

Guideline Concerning the Medical Products Agency's Provisions (LVFS 2005:11) on Labelling and Package Leaflets for Medicinal Products

Translation of the Swedish version

Version 2

In force from 09/02/2019

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Introduction

This guideline is intended to promote the consistent application of the Medical Products Agency's provisions (LVFS 2005:11) on labelling and package leaflets for medicinal products in centralised, mutual, decentralised and national procedures. The guideline is intended for companies who are preparing labelling and package leaflets. The aim of the guideline is to describe and interpret the content of the applicable legislation in order to make labelling and patient information clear and user-friendly, as well as to reduce the risk of mix ups and incorrect use. Guidelines may contain additional information that is not included in the legislation, the aim of which is to improve understanding of the legislative requirements.

Guidelines are not legally binding, rather they contain examples and recommendations that can be helpful in the interpretation and application of legislative provisions. This guideline does not exclude other methods of achieving the results intended in the legislation, instead it represents the Medical Products Agency's interpretation.

The most recent QRD template for medicinal products, approved via centralised, mutual, decentralised and national procedures, with the associated standard wording determined by the EMA should be used. (ref. 1).

Amendments to LVFS 2005:11

LVFS 2005:11 has been amended by the following statutes:

- LVFS 2009:23
- LVFS 2012:17
- Errata to LVFS 2012:17
- LVFS 2018:62 (enters into force on 9 February 2019)

The guideline should be regarded as a complement to the provision and not as an independent document. The paragraphs in this guideline refer to the corresponding paragraphs in the provisions.

The text contained within unbroken borders is taken directly from the most up to date wording of LVFS 2005:11.
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Text without a border is guidance concerning LVFS 2005:11.

For more guidance documents, refer to the Medical Products Agency's website.

Search path: <https://lakemedelsverket.se/english/>

Continue to: Medicinal products/Applications for new authorisations, variations and renewals/Product information

Special medicinal product categories

Medicinal products for clinical trials

- Provisions regarding the labelling of medicinal products for clinical drug trials with human test subjects are found in the Medical Products Agency's provisions (LVFS 2011:19) on clinical trials of medicinal products for human use.
- Provisions regarding the labelling of medicinal products for clinical drug trials of veterinary medicinal products are found in Medical Products Agency's provisions and guidelines (LVFS 2016:78) on clinical trials of medicinal products.

Homeopathic medicinal products

- For labelling of homeopathic medicinal products intended for humans and animals, refer to the Medical Products Agency's provisions (HSLF-FS 2017:75) on homeopathic medicinal products.

Parallel imported medicinal products

- In addition to what is stated in this guideline, the Medical Products Agency's provisions (LVFS 2012:19) on parallel imported medicinal products shall be applied in the design of labelling and package leaflets for parallel imported medicinal products.

Traditional herbal medicinal products

- In addition to what is stated in this guideline, the Medical Products Agency's provisions (LVFS 2006:3) on traditional herbal medicinal products for human use shall be applied in the labelling of traditional herbal medicinal products.

The above-mentioned provisions are available at the Medical Products Agency's website.

Search path: <http://www.lakemedelsverket.se/>

Continue to: Legislation

Definitions and application

Section 1 The regulations shall not apply to medicinal products manufactured in pharmacies. The expressions and terms used in the Medicinal Products Act (2015:315) 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,

the 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,

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,

local representative the company appointed to represent the holder of the marketing authorisation in Sweden,

safety features the type of unique identifier and safety seal referred to in Chapter 3 of the Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use,

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.

Abbreviations

CMDh	Coordination Group for Mutual Recognition and Decentralised Procedures – Human – Group for the coordination within the EU of approval procedures for medicinal products for human use.
CMDv	Coordination Group for Mutual Recognition and Decentralised Procedures – Veterinary – Group for the coordination within the EU of approval procedures for medicinal products for veterinary use.

EMA	European Medicines Agency
MAH	Marketing Authorisation Holder
	In this document, the MAH also indicates those who have permission to market a parallel-imported medicinal product or a registered traditional herbal medicinal product.
QRD	Quality Review of Documents
	Working group within the EU for improving the structure and quality of product information (publishes e.g. product information templates).
ref	Reference
SmPC	Summary of Product Characteristics – applies to medicinal products for human use.
SPC	Summary of Product Characteristics – applies to medicinal products for veterinary use.
SPCS	Supplementary protection certificate (EEA) – alternative meaning of SPC (not the same as Summary of Product Characteristics, and the document is not referred to in this guideline)
QRD template	product information document template for human and veterinary medicinal products (ref. 1).

Other terms

”X”	Is used to indicate the product's name, i.e. relevant use of name or substance.
Words within {...}	Are replaced with the relevant text.
<...>	Indicates the proposed standard wording.
[...]	English explanatory text to Swedish wording.
Blue Box	Further information (not included in the QRD template) that may be required at the national level. These special requirements are published on the websites of the CMDh and the CMDv (ref. 2).
directly distributed medicinal product	Medicinal product that the parallel imported medicinal product refers to in its licence application.
generic name, common name	In LVFS 2005:11 these indicate the approved name of the active substance (INN, pharmacopoeia name or commonly used name).
multiple package	Packaging size approved to contain several smaller packaging units and where the individual packages may not be sold separately
mock-up	Electronic 2D model of outer or immediate packaging showing the labelling on the packaging and the package layout
labelling	Labelling text and mock-up
labelling text	Labelling text document according to QRD template

Labelling of medicinal products for human use

Information about labelling applies to text both on the label and on the packaging, unless otherwise stated.

Information on the outer packaging and immediate packaging

Section 2 The following information shall appear on the outer packaging of the medicinal product or, where there is no outer packaging, on the immediate packaging.

Section 2:1. 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 or pharmacopoeia name shall be given or, if one does not exist, the common name.

- The name of the medicinal product and strength are stated clearly on the packaging and in an easily legible font.
- Use of uppercase letters in the full name (as well as in other text) should be avoided to improve legibility. If the product name has been approved in uppercase letters, it can be written in uppercase letters in the first section of the labelling text, and then in lowercase letters in the following text.
- The medicinal product's name and strength are stated in the same font and size and, if possible, on the same line.
- Nothing may come in between the name of the medicinal product and its strength.
- The medicinal product's full name is stated in the same colour.
- The strength is only stated once on each side of the packaging and in connection to the name of the medicinal product.
- Different strengths of a single medicinal product must be clearly differentiated, for example by using different colours for the strengths.
If the same strength of a medicinal product administered by injection or infusion is available in different total quantities (X ml=Y mg), the total quantity is also differentiated by colours. For parallel imported medicinal products, the colour of the strength is stated in accordance with the directly imported medicinal products colouration.
- The pharmaceutical form is an important part of the identification of a medicinal product and shall always be stated in connection to the name and strength of the medicinal product. For further information, see Section 2:3.
- Active substance is stated in lowercase letters (including the first letter) below the name of the medicinal product and strength, even if this is included in the name of the medicinal product. If the medicinal product contains three or fewer active substances, these shall be stated (in the same order as stated under strength). If the medicinal product contains four or more active substances, these do not need to be stated in connection to the name of the medicinal product.
- The active substance(s) is/are stated on the packaging in a font half the size of that of the name of the medicinal product.
- The active substance is stated in the form that corresponds to the strength. For example, if the medicinal product has a strength of 8 mg and contains buprenorphine hydrochloride 8.64 mg equivalent to buprenorphine 8 mg, then it is buprenorphine that shall be stated in connection to the name of the medicinal product. Please note that, even though the active substance(s) is/are stated in connection with the name of the medicinal product, it/they shall also always be specified in the declaration (see Section 2:2).

Section 2:2. 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.

- The declaration contains a list of the quantity of the form of active substance(s) that correspond to the strength, e.g. buprenorphine hydrochloride equivalent to buprenorphine 8 mg.
- The declaration begins with <1 tablett innehåller...> [1 tablet contains...], <1 ml innehåller...> [1 ml contains...], <1 tablett:...> [1 tablet:...], <1 ml:...> [1 ml:...], or similar. For vaccines write <1 dos innehåller...> [1 dose contains...].
- In those cases where excipients shall be declared, these are stated together with active substance(s) in the declaration on the outer packaging and/or immediate packaging. Further information in Section 2:4.
- For multilingual packaging, the declaration may be given in Latin
 - In centralised procedure: Latin is used in labelling text in cases where Latin is used on the packaging.
 - In decentralised, mutual and national procedures: Swedish is always used in the labelling text, even if Latin is used on the packaging.
 - For (traditional) herbal medicinal products: name of the plant is usually written in Latin and Swedish, both in the Swedish labelling text and on the packaging.

Section 2:3. The pharmaceutical form and the contents by weight, by volume or by number of doses of the product.

- The pharmaceutical form is stated in accordance with the applicable EDQM Standard Terms (ref. 3).
- The complete pharmaceutical form is stated on the front of the packaging. The short term in accordance with the applicable EDQM Standard Terms (ref. 3) may be used on the other sides, if there is a lack of space. If the short term for the medicinal product is used in labelling (e.g. “tablet” instead of “film-coated tablet”, this is shall also stated in the package leaflet in Section 6 (and in SmPC Section 3).
- The pharmaceutical form may, when appropriate, be given as the pack size (= quantitative indication), e.g. <30 tablett> [30 tablets]. If the outer packaging contains several immediate packages, this is stated in conjunction with the pack size, e.g. if there are two containers with 30 tablets in each, this is stated as <60 (2x30) tablett> [60 (2x30) tablets].
- Packaging size for injection products is stated as “X x Y ml” or X vials of Y ml, or for powder “x vial(s)”.
- The quantity for medicinal products administered by injection is indicated in the Swedish labelling as “5 ml = 50 mg” rather than “50 mg/5 ml”.
- Pack size is stated together with the name of the medicinal product, strength and pharmaceutical form on all sides of the packaging, if space permits.
- The pack size is placed in the top left corner on the front of the packaging.
- Different pharmaceutical forms of the same medicinal product are differentiated clearly in order to avoid mix up.
- If the pack contains cannulas, swabs or similar, this shall be stated on the outer packaging.
- Medicinal product packaging that contains pressurised contents shall state both the net and gross volume.

Section 2:4. A list of those excipients known to have a recognized action or effect and included in the guidelines published by the European Commission in accordance with Article 65 of Directive 2001/83/EC, in the annex to the guidelines “Excipients in the label and package leaflet of medicinal products for human use”. However, if the product is injectable, or a topical or eye preparation, all excipients must be stated.

- Topical medicinal products include those that are applied locally, e.g. skin preparations and medicinal products that are administered to the lungs via inhalation. Topical medicinal products also include those that are administered locally on the oral, nasal, rectal or vaginal mucosae.
- For vaccines, the adjuvant/adsorbant is stated both qualitatively and quantitatively.
- In those cases where excipients must be declared, these are stated together with the active substance(s) in the declaration on the outer packaging and/or immediate packaging.

Section 2:5. The method and, if necessary, the route of administration.

- The method of administration is, e.g., <sväljes hela> [to be swallowed whole], <införes i ändtarmen> [for rectal insertion].
- The route of administration is, e.g. <intravenös användning> [intravenous use], <för användning på huden> [for application onto the skin], <för användning i munhålan> [for use in the oral cavity], etc.
- For medicinal products administered by injection or infusion, the route of administration is stated on both the outer packaging and immediate packaging.

Describe non-patient-friendly methods of administration with a more patient-friendly translation.

For example according to the table below:

Standard term	Patient-friendly version
Oral use	Ska sväljas [To be swallowed] (can be completely left out of mock-ups for tablets and capsules but must be provided in the labelling text)
Cutaneous/transdermal use (e.g. creams, gels, ointments)	För användning på huden [To be used on the skin]
Transdermal use (plasters)	Fästes på huden [Applied on the skin]
Ocular use	För användning i ögat [To be used in the eye]
Nasal use	För användning i näsan [To be used in the nose]
Use for inhalation	För inhalation [For inhalation]

Section 2:6. A special warning that the medicinal product must be stored out of the sight and reach of children.

The text <Förvaras utom syn- och räckhåll för barn> [Keep this medicine out of the sight and reach of children.] is used.

Section 2:7. A separate instruction to read the package leaflet, if such exists for the medicinal product in question.

The text <Läs bipacksedeln före användning> [Read the package leaflet before use] shall appear on the outer packaging and/or immediate packaging of all medicinal products that have an approved package leaflet. In exceptional cases, where SmPC is included, instead use the text <Read the Summary of Product Characteristics before use>.

Section 2:8. A special warning, if this is necessary for the medicinal product.

- Medicinal products in aerosol form shall be labelled in accordance with the Swedish Civil Contingencies Agency's statutes.
- Necessary instructions for use, e.g. <tuggas> [to be chewed], <omskakas> [shake before use] <ska spädas> [to be diluted], <löses i ett glas <vatten>> [to be dissolved in a glass [of water]], are stated on the outer packaging and/or immediate packaging.
- Other information that is valuable to the user, e.g. <munnen bör sköljas efter varje inhalation> [rinse mouth after inhalation], <kan färga hud, hår och kläder> [may cause discolouring of skin, hair and clothes], <kan färga urinen/avföringen> [may colour urine/faeces], <kan missfärga mjuka kontaktlinser> [may discolour soft contact lenses], is stated on the outer packaging and/or immediate packaging.
- Provided below are **examples** of standard wording to use for certain substances or groups of medicinal products. Note that this is not an exhaustive list of warnings:

Cytostatics: <Cytostatikum> [Cytostatics]

Paracetamol: <**WARNING! Högre doser än de rekommenderade medför risk för mycket allvarlig leverskada.**> [WARNING! Doses higher than recommended lead to risk of very severe liver damage.]

<Använd inte X utan läkares ordination om du har alkoholproblem eller leverskada eller om du samtidigt använder andra smärtstillande läkemedel som innehåller paracetamol.> [Do not use X without doctor's prescription if you have alcohol problems or if you are using other painkillers containing paracetamol at the same time.]

<Förvaras utom syn- och räckhåll för barn och ungdomar.> [Keep out of the sight and reach of children and adolescents.]

The last sentence replaces the standard wording <Förvaras utom syn- och räckhåll för barn> [Keep out of the sight and reach of children].

Benzoyl peroxide products and tretinoin: <Undvik solning, även i solarier vid behandling med detta läkemedel.> [Avoid sunbathing, including using sunbeds, in connection with treatment with this medicine.]

Steroids for topical use: <Undvik att få <läkemedlet> <salvan> <X> i ögonen.> [Avoid getting the <medicine><ointment><X> in your eyes.]

- For non-prescription medicinal products see Section 2:17.

Section 2:9. The expiry date (month/year).

- The expiry date is preceded by the approved abbreviation <Utg.dat.> [Expiry date] or <EXP> [Expiry date] and is stated in the same way as in the package leaflet.
- If <Utg.dat.> or <EXP> are added during printing, it shall be stated which of the abbreviations will be used and where this will be placed on the outer packaging and/or immediate packaging.
- The month is stated with two numerals or with letters and the year with four numerals.
- The expiry date is the last day of the indicated month stated after <Utg.dat.> or <EXP>.
- If information about shelf life of opened packaging or shelf life following preparation is stated in the SmPC, these are to be stated on the outer packaging and/or immediate packaging.

Section 2:10. Special storage precautions, if any.

- The storage condition(s) shall be consistent with those stated in the SmPC and are presented in accordance with Appendix III of the QRD template (ref. 4).

Section 2:11. If required, information about special precautions for the disposal of unused medicinal products or waste materials derived from medicinal products, and if necessary, references to appropriate collection systems in place.

- State any precautions to take when disposing of unused medicinal products or waste materials from the medicinal product.
- For patches, the following text is used: <Använda plåster viks ihop med den klibbiga sidan inåt och kasseras enligt information i bipacksedeln.> [Used patches shall be folded with the adhesive side inwards and disposed of according to the information in the package leaflet.]

Section 2:12. The name and address of the marketing authorisation holder, and where applicable, the name of the local representative.

- The name and address of the MAH shall be stated.
- The local representative's name and address are stated on the outer packaging (or the immediate packaging if there is no outer packaging) but is not stated in the labelling text. The local representative shall be registered with the Medical Products Agency. Information about the local representative is preceded by the heading <Lokal företrädare> [Local representative]. If the stated company only provides information about the

medicinal product, the name and address are preceded by the heading <Information lämnas av> [Provider of information].

- In those cases where another product stakeholder, in addition to the MAH, is also stated on the outer packaging and/or immediate packaging, one of the following headings is used in order to enable those involved in the product to be differentiated:
 - <Innehavare av godkännande för försäljning> [Marketing Authorisation Holder]
 - <Importör> [Importer] (Only for parallel imported medicinal products.)
 - <Innehavare av registrering för försäljning> [Registration Holder] (Only for traditional herbal medicinal products.)
 - <Lokal företrädare> [Local representative]
 - or <Information lämnas av> [Provider of information]

If space permits, add a heading for both product stakeholders. In case of space restrictions, add a heading for at least one of the product stakeholders (for parallel imported medicinal products, also see below).

- The name, city and country (when the city is not in Sweden) are the minimum requirements for the address information for all product stakeholders. City and country are written in Swedish.
- A reference to a web address is not acceptable.
- E-mail address is acceptable.
- For parallel imported medicinal products, the re-packager and manufacturer's names and addresses shall also be stated. The relevant company group term may be stated instead of the manufacturer's name and address (see Section 12 of the Medical Products Agency's Provisions (LVFS 2012:19) on Parallel Imported Medicinal Products). This information is preceded by <Ompackare> [Re-packager] and <Tillverkare> [Manufacturer].
- If a logotype for a local representative is included, the name and address of the local representative must also be written on the outer packaging (see also Section 25).

Section 2:13. The number of authorisation for placing the medicinal product on the market.

- The marketing authorisation number (referred to as the number of authorisation in the English translation of LVFS 2005:11) is preceded by the term <MTnr:> [Marketing Authorisation number:] and is placed on the packaging together with the name and address of the MAH.

Section 2:14. The batch number.

- The batch number is preceded by the approved abbreviation <Sats> [Batch], <Batch> or <Lot> [Batch].
- The batch number is placed together with the expiry date on the packaging.
- If <Sats>, <Batch> or <Lot> are added during printing, the labelling text should indicate which of the abbreviations will be used and the mock-up should show where this will be placed on the outer packaging and/or immediate packaging.

Section 2:15. The Nordic Product Number (Vnr.).

- The Nordic Article Number (referred to as the Nordic Product Number in the English translation of LVFS 2005:11) is stated in the top right corner on the front of the outer packaging.
- The Nordic Article Number is stated at least once in connection with the name of the medicinal product on the outer packaging or, if there is no outer packaging, on the immediate packaging.
- The Nordic Article Number is stated in numerals in groups of two and is preceded by <Vnr> [Nordic Article Number] (Vnr XX XX XX).
- For medicinal products that will be prepared prior to use, e.g. cytostatics, the Product Number is also stated on the immediate packaging.
- *Multipacks*: It is sufficient that the Nordic Article Number appears on the outer packaging. If the Nordic Article Number also appears on each subsidiary pack, this number shall not be the same as that on the outer packaging, i.e. each subsidiary pack shall not have the multipack's Nordic Article Number.

Section 2:16. A blank space for the pharmacy label.

- Consideration shall be given to allowing the pharmacy label to be placed on the outer packaging without hiding any information. For example, an empty space can be left for the pharmacy label.

Section 2:17. Non-prescription medicinal products shall be labelled with the words “Receptfritt läkemedel” [Non-prescription medicinal product]. Non-prescription medicinal products shall also have information about therapeutic indications, normal dosage, warnings and other necessary information for the medicinal product in question.

- The packaging of non-prescription medicinal products shall also include information about the product's approved non-prescription indication(s) and normal dosage for this/these indication(s).
- The indication is stated in the labelling text as it is stated in the package leaflet. In some cases, an abbreviated form may also be acceptable. If needed, use clarifying headings, e.g. <Framsida> [Front] and <Baksida> [Back] in the labelling text.
- The indication is placed on the *front* of the packaging. If the medicinal product has an acceptable short form for the indication in the labelling text, e.g. “mot halsbränna” [treatment of heartburn], this is placed on the front of the packaging. The complete indication is then placed on another side of the packaging, preferably together with the dosage instructions.
- The packaging of non-prescription medicinal products shall be provided with information about dosage according to the dosage instructions in the package leaflet. The following is stated:
 - Dosage (as well as age intervals, when applicable)
 - Maximum treatment time without consulting a doctor
 - Maximum dose: include what is relevant to the product: maximum daily dosage, maximum dosage when used when needed and dose interval

- Special warnings and instructions shall be stated on the outer packaging as the medicinal product is often purchased without a doctor's prescription. Such a warning may be, e.g., that pregnant women and/or nursing mothers should not use the medicinal product.
- For non-prescription medicinal products, the labelling text and the packages must contain the words “Receptfritt läkemedel” [Non-prescription medicinal product].
- For non-prescription medicinal products, there are OTC substance reports for certain substances published on the Medical Products Agency's website (ref. 5). An OTC substance report is the result of an overview for a substance regarding non-prescription information (including pack sizes approved for non-prescription), which should be stated in the package leaflet/labelling for a medicinal product approved as non-prescription.
- For those substances that do not have published OTC substance reports, additional warnings may be required in accordance with the package leaflet. The following text is an example of the standard wording that is used for a group of medicinal products:

NSAID: <Om du försöker bli eller är gravid ska X undvikas och endast användas efter läkares ordination. Mer information finns i bipacksedeln.> [If you are trying to become or are pregnant, X should be avoided and only used on doctor's prescription. For more information, please refer to the package leaflet.]

<Ska inte användas om du har eller har haft magsår eller om du är överkänslig mot acetylsalicylsyra. Har du astma bör du rådfråga läkare innan du använder X.> [Avoid use if you have or have had stomach ulcers or if you are sensitive to acetylsalicylic acid. If you suffer from asthma you should consult with a doctor before using X.]

- The following shall be stated for traditional herbal medicinal products:
<Traditionellt växtbaserat läkemedel använt {indication}.

Indikationerna för ett traditionellt växtbaserat läkemedel grundar sig uteslutande på erfarenhet av långvarig användning.> [Traditional herbal medicinal product used {indication}. The product is a traditional herbal medicinal product for use in <the specified indication> <specified indications> exclusively based upon long-standing use.]

<Rådgör med läkare om symtomen kvarstår under användningen av läkemedlet eller om biverkningar som inte nämns i bipacksedeln uppträder. > [Consult a doctor if the symptoms persist during the use of the medicinal product or if adverse effects not mentioned in the package leaflet occur.]

- Therapeutic indications for non-prescription herbal medicinal products are stated as follows:
<Växtbaserat läkemedel använt {indication}.> [Herbal medicinal product used {indication}.]

Section 2:18. Natural remedies shall be labelled “Naturläkemedel” [Natural remedy]. In other respects the same requirements apply as for non-prescription medicinal products, see 2.17.

- Products that have been approved as natural remedies shall be labelled <Naturläkemedel> [Natural remedy] on the front side of the packaging.

Section 2:19. All medicinal products specified in Section 5, first paragraph, and Section 5 a, first paragraph, shall be provided with safety features that allow wholesalers and persons authorised or licenced to provide the public with medicinal products to verify the authenticity of the medicinal product, identify individual packaging and to check whether the outer packaging has been manipulated.

Exemptions from the requirements in Section 2 for information on immediate packaging in the form of blister packs and other types of small immediate packaging

Section 3 The following particulars shall at least appear on immediate packaging 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 Section 2.1,
- the name of the holder of the authorisation for placing the product on the market,
- the expiry date,
- the batch number.

- The name of the medicinal product in accordance with Section 2:1 includes the name of the medicinal product followed by its strength, pharmaceutical form and active substance(s). Active substances do not need to be stated if the medicinal product contains four or more active substances. Active substance can be left out of the generic name in case of space limitation.
- In the mock-up, the design of the blister should be presented, i.e., the number of tablets and how they are placed in the blister. This makes it possible to check that the name of the medicinal product, strength and (if relevant) pharmaceutical form are also legible when only one tablet (regardless of which) remains in the blister.
- For medicinal products that are approved with single-dose blister packs, the blister shall be labelled with the name of the medicinal product, strength, active substance(s), expiry date and batch number on each detachable unit in order to ensure traceability. The name of the MAH shall appear on the blister at least once, but does not need to be stated on each detachable unit. For parallel imported medicinal products, the name of the importer shall be stated on each detachable unit in order to ensure traceability (see Section 12 of LVFS 2012:19).
- Perforated blisters are designed like normal blisters, but may well be designed as single-dose blister.
- The name of the marketing authorisation holder can be replaced with a logotype on the packaging, if the name of the MAH is clear from the logotype.

Section 4 At a minimum, the following particulars shall appear on small immediate packaging units on which the particulars laid down in Section 2 cannot be displayed due to space:

- 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,
- in the contents by weight, by volume, or by unit.

- This paragraph is applicable for immediate packaging that is too small to accommodate all the information stated in Section 2, provided there is a completely labelled outer packaging.
- The name of the medicinal product in accordance with Section 2:1 includes the name of the medicinal product followed by its strength, pharmaceutical form and active substance(s). Active substances do not need to be stated if the medicinal product contains four or more active substances.
- For parallel imported medicinal products, the name of the importer shall be stated in order to ensure traceability (see Section 12 of LVFS 2012:19).
- For medicinal products that will be prepared prior to use, e.g. cytostatics, the Nordic Article Number is also stated on the immediate packaging.

Safety features

Section 5 Prescription-only medicinal products for human use shall have safety features. However, this does not apply to radioactive medicinal products or medicinal products listed in Annex I to the Commission Delegated Regulation (EU) 2016/161.

If necessary for reasons of patient safety, prescription-only medicinal products listed in Annex I and radioactive medicinal products may however be given an anti-tampering device that makes it possible to check if the packaging has been broken.

Section 5 a Non-prescription medicinal products for human use shall have safety features only if they contain any of the active substances or are included in any of the product categories listed in Annex II to the Commission Delegated Regulation (EU) 2016/161.

If necessary for reasons of patient safety, non-prescription medicinal products which are not listed in Annex II may however be given an anti-tampering device that makes it possible to check if the packaging has been broken.

- Non-prescription medicinal products which have been subject to counterfeiting shall have safety features (anti-tampering device and unique identifier). In order to limit the risk of counterfeit medicinal products entering the legal supply chain, such medicinal products shall not be sold outside of pharmacies.

Section 5 b The marketing authorisation holder shall report to the Medical Products Agency if the packaging is to have an anti-tampering device in accordance with Section 5, second paragraph or Section 5 a, second paragraph.

Section 5 c Packaging with safety features in accordance with Section 5 may also contain information other than the unique identifier in the two-dimensional bar code if the other requirements in these provisions have been met.

- Examples of other information can be things that are now accessed via a separate QR code on the packaging, e.g. instructions for use, package leaflet, etc.

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.

- The name of the medicinal product (and, if there are more than one strength, its strength) shall appear in Braille on the outer packaging or, if there is no outer packaging, on the immediate packaging.
- Adhere to the Swedish Braille Authority's recommendations for labelling of medicinal products.
- If the strength is indicated, it is preferable, if space permits, to also indicate the unit in Braille. Use Euro-Braille for punctuation (for example in mg/ml).
- If the medicinal product has the same name, but is available in different pharmaceutical forms, it is desirable that the pharmaceutical form also appears in Braille. Generic abbreviation of the pharmaceutical form is acceptable.
- The mock-up indicates the placement of the Braille and a translation of the Braille.
- It is the company's responsibility to ensure that the Braille is correct.
- The Braille is placed so that the legibility of other text is not impaired.
- No Braille is required on medicinal product packaging that is not handled by patients.

General labelling requirements

Section 7 The labelling on the outer packaging and 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 on the outer packaging and 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 2.1, directions for storage and use, and any 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 healthcare 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 Parliament 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 Agency¹.

¹EUT L 136, 30.4.2004, p. 1, (Celex 32004R0726).

- Name, strength, pharmaceutical form and active substance(s) are given a prominent position on the packaging.
- Name, strength, pharmaceutical form, active substance(s), pack size and Nordic Article Number are placed within the same field of view on the front of the packaging.
- The pack size is placed in the top left corner on the front of the packaging.
- The Nordic Article Number is placed in the top right corner on the front of the packaging.
- The packaging is designed in a way that minimises the risk of mix ups.

- If there is more than one medicinal product with the same name, e.g. different pharmaceutical forms or parallel imports, these are differentiated with the help of different colours and/or packaging design.
- Different strengths of a single medicinal product are to be clearly differentiated, for example by using different colours for the strengths on the packaging. If the same strength of a medicinal product administered by injection/infusion is available in different total quantities (X ml=Y mg), the total quantity is also differentiated by colours. For parallel imported medicinal products, possible colour differentiation is stated in accordance with the directly imported medicinal products colouration.
- The text shall be easily legible, even for those who have impaired vision, and in a clear and easily legible font.
- Avoid using upper case letters for better legibility.
- There shall be a clear contrast between the text and the background.
- Text/information that belongs together on the packaging is stated together and against a uniform background.
- All text in the same panel is given the same orientation (horizontally or vertically) on the outer packaging and/or immediate packaging. (Not applicable to Braille).
- Figures stated on the outer packaging and/or immediate packaging are listed together with units, e.g. 1 vial, 1 ml, 1 dose.
- If the label can be folded out, e.g. a package leaflet that can be folded out, the label that is placed directly on the packaging (under the part of the label that folds out) shall be identical to the front of the fold out label.
- The use of more than one language on the packaging may be acceptable if there is space and its legibility is not impaired.
- On multilingual packaging, it is the company's responsibility to ensure that the information in each language used is identical.
- In the case of parallel imported medicinal products, the use of the same packaging material as in the exporting country can sometimes be permitted, provided that it is relabelled to comply with the requirements in LVFS 2005:11. Foreign text may, in this case, be acceptable if it does not conflict with that part of the text that is in Swedish, see Section 12 of LVFS 2012:19.
- For vaccines, the indication should be stated on the packaging as follows: <Vaccin mot...> [Vaccine against...].

Exemptions regarding labelling requirements

Section 7 a If the medicinal product is not dispensed directly to patients, or if there are serious problems in the supply of the medicinal product, it may, if necessary to protect human health, be exempt from the requirement for the labelling to contain the information stated in Section 2. The medicinal product may also be exempt from the requirement pursuant to Section 7 for the labelling to be written in Swedish. An application for exemption from requirements according to the first paragraph shall be submitted 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 Agency²

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 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.

2 International Atomic Energy Agency safety standards series No. TS-R-1, Regulations for the safe transport of radioactive material, 1996 edition (revised 2003).

Dose-dispensed medicinal products

Section 9 Packaging 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 by other medicinal products under the present provisions.

- Packaging only intended to be used for dose dispensing does not need to be supplied with information targeted directly at the patient. These packagings are labelled with <Endast för dosdispensering> [For dose dispensing only]. This is stated even if this text is not included in the approved labelling text document.
- The following information can be excluded:
 - Method and route of administration
 - ”Läs bipacksedeln före användning” [Read the package leaflet before use]
 - ”Se bipacksedeln för ytterligare information” [See package leaflet for further information]
 - ”Förvaras utom syn- och räckhåll för barn” [Keep out of the sight and reach of children]
 - Information in Braille
- Instructions for storage and declaration of active substances and excipients are stated in the same way as on packaging that is not intended for dose dispensing.
- In cases where packaging sizes intended for dose dispensing only are included in the labelling text, no separate labelling text is needed. Instead “Endast för dosdispensering” [For dose dispensing only] can be included after the packaging size in Section 4 of the labelling text.
- Packaging for dose dispensing is not exempt from the requirements for safety features.

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.

Package leaflets for medicinal products for human use

Content of the package leaflet

Section 13 The packaging 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:

- Subheadings where there is a lack of relevant information may be excluded. However, the subheadings “**Graviditet och amning**” [Pregnancy and breast-feeding] and “**Körförmåga och användning av maskiner**” [Driving and using machines] are to be included and contain information in accordance with the SmPC.

Section 13:1. For identification of the medicinal product:

a) The name of the medicinal product, followed by its strength, 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.

- Use of uppercase letters in the full name (and other text in the package leaflet) should be avoided for better legibility. If the product name has been approved with uppercase letters, the product name can be written in uppercase letters in the heading of the package leaflet, but in lowercase letters in the rest of the text.
- If the short term for the pharmaceutical form is used on the labelling (e.g. “tablett” [tablet] instead of “filmdragerad tablett” [film-coated tablet]), it is also stated in the package leaflet in Section 6 (and in the SmPC Section 3). For accepted short terms, see EDQM Standard Terms (ref. 3).
- State the name of the active substance(s), including the first letter, in lowercase letters.
- State the active substance(s) so that it reflects the strength stated directly after the name of the medicinal product. Note that even though the active substance(s) is/are stated in connection with the name of the medicinal product, it/they shall also always be specified in the declaration (see Section 13:7 d).
 - Example 1. If the medicinal product has a strength of 8 mg and contains buprenorphine hydrochloride 8.64 mg equivalent to buprenorphine 8 mg, then it is buprenorphine that shall be stated in connection to the name of the medicinal product.
 - Example 2. If the medicinal product has a strength of 20 mg and contains 20 mg omeprazole hydrochloride equivalent to 19.52 mg omeprazole, then it is omeprazole hydrochloride that shall be stated in connection to the name of the medicinal product.

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b) The pharmacotherapeutic group or type of activity easily comprehensible for the patient.

- Also state the medicinal product’s positive effect(s) in an objective and balanced way.
 - Example 1. X reduces HIV-1 in your body and this strengthens your immune system (your body’s natural defence) and reduces the risk of developing illnesses associated with a HIV infection.
 - Example 2. Repeated blood transfusions can lead to a build-up of excess iron. The reason is that blood contains iron and your body has no natural way of excreting the excess iron that you receive through your blood transfusions. Over time, the excess iron can damage vital organs, such as the liver and heart. Medicinal products referred to as iron chelators are used to remove excess iron and reduce the risk of organ damage.
 - Example 3. X belongs to a group of medicinal products called antidepressants, and you have been prescribed this product to treat your depression. X reduces depressive symptoms, including dejection, inner tension (anxiety), sleep disruptions (less sleep), reduced appetite, concentration difficulties, feelings of worthlessness, loss of interest in favourite activities and a sense of being slow.
 - Example 4. X dilates the blood vessels and thereby reduces the strain on the heart and the heart’s need of oxygen.

Section 13:2 For medicinal products listed in the register referred to in Article 23 of Regulation (EC) No 726/2004 of the European Parliament and of the Council, the following statement shall be included: “This medicinal product is subject to additional monitoring”. This statement shall be preceded by the black symbol referred in Article 23 of Regulation (EC) No 726/2004 and followed by an appropriate standardised explanatory sentence.

- The symbol ▼ and a standardised explanation are included in the QRD template (ref. 1, also see ref. 6).

Section 13:3 Therapeutic indications.

- Medicinal products having both packaging that may be sold without a prescription and packaging that is prescription only, should have separate package leaflets. Indication can be narrower for a non-prescription medicinal product. Non-prescription medicinal products should have separate package leaflets for different strengths to avoid the risk of incorrect doses.
- Use the following text if there is an approved medicinal product containing the same active substance(s) (Blue Box) (ref. 2):

<{Active substance(s)} som finns i {product name} kan också vara godkänd för att behandla andra <sjukdomar> <tillstånd> som inte nämns i denna produktinformation. Fråga läkare, apoteks- eller annan hälso- och sjukvårdspersonal om du har ytterligare frågor och följ alltid deras instruktion.> [{Active substance(s)} in {product name} may also be approved for use in the treatment of other illnesses/conditions not mentioned in this product information. Ask your doctor, pharmacist or other health care professionals if you have any questions and always follow their instructions.]
- The Blue Box concept for package leaflets is not applicable to centralised procedures.
- Therapeutic indications for herbal medicinal products are stated as follows:

<{Växtbaserat läkemedel använt {indication}.> [Herbal medicinal product used {indication}.]

Therapeutic indications for traditional herbal medicinal products are stated as follows:

<{Traditionellt växtbaserat läkemedel använt {indication}}.

Indikationerna för ett traditionellt växtbaserat läkemedel grundar sig uteslutande på erfarenhet av långvarig användning.> [Traditional herbal medicinal product used {indication}. The product is a traditional herbal medicinal product for use in <the specified indication> <specified indications> exclusively based upon long-standing use.] (See also Section 12 a)

Section 13:4 A list of the information needed before the medicinal product can be taken, as follows:

a) contraindications,

- State all of the contraindications.
- Explain why the medicinal product should not be taken in certain circumstances, e.g. “Kan öka risken för hjärtsvikt” [May increase the risk of heart failure].

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b) appropriate precautions for use,

- Clarify how these precautions are taken, e.g. “Ta inte fler tabletter än rekommenderad dos” [Do not take more tablets than the recommended dose]. Explain why, e.g. “Du får inte bättre smärtlindring men risken för biverkningar ökar” [You will not get better pain relief, but the risk of side effects increases].

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c) forms of interactions with other medicinal products, and other forms of interaction (e.g. with alcohol, tobacco and foodstuffs) which may affect the medicinal product's effect,

- Use of the following wording is suggested. “X kan påverka eller påverkas av vissa läkemedel som innehåller följande aktiva substanser:” [X may affect or be affected by certain medicinal products that contain the following active substances:]. This sentence is then followed by a bulleted list of the different substances. State the therapeutic uses to help explain what the substances are, e.g. “erytromycin (används mot infektioner)” [erythromycin (used to treat infections)], and/or the type of medicinal product, e.g. “erytromycin (antibiotikum)” [erythromycin (antibiotic)]. It makes no difference whether the explanation or substance is in parentheses, but be consistent.
If there is a large quantity of medicinal products with which concomitant use is contraindicated, a reference to the section about contraindications may be more suitable than repeating the information as in the example above.
- If it helps the user, there should be an explanation of why the product should not be combined with other medicinal products, e.g. “Kan öka risken för biverkningar” [May increase the risk of side effects], “Effekten av X kan öka/minska om...” [The effect of X

may increase/decrease if...], “Effekten av {the other medicinal product} kan öka/minska om...” [The effect of {the other medicinal product} may increase/decrease if...].

- If there is cause to do so, also state the length of time to allow between taking different medicinal products.
- Interactions with substances that are not registered in Sweden may still be listed. These may be unauthorised medicinal products commonly used under special permission or come into question when medicinal products are obtained abroad.
- The previously used term *naturläkemedel* [natural remedies] should be replaced with:
 1. In general term, “naturläkemedel” [natural remedies] is replaced with “(traditionella) växtbaserade läkemedel och naturläkemedel” [(traditional) herbal medicinal products and natural remedies], e.g. “Tala om för läkare eller apotekspersonal om du tar eller nyligen har tagit andra läkemedel, inklusive (traditionella) växtbaserade läkemedel och naturläkemedel” [Tell your doctor or pharmacist if you are taking or have recently taken other medicinal products, including (traditional) herbal medicinal products and natural remedies].
 2. In specific cases, e.g. that of St. John's wort, “naturläkemedel som innehåller johannesört” [natural remedies containing St. John's wort] is replaced with “(traditionella) växtbaserade läkemedel som innehåller johannesört” [(traditional) herbal medicinal products containing St. John's wort].
- Explain why medication should not be combined with certain foods/drinks, e.g. grapefruit juice, other acidic fruit juice, milk. If there is cause to do so, also state the length of time to allow between the food/drink and the medicinal product they interact with.
- Where appropriate, provide information about combining the medicinal product with alcohol. Explain why this combination is inappropriate (increased risk of side effects, interaction, inappropriate in conjunction with certain diseases, etc.)

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d) special warnings.

- The following are a few examples of standard texts to be used for certain substances or groups of medicinal products. Note that this is not an exhaustive list of warnings:

Acetylsalicylic acid:

<Läkemedel som innehåller acetylsalicylsyra ska inte ges till personer under 18 år med feber utan att läkare tillfrågats beroende på risken för uppkomst av Reyes syndrom, ett sällsynt men allvarligt sjukdomstillstånd.> [Medicinal products containing acetylsalicylic acid is not to be given to individuals below 18 years of age with fever without consulting a doctor due to the risk of developing Reye's syndrome, a rare but severe condition.]

Cytostatics:

<Om <tabletten> <kapseln> går sönder eller löses upp, tvätta händerna omsorgsfullt med vatten.> [If the <tablet><capsule> breaks apart or is dissolved, wash hands carefully with water.]

NSAID:

<Ska inte användas om du har eller har haft magsår eller om du är överkänslig mot acetylsalicylsyra. Har du astma bör du rådfråga läkare innan du använder X.> [Do not use if you have or have had stomach ulcers or you are sensitive to acetylsalicylic acid. You should consult a doctor before using X if you have asthma.]

Paracetamol:

<Använd inte X utan läkares ordination om du har alkoholproblem eller leverskada och använd inte heller X tillsammans med alkohol. Berusningseffekten av alkohol ökar inte genom tillägg av X. Om du använder andra smärtstillande läkemedel som innehåller paracetamol ska du inte använda X utan att först tala med läkare eller apotekspersonal. Ta aldrig mer X än vad som står under doseringsanvisningarna. *Högre doser än de rekommenderade ger inte bättre smärtlindring utan medför istället risk för mycket allvarlig leverskada.* Symtomen på leverskada kommer normalt först efter ett par dagar. Därför är det viktigt att du kontaktar läkare omedelbart om du har tagit för stor dos, *även om du mår bra.*> [Do not use X without doctor's prescription if you have alcohol problems or liver damage and also do not use X with alcohol. The intoxicating effect of alcohol does not increase through the use of X. If you use other analgesics containing paracetamol you must not use X without first consulting a doctor or pharmacist. Never take more X than what is stated in the dosing instructions. *Higher doses than recommended will not lead to better pain relief, instead it increases the risk of very severe liver damage.* The symptoms of liver damage usually appear after a few days. It is therefore important that you contact a doctor immediately if you have taken too high a dose, *even if you are feeling fine.*]

<Förvaras utom syn- och räckhåll för barn och ungdomar.> [Keep this medicine out of the sight and reach of children and adolescents.]

The last sentence replaces the standard wording <Förvaras utom syn- och räckhåll för barn> [Keep this medicine out of the sight and reach of children.].

Benzoyl peroxide products and tretinoin:

<Undvik solning, även i solarier vid behandling med detta läkemedel.> [Avoid sunbathing, including using sunbeds, in connection with treatment with this medicinal product.]

Steroids for topical use:

<Undvik att få <läkemedlet> <salvan> <X> i ögonen.> [Avoid getting <the medicinal product><ointment><X> in your eyes.]

Section 13:4 The list must

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

- All information according to SmPC shall be reflected here. It is not enough to refer to a doctor. If a contraceptive is recommended, it must also say that the patient should discuss the choice of contraceptive with the doctor.
- In cases where the medicinal product (e.g. NSAID/acetylsalicylic acid) is contraindicated during the third trimester and the medicinal product may be used with care during the rest of the pregnancy, use the following text:
<Gravida kvinnor ska inte använda X under de sista tre månaderna av graviditeten. Intag av X ska undvikas av kvinnor som planerar graviditet eller är gravida. Behandling under någon del av graviditeten ska endast ske efter läkares ordination.> [Pregnant women must not use X in the last three months of pregnancy. Use of X should be avoided by women who are planning pregnancy or who are pregnant. Treatment during any part of pregnancy should take place only on doctor's prescription.]
- It must be clearly stated whether you can or cannot use the medicinal product during pregnancy or breastfeeding.
- The standard phrase on pregnancy shall only be used when relevant.

Examples where the phrase should not be used:

- Medicinal products intended for children only.
- Medicinal products that must never be used during pregnancy and breastfeeding.
- Medicinal products that can be used during pregnancy and breastfeeding without restrictions.
- If the medicinal product may have an effect on fertility, this must be indicated (e.g. cytostatic). If no such effect exists/has been studied, nothing is indicated.
- In cases where the medicinal product may affect fertility and male/female reproduction, replace these terms with, e.g., “möjlighet att få barn” [the ability of having children]. The section “Pregnancy, breastfeeding and fertility” can be perceived as irrelevant for men or for women who are not planning a pregnancy. It may be necessary to add subheadings such as

<Preventivmedel för <män> <och> <kvinnor>> [Contraceptives for <men> <and> <women>]

<Fertilitet för <män> <och> <kvinnor>> [Fertility in <men> <and> <women>]

<Män:> [Men:]

<Kvinnor:> [Women:]

<Om du planerar att skaffa barn> [If you are planning on having children]

- Information regarding contraceptives (such as need for multiple forms of protection, including at least one barrier method) should be indicated, for example in the section on special warnings.

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

- The following types of sentence may be used:
<Kör inte bil eller annat fordon därför att...> [Do not drive a car or other vehicle due to...]
<Använd inte verktyg eller maskiner därför att...> [Do not operate tools or machines due to...]
- Include any adverse reactions from the SmPC that may affect the ability to drive a vehicle or use machinery. Examples of such adverse reactions are tiredness, dizziness or impaired vision. Please note that even if studies show that the medicinal product has a small or no effect on the ability to drive, it may be of value to include supplementary information about disease symptoms and adverse reactions in both the SmPC and the package leaflet.
- Include the following text for the majority of medicinal products (Blue Box) (ref. 2).
<Du är själv ansvarig för att bedöma om du är i kondition att framföra motorfordon eller utföra arbeten som kräver skärpt uppmärksamhet. En av faktorerna som kan påverka din förmåga i dessa avseenden är användning av läkemedel på grund av deras effekter och/eller biverkningar. Beskrivning av dessa effekter och biverkningar finns i andra avsnitt. Läs därför all information i denna bipacksedel för vägledning. Diskutera med läkare eller apotekspersonal om du är osäker.> [You are responsible for judging whether you are fit to drive motorised vehicles or carry out work that needs focused attention. One of the factors that can affect your abilities in these respects is the use of medicines due to their effects and/or side effects. Therefore read all the information in this package leaflet for guidance. Discuss the matter with a doctor or pharmacist if you are unsure.]

- Exceptions from the introduction of the Blue Box wording may be made for those medicinal products that contain information in the corresponding section of the SmPC that the medicinal product has no effect or a negligible effect on the ability to drive vehicles and use machinery. Exceptions may also be made for certain types of medicinal product for which the Blue Box is deemed to be irrelevant, e.g. vitamin preparations, emollients and ointments.
- Please note that the Blue Box wording shall be included in the package leaflet if the SmPC and package leaflet list adverse reactions that may affect the ability to drive vehicles etc., even if the SmPC indicates that the medicinal product has no effect or a negligible effect on the capacity to drive a vehicle or use machinery.
- The Blue Box concept for package leaflets is not applicable to centralised procedures. However, the information as such can be used.

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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.

- Annex to the European Commission guideline on ‘Excipients in the labelling and package leaflet of medicinal products for human use’ and its translations (ref. 7) is available on the EMA website. There is also a document with background information and FAQs.

Section 13:5 The customary instructions required for correct use, in particular:

- a) the dosage,
- b) method of administration and, if necessary, route of administration,
- c) how often the medicinal product is to be administered, if needed with indication of suitable time when the product can or must be administered.

- a) State how the patient/healthcare professionals shall dose and administer the medicinal product. In the case of long or complicated dosage instructions, the following may be written, e.g.: “Läkaren kommer att avgöra vilken dos som är lämplig för dig” [Your doctor will decide which dose is appropriate for you].

Information about how the medicinal product is to be taken (e.g. with or without food/drink) is provided. If there is reason to do so, also give a time interval in relation to food/drink (also see Section 13:4 c)

- b) State the route of administration in a way that is easy for patients to understand. The following types of sentence may be used:
 - <Svälj <pharmaceutical form> <X> med ett glas <vätska> <vatten>.> [Swallow <pharmaceutical form> <X> with a glass of <liquid><water>.]
Where appropriate, this is combined with <Får inte tuggas eller krossas.> [May not be chewed or crushed.], followed by an explanation.
 - Include relevant instructions, e.g. <tuggas> [to be chewed, <omskakas> [shake before use], <ska spädas> [to be diluted], <löses i ett glas <vätska> <vatten>> [dissolve in a glass of <liquid><water>]. Specify appropriate liquids in cases where water is not stated.

- Possibly supplement this information with images. Detailed instructions for use may be placed at the end of the package leaflet. This should be referenced in the administration section. The package leaflet and instructions for use must be attached as a cohesive unit. They may not be separated into two parts (sheet/leaflet) in the packaging. If the packaging has multiple languages, one language can be indicated per unit. The user instruction can be a “tear off”.
- Describe non-patient-friendly methods of administration with a more patient-friendly translation. For example according to the table below:

Standard term	Patient-friendly version
Oral use	Ska sväljas [To be swallowed] (can be completely left out of mock-ups for tablets and capsules but must be provided in the labelling text)
Cutaneous/transdermal use (e.g. creams, gels, ointments)	För användning på huden [To be used on the skin]
Transdermal use (plasters)	Fästes på huden [Applied on the skin]
Ocular use	För användning i ögat [To be used in the eye]
Nasal use	För användning i näsan [To be used in the nose]
Use for inhalation	För inhalation [For inhalation]

For more complicated pharmaceutical forms, complement this section with a description of the pharmaceutical form that includes clarifying information, e.g.

- Modified-release tablets: Tabletterna är utformade så att det verksamma ämnet finns i två lager. Från det ena lagret frisätts det verksamma ämnet snabbt och från det andra sker frisättningen stegvis under lång tid. På så sätt har läkemedlet både en snabb och långvarig verkan. [The tablets are formulated so that the active ingredient is in two layers. The active ingredient is released quickly from one layer and gradually, over a long period, from the other. This allows the product to have an effect that is both quick and long lasting].
- Oral suspension/solution: it is important to state that this liquid is to be swallowed.
- Orodispersible tablet: Löser upp sig i munnen [Dissolves in the mouth].

Other information that is valuable to the user, e.g. <munnen bör sköljas efter varje inhalation> [rinse mouth after inhalation], <kan färga hud, hår och kläder> [may cause discolouring of skin, hair and clothes], <kan färga urinen/avföringen> [may colour urine/faeces], <kan missfärga mjuka kontaktlinser> [may discolour soft contact lenses], may be provided.

Instructions for use directed at healthcare professionals is placed at the end of the package leaflet. The information should primarily cover preparation instructions, storage conditions (including following preparation), shelf life, any protective stipulations for the healthcare professionals and, e.g., warnings about reactions that may occur during administration.

Section 13:5 and, when appropriate due to the nature of the medicinal product:

- d) length of treatment period, if this needs to be limited,
- e) which measures are to be taken in the event of an overdose (e.g. symptoms, acute measures),
- f) what needs to be done when one or more doses have not been taken,
- g) if necessary, the risks of withdrawal effects,
- h) a special recommendation to consult a doctor or pharmacist to get more detailed information, if needed, about how the product is to be used.

d) If possible, state how long the course of treatment should continue (short course/long term treatment). Include a recommendation to contact a doctor if the expected effect is not achieved, if relevant. Specify what the expected effect involves, or which symptoms the patient is to be observant of.

e) Include the following phrase in the section with the following sentence (Blue Box) (ref. 2):

“Om du fått i dig för stor mängd läkemedel eller om t.ex. ett barn fått i sig läkemedlet av misstag kontakta omedelbart läkare, sjukhus eller Giftinformationscentralen (tel. 112) för bedömning av risken samt rådgivning.” [If you have taken too large a dose of the medicinal product, or if a child mistakenly taken the product, contact a doctor, hospital or poison information centre (tel: 112) immediately for risk assessment and advice.]

For hospital products, this Blue Box text will often need to be reformulated or excluded. In case of translations from English, it may be necessary to reformulate/adapt the text in this section in order to avoid repetition in the Swedish text.

The Blue Box concept for package leaflets is not applicable to centralised procedures.

f) Provide examples of what to do when one prescribed dose has been missed, e.g. in conjunction with a meal or bedtime.

Also state the period of time that applies to different measures, e.g. after how long the dose shall be skipped completely.

g) List the symptoms that can arise when the medicinal product is withdrawn. Also provide information about medicinal products that require gradual reduction. Reference to the section on adverse reactions can be made.

h) -

Section 13:6 A description of any suspected adverse reactions that may occur under normal use of the medicinal product, and if necessary, the action to be taken in such cases. The patient must be told to communicate any suspected adverse reaction to healthcare professionals or directly to the Medical Products Agency. It must also state that it is possible to submit the report electronically or by mail.

- All adverse reactions that are listed in the SmPC shall be included in the package leaflet.

First part of this section – serious adverse reactions:

- The section starts with the following: <Sluta ta X och> kontakta <**omedelbart**> <snarast> läkare eller uppsök närmaste akutmottagning om du upplever följande symtom: [<Stop taking X and> <**immediately**> <promptly> contact a doctor or go to the emergency centre if you experience the following symptoms:]
- Consider the adverse effects listed for similar medicinal products.
- The frequency should be indicated for the patient to know how often/rarely they occur, so that the message is not unnecessarily disconcerting.
- The following texts should be used if any of the following conditions are named as a warning or side effect in the SmPC:
-

Agranulocytosis:

<Sluta ta X och kontakta **omedelbart** läkare om du får något av följande symtom (agranulocytos): feber i kombination med kraftigt försämrat allmäntillstånd eller feber i kombination med ont i halsen/svalget/munnen eller svårt att kissa, vilket är tecken på infektion. Eftersom X i sällsynta fall kan leda till ett försämrat infektionsförsvar på grund av brist på vita blodkroppar kan infektioner bli allvarliga. Därför är det viktigt att du i dessa situationer också informerar om din medicinering.>

[<Stop taking X and **immediately** contact a doctor if you experience one of the following symptoms (agranulocytosis): fever coupled with a severely deteriorated general state of health or a fever in combination with sore throat/mouth or difficulty urinating, which are signs of infection. As X can in rare cases lead to a deteriorated immune system due to a lack of white blood cells, infections can become serious. For this reason, it is also important that you inform health care personnel about your medication.>]

Stevens-Johnson syndrome / TEN / DRESS / AGEP:

<Sluta ta X och kontakta **omedelbart** läkare eller uppsök närmaste akutmottagning om du upplever följande symtom:

Extremt kraftiga och allvarliga hudbiverkningar såsom <Stevens-Johnsons syndrom>, <toxisk epidermal nekrolys>, <läkemedelsreaktion med eosinofili och systemiska symtom (DRESS)>, <akut generaliserad exantematös pustulos (AGEP)> har rapporterats vid användning av X.

Hudbiverkningarna kan bestå av utslag med eller utan blåsor. Även hudrodnad, <sår eller svullnad i mun, hals, ögon, näsa och runt könsorganen (Stevens-Johnsons syndrom)>, <ödem (DRESS)> samt feber och influensaliknande symtom kan förekomma.>

[<Stop taking X and **immediately** contact a doctor or go to the emergency department if you experience the following symptoms:

Extremely intense and serious skin reactions, such as <Stevens-Johnson syndrome>, <toxic epidermal necrolysis>, < drug rash with eosinophilia and systemic symptoms (DRESS syndrome)>, <acute generalised exanthematous pustulosis (AGEP)> have been reported during use of X.

The adverse reaction of the skin may appear as rashes with or without blisters. Skin irritation, <sores or swelling in the mouth, throat, eyes, nose and around the genitals (Stevens-Johnson syndrome)>, <oedema (DRESS syndrome)> and fever and flulike symptoms may occur.>]

If Stevens-Johnson syndrome / toxic epidermal necrolysis is/are included, add the following:

< Hudutslagen kan utvecklas till allvarlig utbredd hudskada (hudavlossning av överhuden och ytliga slemhinnor) med livshotande följder.>

[<The skin rashes may develop into serious widespread skin damage (peeling of the epidermis and superficial mucous membranes) with life-threatening consequences.>]

If DRESS syndrome is included, add the following:

<Symtom på DRESS utvecklas vanligen cirka 2-6 veckor (eventuellt upp till 8 veckor) efter behandlingsstart.>

[<Symptoms of DRESS syndrome usually appear approximately 2–6 weeks (possibly up to 8 weeks) after treatment begins.>]

If AGEP is included, add the following:

<Om symtom på AGEP uppstår sker detta ofta i nära anslutning till behandlingsstart.>

[<If symptoms of AGEP appear, it usually occurs in conjunction with the start of treatment.>]

Angiooedema:

<Sluta ta X och kontakta **omedelbart** läkare om du får något av följande symtom (angioödem):

svullnad av ansikte, tunga eller svalg; svårigheter att svälja; nässelutslag och andningssvårigheter.>

[Stop using X and **immediately** contact a doctor if you experience any of the following symptoms (angiooedema):

swelling of the face, tongue or throat; difficulty swallowing; hives and breathing difficulties.]

Rhabdomyolysis:

<Sluta att ta X och kontakta läkare snarast möjligt om du får oförklarlig muskelsmärta, muskelkramper eller muskelsvaghet.>

[Stop using X and contact a doctor as soon as possible if you experience inexplicable muscle pains, muscle cramps or muscle weakness.]

Second part of this section – other adverse reactions:

- Must be based on the list of other adverse reactions from 4.8 of SmPC. A heading should separate the paragraph from the previous one relating to serious adverse reactions, e.g. “Other side effects that may occur”.
- Adverse reactions may be grouped in cases where there are several different adverse reactions within the same organ system with similar symptoms. For example, various cardiac diagnoses can be described as <påverkan på hjärtats rytm> [effects on heart rate]. Information may be supplemented with <som visar sig vid <blodprov>, <EKG>, <provtagning> [that can be seen in <blood sample>, <ECG>, <medical sampling>].
- State the adverse reactions with terms that primarily describe symptoms. Use simple language. For certain groups of patients that can be expected to be better informed about their disease, a few more specific terms may be used. If medical terminology is used, this should be explained in Swedish terms or by using symptoms. If medical terminology is used, there should be a specific purpose, e.g. the term is recognised by the general public or the medical term describes the condition better or facilitates the search for further

information. User tests have shown that medical terminology interrupts the reader's flow and makes it harder for the patient to absorb the information.

- Adverse reactions should be listed based on how frequently they occur, if this has been specified in the SmPC (avoid using %).

The following description of frequency is recommended:

Mycket vanliga (kan förekomma hos fler än 1 av 10 användare)

[Very common: may affect more than 1 in 10 people]:

Vanliga (kan förekomma hos upp till 1 av 10 användare)

[Common: may affect up to 1 in 10 people]:

Mindre vanliga (kan förekomma hos upp till 1 av 100 användare)

[Uncommon: may affect up to 1 in 100 people]:

Sällsynta (kan förekomma hos upp till 1 av 1000 användare)

[Rare: may affect up to 1 in 1,000 people]:

Mycket sällsynta (kan förekomma hos upp till 1 av 10 000 användare)

[Very rare: may affect up to 1 in 10,000 people]:

Har rapporterats (förekommer hos ett okänt antal användare)

[Not known: frequency cannot be estimated from the available data]:

- The following text is recommended for reporting adverse reactions (also see ref. 8):

Rapportering av biverkningar

Om du får biverkningar, tala med <läkare> <eller> <,> <apotekspersonal> <eller sjuksköterska>. Detta gäller även biverkningar som inte nämns i denna information. Du kan också rapportera biverkningar direkt (se detaljer nedan). Genom att rapportera biverkningar kan du bidra till att öka informationen om läkemedels säkerhet.

[Reporting of side effects

If you get any side effects, talk to your <doctor> <or> <,> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see contact details below). By reporting side effects, you can help provide more information on the safety of this medicine.]

Läkemedelsverket

Box 26

751 03 Uppsala

www.lakemedelsverket.se

Section 13:7 A reference to the expiry date that appears on the label and

- a) a warning against using the medicinal product after that date,
- b) special storage precautions,

- The following phrase is used to inform the user of the expiry date:
Används före utgångsdatum som anges på <etiketten> <kartongen> <flaskan> <...>
<efter {<Utg.dat.> eller <EXP> eller <Utg.dat. eller EXP>}.> <Utgångsdatumet är den sista dagen i angiven månad.>
[Do not use this medicine after the expiry date which is stated on the <label> <carton>

<bottle> <...> <after {abbreviation used for expiry date}.> <The expiry date is the last day of the month specified.>]

- If specific instructions apply to destruction of the product, one of the following may be used:

Text for the pharmaceutical form patches

<Använt plåster ska vikas ihop med den klibbiga sidan inåt och förvaras på ett säkert sätt så att barn inte kommer åt plåstret. Återlämna använt plåster till apotek, helst i originalförpackningen. > [Used patches shall be folded with the adhesive side inwards and stored in a safe way so that children cannot reach the patches. Return used patches to the pharmacy, preferably in the original package.]

Medicinal products for asthma (inhalers) and similar.

<Eftersom läkemedelsrester kan finnas kvar i de tomma förpackningarna bör man inte kasta dessa i soporna utan även de tomma förpackningarna bör återlämnas till apotek.> [Due to the possibility that pharmaceuticals may remain in the empty containers, these should not be disposed of in the household waste, the empty containers should be returned to the pharmacy.]

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- c) if necessary, a warning concerning certain visible signs of a deterioration

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- d) a full qualitative composition (in active substance(s) and excipient(s)) and the quantitative composition inactive substance, using the common names for each presentation of the medicinal product,

- The declaration contains a list of the quantity of the form of the active substance(s) that correspond to the strength, e.g. buprenorphine hydrochloride equivalent to buprenorphine 8 mg.

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- e) for each presentation of the product, the pharmaceutical form and content in weight, volume or unit of dosages,

- Include a description of the pharmaceutical form and the medicinal product's appearance.
- In case of granules that have to be reconstituted to make an antibiotic suspension, <Bereds på apotek till oral suspension> [For preparation to oral suspension at pharmacy] can be written as the customer only sees the prepared suspension.
- All pack sizes shall be listed in accordance with the SmPC.
- For package leaflets for non-prescription medicinal products, only list the non-prescription pack sizes.
- For package leaflets for prescription-only medicinal products, list all pack sizes.

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- f) the name and address of the marketing authorisation holder, and where appropriate, the name of the local representative,

- Use the heading <Innehavare av godkännande för försäljning> [Marketing authorisation holder]
- The subheading <Marketing authorisation holder> is replaced by <Importör/information lämnas av:> [Importer/provider of information:] or <Importör:> [Importer:] for parallel imported medicinal products.
- The subheading <Marketing authorisation holder> is replaced by <Innehavare av registrering för försäljning> [Registration holder] for traditional herbal medicinal products.
- The local representative is stated, if it is registered as such at the Medical Products Agency. Use the heading <Lokal företrädare> [Local representative].
- If the stated company is not registered as a local representative at the Medical Products Agency, but only provides information about the medicinal product, the heading <Information lämnas av:> [Provider of information:] may be used instead.
- Complete address (preferably postal address) is stated in the package leaflet. In addition, telephone number, fax number and/or e-mail address may also be added. A reference to a web address is not acceptable.

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- g) the name and address of the manufacturer.

- The term manufacturer denotes the manufacturer responsible for releasing the batch (see the definition in Section 1 of LVFS 2005:11).
- If the manufacturer is a company other than the MAH, the manufacturer is stated separately. Use the heading <Tillverkare> [Manufacturer]
- If the manufacturer is in the same group of companies as the MAH, the manufacturer does not need to be stated. Use the heading <Innehavare av godkännande för försäljning och tillverkare > [Marketing authorisation holder and manufacturer]
- For parallel imported medicinal products, the re-packager's and manufacturer's names and addresses shall be stated. The company group term may be stated instead of the manufacturer's name and address, see Section 13 of LVFS 2012:19. This information is preceded by <Ompackare> [Re-packager] and <Tillverkare> [Manufacturer].

Section 13:8 If the medicinal product has been authorised for sale through the procedure for mutual recognition or the 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.

Section 13:9 The date of the most recent version of the package leaflet.

- The Medical Products Agency will add the date once the package leaflet is ready for approval.

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 of these languages and that it is grouped by language.

The text in the package leaflet shall be written in a clear and easily understandable 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 healthcare 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.

- Information in the package leaflet shall be consistent with the content of the SmPC and be otherwise beneficial for the user.
- The information should be concise.
- It is preferable to use the active form, e.g. "Ta tabletten med mat" [Take the tablets with food] instead of "Tabletterna tas med mat" [The tablets are taken with food].
- The medicinal product's positive properties should be presented in a balanced way, but may *not* contain advertising messages or emotive language.
- Particularly important information is given the appropriate prominence in each section. Prominent placement can be done with the help of bulleted lists, boxes or starting each section with particularly important information. Additional subheadings, aside from those already stipulated, may be used.
- For non-prescription medicinal products, the package leaflet and labelling shall contain sufficient information and be designed to allow the patient/customer to use the medicinal product without contacting a doctor.
- For non-prescription medicinal products, there is a special QRD template for package leaflets.
- For non-prescription medicinal products, there are OTC substance reports for certain substances published on the Medical Products Agency's website (ref. 5). An OTC substance report is the result of an overview for a substance regarding non-prescription information (including pack sizes approved for non-prescription), which should be stated in the package leaflet/labelling for a medicinal product approved as non-prescription.

- A combined package leaflet may be used if the package leaflets are identical for more than one strength. In these cases, only the strength-specific information may differ. The aim of the combined package leaflet will be to clarify dosage instructions for the user, e.g. when a patient changes from one strength to another during their treatment. However, non-prescription medicinal products should have separate package leaflets for different strengths in order to avoid the risk of incorrect dosage.
- It is sufficient to provide *one* package leaflet in multipacks. Multipacks of a parallel imported medicinal product should contain the same number of package leaflets as the directly imported medicinal product.
- The printed package leaflet shall be easily legible, even for those with impaired vision. The use of uppercase letters must be avoided. Good legibility may also be achieved by splitting the text up into short paragraphs with spaces between them. Use a clear and easily legible font. Avoid paper of a quality that allows text from one side to be visible on the other. Text divided up into a larger number of narrow columns is more easily legible than a small number of wide columns.
- Only information relating to the Swedish market may be stated in the Swedish package leaflet authorised by the Medical Products Agency.
- For traditional herbal medicinal products, it shall be stated that the user should consult a doctor if the symptoms persist during the use of the medicinal product or if adverse reactions not listed in the package leaflet occur.

Exemptions relating to the package leaflet obligations

Section 15 a Where the medicinal product is not intended to be given 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 exemption to the obligation in Section 15 that the package leaflet should be written in Swedish.

Applications for exemption from the obligations under the first paragraph shall be made to the Medical Products Agency.

- Dose-dispensed medicinal products: the packaging does not need to contain package leaflets.
- Medicinal products that are not marketed in Sweden: prior to marketing, proposed package leaflets shall be sent to the Medical Products Agency for review and authorisation.
- For medicinal gases that are only made available in hospitals, and when the Medical Products Agency has accepted that the package leaflet will only be made available on Medical Products Agency's website, the following text appears on the labelling: "Läs produktinformation som finns tillgänglig på www.lakemedelsverket.se" [Read the product information published on the Medical Products Agency's website: www.lakemedelsverket.se]
(What is stated above is valid when gas cylinders are stored in a gas storage facility and the gas is distributed via a pipe system to the treatment room).
- In addition to what is stated above, there are no general product categories that are granted exemptions, instead each individual case should be justified in the application.
- Please note that hospital products and radioactive medicinal products are, in general, not granted exemptions from the requirement to supply a package leaflet in the packaging. Patients who receive these medicinal products shall be able to obtain a package leaflet

from healthcare professionals and be able to find this information retrospectively on the Medical Products Agency's website.

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.

Labelling of medicinal products for veterinary use

Information on labelling refers to both labelling text and printed packaging (mock-up) unless otherwise stated.

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:

Section 17:1 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.

- The name of the medicinal product and strength are stated clearly and in an easily legible font on the packaging.
- The name of the medicinal product and strength are stated in the same font and size and, if possible, on the same line.
- Nothing may come in between the name of the medicinal product and its strength.
- The medicinal product's full name is stated in the same colour.
- The strength is only stated once on each side of the packaging and in connection to the name of the medicinal product.
- Different strengths of a single medicinal product are to be clearly differentiated, for example by using different colours for the strength on the packaging. If the same strength of a medicinal product administered by injection or infusion is available in different total quantities (X ml=Y mg), the total quantity is also differentiated by colours. For parallel-imported medicinal products, the any colour differentiation is stated in accordance with the directly imported medicinal products colouration.
- If the medicinal product has an invented name and only contains one active substance, this shall be stated in lowercase letters (including the first letter) below the name of the medicinal product and strength. If the medicinal product contains more than one active substance, these do not need to be stated in connection to the name of the medicinal product.
- The active substance is stated on the packaging in a font half the size of that of the name of the medicinal product.
- The active substance shall be stated in the form that corresponds to the strength. For example, if the medicinal product has a strength of 2 mg/ml and contains dexamethasone disodium phosphate 2.77 mg/ml equivalent to 2 mg/ml dexamethasone, then it is dexamethasone that shall be stated in connection to the name of the medicinal product. Please note that, even though the active substance is stated in connection to the name of the medicinal product, it shall also always be specified in the declaration (see Section 17:2).
- The pharmaceutical form is an important part of the identification of a medicinal product and shall always be stated in connection to the name and strength of the medicinal product. If the animal type or target group is indicated in the name in Section 1 of SPC, it shall also be stated here (in the same way as in SPC).

- The pharmaceutical form shall be stated in accordance with the applicable EDQM Standard Terms (ref. 3).
- The complete pharmaceutical form is stated on the front of the packaging. On the other sides, if there is a lack of space, the short term in accordance with the applicable EDQM Standard Terms (ref. 3) may be used.
- Different pharmaceutical forms of the same medicinal product are differentiated clearly on the packaging in order to avoid mixup.
- The pharmaceutical form may, when appropriate, be composed of the pack size (= quantitative indication), e.g. <30 tableter> [30 tablets]. If the outer packaging contains several immediate packages, this is stated in conjunction with the pack size, e.g. if there are two containers with 30 tablets in each, this is stated as <60 (2x30) tableter> [60 (2x30) tablets]. The size of the packaging for products administered by injection can be indicated as “X x Y ml” or as “X injection vials of Y ml”, or for powder “x vial(s)”.
- The quantity for medicinal products administered by injection is indicated in the Swedish labelling as “5 ml = 50 mg” rather than “50 mg/5 ml”.
- Pack size is stated together with the name of the medicinal product, strength and pharmaceutical form on all sides of the packaging, if there is space.
- The pack size is placed in the top left corner on the front of the packaging.
- If the pack contains cannulae, swabs or similar, this shall appear on the outer packaging.
- Medicinal product packaging that contains pressurised contents shall state both the net and gross volume.
- For vaccines, the indication shall be stated on the packaging as follows: <Vaccin mot...> [Vaccine against...].

Section 17:2 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.

- The declaration contains a list of the quantity of the form of active substance(s) that correspond to the strength, e.g. buprenorphine hydrochloride equivalent to buprenorphine 8 mg.
- The declaration begins with <1 tablett innehåller...> [1 tablet contains...], <1 ml innehåller...> [1 ml contains...] or similar. For vaccines write <1 dos innehåller...> [1 dose contains...].
- Active substance(s) and relevant excipients are specified together on the outer packaging and/or immediate packaging. Further information in Section 17:3.

Section 17:3 A listing of excipients included in the summary of product characteristics.

- The excipients stated in Section 2 of the SPC are specified in the declaration on the outer packaging and/or immediate packaging.
- Active substance(s) and relevant excipients are specified together in the declaration on the outer packaging and/or immediate packaging.
- For vaccines, the adjuvant/adsorbant is stated both qualitatively and quantitatively.

Section 17:4 The batch number.

- The batch number is preceded by the approved abbreviation <Sats> [Batch], <Batch> or <Lot> [Batch].
- The batch number is placed together with the expiry date on the packaging.
- If <Sats>, <Batch> or <Lot> are added during printing, it should be stated on the mock-up which of the abbreviations will be used and where this will be placed on the outer packaging and/or immediate packaging.

Section 17:5 The marketing authorisation number.

- The marketing authorisation number is preceded by the term <MTnr:> [MA no.] and is placed on the packaging together with the name and address of the MAH.

Section 17:6 The Nordic Product Number (Vnr).

- The Nordic Article Number (referred to as the Nordic Product Number in the English translation of LVFS 2005:11) is stated in the top right corner on the front of the outer packaging.
- The Nordic Article Number is stated at least once in connection with the name of the medicinal product on the outer packaging or, if there is no outer packaging, on the immediate packaging.
- The Nordic Article Number is stated in numerals in groups of two and is preceded by <Vnr> [Nordic Article Number] (Vnr XX XX XX).
- For medicinal products that will be prepared prior to use, e.g. cytostatics, the Nordic Article Number is also stated on the immediate packaging.
- *Multipacks*: It is sufficient that the Nordic Article Number appears on the outer packaging. If the Nordic Article Number also appears on each subsidiary pack, this number shall not be the same as that on the outer packaging, i.e. each subsidiary pack shall not have the multipack's Nordic Article Number.

Section 17:7 The name and address of the marketing authorisation holder and local representative, if any.

- The name and address of the MAH shall be stated.
- The local representative's name and address may be stated. The local representative shall be registered with the Medical Products Agency. Information about the local representative is preceded by the heading <Lokal företrädare> [Local representative]. If the stated company only provides information about the medicinal product, the heading <Information lämnas av:> [Provider of information] is used.
- In those cases where another product stakeholder, in addition to the MAH, is also stated on the outer packaging and/or immediate packaging, one of the following headings shall be used in order to enable those involved in the product to be differentiated:
 - <Innehavare av godkännande för försäljning> [Marketing Authorisation Holder]
 - <Importör> [Importer] (Only for parallel imported medicinal products.)
 - <Lokal företrädare> [Local representative]
 - or <Information lämnas av> [Provider of information]

If space permits, add a heading for both product stakeholders. In case of space restrictions, add a heading for at least one of the product stakeholders (for parallel imported medicinal products, also see below).

- The name, city and country (when the city is not in Sweden) are the minimum requirements for all product stakeholders. City and country are written in Swedish.
- A reference to a web address is not acceptable.
- For parallel imported medicinal products, the re-packer and manufacturer's names and addresses shall also be stated. The relevant company group term may be used instead of the manufacturer's name and address. This information is preceded by <Ompackare> [Re-packer] and <Tillverkare> [Manufacturer].

Section 17:8 The species of animal for which the veterinary medicinal product is intended, the method and, if necessary, the route of administration.

- The labelling shall contain information about the target species. This stated in singular form.
- A picture of the target species (the type(s) of animals to receive the treatment) may be accepted as a complement or clarification. The picture may not be dominant in relation to the information text on the packaging (ref. 9). Further information in Section 25.
- In small immediate packaging, specification of the type of animal can be replaced by an image (ref. 9).
- The method of administration is, e.g. <införes i ändtarmen> [for rectal insertion].
- The route of administration is, e.g. <intravenös användning> [for intravenous use].
- For medicinal products administered by injection or infusion, the route of administration is stated on both the outer packaging and immediate packaging.
- Describe non-user-friendly methods of administration with a more user-friendly translation.

For example according to the table below:

Standard term	Patient-friendly version
Oral use	<Ges via munnen> [Is given through the mouth]
Cutaneous/transdermal use	<För användning på huden> [To be used on the skin]
Ocular use	<För användning i ögat> [To be used in the eye]

Section 17:9 The withdrawal period for veterinary medicinal products to be administered to food-producing species, for all the species concerned and for the various foodstuff (meat and slaughter by-products, eggs, milk, honey), including those for which the withdrawal period is zero.

- Preceded by: <Karenstid(er):> [Withdrawal period(s):]
- Withdrawal period is not indicated in “dagar” [days], use “dygn” [24-hour period].

Section 17:10 Expiry date (month/year).

- The expiry date is preceded by the approved abbreviation <Utg.dat.> [Expiry date] or <EXP> [Expiry date] and is stated in the same way as on the package leaflet.
- If <Utg.dat.> or <EXP> are added during printing, it should be stated which of the abbreviations will be used and where this will be placed on the outer packaging and/or immediate packaging.
- The month will be stated with two numerals or with letters and the year with four numerals.
- The date stated after <Utg.dat.> or <EXP> means that the medicinal product can be used until the end of the month stated and replaces <Anv. före> [Use before], which was used previously. (The date that is stated after <Anv. före> means that the medicinal product can be used until the month stated.) In the case of approved medicinal products that are still marked with <Anv. före> [Use before], this is corrected in conjunction with another update.
- If appropriate, the shelf life of opened packages or shelf life following preparation shall also be stated.

Section 17:11 Special storage precautions, if any.

- The storage precaution(s) shall be consistent with those stated in the SPC and are presented in accordance with the QRD template (ref. 1)

Section 17:12 If required, information about special precautions for the disposal of unused medicinal products or waste materials from medicinal products, and if necessary, references to appropriate collection systems in place.

- Information concerning disposal is stated in accordance with the SPC and/or the labelling text.

Section 17:13 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.

- The following are examples of warnings and information that are directed at those administering the medicinal product and that should be stated if relevant:

<Oavsiktlig injektion är farlig – se bipacksedeln före användning.> [Unintentional injection is dangerous – read the package leaflet before use.]

<<Oavsiktlig administrering> / <kontakt med slemhinnor> är farlig – se bipacksedeln före användning.> [Unintentional administration/contact with mucosae is dangerous – read the package leaflet before use.]

<Officiella riktlinjer för inblandning av premix till medicinfoder bör beaktas.> [Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds]

<Cytostatikum>

- Medicinal products for veterinary use that contain pesticides shall be labelled in accordance with the Swedish Chemicals Agency's regulations.
- The text <Förvaras utom syn- och räckhåll för barn> [Keep this medicine out of the sight and reach of children] is used.
- Necessary instructions for use, e.g. <omskakas> [shake before use], <ska spädas> [to be diluted], are stated on the outer packaging and/or immediate packaging.
- Other information that is valuable to the user, e.g. <kan färga urinen/avföringen> [may colour urine/faeces], is stated on the outer packaging and/or immediate packaging.

Section 17:14 The text “For animals” or, for prescription medicinal products, the text “For animals – prescription only”.

- Stated on the outer packaging and/or immediate packaging/blister.

Section 17:15 A blank space shall be left for the pharmacy label.

- Consideration shall be given to allowing the pharmacy label to be placed on the outer packaging without hiding any information. For example, an empty space can 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 outer packaging and an immediate packaging, the pharmaceutical form and amount by weight, volume or number of units needs 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,
- 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,
- batch number,
- date of expiry,

- Blisters may, on condition that this does not imply any danger when they are used, be labelled with only the following:
 - The name of the medicinal product and strength
 - Name of the MAH
 - Expiry date
 - The batch number
 - The words <För djur.> [For animals.]
- The expiry date and batch number are preceded by the approved abbreviation. Further information in Section 17:4 and 10.
- The design of the blister is marked on the mock-up (number of tablets and how they are placed in the blister). This is to ensure that the name of the medicinal product, strength and (if relevant) pharmaceutical form are legible when only one tablet (regardless of which) remains in the blister.
- Small single-dose packs other than ampoules can e.g. be pipettes, small single-dose syringes with paste for oral use and blisters approved as single-dose blisters.
- For parallel imported medicinal products, ampoules, blisters and small single-dose packs shall also be labelled with the name of the importer in order to ensure traceability (see Section 12 of LVFS 2012:19).

General labelling requirements

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.

Labelling on the outer packaging and 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 in accordance with Section 17: 1, directions for storage and use and warnings; all of which are essential to the user's correct use the medicinal product. It is important that the labelling be designed in such a way that the medicinal product can be handled within the veterinary medical care and be dispensed from pharmacies without the risk of mix-ups.

- Name, strength, pharmaceutical form and active substance are given a prominent position on the packaging.
- Name, strength, pharmaceutical form, active substance, pack size and Nordic Article Number are placed within the same field of view on the front of the packaging.
- The pack size is placed in the top left corner on the front of the packaging.
- The Nordic Article Number is placed in the top right corner on the front of the packaging.
- The labelling is designed in a way that minimises the risk of mix ups.
- If there are more than one medicinal product with the same name, e.g. different pharmaceutical forms or parallel imported medicinal products, these are differentiated with the help of different colours and/or packaging design.
- Different strengths of a single medicinal product are to be clearly differentiated, for example by using different colours for the strengths on the packaging. If the same strength of a medicinal products administered by injection or infusion is available in different total quantities (X ml=Y mg), the total quantity is also differentiated by colours. For parallel imported medicinal products, any colour differentiation is stated in accordance with the directly imported medicinal products colouration.
- The text shall be easily legible, even for those who have impaired vision, and in a clear and easily legible font.

- Avoid using upper case letters for better legibility.
- There shall be a clear contrast between the text and the background.
- Text/information that belong together on the packaging is stated together and against a uniform background.
- All text is given the same orientation (horizontally or vertically) on the outer packaging and/or immediate packaging.
- Figures stated on the outer packaging and/or immediate packaging are listed together with units, e.g. 1 vial, 1 ml, 1 dose.
- The text <Läs bipacksedeln före användning> [Read the package leaflet before use] shall appear on the outer packaging and/or immediate packaging of all medicinal products that have an authorised package leaflet.
- The packaging of non-prescription medicinal products should also include information about the product's approved non-prescription indication(s) and normal dosage for these indications.
- The indication is placed on the *front* of the packaging. If the indication has an accepted abbreviated form, e.g. “Mot fästingar och loppor” [Against ticks and fleas], this is placed on the front of the packaging. The complete indication according to the package leaflet and/or labelling text is then placed in another place on the packaging, preferably together with the dosage instructions.
- The packaging of non-prescription medicinal products shall include the phrase “Receptfritt läkemedel” [Non-prescription medicinal product]. (New in 2018.)
- If the label can be folded out, e.g. a package leaflet that can be folded out, the label that is placed directly on the packaging (under the part of the label that folds out) shall be identical to the front of the fold out label.
- The use of more than one language on the packaging may be acceptable if there is space and its legibility is not impaired.
- On multilingual packaging, it is the company's responsibility to ensure that the information in each language used is identical.
- In the case of parallel imported medicinal products, the use of the same packaging material as in the exporting country is permitted, provided that it is relabelled to comply with the requirements in LVFS 2005:11. Foreign text may, in this case, be acceptable if it does not conflict with that part of the text that is in Swedish (see Section 12 of LVFS 2012:19).

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.

Package leaflets for medicinal products for veterinary use

Content of the package leaflet

Section 23 The packaging 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 may 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 and in the sequence given:

1. The name and address of the marketing authorisation holder, the manufacturer, and the local representative, if any.

- If the manufacturer and the MAH are not the same, <och tillverkare ansvarig för frisläppande av tillverkningsats> [and manufacturer responsible for batch release] is excluded from the subheading of the QRD template.
- If the manufacturer is part of the same group of companies as the MAH, they do not need to be listed separately under the heading <Tillverkare ansvarig för frisläppande av tillverkningsats:> [Manufacturer responsible for batch release:]. This heading may in this case be omitted.
- For parallel imported medicinal products, heading 1 shall be changed to:
NAMN PÅ OCH ADRESS TILL DEN SOM INNEHAR TILLSTÅND ATT SÄLJA ETT PARALLELLIMPORTERAT LÄKEMEDEL OCH NAMN PÅ OCH ADRESS TILL INNEHAVAREN AV TILLVERKNINGSTILLSTÅND SOM ANSVARAR FÖR FRISLÄPPANDE AV TILLVERKNINGSSATS, OM OLIKA
[NAME AND ADDRESS OF THE MARKET AUTHORISATION HOLDER FOR A PARALLEL IMPORTED MEDICINAL PRODUCT AND NAME AND ADDRESS OF THE LICENCED MANUFACTURER RESPONSIBLE FOR THE RELEASE OF THE BATCH, IF THEY ARE NOT ONE AND THE SAME]
- For parallel imported medicinal products, the subheading <Innehavare av godkännandet för försäljning> [Marketing Authorisation Holder] is replaced with <Importör/information lämnas av:> [Importer/provider of information:] or <Importör:> [Importer:].
- For parallel imported medicinal products, the re-packager and manufacturer's names and addresses shall be stated. The relevant company group term may be used instead of the manufacturer's name and address, see Section 13 of LVFS 2012:19. This information is preceded by <Ompackare> [Re-packager] and <Tillverkare> [Manufacturer].
- A local representative can be indicated. The local representative must be registered with the Medical Products Agency. Use the heading <Lokal företrädare> [Local representative].
- If the stated company is not registered as a local representative at the Medical Products Agency, but only provides information about the medicinal product, the heading <Information lämnas av:> [Provider of information:] may be used instead.
- The name, city and country (when the city is not in Sweden) are the minimum requirements. Complete address (preferably postal address), a telephone number, a fax number and/or an e-mail address may also be stated
- A reference to a web address is not acceptable.

Section 23:2 The name of the veterinary medicinal product for, 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 the names authorised in each member state shall be included.

- Also indicate the active substance. The active substance, including the first letter, is written in lowercase letters.
- The information, possibly including target species, is provided as specified in the first section of the SPC. The target species can be listed following the pharmaceutical form. See also Section 23:6.

Section 23:3 A statement of the active substances and excipients included in the summary of product characteristics.

- State the active substance(s) that reflects the strength stated directly after the name of the medicinal product. Please note that, even if the active substance(s) is/are stated in connection with the name of the medicinal product, it/they shall always be specified in the declaration as well (see Section 13:6 d).
 - Example 1. If the medicinal product has a strength of 8 mg and contains buprenorphine hydrochloride 8.64 mg equivalent to buprenorphine 8 mg, then it is buprenorphine that shall be stated in connection to the name of the medicinal product.
 - Example 2. If the medicinal product has a strength of 20 mg and contains 20 mg omeprazole hydrochloride equivalent to 19.52 mg omeprazole, then it is omeprazole hydrochloride that shall be stated in connection to the name of the medicinal product.
- State the excipients listed in Section 2 of the product summary.
- A description of the medicinal product's appearance should be included.

Section 23:4 Therapeutic indications.

- Based on the information in the indication section and relevant information in the pharmacodynamic section of the SPC.
- A short explanatory text may also be included in this section in order to describe the medicinal product's positive effect(s); this information shall be presented in an objective and balanced way.

Section 23:5 Contraindications and adverse reactions.

Contraindications

- Based on the information in the section concerning contraindications in the SPC.
- All contraindications shall be listed.

Adverse reactions

- Based on the information in the adverse reaction section in the SPC.
- All adverse reactions that are listed in the SPC shall be included in the package leaflet. Adverse reactions may be grouped in cases where there are several different adverse reactions within the same organ system with similar symptoms. For example, various cardiac diagnoses can be described as <påverkan på hjärtats rytm> [effects on heart rate]. Information may be supplemented with <som visar sig vid <blodprov>, <provtagning> [that appear in connection with <blood sample>, <medical sampling>].
- Adverse reactions should be listed based on how often they occur, if this has been specified in the SPC.

- The package leaflet shall be easily understood by animal healthcare professionals, farmers **and** animal owners. It is appropriate to describe symptoms rather than the exact medical term for a certain side effect. It is recommended that the medical terminology be provided in parentheses.

The following text is recommended for the reporting of adverse reactions:
You can also report adverse reactions via the national reporting system.

Läkemedelsverket
Box 26
751 03 Uppsala
www.lakemedelsverket.se

Section 23:6 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, if necessary.

Target species

- Target species are listed in accordance with the target species in the SPC.
If there is a risk of confusion, the target species must be listed following *Name, strength, pharmaceutical form* in the introduction of the package leaflet, e.g. if the same product name is approved for different target species.

Dosage

- Based on the information in the dosage section in the SPC.
- State the dosage for each target species.
- Preferably, only state the most common dosage and, if applicable, the maximum dose.
- Include relevant instructions, e.g. < omskakas> [shake before use], <löses i vätska> [dissolve in liquid].
- State the route of administration in a user-friendly way.

Administration

- Provide more practical instructions for use that are directed at animal healthcare professionals, farmers or animal owners. If necessary this can be more detailed than in the SPC.

For example: Låt vaccinet anta rumstemperatur före användning, Ges tillsammans med foder. [Allow the vaccine to warm to room temperature before use; Is given together with food.]

- If possible, include advice on what to do if a dose is missed. For example, this may be relevant in the case of treatment with antibiotics, contraceptive pills for cats or other continuous treatments.
- Describe non-user-friendly methods of administration with a more user-friendly translation.

For example according to the table below:

Standard term	Patient-friendly version
Oral use	<Ges via munnen> [Is given through the mouth]
Cutaneous/transdermal use	<För användning på huden> [To be used on the skin]
Ocular use	<För användning i ögat> [To be used in the eye]

Section 23:7 The withdrawal period, even if this is nil, in the case of veterinary medicinal product administered to food-producing animals.

- Based on the information in the withdrawal period section in the SPC. The withdrawal period shall be stated, even if it is zero days.
- The withdrawal period is only stated for food-producing animals.
- When appropriate, this section also includes separate text; general information that is not connected to specific types of withdrawal or the withdrawal period for a certain target species according to the SPC.

For example: < Mjölk från ston får ej användas för human konsumtion. > [Milk from mares may not be used for human consumption]
< Ej till fjäderfä som producerar ägg för human konsumtion. > [Not for poultry producing eggs for human consumption]
(additional examples may be found in the list “Karenstider för alla i Sverige godkända läkemedel avsedda för livsmedelsproducerande djur” (ref. 10).

Section 23:8 Special storage precautions, if any.

- Based on the information in the section on storage in the SPC.
- The following text is used to inform the user of the expiry date:
Använd inte detta läkemedel efter utgångsdatumet på <etiketten> <kartongen> <flaskan> <...><efter { <Utg.dat.> eller <EXP> eller <Utg.dat. eller EXP> }. <Utgångsdatumet är den sista dagen i angiven månad.>
[Do not use this medicinal product after the expiry date indicated on the <label><box><bottle><...> <after {<Exp.date.> or <EXP> or <Exp.date. or EXP> }. <The expiry date is the last day of the month specified.>]
- The storage precautions shall be the same as those in the SPC and should be expressed as stated in the package leaflet in the QRD template (ref. 1).

Section 23:9 Information important for the fulfilment of the requirement for safety and protection of public health, including special precautions to be during use, and other warnings, if such are required for the veterinary medicinal product in question.

- Subheadings in accordance with the QRD template should be used in this section in order to make the information clear (ref. 1).
- The information is based on the warning section in the SPC.
- The following information should be included in this section.
 - Information about pregnancy, lactation and lay, based on the corresponding section in the SPC.
 - Information about interactions, based on the corresponding section in the SPC.
 - Information about overdosing, symptoms and any practical advice for the animal owner in the event of an overdose, based on the corresponding section in the SPC.

- Information about special warnings or other information that is strictly directed at veterinarians may well be included in the section *Other Information* that comes at the end of the package leaflet.
- Standard wordings for warnings for animals and for people who administer the medicinal product, respectively, and that are stated in the QRD template for the SPC should also be listed on the package leaflet (ref. 1).

Section 23:10 Specific precautions for the disposal of unused medicinal product or waste derived from medicinal products, if required.

- Based on the information in Section 6.6 of the SPC.
- Standard wordings in accordance with the QRD template for medicinal products for veterinary use should be used (ref. 1).

Section 23:11 The date of the most recent version of the package leaflet.

- The Medical Products Agency will add the date once the package leaflet is ready for approval.

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.

- Information in the package leaflet shall be consistent with the content of the SPC and be otherwise beneficial for the user.
- The user may be animal healthcare professional, farmer and/or animal owner.
- The package leaflet shall be written in a way that the general public can understand. The language shall be easy to understand (or complemented with explanations) and adapted to the user and animal owner.
- The information should be concise.
- The package leaflet may also cover, e.g., information on the practical handling of equipment when the medicinal product shall be mixed into large quantities of food or drinking water for whole groups of livestock. However, the information may not conflict with the information provided in the SPC.
- The medicinal product's positive properties should be presented in a balanced way, but may *not* contain advertising messages of emotive language.
- Particularly important information is given the appropriate prominence in each section. Prominent placement can be done with the help of bulleted lists, boxes or starting each

section with particularly important information. Additional subheadings, aside from those already stipulated, may be used.

- If there is no information under a certain heading, “Ej relevant” [not applicable] is written under the heading.
- A combined package leaflet may be used if the package leaflets are identical for more than one strength. In these cases, only the strength-specific information may differ. The aim of the combined package leaflet is to make the dosage instructions clear to the user.
- It is sufficient to provide *one* package leaflet in multipacks. Multipacks of a parallel imported medicinal product should contain the same number of package leaflets as the directly imported medicinal product.
- The printed package leaflet shall be easily legible, even for those with impaired vision. The use of upper case letters should be avoided. Good legibility may also be achieved by splitting the text up into short paragraphs with spaces between them. Use a clear and easily legible font. Avoid paper of a quality that allows text from one side to be visible on the other.
- The following information may be written in the section Other Information.
 - *Pack sizes*: All pack sizes shall be listed in accordance with the SPC.
 - *Information for veterinarians or animal health professionals*: The Other Information section may contain information about pharmacodynamics, pharmacokinetics and information directed at veterinarians or animal health professionals.
- Only information relating to the Swedish market shall be included in the Swedish package leaflet (in Word format) approved by the Medical Products Agency.

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.

Common regulations

Relating to the labelling and package leaflets of medicinal products for human and veterinary use.

Symbols and pictograms

Section 25 The labelling on the outer packaging, immediate packaging or package leaflet may not include information, symbols or pictograms product-promotion 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, 3, 17 and 23, as well as other information which is consistent with the summary of product characteristics, and of use to the patient.

- Symbols, information and/or images may not constitute advertising.
- Symbols, colours and/or images may not be dominant in relation to the textual information on the packaging and may not disrupt the text printed on the packaging either.
- Symbols and images that aim to clarify information may be allowed on the packaging, especially if there is a risk of incorrect use. In this case, the information shall also be included in the package leaflet, labelling text, and SmPC/SPC.
- No images of different organs to clarify their area of use may appear on the packaging of prescription-only medicinal products.
- If the pharmaceutical form is pictured, the image shall be actual size.
- The logo of the MAH and the local representative may appear on the packaging and on the printed package leaflet.
- The logo may not dominate the packaging.
- One condition of the logo being accepted is, however, that the company (name and address) also is stated in clear text.
- For parallel imported medicinal products, the manufacturer's logo may be accepted.

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.

Variations of the labelling/package leaflet

Section 27 Six months after the variation has been approved, no packaging with the previously approved labelling or package leaflet may be released onto the market, unless otherwise decided by the Medical Products Agency.

The Medical Products Agency can decide that parallel sales of packaging with previously approved and new labelling/package leaflet may take place for a limited transitional period.

When it comes to certain changes (such as name, strength or pharmaceutical form, serious safety updates, certain contraindications and quality changes, *etc.*), the Medical Products Agency may decide to prohibit parallel sales, or alternatively to limit the time of parallel sales.

After name changes, parallel sales of packaging with previously approved and new labelling/package leaflet are usually allowed for 1 month.

Exemptions

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

References

LVFS

The Swedish Medical Products Agency's codes of statutes, published on the Medical Products Agency's website:

<https://lakemedelsverket.se/english/overview/Legislation/>

The Medical Products Agency also publish a consolidated version of LVFS 2005:11 on <https://lakemedelsverket.se/>, containing the amendments, but the consolidated document has been compiled for the purposes of information. Consequently, always check the wording of the printed version. See the respective statute for information about temporary provisions that are no longer current or are due to come into force, as well as all the footnotes.

References

ref. 1	<p>QRD templates for medicinal products for both human and veterinary use</p> <p>Search path http://www.ema.europa.eu/ema/</p> <p>Continue to:</p> <ul style="list-style-type: none">• Human regulatory/ Marketing authorisation/ Product Information/ Templates (For medicinal products for human use, there are separate templates for medicinal products within centralised and mutual/decentralised/national procedures, respectively.)• Veterinary regulatory/Marketing authorisation/Product Information/ Templates <p>Search path http://www.hma.eu/</p> <p>Continue to:</p> <ul style="list-style-type: none">• Human Medicines/ CMDh/ Templates/ QRD• Veterinary Medicines/ CMDv/ Procedural guidance/ SPC, Labelling and Package leaflet
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ref. 2	<p>Blue Box</p> <p>Medicinal products for human use: Blue-box requirements</p> <p>Search path: The CMDh website http://www.hma.eu/cmdh.html</p> <p>Continue to: Procedural Guidance/ Application for MA/ 'Blue-box' requirements</p> <p>Medicinal products for veterinary use:</p> <p>CMDv GUI-27 Packaging 'blue-box' requirements in MRP/DCP</p> <p>Search path: The CMDv website http://www.hma.eu/cmdv.html</p> <p>Continue to: Procedural Guidance/ Packaging 'blue-box' requirements in MRP/DCP</p>
ref. 3	<p>EDQM Standard Terms</p> <p>Search path https://standardterms.edqm.eu/</p>
ref. 4	<p>Appendices to QRD templates for medicinal products for human use</p> <p>Appendix III (appendix to the Quality Review of Documents templates for human medicinal products)</p> <p>Appendix IV (Terms for batch number and expire date to be used on outer and/or inner labelling)</p> <p>Appendix V (Adverse-drug-reaction reporting details)</p> <p>Search path http://www.ema.europa.eu/ema/</p> <p>Continue to: Human regulatory/ Marketing Authorisation/Product Information/ Templates</p>
ref. 5	<p>OTC substance reports</p> <p>Search path: https://lakemedelsverket.se/english/product/Medicinal-products/OTC/</p>
ref. 6	<p>EMA List of medicines under additional monitoring</p> <p>Search path: http://www.ema.europa.eu/ema/</p> <p>Continue to:</p> <p>Human regulatory/ Post-authorisation/ Pharmacovigilance/ Medicines under additional monitoring/ List of medicines under additional monitoring</p>
ref. 7	<p>Excipients and information for the package leaflet</p> <p>English version and Swedish translation of the applicable Annex:</p> <p>Excipients in the label and package leaflet of medicinal products for human use</p> <p>Search path http://www.ema.europa.eu/ema/</p> <p>Continue to:</p> <p>Human regulatory/Marketing authorisation/Product Information/ Reference and guidelines/ Excipients labelling</p>
ref. 8	<p>Alternatives for how to indicate reporting of adverse reactions</p> <p>Search path http://www.lakemedelsverket.se/</p> <p>Continue to:</p> <p>Företag/ Läkemedel/ Nya godkännanden, ändringar och förnyelser/ Produktinformation/ Biverkningsrapportering i SmPC och PL</p>

ref. 9	<p>Quality review of documents (QRD) guidance on the use of approved pictograms on the packaging of veterinary medicinal products authorised via the centralised (CP), mutual recognition (MRP) and decentralised procedures (DCP)</p> <p>Search path http://www.ema.europa.eu/ema/</p> <p>Continue to:</p> <p>Veterinary regulatory/ Marketing authorisation/ Product Information/ Reference and guidelines</p>
ref. 10	<p>Withdrawal periods for all veterinary medicinal products to be administrated to food-producing species that have been approved in Sweden</p> <p>Search period: http://www.lakemedelsverket.se/</p> <p>Continue to:</p> <p>Hälso- & sjukvård/Förskrivning/Veterinärmedicinska läkemedel/Karenstider</p>