precautions for disposal of unused medicinal products or waste materials from medicinal products, and if necessary, references to appropriate collection system in place.
13. Information important for the fulfilment of the requirement for safety and protection of public health, including special precautions to be observed during use, and other warnings, if such are required for the veterinary medicinal product in question.
14. The text "For animals" or, for prescription medicinal products, the text "For animals – by prescription only".
15. A blank space shall be left for the pharmacy label.

Exemptions from the requirements in section 17 for information on the immediate packaging

Section 18
If the medicinal product is packaged in both an outer packaging and an immediate packaging, the pharmaceutical form and the amount by weight, volume or number of dose units need only appear on the outer packaging.

At a minimum, the following information shall appear on immediate packaging in the form of ampoules placed in outer packaging which meets the requirements of section 17:
- the veterinary medicinal product's name,
- its strength,
- route of administration,
- manufacturer's batch number,
- date of expiry,
- "For animals".

With regard to small immediate packaging containing a single dose other than ampoules, on which it is not possible to state the information listed above, the outer packaging shall be labelled in accordance with the requirements in section 17. At a minimum, the single-dose immediate packaging shall be labelled with:
- the veterinary medicinal product's name,
- its strength,
- manufacturer's batch number,
- date of expiry.

General requirements for labelling

Section 19
The labelling on the outer packaging and the immediate packaging referred to in section 17 6-15 shall be in Swedish. Other languages may also feature, on condition that the information given is the same in all the languages.

The labelling of the outer packaging and the immediate packaging shall be easily legible, clearly comprehensible, and indelible. Some of the information shall be given a prominent position and an especially clear design. This applies to particulars such as the medicinal product's name as specified in section 17.1, directions for storage and use, and warnings, all of which are essential to the user's correct use of the medicinal product. It is important that the labelling be designed in such a way that the medicinal product can be handled within veterinary medical care and be dispensed from pharmacies without the risk of mix-ups. *(LVFS 2012:17)*

Exemptions relating to labelling obligations

Section 19 a
If the medicinal product is solely intended to be administered by a veterinarian the medicinal product may be granted an exemption from the obligation that all the particulars in section 17 should appear on the labelling.

Application for exemption from the obligations under the first paragraph shall be made to the Medical Products Agency. *(LVFS 2012:17)*

Medicinal products for clinical trials

Section 20
The stipulations of the Medical Products Agency's provisions and guidelines (LVFS 1996:17)[7] on clinical trials of medicinal products for human use shall be applied when labelling veterinary medicinal products for clinical trials.

Homeopathic medicinal products intended for animals

Section 21
The stipulations of the Medical Products Agency's provisions and guidelines (LVFS 1997:9)[8] on the registration of certain homeopathic products shall be applied when labelling homeopathic medicinal products intended for animals.

Parallel imported medicinal products intended for animals

Section 22
Further to the stipulations of the present provisions, the Medical Products Agency's provisions (LVFS 2012:19) on parallel imported medicinal products shall be applied when labelling veterinary medicinal products obtained through parallel importation. *(LVFS 2012:17)*

Package leaflets for veterinary medicinal products

Contents of the package leaflet

Section 23
The package shall contain user information in the form of a package leaflet, or if there is space, as text on the outer packaging or the immediate packaging. In the latter case, however, the text must not limit the legibility of the other information required on the package. The package leaflet shall be written in accordance with the summary of product characteristics. At a minimum, it shall contain the following information, laid out as indicated below and in the sequence given:

1. The name and address of the marketing authorisation holder, the manufacturer, and the local representative, if any. *(LVFS 2009:23)*
2. The name of the veterinary medicinal product, followed by its strength and pharmaceutical form. The common name shall appear if the product contains only one active substance and if its name is an invented one. When the medicinal product is authorised in accordance with the mutual recognition procedure and has different names in the different member states, a list of all the names authorised in each member state shall be included.

[7] Most recently amended by LVFS 1999:3
[8] Amended and reprinted by LVFS 2003:2

3. A statement of active substances and excipients included in the summary of product characteristics.
4. Therapeutic indications.
5. Contra-indications and adverse reactions.
6. The animal species for which the veterinary medicinal product is intended, the dosage for each species, the method and route of administration. Directions for correct use, if necessary.
7. The withdrawal period, even if this is nil, in the case of veterinary medicinal products administered to food-producing animals.
8. Special storage precautions, if any.
9. Information important for the fulfilment of the requirement for safety and protection of public health, including special precautions to be observed during use, and other warnings, if such are required for the veterinary medicinal product in question.
10. Special precautions for the disposal of unused medicinal products or waste derived from medicinal products, if required.
11. The date of the most recent version of the package leaflet.

General requirements for the package leaflet

Section 24
The package leaflet shall be written in Swedish. It may, however, be printed in several languages, on condition that the same information is given in all these languages and that it is grouped by language.

The text in the package leaflet shall be written in a clear and easily understandable way. It shall be designed in such a way that the user is able to handle and use the medicinal product in the intended way.

Exemptions relating to package leaflet obligations

Section 24 a
If the medicinal product is solely intended to be administered by a veterinarian the medicinal product may be granted an exemption from the obligation that all the particulars in section 23 should appear in the package leaflet and that the package leaflet should be written in Swedish in accordance with what is stated in section 24.

Application for exemption from the obligations under the first paragraph shall be made to the Medical Products Agency. *(LVFS 2012:17)*

Common regulations

Symbols and pictograms

Section 25
The labelling on the outer packaging, the immediate packaging or the package leaflet may not include information, symbols or pictograms with product-promoting content. An exception is made for the logotype of the marketing authorisation holder. The outer

package and the package leaflet may include symbols or pictograms intended to clarify certain information required in sections 2, 13, 17 and 23, as well as other information which is consistent with the summary of product characteristics, and of use to the patient.

Variations of the labelling/package leaflet

Section 26
Variations of the labelling or the package leaflet which do not affect the summary of product characteristics may be made if the Medical Products Agency does not oppose a submitted variation application within 90 days.

Section 27
The production of packaging with altered labelling or package leaflet shall begin no later than six months after the alteration has been approved.

Exemptions

Section 28
The Medical Products Agency may grant exemptions from the present provisions.

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1. The present provisions come into force on 1 December 2005. They thereby supersede Chapters II-V of the Medical Products Agency's provisions and guidelines (LVFS 1994:11) on medicinal product containers and the labelling of medicinal products.
2. Applications for market authorisation and applications for variations of the labelling/package leaflet received by the Medical Products Agency prior to the entry into force of the present provisions shall be considered under the previous provisions (LVFS 1994:11).
3. The present provisions shall be the basis of consideration for applications for market authorisation and applications for variation of the labelling and package leaflet received by the Medical Products Agency after 30 November 2005. However, section 6 of the new provisions shall only be applied to market authorisation applications and not to labelling variation applications.
4. Previously authorised medicinal products which do not fulfil the requirements of the new provisions may be marketed up to five years after the date of the product's last market authorisation. This also applies to the regulation regarding Braille in section 6. Applications for variations to fulfil the requirements of the present provisions must have been received by the Medical Products Agency no later than four years and six months after the date of last market authorisation. However, for medicinal products authorised between 1 December 2000 and 30 November 2001, the variation application need not be received until 1 June 2006.

Transitional rules for the removal of warning triangles on packages[10]

[10] To LVFS 2004:17

Medicinal product containers approved prior to 1 July 2005 and whose labelling includes warning triangles may be sold up to and including 31 December 2006 despite the new wording of the provisions in section 2. If an application to alter the medicinal product's labelling is made before 1 January 2007, the medicinal product may be sold up to and including 30 June 2007.

Transitional rules for LVFS 2009:23

1. The present provisions come into force on 14 December 2009.
2. The concept of local representative referred to in section 2, 13, 17 and 23 shall be inserted in the labelling and package leaflets in relation to that other changes are made in the labelling or package insert after the regulations come into force.

Transitional rules for LVFS 2012:17

1. The present provisions come into force on 21 July 2012.