

# **Guideline to the Medical Products Agency’s regulation (2005:11) on labelling and package leaflets for medicinal products.**

## **Contents**

|  |           |
|--|-----------|
| <b>Introduction .....</b>  | <b>1</b>  |
| <b>Labelling for human medicines .....</b>   | <b>2</b>  |
| <b>Package leaflets for medicinal products for human use .....</b>                 | <b>8</b>  |
| <b>Labelling of veterinary medicinal products .....</b>                            | <b>18</b> |
| <b>Package leaflets for veterinary medicinal products .....</b>                    | <b>23</b> |
| <b>Common regulations (applies to products for human and veterinary use) .....</b> | <b>30</b> |

## **Introduction**

This guideline is intended to promote a consistent application of the Medical Products Agency’s regulation on labelling and package leaflets for medicinal products. The guideline is aimed at the companies that will be producing labelling and package leaflets. The intention of the guideline is to describe and to interpret the contents of current legislation. A guideline may contain additional information compared with the legislation, in order to improve understanding of the requirements of the legislation.

Guidelines are not legally binding, but rather they represent examples and recommendations that may be useful in the assessment and application of the legislation. The guideline does not exclude other approaches for achieving the intended results of the legislation, but rather it presents the understanding of the Medical Products Agency.

## Labelling for human medicines

The Guideline should be read as a supplement to the regulation and not as a freestanding document. In the following, the section numbers refer to equivalent sections in the regulation. Not all the sections in the regulation are to be found in the guideline but instead only those sections that are intended to clarify the regulation are included.

The external dimensions of the label shall be stated on submitted labelling proposals, and where possible these shall be submitted as full scale examples. If manufacturing batch numbers and expiry dates are to be printed, this shall be stated when labels are submitted. The design of the blister shall be stated (number of tablets and how they are arranged in the blister). This is to ensure that the name of the drug and its strength are legible when there is only one tablet left.

Proposed standard texts, shown within <...>, should be used. The guideline states whether deviations are permissible.

Words within {...} are replaced by relevant text.

The following abbreviations are used: SPC=summary of product characteristics, MAH=Marketing authorisation holder.

### *Information on outer packaging and immediate packaging*

**Section 2(1).** The name of the drug and its strength shall be stated clearly and in an easily legible font. If possible, the name and strength should be stated on the same line and in the same style and size.

There may not be anything else between the name and the strength. The entire name of the medicinal product shall be given in the same colour. Different colours may be used to distinguish between different strengths of the same drug. The strength is marked in different colours next to the name. The strength is stated only once on each side of the package. For parallel-imported products, the colour marking shall be the same as that used for the direct import.

The pharmaceutical form is an important identifying component for a medicinal product, and it shall always be stated next to the name and strength.

The generic name (active substance) shall be given beneath the name of the medicinal product, even if it already forms a part of the medicinal product's name. If the product contains 3 or less active substances, the generic name shall be stated. If it contains four or more active substances, the generic names do not have to be shown next to the name of the medicinal product. The generic name should be shown in a font size that is half the size used for the name of the medicinal product. The generic name shall be shown in the form that corresponds to the strength. E.g. if the strength of the product is 8 mg and it contains buprenorphine hydrochloride 8.64 mg equivalent to buprenorphine 8 mg, then it is buprenorphine that is shown next to the name of the medicinal product. Note that despite the presence of any generic names shown next to the name of the medicinal product, they shall always be stated in the declaration (see section 2(2)).

For immunological products, the indication should be stated on the packaging. For vaccines, this is given as follows. <Vaccin mot...>

Immunological products are taken to mean vaccines, toxins, sera and allergens.

**Section 2(2).** The declaration includes a statement of the form of the active substance, given as an amount, that is equivalent to the strength. Any other forms are given without amounts e.g. buprenorphine hydrochloride equivalent to buprenorphine 8 mg. The declaration should begin with <1 tablett innehåller...> <1 ml innehåller...> or similar. For vaccines, the wording is as follows <1 dos innehåller...>. Nationally, the declaration in Latin is accepted on packages with labelling in a number of different languages.

**Section 2(3).** The pharmaceutical form shall be stated in accordance with the applicable Standard Terms<sup>1</sup> using either the full name or the shortened form as stated in the Standard Terms<sup>1</sup>. Where appropriate, the pack size may be used as the pharmaceutical form, e.g. <30 tableter>. If the outer packaging contains several drug containers, this should be indicated by the pack size, e.g. if there are two jars each containing 30 tablets, this should be stated as <60 (2x30) tableter>. If there is sufficient space, the pack size shall always be shown on all the sides of the package where the name, strength and pharmaceutical form are stated.

The outer packaging shall also state whether the package contains any cannulas, swabs or such like.

Where the contents of medicinal product packages are pressurised, both net and gross weights shall be given.

**Section 2(4).** Products for external use are in this case taken to include locally applied products. Examples of such products are skin products and products that are administered to the lungs via inhalation, and products that are administered and which act locally on the oral, nasal, rectal or vaginal mucosa. For vaccines, there shall be both a qualitative and quantitative statement of any adjuvant/adsorbent present.

**Section 2(5).** Method of administration is e.g. <sväljes hela> <införes i ändtarmen>. Route of administration is e.g. orally, rectally, intravenously, etc. The route of administration does not have to be stated if administration is oral. For injection and infusion drugs, the route of administration is stated on both the outer packaging and on the immediate packaging.

**Section 2(6).** <Förvaras utom syn- och räckhåll för barn> replaces the previously used <Förvaras oåtkomligt för barn>. For previously approved products, this change is made at the same time as other updating of the labelling.

**Section 2(7).** The text <Läs bipacksedeln före användning> shall be on the outer packaging for all products with an approved package leaflet.

**Section 2(8).** Flammable medicinal products shall be labelled in accordance with the statutes of the Swedish Rescue Services Agency.

This labelling shall include any necessary instructions for use, e.g. <omskakas> <ska spädas> <upplöses i ett glas vatten>.

Also give any other information that may be useful to the user, e.g. <munnen bör sköljas efter varje inhalation> <kan färga hud, hår och kläder> <kan färga urinen/avföringen> <kan missfärga mjuka kontaktlinser>.

The following texts are examples of standard texts that should be used for each product type or content.

*Cytostatics:* <Cytostatikum>

*Dextropropoxiphene:* <Intag av X tillsammans med vissa läkemedel eller alkohol liksom överdos av X kan snabbt medföra livshotande andningsförlamning och hjärtpåverkan. Alkohol ska aldrig tas tillsammans med X. Drick aldrig alkohol inom 1 dygn före eller minst 2 dygn efter intag av X. Förvaras utom syn- och räckhåll för barn och ungdomar.>

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<sup>1</sup> Standard Terms: Pharmaceutical dosage forms, Routes of administration, Containers as published by EDQM (European Directorate for the Quality of Medicines), see also [www.pheur.org](http://www.pheur.org).

The final sentence replaces the standard text <Förvaras utom syn- och räckhåll för barn>.

*NSAIDs, OTC packages:* <Om du försöker bli eller är gravid ska X undvikas och endast användas efter läkares ordination. Mer information finns i bipacksedeln.>

<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.>

*Paracetamol:* <**VARNING! Högre doser än de rekommenderade medför risk för mycket allvarlig leverskada.**>

<Använd inte X utan läkares ordination om du har alkoholproblem eller leverskada eller om du samtidigt använder andra smärtstillande läkemedel som innehåller paracetamol.>

<Förvaras utom syn- och räckhåll för barn och ungdomar.>

The final sentence replaces the standard text <Förvaras utom syn- och räckhåll för barn>.

The following texts are examples of suitable warning texts that must be used for each product type or content.

*Acetylsalicylic acid, OTC packages:* <Ges inte till personer under 18 år med feber utan att läkare tillfrågats.>

*Benzoyl peroxide products and tretinoin:* <Undvik solning, även i solarier vid behandling med detta läkemedel.>

*Steroids and steroid derivatives for external use:* <Undvik att få <läkemedlet> <salvan> <X> i ögonen.>

**Section 2(9).** The expiry date is shown as <Utg.dat.>. In the expiry date, the month shall be indicated as two digits or using letters and the year shall be shown using four digits. The expiry date can also be written as <EXP> on small packages if required due to lack of space. The date given after <Exp. date> or <EXP> means that the medicine may be kept up to and including the indicated month. <Utg.dat.> replaces the previously-used <Anv. före>. The date given after <Anv. före> means that the medicine can be kept up until the indicated month. For previously approved products, this change is made at the same time as other updating of the labelling.

Where appropriate, the shelf-life is given for opened packages or for the product after preparation.

**Section 2(10).** The same storage instruction(s) that are given in the SPC shall be used and expressed as follows.

<Förvaras vid högst <25°C> <30 °C>>  
<Förvaras i kylskåp>  
<Förvaras och transporteras kallt>  
<Förvaras i djupfrost tillstånd>  
<Förvaras och transporteras i djupfrost tillstånd>  
<Förvaras i skydd mot kyla> <eller> <Får ej frysas>  
<Förvaras i originalförpackningen>  
<Tillslut {container}<sup>2</sup> väl>  
<Förvara {container}<sup>2</sup> i ytterkartongen>

Use <Ljuskänsligt> <Fukt känsligt> in addition to the storage instructions <Förvaras i originalförpackningen> <Tillslut {container} väl> and <Förvara {container} i ytterkartongen>

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<sup>2</sup> The packaging is replaced by whatever type of packaging it is, e.g. jar, blister, etc.

If the storage instructions according to the SPC are <Inga särskilda förvaringsanvisningar> or <Inga särskilda temperaturanvisningar>, this shall not be included in the labelling.

**Section 2(11).** State any special precautions for disposal if disposing of unused medicine or waste deriving from the medicine. The following text may be used for plasters. <Använt plåster viks ihop med häftmassan inåt och kasseras på ett säkert sätt så att barn inte kommer åt plåstret.>

**Section 2(12).** The name and address of the MAH shall be given. The name and address of a local representative may be given, though this is not a requirement. The local representative shall be registered with the Medical Products Agency. If a stated company only provides information about the medicine, then the heading <Information lämnas av> may be used instead.

If only MAH is given on the labelling, the heading Marketing Authorisation Holder does not have to be used. Where the local representative/information-provider is also identified on the labelling, at least one heading shall be given to allow a distinction to be made between the parties with an interest in the product. For parallel-imported medicines, the re-packager and manufacturer shall also be identified.

The minimum requirement is name, town/city and, where appropriate, country (i.e. when the town/city is not in Sweden). References to websites are not acceptable.

**Section 2(13).** The marketing authorisation number shall be preceded by <MTnr>. On multilingual packaging <MTnr> only needs to be given *once*. Each number is then followed by the appropriate national code, with <SE> used for Sweden. An appropriate place for the MA number is together with the name and address of the MAH.

**Section 2(14).** The manufacturer's manufacturing batch number should be preceded by e.g. <Satsnr> <Batchnr> <Lot>. It is best if this is placed next to the expiry date.

**Section 2(15).** The Nordic article number (abbreviated to <Vnr> on the packaging) shall be stated at least once alongside the name of the medicinal product, on the outer packaging or if there is no outer packaging, on the immediate packaging. The item number should be placed in the top-right corner on the front of the packaging.

It is extremely desirable from a safety perspective that the item number should also be given as a barcode, and if possible also on the inner packaging, e.g. fluid bags. The company is responsible for ensuring the accuracy of the information in the barcode.

Where drugs are to be prepared prior to use, e.g. cytostatics, it is desirable for the item number also to be included on the inner packaging.

*Multiple packs:* It is sufficient for the item number to be shown only on the outer packaging. If an item number is also shown on each sub-package, then this number must not be identical to the one on the outer packaging, i.e. the various sub-packs may not have the same item number as is given on the multiple pack.

**Section 2(16).** The possibility of placing the pharmacy label on the packaging without obscuring any information shall be born in mind. E.g. a space can be left for the pharmacy label.

**Section 2(17).** OTC medicine packages shall carry information about indication(s) approved for non-prescription treatment and ordinary dose levels for these indications. The indication shall be placed on the *front* of the packaging. If there is an approved abbreviated form for the indication (e.g. "for sore throats") this may be stated, though in that case it is placed on the front of the packaging. A full indication as on the package leaflet shall be placed elsewhere on the packaging, ideally with the dosage instructions.

Special warnings and information shall be given on the outer packaging, since in most cases the medicine will be bought without the patient having been prescribed it by a doctor. A warning of this kind may be e.g. that pregnant and/or breast-feeding women must not use the medicine.

**Section 2(18).** Where a product has been approved as a natural remedy, the text <Naturläkemedel> shall be placed on the front of the packaging.

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

**Section 3** The name of the medicinal product as in section 2(1) means the name of the medicinal product following by its strength and pharmaceutical form. Active substance/s shall also be stated.

**Section 4** The name of the medicinal product as in section 2(1) means the name of the medicinal product following by its strength and pharmaceutical form. The following is applicable, in addition to the minimum requirements.

For parallel-imported products, the importer's name and address shall also be given in order to ensure traceability. Where drugs are to be prepared prior to use, e.g. cytostatics, it is desirable also to have the item number on the inner packaging, see 2(15).

**Section 5** Has been abolished with effect from 14 December 2009.

*Braille*

**6 §** The name of the medicinal product (and if available in different strengths, also its strength) shall be printed in Braille on the outer packaging or, if there is no outer packaging, on the immediate packaging. The proposed labelling shall include the location of Braille text and also a translation of the text into Swedish to allow the Medical Products Agency to assess that the correct text is included. The company is responsible for ensuring that the Braille text on the labelling is correct. Braille text must not be placed so as to make other text difficult to read. Braille text is not required on medicinal product packaging that is not handled by the patient.

Products approved prior to 30 November 2005 are subject to transitional regulations on the introduction of Braille text as follows:

Braille text must be introduced on packaging *no later than 5 years* after the medicinal product was last approved.

*Example:* The medicinal product was approved for sale of 01 May 2002. The packaging must therefore be labelled with Braille text no later than 01 May 2007.

For parallel-imported medicinal products, the date used is when the parallel-imported product was most recently approved. Parallel imports do not follow direct imports in this case.

*General requirements for labelling*

**Section 7** A medicinal product is identified by name, strength, pharmaceutical form, pack size and item number. This information should be placed within the same visual field. The pack size is placed in the top-left corner. The Nordic item number is placed in the top-right corner on the front of the packaging.

The labelling should be designed so as to minimise the risk of confusion. This is done e.g. by using colours or coloured strips to distinguish between strengths and different products. If there is more than one product with the same pharmaceutical name, e.g. different pharmaceutical forms or in case of parallel import, the products should be distinguished by means of different packaging designs. Parallel-imported products shall be distinguished both from identical direct-imported products and from other parallel-imported products. The contrast between text and background shall be clear. The layout should not contain any figures, lines or anything else that impedes legibility. All text should run in the same direction (preferably horizontally) on the labelling. See also *Symbols and pictograms* section 25.

More than one language on the packaging may be acceptable if there is sufficient space. On multilingual packaging, information in the various languages should be collected together. The languages should not be presented as continuous text separated by slashes. E.g. the various sides of a package can be used for different languages. The company is responsible for ensuring that the information in all the languages is identical. For parallel-imported medicinal products, the same packaging material may be used as is used in the exporting country and the packaging material may be re-labelled so as to ensure compliance with LVFS 2005:11. In these cases, foreign text may be accepted as long as it is not in conflict with the labelling in Swedish.

The labelling shall be easily legible, including for people with impaired vision. The size of the letters should be at least Times New Roman 9 point, and larger if possible. The use of capital letters should be avoided.

If the labelling consists of a fold-out label, e.g. a fold-out package leaflet, then the label that sits directly on the packaging (beneath the fold-out label) shall be identical to the fold-out label.

#### *Dose-dispensed medicinal products*

**Section 9** Packages that are intended to be used only for dose-dispensing and which may not therefore be prescribed to an individual patient do not need to have full labelling. Examples of information that may be excluded are <Förvaras utom syn- och räckhåll för barn> and other warning texts that are directed only at the patient. These packages shall however be labelled with <Endast för dosdispensering>. Package leaflets also do not have to be included in these packages.

## Package leaflets for medicinal products for human use

### General comments

- The following abbreviations are used: SPC=summary of product characteristics, MAH=Marketing authorisation holder.
- The information in the package leaflet shall agree with the contents of the SPC and otherwise be helpful for the patient.
- The language shall be easily comprehensible (or be supplemented with a clarification), and also suitable for the user.
- The information should be concise.
- The package leaflet shall be written in Swedish.
- The final printed package leaflet may contain more than one language, though the information presented in all the languages must be identical. All information in the various languages should be collected together in one place. The company is responsible for ensuring that the information in all the languages is identical.
- Indicated standard texts, shown within <...>, shall be used. The guideline states whether deviations are permissible.
- Words within { ... } are replaced by relevant text.
- The active form shall be used where possible, i.e. <Du bör vara försiktig vid...> instead of <Försiktighet rekommenderas vid...>.
- The positive properties of the medicinal product should be presented in a balanced way, though they may *not* contain advertising messages or any loaded wording.
- Particularly important information should ideally be given a prominent position in any one section. A prominent position may be provided by means of bulleted lists or frames, or by placing particularly important information first in any one section. Additional subheadings, in addition to those already stipulated, may be used.
- Subheadings that lack relevant information may be deleted. The Medical Products Agency requires however that the subheadings "Pregnancy and breast-feeding" and also "Driving and using machines" be included and that these contain information in accordance with the SPC.
- If the package leaflets are identical for several different strengths, a combined package leaflet may be used. In these cases, only strength-specific details may be different. The purpose of the combined package leaflet shall be to make the dosage instructions clear for the user, e.g. when a patient undergoing treatment changes from one strength to another.
- Package leaflets for medicinal products with both OTC and on prescription indications should be separated if possible.
- The printed package leaflet shall be easily legible, including for people with impaired vision. The size of the letters should be at least Times New Roman 9 point, and 12 point if possible. The use of capital letters should be avoided. Good legibility can also be achieved by dividing the text into several short paragraphs that are separated by spaces. Use a clear and easily legible font.
- Long package leaflets should be printed on A4/A5 format paper. The weight of the paper should be no less than 40 g/m<sup>2</sup>. On thinner paper, text can show through on the other side, thus making the package leaflet difficult to read.
- The latest package leaflet template for products approved via a mutual or decentralised procedure, together with standard texts as stipulated by EMEA, shall be used. Template version 07/2008 is inserted below. The template is available from EMEA's website. Explanatory text has been inserted in each section as a supplement or clarification of the requirements as stated in the regulation.



## PACKAGE LEAFLET: INFORMATION FOR THE USER

{(Invented) name strength pharmaceutical form}  
{ Active substance(s)}

If the short form for the pharmaceutical form is used in the labelling (e.g. “tablet” for “film-coated tablet”), this must also be used in the package leaflet. The short form is given in parenthesis after the full pharmaceutical form.

Always use the following introduction for medicinal products available on prescription only.

**<Läs noga igenom denna bipacksedel innan du börjar <ta> <använda> detta läkemedel.**

- Spara denna information, du kan behöva läsa den igen.
- Om du har ytterligare frågor vänd dig till läkare eller apotekspersonal.
- <Detta läkemedel har ordinerats åt dig. Ge det inte till andra. Det kan skada dem, även om de uppvisar symtom som liknar dina.>
- Om några biverkningar blir värre eller om du märker några biverkningar som inte nämns i denna information, kontakta läkare eller apotekspersonal.>

Always use the following introduction for medicinal products available without a prescription.

**<Läs noga igenom denna bipacksedel. Den innehåller information som är viktig för dig.**

Detta läkemedel är receptfritt. X måste trots det användas med försiktighet för att uppnå det bästa resultatet.

- Spara denna information, du kan behöva läsa den igen.
- Vänd dig till apotekspersonalen om du behöver mera information eller råd.
- Du måste kontakta läkare om symtomen försämras eller inte förbättras <inom {number} dagar.>
- Om några biverkningar blir värre eller om du märker några biverkningar som inte nämns i denna information, kontakta läkare eller apotekspersonal.>

### **In this leaflet:**

1. What X is and what it is used for
2. Before you <tar> <använder> X
3. How to <tar> <använder> X
4. Possible side effects
5. How to store X
6. Further information

### **1. WHAT X IS AND WHAT IT IS USED FOR**

Based on data contained in sections 4.1 and 5.1 of the SPC.

Provide a brief account of the medicinal product's mode of action, e.g. <Påverkar hormonhalten...>  
<Påverkar halten serotonin så att du...>.

A brief explanatory text may also be included in this section to provide an objective and balanced description of the positive effect(s) of the medicinal product.

This section may contain the following text, if relevant.

<{Generic name} som finns i {Product name} kan också vara godkänd för att behandla andra sjukdomar som inte nämns i denna bipacksedel. Fråga läkare, apotekspersonal eller annan hälso- och sjukvårdspersonal om du har ytterligare frågor och följ alltid deras instruktion.>

Use the following sentence for medicinal products that are intended only for diagnostic purposes.

<Endast avsett för diagnostik.>

Use the following sentences for all traditional plant-based medicinal products.  
<{Product name} är ett traditionellt växtbaserat läkemedel använt som {indication}

The indications for a traditional plant-based medicinal product are based solely on experience derived from long-term use.>

## 2. BEFORE YOU <TAR> <ANVÄNDER> X

### Do not <Ta> <Använd> X

Based on data contained in section 4.3 of the SPC.

All contraindications must be given.

Begin the section with the following sentence.

<om du är allergisk (överkänslig) mot {active substance(s)} eller mot något av övriga innehållsämnen i X.>

If possible, explain why the medicinal product must not be taken for certain conditions, e.g. <Kan öka risken för hjärtsvikt.>

The following texts are examples of standard texts that should be used for products that contain dextropropoxifene.

**<Intag av X tillsammans med vissa läkemedel eller alkohol liksom överdos av X kan snabbt medföra livshotande andningsförlamning och hjärtpåverkan. Drick aldrig alkohol tillsammans med X. Läs även under <Intag> <Användning> av andra läkemedel.**

Om du har druckit alkohol måste 1 dygn passera innan du kan påbörja en behandling med X. Det verksamma ämnet dextropropoxifen bryts ned och försvinner ut ur kroppen olika snabbt hos olika personer. Minst 2 dygn ska ha passerat efter avslutad behandling med X innan du kan dricka alkohol. X ska inte användas till barn och ungdomar under 18 år.>

### Take special care with X

Based on relevant data contained in section 4.4 of the SPC.

If possible, explain how to go about taking "care". The following types of sentences may be used. <om du ...> <när ...> <Före behandling med X...>

Reference can be made to the section "Pregnancy and breast-feeding" below if the product affects fertility and male reproduction.

The following texts are examples of suitable warning texts that must be used for each product type.

*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.>

*Cytostatics:* <Om <tabletten> <kapseln> går sönder eller löses upp ska händerna tvättas omsorgsfullt med vatten.>

*NSAIDs:* <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.>

The following texts are examples of standard texts that should be used for each product type or symptom.

*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.

Tag 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 så snart som möjligt om du har tagit för stor dos.>

<Förvaras utom syn- och räckhåll för barn och ungdomar.>

The final sentence replaces the standard text <Förvaras utom syn- och räckhåll för barn>.

*Agranulocytosis:* If agranulocytosis is mentioned in section 4.4 or 4.8 of the SPC, the following warning should be included on the package leaflet in the section "Take special care with X" or "POSSIBLE SIDE EFFECTS".

<X kan i sällsynta fall påverka de vita blodkropparna så att infektionsförsvaret försämras. Om du får en infektion med symtom såsom feber med kraftigt försämrat allmäntillstånd eller feber med lokala infektionssymtom såsom exempelvis ont i halsen/svalget/munnen eller vattenkastningsbesvär, ska du snarast uppsöka läkare så att man via blodprov kan utesluta en brist på vita blodkroppar (agranulocytos). Det är viktigt att du då informerar om din medicinering.>

*Angio-oedema:* If angio-oedema is mentioned in section 4.4 or 4.8 of the SPC, the following warning should be included on the package leaflet in the section "Take special care with X" or "POSSIBLE SIDE EFFECTS".

<Sluta att ta X och kontakta omedelbart läkare om du får något av följande symptom (angioödem)

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

*Rhabdomyolysis:* If rhabdomyolysis is mentioned in section 4.4 or 4.8 of the SPC, the following warning should be included on the package leaflet in the section "Take special care with X" or "POSSIBLE SIDE EFFECTS".

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

#### **<Intag> <Användning> other medicines**

Based on relevant data contained in section 4.5 of the SPC.

Explain why it should not be combined with other products. The following types of sentences may be used. <Kan öka risken för biverkningar.> <Effekten av X kan öka/minska om...> <Effekten av {the other medicinal product} kan öka/minska om...>.

If there is sufficient reason to do so, also state the time interval between taking different medicines.

Always include one of the following sentences.

<Tala om för läkare eller apotekspersonal om du tar eller nyligen har tagit andra läkemedel, även receptfria sådana, naturläkemedel eller andra naturprodukter.>

<Tala om för läkare eller apotekspersonal om du tar eller nyligen har tagit andra läkemedel, även receptfria sådana.>

For example, the following text layout could be used. <X kan påverka eller påverkas av vissa läkemedel som innehåller följande verksamma ämne/ämnen:> This sentence is then followed by a bulleted list of the various substances and, for each of these, a description of its area of application. An ordinary indication for an interacting medicine can also be mentioned as a description of the medicine, e.g. <mot epilepsi> <behandling av allergi> <används vid rökavvänjning>.

Interactions with substances that are not registered in Sweden may nevertheless be stated. These may be commonly-occurring licensed medicines or they may be of relevance where medicines have been previously acquired abroad.

Include the following sentence for non-prescription painkillers.

<Använd aldrig flera olika smärtstillande medel samtidigt utan att rådfråga läkare eller apotekspersonal.>

#### **<Intag> <Användning> X with food and drink**

If certain foods or drinks are contraindicated, a reference to the section "Do not <Ta><Använd> X" shall be included.

Explain why the medicine must not be combined with certain foods.

Where appropriate, specify which fluid is suitable/unsuitable for consumption with the medicine, e.g. grapefruit juice, other acidic fruit juice, milk.

Where appropriate, provide information about the combination with alcohol. Explain why the combination is unsuitable (increased risk of side effects, interaction, unsuitable in combination with certain diseases, etc.).

If there is reason to do so, also state the time intervals for food/drink.

#### **Pregnancy and breast-feeding**

Based on relevant information in section 4.6 of the SPC.

If the medicinal product is contraindicated during pregnancy and/or when breast-feeding, there must be information in the section "Pregnancy and breast-feeding" and "Do not <Ta> <Använd> X".

If the medicinal product affects fertility and male reproduction, information about this shall be provided here. For example, fertility and male reproduction is explained as reducing the chances of having children.

The following texts are examples of standard texts that should be used for products that contain NSAIDs/acetylsalicylic acid.

Where the medicinal product is contraindicated during the final trimester and the medicinal product may be used with caution during the rest of the pregnancy, the following text shall be included in the package leaflet.

<Gravida kvinnor ska inte använda X under de tre 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.

X passerar över i modersmjölk, men påverkar troligen inte det ammade barnet.>

Insert the following sentence if relevant.

<Rådfråga läkare eller apotekspersonal innan du tar något läkemedel.>

#### **Driving and using machines**

Based on data contained in section 4.7 of the SPC.

The following types of sentences may be used.

<Kör inte bil därför att...>

<Använd inte verktyg eller maskiner.>

Include any side effects that may influence the risk of negative effects. Examples of such side effects are tiredness, dizziness and visual disorders.

Pay attention to any symptoms of illness that may affect the ability to drive or use machines.

Include the following text for most medicines.

<Du är själv ansvarig för att bedöma om du är i kondition att framföra motorfordon eller utföra arbete 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.>

Exceptions are made for those medicinal products that, under 4.7 of the SPC, have the text "X has no or negligible influence on the ability to drive and use machines", and also for certain types of medicinal product for which the text is not considered relevant, such as vitamin preparations, softening agents and ointments and vaccines intended for paediatric use.

### **Important information about some of the ingredients of X**

Include warning texts about excipients in accordance with the List of Excipients<sup>3</sup>.

### **3. HOW TO <TAR> <ANVÄNDER> X**

Based on relevant data contained in section 4.2 of the SPC.

State how the patient is to dose and administer the medicinal product. Preferably only the most commonly occurring dose level should be given. A sentence can be inserted to the effect that the dose level may be individually adjusted (possibly dependent on bodyweight, symptoms, etc.). Avoid long and complicated descriptions, e.g. for different patient groups or for different indications.

The following types of sentences may be used.

<<Ta> <Använd> alltid X enligt läkarens anvisningar. Följ alltid läkarens ordination och anvisningarna på apoteksetiketten. Rådfråga läkare eller apotekspersonal om du är osäker.> <Vanlig dos är...>

Include any relevant instructions, e.g. <tuggas> <omskakas> <löses i ett glas vätska> <tas vid samma tidpunkt som...>.

State the route of administration in a way that is patient-friendly.

For more complicated pharmaceutical forms, a description of the pharmaceutical form is supplemented with clarifying information as in the following examples.

Modified-release capsule: explain what modified release entails.

Oral suspension: it is important that it is clear that it must be swallowed.

Orodispersible tablet: may be described using the text <löser upp sig i munnen>.

The following types of sentences may be used.

<Svälj <läkemedelsformen> <X> med ett glas vätska.>

Combined as appropriate with <Får inte tuggas eller krossas.>

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<sup>3</sup> For the List of Excipients, see the guidelines issued by the European Commission in July 2003: Guidelines for Medicinal products for human use, Safety, environment and information, Excipients in the label and package leaflet of medicinal products for human use (Notice to applicants, Volume 3B), for the Swedish translation see [www.lakemedelsverket.se](http://www.lakemedelsverket.se) / Företag / Läkemedel / Nya godkännanden, ändringar och förnyelser / Märkning, produktresuméer och bipacksedlar / Excipientlistan.

Specify a suitable liquid. For further information, refer to the section "<Intag> <Användning> X with food and drink".

If possible, state for how long the medication is to continue (short course/long-term treatment).  
If relevant, include advice to contact a doctor if the anticipated effect is not obtained.

Consider using a bulleted list to clarify the dosing instructions. Include pictures if appropriate.  
Detailed instructions for use may be placed at the end of the package leaflet, with a reference in the section "HOW TO <TAR> <ANVÄNDER> X".

Handling instructions directed at nursing staff are put at the end of the package leaflet.

#### **If you <har tagit> <använt> more X than you should**

Begin the section with the following sentence.

<Om du fått i dig för stor mängd läkemedel eller om t.ex. ett barn fått i sig läkemedlet av misstag kontakta läkare, sjukhus eller Giftinformationscentralen (tel. 112) för bedömning av risken samt rådgivning.>

Add possible symptoms of overdosing.

#### **If you forget to <ta> <använda> X**

Begin the section with the following sentence, if relevant.

<Ta inte dubbel dos för att kompensera för glömd <tablett> <dos> <...>.>

Give an example of what to do if you forget to take a dose as prescribed, e.g. with a meal or before going to bed.

#### **If you stop <ta> <använda> X**

Indicate any withdrawal effects that may result from ending the treatment. Also provide information about medicines that have to be gradually reduced. Refer if necessary to the section "POSSIBLE SIDE EFFECTS".

Insert the following sentence if relevant.

<Om du har ytterligare frågor om detta läkemedel kontakta läkare eller apotekspersonal.>

## **4. POSSIBLE SIDE EFFECTS**

Based on data contained in section 4.8 of the SPC.

All undesirable effects in the SPC must also be included in the package leaflet.

Begin the section with the following sentence.

<Liksom alla läkemedel kan X orsaka biverkningar men alla användare behöver inte få dem.>

Particularly severe side effects should be clarified by being written out separately. Include information about what a patient who is suffering from side effects must do (see the doctor, etc.).

The side effects should be shown according to frequency as in the SPC (avoid %). Below is one way of describing the frequency of side effects

Very common (occurs in more than 1 in 10 users):

Common (occurs in more than 1 in 100 users):

Uncommon (occurs in fewer than 1 in 100 users):

Rare (occurs in fewer than 1 in 1,000 users):

Very rare (occurs in fewer than 1 in 10,000 users):

Has been reported (occurs in an unknown number of users):

The side effects should be described using terms that primarily describe symptoms. Use simple language. For certain patient groups who can be expected to be more familiar with their conditions, slightly more specialised terms may be used.

For descriptions of agranulocytosis, angio-oedema and rhabdomyolysis, see under section 2.

Certain severe side effects of the skin may be described as follows.

Stevens-Johnson syndrome: changes to the skin and the mucosa (sometimes severe).

Lyell's syndrome, epidermal necrolysis: severe extensive skin damage (skin peeling).

Where several side effects occur in the same organ system and produce similar symptoms, these side effects may be grouped. E.g. various heart diagnoses may be described as <påverkan på hjärtats rytm> and various diagnoses may be described as <påverkan på blodbildningen>.

Side effects may occur as a result of gradual withdrawal. Information about this is included in the section entitled "If you stop <ta> <använda> X".

Include the following sentence at the end of this section <Om några biverkningar blir värre eller om du märker några biverkningar som inte nämns i denna information, kontakta läkare eller apotekspersonal.>.

## 5. HOW TO STORE X

Based on data contained in section 6.4 of the SPC.

The following sentences must always be included

<Förvaras utom syn- och räckhåll för barn.>

<Används före utgångsdatum som anges på <etiketten> <kartongen> <flaskan><...><efter {abbreviation used for the expiry date}.>

<Utgångsdatumet är den sista dagen i angiven månad.>

Where abbreviations for expiry dates are given on the labelling, the complete term shall be given in the package leaflet together with the abbreviation used.

<Använd inte X om {description of visible deterioration}.>

This sentence may be moved to the end of the section under the heading "The following information is intended for medical or healthcare professionals only" if some other text is inserted there.

The same storage instruction(s) that are given in the SPC shall be used and expressed as follows.

<Förvaras vid högst <25 °C> <30 °C>>

<Förvaras i kylskåp (2 °C-8 °C)>

<Förvaras och transporteras kallt (2 °C-8°C)>

<Förvaras i djupfrost tillstånd {temperature range}>

<Förvaras och transporteras i djupfrost tillstånd {temperature range}>

<Förvaras i skydd mot kyla> <eller> <Får ej frysas>

<Förvaras i originalförpackningen>

<Tillslut {container}<sup>2</sup> väl>

<Förvara {container}<sup>2</sup> i ytterkartongen>

<Inga särskilda förvaringsanvisningar>

<Inga särskilda temperaturanvisningar>

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<sup>2</sup> The packaging is replaced by whatever type of packaging it is, e.g. jar, blister, etc.

Use <Ljuskänsligt> <Fuktkänsligt> in addition to the storage instructions <Förvaras i originalförpackningen> <Tillslut {container} väl> and <Förvara {container} i ytterkartongen>.

Include the following text (not applicable for the pharmaceutical form plasters).

<Medicinen ska inte kastas i avloppet eller bland hushållsavfall. Fråga apotekspersonalen hur man gör med mediciner som inte längre används. Dessa åtgärder är till för att skydda miljön.>

*Text for the pharmaceutical form plasters*

<Använt plåster ska vikas ihop med den klibbiga sidan inåt och kasseras på ett säkert sätt så att barn inte kommer åt plåstret. Om din kommun bränner hushållsavfall går det bra att kasta plåstret tillsammans med hushållssoporna. Annars lämnas använt plåster tillbaka till apotek, helst i originalförpackningen. Oanvänt läkemedel ska inte spolans ner i toaletten eller kastas bland hushållsavfall. Fråga apotekspersonalen hur man gör med läkemedel som inte längre används. Dessa åtgärder är till för att skydda miljön.>

*Asthma medicines (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.>

## 6. FURTHER INFORMATION

### What X contains

The declaration of contents must be stated in accordance with the SPC and it should be expressed as follows

<Den (de) aktiva substansen(erna) är...>

<Övriga innehållsämnen är...>

The generic name must be stated as an equivalent of the strength.

Option 1: <rosuvastatinkalcium motsvarande 10 mg rosuvastatin> (not 10.34 mg rosuvastatin calcium).

Option 2: <20 mg omeprazolhydroklorid> (not 19.52 mg omeprazole).

### What X looks like and contents of the pack

Include a description of the pharmaceutical form.

For granulate that is intended to be diluted to form an antibiotic suspension, the text <Beredes på apotek till oral suspension> can be written since the customer only sees the prepared suspension.

All pack sizes must be stated in accordance with the SPC.

Include the following sentence if relevant.

<Eventuellt kommer inte alla förpackningsstorlekar att marknadsföras.>

### Marketing Authorisation Holder <och tillverkare> <, tillverkare och ompackare>

If the manufacturer is not the same as the MAH, then <och tillverkare> is deleted from the heading {Name and address}

<tel>

<fax>

<e-post>

The minimum requirement is name, town/city and, where appropriate, country (i.e. when the town/city is not in Sweden). Full address (preferably postal address), a telephone number, a fax number and/or an e-mail address can also be given. References to websites are not acceptable.

### <Tillverkare>

If the manufacturer is not identical to the MAH this heading is also used.



{Name and address }

If the manufacturer is part of the same group as the MAH, the manufacturer does not have to be stated.

Repackagers must always be stated for parallel-imported products.

**<Ompackare>**

{Name and address }

The name of a local representative may be given, though this is not a requirement. The local representative must be registered with the Medical Products Agency. If a stated company only provides information about the medicine, then the heading <Information lämnas av:> may be used instead.

<För ytterligare upplysningar om detta läkemedel, kontakta den lokala företrädaren för innehavaren av godkännande för försäljning:>

**<Lokal företrädare> <Information lämnas av>**

<Namn>

<Adress>

<tel>

<fax>

<e-post>

The minimum requirement is name, town/city and, where appropriate, country (i.e. when the town/city is not in Sweden). Full address (preferably postal address), a telephone number, a fax number and/or an e-mail address can also be given. References to websites are not acceptable.

<Detta läkemedel är godkänt inom Europeiska ekonomiska samarbetsområdet under namnen:>

<{name of the member state}> <{name of the medicinal product}>

<{name of the member state}> <{name of the medicinal product}>

**This leaflet was last approved in {MM/YYYY}** <and the most substantial changes are in section {X}-> {specify heading/paragraph }

The Medical Products Agency will add the date, <ÅÅÅÅ-MM-DD>, once the package leaflet is ready for approval. For parallel-imported products the applicable date is the one written by the applicant in the package leaflet that was submitted for approval.

<[Kompletteras nationellt]>

<Detta läkemedel har godkänts i enlighet med reglerna om ”godkännande i undantagsfall”. Detta innebär att det inte varit möjligt att få fullständig information om detta läkemedel <beroende på att sjukdomen är sällsynt> <av vetenskapliga skäl> <av etiska skäl>.

{name of the member state/national enterprise } kommer att granska all ny information som kan bli tillgänglig varje år och uppdatera information till användaren om det är nödvändigt.>

<Information om detta läkemedel finns tillgänglig på {name of the member state/national authority } hemsida>

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If comprehensive instructions for use are required, these may be placed under the heading <Bruksanvisning>. A reference should then be entered under the section "HOW TO <TAR> <ANVÄNDER> X".

General health information can be included here that does not relate directly to the medicine, e.g. instructions on how to avoid acid reflux or tips for avoiding allergic reactions. Select a suitable sub-heading.

If special instructions are required for medical or healthcare professionals, these are entered under the following heading

<Följande uppgifter är endast avsedda för hälso- och sjukvårdspersonal>.

The information shall consist primarily of preparation instruction, storage instructions (including after preparation), shelf life, any safety instructions for personnel and also e.g. warnings about reactions they may occur when the medicine is administered.

## Labelling of veterinary medicinal products

The guideline should be read as a supplement to the regulation and not as a freestanding document. In the following, the section numbers refer to equivalent sections in the regulation. Not all the sections in the regulation are to be found in the guideline but instead only those sections are included that are intended to clarify the regulation.

The external dimensions of the label shall be stated on submitted labelling proposals, and where possible these shall be submitted as full scale examples. If manufacturing batch numbers and expiry dates are to be printed, this shall be stated when labels are submitted. The design of the blister shall be stated (number of tablets and how they are arranged in the blister). This is to ensure that the name of the drug and its strength are legible when there is only one tablet left.

Proposed standard texts, state within <...>, should be used. The guideline states whether deviations are permissible.

Words within { ... } are replaced by relevant text.

The following abbreviations are used: SPC=summary of product characteristics, MAH=Marketing authorisation holder.

### *Information on the outer packaging and the immediate packaging*

**Section 17(1).** The name of the medicinal product and its strength shall be stated clearly and in an easily legible font. If possible, the name and strength should be stated on the same line and in the same style and size. There may not be anything else between the name and the strength. The entire name of the medicinal product shall be given in the same colour. Different colours may be used to distinguish between different strengths of the same drug. The strength is marked in different colours next to the name. The strength is stated only once on each side of the package.

The pharmaceutical form is an important identifying component for a medicinal product, and it must always be stated next to the name and strength.

The pharmaceutical form shall be stated in accordance with the applicable Standard Terms<sup>1</sup> either using the full name or using the shortened form as stated in the Standard Terms<sup>1</sup>. Where appropriate, the pack size may be used as the pharmaceutical form, e.g. <30 tableter>. If the outer packaging contains several drug containers, this should be indicated by the pack size, e.g. if there are jars each containing 30 tablets, this should be stated as <60 (2x30) tableter>. If there is sufficient space, the pack size should always be shown on all sides of the packaging wherever the name, strength and pharmaceutical form is stated.

The outer packaging shall also state whether the packaging contains any cannulas, swabs or such like.

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<sup>1</sup> Standard Terms: Pharmaceutical dosage forms, Routes of administration, Containers as published by EDQM (European Directorate for the Quality of Medicines), see also [www.pheur.org](http://www.pheur.org).

Where the contents of medicinal product packs are pressurised, both net and gross weights shall be given.

The generic name (active substance) should be given beneath the name of the medicinal product even if it already forms a part of the medicinal product's name. If the product contains an active substance, a generic name must be given. If the product contains several active substances, the generic names do not have to be shown next to the name of the medicinal product. The generic name should be shown in a font size that is half the size used for the name of the medicinal product. The generic name shall be shown in the form that corresponds to the strength. E.g. if the product has the strength 2 mg/ml and it contains dexamethasone disodium phosphate 2.77 mg/ml equivalent to 2 mg/ml dexamethasone, then it is the dexamethasone that is stated together with the name of the medicinal product. Note that despite the presence of the generic name shown next to the name of the medicinal product, it must always be stated in the declaration (see section 17(2)).

For immunological products, the indication is stated on the packaging. For vaccines, this is given as follows. <Vaccin mot...>

Immunological products are taken to mean vaccines, toxins, sera and allergens.

**Section 17(2).** The declaration shall include a statement of the form of the active substance, given as an amount, that is equivalent to the strength. Any other forms are given without amounts e.g. dexamethasone disodium phosphate equivalent to 2 mg/ml dexamethasone. The declaration should begin with <1 tablett innehåller...> <1 ml innehåller...> or similar. For vaccines, the wording is as follows <1 dos innehåller...>. Nationally, declarations in Latin are accepted on packages with labelling in a number of different languages.

**Section 17(3).** However, if the product is injectable, or a topical or an eye preparation, it is desirable for all excipients to be stated with a complete declaration of contents.

Products for external use are in this case taken to include locally applied and locally acting products. Examples of such products are skin products and products that are administered to the lungs via inhalation. Topical products are taken to mean those that are administered or that act locally on the oral, nasal, rectal or vaginal mucosa. For vaccines, there should be both a qualitative and quantitative statement of any adjuvant/adsorbent present.

**Section 17(4).** The manufacturer's manufacturing batch number should be preceded by e.g. <Satsnr> <Batchnr> <Lot>. It is best if this is placed next to the expiry date.

**Section 17(5).** The marketing authorisation number must be preceded by <MTnr>. On multilingual packaging, <MTnr> only needs to be given *once*. Each number is then followed by the appropriate national code, with <SE> used for Sweden. An appropriate place for the MA number is together with the name and address of the MAH.

**Section 17(6).** The Nordic article number (abbreviated to <Vnr> on the packaging) shall be stated at least once alongside the name of the medicinal product, on the outer packaging or if there is no outer packaging, on the immediate packaging. The item number should be placed in the top-right corner on the front of the packaging.

It is extremely desirable from a safety perspective that the item number should also be given as a barcode, and if possible also on the inner packaging, e.g. fluid bags. The company is responsible for ensuring the accuracy of the information in the barcode.

Where drugs are to be prepared prior to use, e.g. cytostatics, it is desirable for the item number also to be included on the inner packaging.

*Multiple packs:* It is sufficient for the item number to be shown only on the outer packaging. If an item number is also shown on each sub-package, then this number may not be identical to the one on the outer packaging, i.e. the various sub-packs may not have the same item number as is given on the multiple pack.

**Section 17(7).** The name and address of the MAH must be given. The name and address of a local representative may be given, though this is not a requirement. The local representative must be registered with the Medical Products Agency. If a stated company only provides information about the medicine, then the heading <Information lämnas av> may be used instead.

If only MAH is given on the labelling, the heading Marketing Authorisation Holder does not have to be used. Where the local representative/information-provider is also stated on the labelling, at least one heading must be given to allow parties with an interest in the product to be ascertained. For parallel-imported medicines, the re-packager and manufacturer shall also be identified.

The minimum requirement is name, town/city and, where appropriate, country (i.e. when the town/city is not in Sweden). References to websites are not acceptable.

**Section 17(8).** The labelling shall contain information about the species in question in the singular. Pictures of the species in question are acceptable as a supplement or as clarification. Pictures may not be dominating relative to the information text on the packaging.

Information about method of administration shall be provided, e.g. <sväljes hela>, <införes i ändtarmen>. Route of administration is e.g. orally, rectally, intravenously, etc. The route of administration does not have to be given if administration is oral. For injection and infusion drugs, the route of administration is given on both the outer packaging and on the immediate packaging.

OTC medicine packages shall additionally carry information about indication(s) approved for non-prescription treatment and ordinary dose levels for these indications. The indication must be placed on the *front* of the packaging.

For those products that have been approved as natural remedies, the front of the packaging must bear the text <Naturläkemedel>.

The text <Läs bipacksedeln före användning.> shall be on the outer packaging for all products with an approved package leaflet.

**Section 17(10).** The expiry date is shown as <Utg.dat.>. In the expiry date, the month shall be indicated as two digits or using letters, and the year shall be shown using four digits. The expiry date can also be written as <EXP> on small packages if required due to lack of space. The date given after <Utg.dat.> or <EXP> means that the medicine may be kept up to and including the indicated month. <Utg.dat.> replaces the previously-used <Anv. före>. The date given after <Anv. före> means that the medicine can be kept up until the indicated month. For previously approved products, this change is made at the same time as other updating of the labelling.

Where appropriate, the shelf-life is given for opened packages or for the product after preparation.

**Section 17(11).** The same storage instruction(s) that are given in the SPC shall be used and expressed as follows.

<Förvaras vid högst <25 °C> <30 °C>>  
<Förvaras i kylskåp>  
<Förvaras och transporteras kallt>  
<Förvaras i djupfryst tillstånd>  
<Förvaras och transporteras i djupfryst tillstånd>  
<Förvaras i skydd mot kyla> <eller> <Får ej frysas>  
<Skyddas mot frost>

<Förvaras i <originalförpackningen>>  
<Tillslut {container}<sup>2</sup> väl>  
<Förvara {container}<sup>2</sup> i ytterkartongen>  
<Skyddas mot direkt solljus>

Use <Ljuskänsligt> <Fuktkänsligt> in addition to the storage instructions <Förvaras i <originalförpackningen>> <Förvara {container} i ytterkartongen> and <Tillslut {container} väl>

If the storage instructions according to the SPC are <Inga särskilda förvaringsanvisningar> or <Inga särskilda temperaturanvisningar>, this shall not be included in the labelling.

**Section 17(12).** Information relating to disposal is provided in accordance with section 6.6 of the SPC. If there is insufficient space, a brief reference may be given to the package leaflet.

**Section 17(13).** The following important warnings and information intended for the person who is to administer the medicine shall be provided if relevant.

<Oavsiktlig injektion är farlig – se bipacksedeln före användning.>  
<Oavsiktlig administrering> <kontakt med slemhinnor> är farlig – se bipacksedeln före användning.>  
<Officiella riktlinjer för inblandning av premix till medicinfoder bör beaktas.>

Veterinary medicines containing pesticides shall be labelled in accordance with the regulations of the Swedish Chemicals Agency.

<Förvaras utom syn- och räckhåll för barn> must always be stated and replaces the previously used <Förvaras oåtkomligt för barn>. For previously approved products, this change is made at the same time as other updating of the labelling.

This labelling shall also include any necessary instructions for use, e.g. <omskakas> <ska spädas>. Also give any other information that may be useful to the user, e.g. <kan färga urinen/avföringen>.

Information and/or warnings shall also be provided for each product type or ingredient.  
*Cytostatics:* <Cytostatikum>

**Section 17(15).** It shall be possible to place the pharmacy label on the packaging without obscuring any information. E.g. a space can be left for the pharmacy label.

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

**Section 18** Small single-dose containers other than ampoules may be e.g. pipettes and small single-dose syringes containing paste for oral use.

For parallel-imported medicinal products, ampoules and small single-dose containers shall also be labelled with the importer's name and address in order to ensure traceability.

Blisters shall be labelled with the following: the name, strength and pharmaceutical form of the medicinal product, the active substance, name of the MAH, expiry date, manufacturing batch number and the text <För djur>.

Perforated blisters are just like ordinary blisters, though with the advantage that they may be designed as single-dose blisters with the name of the medical product, its strength, pharmaceutical form, expiry date and manufacture number on each detachable unit. The following is applicable, in addition to the minimum requirements.

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<sup>2</sup> The packaging is replaced by whatever type of packaging it is, e.g. jar, blister, etc.

The name of the MAH must also be included on the blister, though it does not have to be on each detachable unit. For parallel-imported medicinal products, the importer's name should be included on each detachable unit to ensure traceability.

#### *General requirements for labelling*

**Section 19** A medicinal product is identified by name, strength, pharmaceutical form, pack size and item number. This information must be placed within the same visual field. The pack size is placed in the top-left corner. The Nordic item number is placed in the top-right corner on the front of the packaging.

The labelling should be designed so as to minimise the risk of confusion. This is done e.g. by using colours or coloured strips to distinguish between strengths and different products. If there is more than one product with the same pharmaceutical name, e.g. different pharmaceutical forms or in case of parallel import, the products should be distinguished by means of different packaging designs. Parallel-imported products must be distinguished both from identical direct-imported products and from other parallel-imported products. The contrast between text and background must be clear. The layout should not contain any figures, lines or anything else that impedes legibility. All text should run in the same direction (preferably horizontally) on the labelling. See also *Symbols and pictograms section 25*.

More than one language on the packaging may be acceptable if there is sufficient space. On multilingual packaging, information in the various languages must be collected together. The languages should not be presented as continuous text separated by slashes. E.g. the various sides of a package can be used for different languages. The company is responsible for ensuring that the information in all the languages is identical.

For parallel-imported medicinal products, it is permissible to use the same packaging material as is used in the exporting country and to re-label the packaging material so as to ensure compliance with LVFS 2005:11. In these cases, foreign text may be accepted as long as it is not in conflict with the labelling in Swedish.

The labelling shall be readily legible, including for people with impaired vision. The size of the letters should be at least Times New Roman 9 point, and larger if possible. The use of capital letters should be avoided.

If the labelling consists of a fold-out label, e.g. a fold-out package leaflet, then the label that sits directly on the packaging (beneath the fold-out label) shall be identical to the fold-out label.

## Package leaflets for veterinary medicinal products

### General comments

- The following abbreviations are used: SPC=summary of product characteristics, MAH=Marketing authorisation holder.
- The information in the package leaflet shall agree with the content in the SPC and otherwise be helpful for the user.
- Users may be veterinary healthcare professionals, farmers or animal owners.
- The language shall be easily comprehensible (or be supplemented with a clarification), and also suitable for the user.
- Where the product is handled only by veterinarians or veterinary healthcare professionals, the same text may be used in both the SPC and the package leaflet. Alternatively the SPC may be enclosed in the packaging.
- The information should be concise.
- The package leaflet shall be written in Swedish.
- The final printed package leaflet may contain more than one language, though the information presented in all the languages must be identical. All information in the various languages should be collected together in one place. The company is responsible for ensuring that the information in all the languages is identical.
- The package leaflet must contain the following headings or information. The information may also include e.g. information on the practical handling of devices when mixing medicinal products into large quantities of feed or drinking water for entire stocks of animals. The information may not however contradict the information given in the SPC.
- Indicated standard texts, shown within <...>, shall be used. The Guideline states whether deviations are permissible.
- Words within {...} are replaced by relevant text.
- The positive properties of the medicinal product should be presented in a balanced way, though they may *not* contain advertising messages or any loaded wording.
- Particularly important information should ideally be given a prominent position in any one section. A prominent position may be provided by means of bulleted lists or frames, or by placing particularly important information first in any one section. Additional subheadings, in addition to those already stipulated, may be used.
- For certain products, headings that are not relevant may be removed, e.g. withdrawal period for non-foodstuff-producing animals. The order of the headings is retained, though it is re-numbered.
- If the package leaflets are identical for several different strengths, a combined package leaflet may be used. In these cases, only strength-specific details may be different. The purpose of the combined package leaflet shall be to make the dosage instructions clear for the user.
- Package leaflets for medicinal products with both OTC and on prescription indications should be separated if possible.
- The printed package leaflet shall be easily legible, including for people with impaired vision. The size of the letters should be at least Times New Roman 9 point, and 12 point if possible. The use of capital letters should be avoided. Good legibility can also be achieved by dividing the text into several short paragraphs that are separated by spaces. Use a clear and easily legible font.
- Long package leaflets should be printed on A4/A5 format paper. The weight of the paper should be no less than 40 g/m<sup>2</sup>. On thinner paper, text can show through on the other side, thus making the package leaflet difficult to read.
- The latest package leaflet template for products approved via a mutual or decentralised procedure, together with standard texts as stipulated by EMEA, shall be used. Template version 12/2008 is inserted below. The template is available from EMEA's website.

Explanatory text has been inserted in each section as a supplement or clarification of the requirements as stated in the regulation.



## PACKAGE LEAFLET

{(Invented) name of veterinary medicinal product <styrka> pharmaceutical form <djurslag>}

Product name, strength and pharmaceutical form shall be stated in accordance with the SPC. Animal species may be added if there is a risk of confusion, e.g. if the medicinal product is available in several different strengths or pharmaceutical forms intended for use in different species. If the short form for the pharmaceutical form is used in the labelling (e.g. “tablet” for “film-coated tablet”), this must also be used in the package leaflet. The short form is given in parenthesis after the full pharmaceutical form.

### 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

#### **Marketing authorisation holder <och tillverkare> <, tillverkare och ompackare>**

If the manufacturer is not the same as the MAH, then <och tillverkare> is deleted from the heading.

{Name and address }

<tel>

<fax>

<e-post>

References to websites are not acceptable.

#### **<Tillverkare>**

If the manufacturer is not identical to the MAH, this heading is also used.

{Name and address }

<tel>

<fax>

<e-post>

References to websites are not acceptable.

If the manufacturer is part of the same group as the MAH, the manufacturer does not have to be stated.

Repackagers must always be stated for parallel-imported products.

#### **<Ompackare>**

{Name and address }

<tel>

<fax>

<e-post>

References to websites are not acceptable.

The minimum requirement is name, town/city and, where appropriate, country (i.e. when the town/city is not in Sweden). Full address (preferably postal address), a telephone number, a fax number and/or an e-mail address can also be given.

### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

{(Invented) name, strength, pharmaceutical form <djurslag>}

{Active substance(s)}

Species only needs to be stated where there is a risk of confusion, e.g. the same product name approved in different strengths for different species.

### **3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS**

The declaration of contents must be stated in accordance with the SPC and it should be expressed as follows

<Den (de) aktiva substanser(erna) är...>

<Övriga innehållsämnen är...>

The generic name must be stated as an equivalent of the strength.

Option 1: <amoxicillintrihydrat motsvarande 40 mg amoxicillin> (not 45.91 mg amoxicillin trihydrate).

Option 2: <6 mg tolfenaminsyra> (not 5.82 mg tolfenamin).

A description of the appearance of the medicinal product should be included.

### **4. INDICATION(S)**

Based on data contained in section 4.2 and also relevant data contained in section 5 of the SPC.

A brief explanatory text may also be included in this section to provide a description of the positive effect(s) of the medicinal product. The information must be presented in an objective and balanced way.

### **5. CONTRAINDICATIONS**

Based on data contained in section 4.3 of the SPC.

All contraindications must be given.

### **6. ADVERSE REACTIONS**

Based on relevant data contained in section 4.6 of the SPC.

All undesirable effects in the SPC must also be included in the package leaflet.

The side effects should be reported according to their incidence if this has been defined in the SPC (avoid using %). Below is one way of describing the frequency of side effects

Very common (occurs in more than 1 in 10 users):

Common (occurs in more than 1 in 100 users):

Uncommon (occurs in fewer than 1 in 100 users):

Rare (occurs in fewer than 1 in 1,000 users):

Very rare (occurs in fewer than 1 in 10,000 users):

Has been reported (occurs in an unknown number of users):

For products where the package leaflet is directed primarily at small-scale animal owners, it may be appropriate to describe symptoms rather than use the precise medical term for a specific side effect.

Include the following sentence at the end of the section <Om du observerar allvarliga biverkningar eller andra effekter som inte nämns i denna information, tala om det för veterinären.>

### **7. TARGET SPECIES**

Species and any subgroups as in section 4.1 of the SPC.

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Based on data contained in section 4.9 of the SPC.

State the dosage for each species.

Include any relevant instructions, e.g. <omskakas> <löses i vätska>.

State the route of administration in a user-friendly way.

## 9. ADVICE ON CORRECT ADMINISTRATION

Give the more practical handling instructions that are directed at veterinary professionals, farmers or animal owners. If necessary, this can be written in greater detail than in the SPC.

<Låt vaccinet anta rumstemperatur före användning.> <Ges tillsammans med foder.>

If possible, provide advice in case a dose is forgotten. This may be relevant in case of e.g. antibiotic therapy, contraceptive pills for cats, or other continuous treatment.

## 10. WITHDRAWAL PERIOD

Based on relevant data contained in section 4.11 of the SPC. Even a withdrawal period of zero days must be stated.

## 11. SPECIAL STORAGE PRECAUTIONS

Based on data contained in section 6.4 of the SPC.

The following sentences must always be stated.

<Förvaras utom syn- och räckhåll för barn.>

<Använd inte detta läkemedel efter utgångsdatumet på <etiketten> <kartongen> <flaskan> <...>

<efter {abbreviation for the expiry date}>.>

Where abbreviations for expiry date are given on the labelling, the complete term shall be given in the package leaflet together with the abbreviation used.

The same storage instruction(s) that are given in the SPC shall be used and expressed as follows.

<Förvaras vid högst <25 °C> <30 °C>>

<Förvaras i kylskåp (2 °C-8 °C)>

<Förvaras och transporteras kallt (2 °C-8 °C)>

<Förvaras i djupfryst tillstånd {temperature range}>

<Förvaras och transporteras i djupfryst tillstånd {temperature range}>

<Förvaras i skydd mot kyla> <eller> <Får ej frysas>

<Skyddas mot frost>

<Förvaras i <originalförpackningen>>

<Förvara {container}<sup>2</sup> i ytterkartongen>

<Tillslut {container}<sup>2</sup> väl>

<Inga särskilda förvaringsanvisningar>

<Inga särskilda temperaturanvisningar>

<Skyddas mot direkt solljus>

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<sup>2</sup> The packaging is replaced by whatever type of packaging it is, e.g. jar, blister, etc.

Use <Ljuskänsligt> <Fuktkänsligt> in addition to the storage instructions <Förvaras i <originalförpackningen>> <Förvara {container} i ytterkartongen> and <Tillslut {container} väl>

Include the following sentences if relevant.

<Hållbarhet i öppnad förpackning.>

<Hållbarhet efter spädning eller beredning enligt anvisning.>

<Använd inte {name of the medicinal product} om du ser att {description of visible signs of deterioration}.>

## 12. SPECIAL WARNING(S)

Sub-headings may be used in this section to clarify the information.

The information is based on section 4.4 and section 4.5 of the SPC.

The following information should also be included in this section.

- Information on pregnancy, lactation or lay is based on data contained in section 4.7 of the SPC.
- Information about interactions is based on data contained in section 4.8 of the SPC.
- Information on overdose, symptoms and any practical advice for animal owners in case of overdose is based on data contained in section 4.10 of the SPC.

Information on special warnings or other information that is strictly aimed at veterinarians does not have to be included however.

Include the following texts if relevant.

The following warnings should be placed in this section.

<Vid oavsiktlig(t) <självmedicinering> <självinjektion> <intag> <spill på huden>, uppsök genast läkare och visa bipacksedeln eller etiketten.>

<Personer som är överkänsliga för {ingredient} <ska undvika kontakt med det veterinärmedicinska läkemedlet.> <Läkemedlet ska administreras försiktigt.>

<Skyddsutrustning som består av {specify} ska bäras vid hantering av det veterinärmedicinska läkemedlet.>

<Produkten bör inte administreras av gravida kvinnor.>

<Vaccinet kan orsaka smittöverföring till människa. Trots att vaccinet har framställts med levande, försvagade mikroorganismer, bör lämpliga åtgärder vidtas för att förhindra kontamination av den person som hanterar vaccinet eller andra personer som medverkar vid hanteringen.>

<Vaccinerade {species} kan utsöndra vaccinstammen upp till {x days/weeks} efter vaccinationen. Personer med nedsatt immunförsvar avråds från kontakt med vaccinet och vaccinerade djur under {time period}.>

<Vaccinstammen kan finnas kvar i miljön i upp till {x days/weeks}. Personal som sköter om vaccinerade {species} bör följa de allmänna principerna för hygien (byta kläder, använda handskar, rengöra och desinficera stövlar) och vara särskilt försiktiga vid hanteringen av strö från nyligen vaccinerade {species}.>

<Till användaren:

Denna produkt innehåller mineralolja. Oavsiktlig injektion/självinjektion kan leda till svår smärta och svullnad, särskilt om produkten injiceras i en led eller i ett finger. I sällsynta fall kan det leda till förlust av fingret, om man inte kommer under medicinsk vård omedelbart.

Vid oavsiktlig injektion med denna produkt, uppsök snabbt läkare - även om endast en väldigt liten mängd injicerats - och ta med bipacksedeln.

Om smärtan kvarstår i mer än 12 timmar efter läkarundersökning, kontakta läkare igen.

Till läkaren:

Denna produkt innehåller mineralolja. Även om små mängder injicerats, kan en oavsiktlig injektion med denna produkt orsaka intensiv svullnad, som till exempel kan leda till ischemisk nekros och även till förlust av ett finger. Sakkunniga, SNABBA, kirurginsatser krävs och det kan bli nödvändigt med incision och irrigation av det injicerade området, särskilt om det rör sig om mjukdelar eller senor i ett finger.>

### **13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

Based on data contained in section 6.6 of the SPC.

Always include the following sentence.

*General text, applies to all:* <Medicinen ska inte kastas i avloppet eller bland hushållsavfall.>

Insert the following texts if relevant.

*For larger amounts of medicinal product, used primarily in agriculture:* <Fråga veterinären hur man gör med mediciner som inte längre används. Dessa åtgärder är till för att skydda miljön.>

*The following text may be relevant for e.g. smaller packages of deworming agents for small animals:* <Av miljö- och säkerhetsskäl ska överblivet eller för gammalt läkemedel från allmänheten lämnas till apotek för omhändertagande.>

### **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

The Medical Products Agency will add the date, <ÅÅÅÅ-MM-DD>, once the package leaflet is ready for approval. For parallel-imported products the applicable date is the one written by the applicant in the package leaflet that was submitted for approval.

### **15. OTHER INFORMATION**

All pack sizes must be stated in accordance with the SPC.

Include the following sentence if relevant.

<Eventuellt kommer inte alla förpackningsstorlekar att marknadsföras.>

The name and address of a local representative may be given, though this is not a requirement. The local representative must be registered with the Medical Products Agency. If a stated company only provides information about the medicine, then the heading <Information lämnas av:> may be used instead.

The following can be written if there is a local representative/information-provider

<För ytterligare upplysningar om detta läkemedel, kontakta den lokala företrädaren för innehavaren av godkännande för försäljning.>

**<Lokal företrädare> <Information lämnas av>**

<Namn>

<Adress>

<tel>

<fax>

<e-post>

The minimum requirement is name, town/city and, where appropriate, country (i.e. when the town/city is not in Sweden). Full address (preferably postal address), a telephone number, a fax number and/or an e-mail address can also be given. References to websites are not acceptable.

## **Common regulations (applies to products for human and veterinary use)**

### *Symbols and pictograms*

**Section 25** Symbols may not be of an advertising nature and may not disrupt the text printed on the packaging. Symbols or coloured strips may not be dominant compared to the information text on the packaging.

Drawn images with a health-promoting value may be included on packaging, especially if there is a risk of incorrect usage, though subject to the condition that the images are not of an advertising nature. Images of various organs intended to clarify the indication(s) may not be reproduced on packaging for prescription only medicines.

If the pharmaceutical form is depicted, the image shall be full size.

The MAH's logo may be depicted. A local representative's logo may also be accepted. No other corporate logos are accepted.

For parallel-imported products, this means that the parallel-importer's logo may be depicted, though not that of the direct importer, since the direct importer is not the holder of this authorisation.

Acceptance of the logo is however conditional on the company (name and address) also being given in clear text on the labelling. For parallel-imported products, the manufacturer's logo is also accepted.

**Section 27** Existing stocks of previously approved labelling and package leaflet material may be sold out, unless the Medical Products Agency decides otherwise.

For further tips on drafting package leaflets and labelling, see the following links which were up-to-date when this Guideline was last revised.

Guideline on the readability of the labelling and package leaflet of medicinal product for human use, revision 1 (12 January 2009) and Guideline on the packaging information of medicinal products for human use authorised by the Community (February 2008)

<http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev2.htm>

QRD Annotated template human

[http://www.hma.eu/uploads/media/QRD\\_annotated\\_template\\_CMDh.pdf](http://www.hma.eu/uploads/media/QRD_annotated_template_CMDh.pdf)

QRD Annotated template veterinary

<http://www.emea.europa.eu/htms/vet/qrd/docs/Vannotatedtemplate.pdf>

Guideline on the packaging information of veterinary medicinal products authorised by the Community - (blue box) (January 2008)

<http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev6.htm>

*Guideline revised*

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