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NOTICE TO APPLICANTS

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GUIDELINE ON THE PACKAGING INFORMATION OF VETERINARY MEDICINAL PRODUCTS AUTHORISED BY THE COMMUNITY

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This Guideline will be included in The Rules governing Medicinal Products in the European Community
The Notice to Applicants Volume 6C Regulatory guidelines

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GUIDELINE ON THE PACKAGING INFORMATION OF VETERINARY MEDICINAL PRODUCTS AUTHORISED BY THE COMMUNITY

Introduction

1. Legal framework

Council Regulation (EEC) No 2309/93[1] lays down a centralised Community procedure for the authorisation of medicinal products, for which there is a single application, a single evaluation and a single authorisation allowing direct access to the EU market of a veterinary medicinal product bearing a single set of information.

Article 31.3 (d) of Council Regulation 2309/93 requires that the text of the labelling and packaging insert must be in accordance with Directive 2001/82/EC[2] of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, which in turn requires these texts to be in accordance with the summary of products characteristics (SPC). For products authorised by the Community there is a single SPC agreed at Community level, which forms part of the Community Decision.

The labelling and package insert of the veterinary medicinal product forms part of the authorisation of the product and they must therefore be included in the opinion of the competent authority, i.e. the European Agency for the Evaluation of Medicinal Products (EMEA), on the basis of which an authorisation can be granted by the Community. Indeed, Article 31(1) of Regulation (EEC) No 2309/93 provides that the Committee for Veterinary Medicinal Products (CVMP) opinion will not be in favour of granting the authorisation to market the veterinary medicinal product if the text of the labelling or package insert is not in compliance with Directive 2001/82/EC. In the case of a favourable opinion, the text of the labelling will be attached to the opinion, and will later on be annexed to the Community Decision [articles 31(3)(d) and 32(1)].

2. Purpose

This guideline has been prepared in order to describe how the provisions of Directive 2001/82/EC apply in the case of an authorisation to be granted by the Community.

3. Legal Status

The legal status and the text of the label and the package insert form part of the Community Decision.

3.1. Article 31(3) (c) of Council Regulation 2309/93

Regulation (EEC) No 2309/93 provides that the **legal status** of medicinal products for veterinary use to be authorised by the Community shall be fixed in accordance with the criteria lay down in Directive 2001/82/EC. The Community Decision includes "*details of any conditions or restrictions which should be imposed on the supply or use of the veterinary medicinal product concerned, including the conditions under which the veterinary medicinal product may be made available to users, in accordance with the criteria laid down in Directive 2001/82/EC.*"

[1] OJ N° L214 of 24.08.1993, p.1.

[2] OJ N° L311 of 28.11.2001, p.1.

3.2. The Community Decision

The legal status is included in Annex II of the Community Decision. It follows that the EEA countries may avail themselves of the sub-categories, despite the fact that these are not harmonised. Furthermore, more than one of the sub-categories may be used for one veterinary medicinal product.

Even if the legislation in a Member State does not provide for certain sub-categories, the marketing authorisation holder is under an obligation to ensure that the medicinal product is marketed, all over the Community, subject to the conditions laid down in the Commission Decision. Therefore, EEA countries have to find suitable ways to allow the marketing authorisation holder of a medicinal product authorised by the Community, to fulfil all the conditions laid down in the Community Decision granting the Marketing Authorisation. This need not necessarily be done by introducing the optional sub-categories into legislation in all EEA countries, but may also be achieved by other practical measures within their existing administrative framework.

4. Changes to the labelling and/or package insert

All proposed changes to the text of the labelling and package insert, which are not connected with the SPC, shall be notified to the EMEA. Therefore, if the holder of a Community marketing authorisation wishes either to introduce any text additional to that in the Decision or to change any aspect of the labelling and/or package insert, including layout/format/pictograms, he must first notify this change to the EMEA, who will inform the Commission if the proposed change is accepted. If necessary, the Commission shall amend the Decision granting the marketing authorisation.

Where a change in the labelling and/or package insert is a consequence of a modification of the SPC it will be dealt with under the procedure laid down for that purpose (see Regulation (EEC) No 542/95[3]).

Section A - Label

1. Legal Status on the label

In addition to appearing in Annex II of the Community Decision, the legal status shall appear in the label text, which is included in Annex III A of the Community Decision. However, the expression of the legal status in the label text in the Commission Decision is limited, at present, to one of the main classifications following the criteria of Article 67 of Directive 2001/82/EC ("veterinary medicinal product subject to prescription") which is common to all EEA countries. Where sub-categories exist in some EEA countries they shall not be stated in Annex IIIA but shall be included in the blue box area covered in point 4.

2. The label text

The Community authorisation for a veterinary medicinal product includes the label text, which content is identical for all packs of the same size of that medicinal product throughout the Community, without prejudice to exceptions covered in point 4 as indicated below. The particulars in the label shall be easily legible, clearly and easily understood.

3. Language

The content of all language versions must be identical (apart from text appearing in the boxed area referred in 4). If more than one language is used, then all of the text must be in each language.

In accordance with Article 58(4) of Directive 2001/82/EC, the labelling must be presented at least in the language or languages of the Member State(s) where the product is placed on the market. The EU language(s) used on the label must be the same as the language(s) used in the package insert.

[3] OJ N°L 55 of 11.03.1995, p.15

4. <u>Additional labelling information required by some EEA countries</u> – The so-called *Blue-Box*

Additional information on the labelling which may be required nationally must go into the so-called Blue-Box providing it is not contradictory to Community legislation (article 63 of Directive 2001/82/EC) or to the Decision. Therefore, EEA countries may require the use of certain forms of labelling making it possible to indicate, in particular:

- the legal status for supply;
- identification.

The information currently required by the EEA countries is outlined in the Annex.

The information specific to a Member State should be placed on the label in a boxed area[4], to appear on one side of the pack. Each boxed area (the so-called ***blue box),*** should only be presented in the official language or languages of the Member State concerned and should state the name of that Member State. The location of the *blue box* on the package should be the same for all language versions. When one pack is intended for marketing in several EEA countries, it is preferable to have only <u>one</u> *blue box* on the pack. This box will contain different information in each Member State. This could be achieved in practice for instance by printing a blank *blue box* on this pack onto which a sticker with the appropriate Member State information can be securely affixed. When in exceptional circumstances, this can not be achieved, each *blue box* should have the same dimensions and appear on the same side of the pack.

The name of the local representative as referred to in section B (4) may be indicated.

4.1 Legal status

As far as the legal status is concerned, it should be noted that the main category, "medicinal product subject to veterinary prescription" may already be included in the labelling. Hence, the boxed area may only contain the specific sub-category and/or a symbol expressing this main category. See also, Section B hereafter. Symbols used in some EEA countries to designate the legal status on the label shall appear in the boxed area referred in Section A and these are given in the Annex.

4.2 Optional information

In some EEA countries certain expressions, including symbols and pictograms have become established for expressing certain items of information. These items are outlined in the Annex.

As these particulars are only known or relevant in some EEA countries, they should appear in the corresponding blue box.

The outer packaging may include symbols or pictograms (designed to clarify certain information mentioned already in the label) and other information compatible with the Summary of Product Characteristics which is useful to the veterinarian and the end user to the exclusion of any element of promotional nature.

Additional use of label information in Braille is possible, even if it is not mentioned in Directive 2001/82/EC.

5. <u>Marketing authorisation number</u>

This is the Community registration number consisting of "EU" followed by a nine digit number (e.g. "EU/2/97/003/000"). It must not be accompanied by any suffix or prefix.

This number must appear on the package. Any other (national) identification number or reference, if any, can only appear (once) in the boxed area (see 4. above).

Section B - Package Insert

[4]A blue outline is recommended to avoid confusion with other colours used in labelling.

1. The text of the package insert

The text of the package insert forms part of the Community authorisation and must therefore be approved by the EMEA on behalf of the Commission (or the Council, as the case may be). Thus, the Community authorisation of a veterinary medicinal product includes the text of the package insert, which is the same for all packs of that medicinal product throughout the Community.

The package insert must be written in clearly and easily understood terms for the users and clearly legible.

2. Language

The package insert must be presented at least in the language(s) of the Member State(s) where the product is placed on the market (article 61 of Directive 2001/82/EC). The EU language(s) used in the package insert must be the same as the language(s) used on the label. The content of all language versions must be identical. However, a multi-lingual pack insert may also contain other languages.

3. Additional package insert text

The approved package insert may include other particulars essential for safety or health protection at the discretion of the CVMP. According to article 26(1) of Directive 2001/82/EC it may include any precautions relating to the use and any other warnings resulting from the clinical and pharmacological trials or from experience gained during the use of the veterinary medicinal product once it has been marketed. Any element of a promotional nature must be excluded.

4. Local representative

Some holders of Community marketing authorisations have requested that a local contact point be identified in the package insert and on the label. This would normally be the holder of the Community marketing authorisation. However, where a marketing authorisation holder wishes to add the name of another (local) contact point in some or all EEA countries, the *local representative* may be indicated:

- in the package insert by name, address, telephone number and electronic mail address
- in the *blue box* on the label (referred to in section A) by name and, if space permits, by address, telephone number and electronic mail address

If the marketing authorisation holder wishes to mention local representatives, they can be mentioned under the relevant heading of the package insert, but where used a representative shall be indicated for all EEA countries. However, a representative may be designated for more than one EEA country and may also be the Community marketing authorisation holder where no other local representative is indicated.

References to addresses on the Internet are not allowed, neither for the marketing authorisation holder nor the local representatives.

Local Representative shall be taken to mean: any private *or* legal person established in the Community charged, through a civil contract with the marketing authorisation holder, with representing him in a defined (geographical) area; this contract excludes any transfer of any responsibility imposed on the marketing authorisation holder by Community law and by national law, regulation and administrative action implementing such Community law.

Designation of a local representative cannot be a requirement but, when the holder of a Community marketing authorisation wishes to identify a local representative in the package insert, all of the Community must be covered so that the final user of the product in each EEA country has equivalent access to a representative of the marketing authorisation holder or a local company (e.g. local company branch).

There has been some confusion with regard to terms such as '*exploitant*', *'technical director'*, *'distributor',* etc. Since there is neither a commonly agreed understanding of these terms nor equivalent legal definitions of these terms amongst the EEA countries, and in the absence of any

reference or definition in Community law, reference to such terminology will not be accepted for a medicinal product authorised by the Community.

It must be recalled that, under the case-law of the EC Court of Justice, EEA countries may not require that a local representative of the marketing authorisation holder be appointed for their territory. Therefore, the arrangements outlined above are purely optional for holders of Community marketing authorisations.

The attention should be drawn to the fact that in cases where the manufacturer is different from the marketing authorisation holder, only the actual manufacturer responsible for batch release should be mentioned in the package insert in addition to the marketing authorisation holder.

Section C - Presentation of the medicinal product

Pack design (logo, colour, etc.)

As provided in Article 12(3)(k) of Directive 2001/82/EC an application for a Community marketing authorisation must include one or more specimens or mock-ups of the outer packaging and of the immediate packaging of the medicinal product, together with the draft package insert.

A mock-up is a flat artwork design in full colour, presented so that, (following cutting and folding, where necessary), it provides a full size replica of both the outer and immediate packaging so that the three dimensional presentation of the label text is clear.

The text to include in those specimens must be provided in each of the eleven languages at the time of the submission of the application.

For practical and linguistic reasons holders of Community marketing authorisations are therefore likely to present the medicinal product packaging in several linguistic and/or "national" versions (i.e. with the relevant boxed areas). In such cases, the logo, format, layout, style, colour scheme and pack dimensions must be identical for all the versions of packs of that medicinal product throughout the Community. Thus, mock-ups of the outer packaging and of the immediate packaging should be provided.
Once the Community marketing authorisation has been granted and before the product is placed on the market in the European Union, specimens of all sale presentations of the final outer and immediate packaging and of the package insert should be submitted to the EMEA in order to check that the text of the specimens is in conformity with the text of the Annexes to the Commission Decision and that the text required by Member States is in accordance with this guideline. Specimens of sales presentations of the final outer and immediate packaging and of the package insert to be put on the market in the EFTA States Iceland and Norway should be submitted to the respective competent authorities of these countries for checking.

This mechanism ensures that any changes introduced during the Decision making process have been incorporated and that the information on the label required by some EEA countries is in conformity with legislative provisions and is correctly presented.

All proposed changes to any aspect of the presentation should be submitted to the EMEA, who will inform the Commission.

Annex

Information on the outer package or if there is no outer package on the immediate label, which may be required by EEA countries

AUSTRIA

Price

The price is not required and not wanted on the label.

Legal status

The following are the specific requirements for the expression of the legal status in the boxed area:-

- "rezept- und apothekenpflichtig" = available only on prescription and only in pharmacies or
- "Abgabe nur durch Apotheken und Drogerien" = supply only in pharmacies and drugstores.

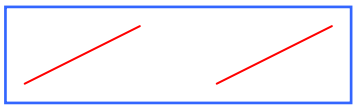
Identification

The Europäische Artikelnummerierung (EAN, barcode) is accepted on the label, but not required.

BELGIUM

Legal status

For medicinal products restricted to special prescription (narcotics), a number code assigned by the Minister of Health and a double red line are mandatory. This double red line must be as large as the largest character on the label. The red lines should be parallel, 1 – 3 cm apart and in an angle of 45° starting from the left lower corner to the right upper corner.



For medicinal products intended for cutaneous or topical use, external use should be printed in black letters on red-orange background in the three national languages French, Dutch and German (Usage externe – Uitwendig gebruik – Zur äusserlichen Anwendung).

Usage externe – uitwendig gebruik - Zur äusserlichen Anwendung

Identification

Both a barcode and a national code are accepted on the label, but not required.

BULGARIA

The primary and outer packaging of the VMP containing narcotic substances shall be identified (marked) diagonally by two red lines (strips), while the psychotropic ones shall be marked by two blue strips.

In the cases where the marketing authorisation of VMP has been issued in accordance with the centralized procedure, each authorized or required by the National Veterinary Service (NVS) additional information shall be placed (written) within an area bordered by a frame that shall clearly outline it from all the other data.

The data placed on the primary and on the outer packaging and also in the instruction for use shall be written in Bulgarian language. The labels of the homeopathic VMPs shall involve the note **'Хомеопатичен ветеринарномедицински продукт'**.

The note **‘Само за ветеринарномедицинска употреба’** shall be placed on each primary and outer packaging of any VMP.

The data in the instruction for use may be written in several languages, one of which must be Bulgaria, but if only the data written in all these languages are identical.

Where the VMP must be sold and used under veterinarian’ s prescription, the note **‘По лекарско предписание’** shall be placed on each primary and outer packaging of the VMP concerned, excluding the homeopathic ones. In the other cases the note **‘Без лекарско предписание’** shall be placed on each primary and outer packaging of the VMP. All VMPs intended for food production animals and the VMPs, which are subject to special measures to be taken by the veterinarian in order to avoid any risk related to the animals treated or the persons applying the VMP or the environment, shall also be subject to the same requirements, i.e. mandatory identification by the note **‘По лекарско предписание’.**

CYPRUS

Legal Status

There is no requirement for the legal status to appear on the label.

Identification

Information for the identification and authenticity are not required on the label. Bar codes are accepted on the label but are not required.

CZECH REPUBLIC

Legal Status

The words “**Indikační omezení**” (prudent use) are required for certain veterinary medicinal products containing antimicrobial substances, in accordance with national law.

Identification

There is no requirement for the EAN[5] bar codes to appear on the label.
The EAN bar codes are accepted when they are put on the label.

Additional information

Recycling symbols are accepted.

DENMARK

Legal status

There is no specific requirement in respect of the legal status.

Identification

The Nordic number is required on the outer label of all medicinal products, except radiopharmaceuticals, certain vitamins and mineral products, homeopathic and herbal remedies. It is written as "Vnr XX XX XX". A barcode is accepted on the label but not required.

[5] European Article Number

Additional information:

Products containing inflammable material must bear the international warning symbol:- 

ESTONIA

There are no additional requirements.

FINLAND

Legal status

There is no requirement for the legal status to appear on the label.

Identification

The Nordic number is required on the label of all medicinal products except for radiopharmaceuticals and herbal remedies. It is written as "Vnr XX XX XX". A barcode is accepted on the label but not required.

Additional warnings:

Products containing inflammable material must bear the international warning symbol:- 

FRANCE

Legal status

The information that the product is a prescription only medicine has to appear in dark ink on a red background rectangle as:

“A NE DELIVRER QUE SUR ORDONNANCE” for products intended for non-food producing animals or for food-producing animals for products with no withdrawal period.

“A NE DELIVRER QUE SUR ORDONNANCE DEVANT ETRE CONSERVEE PENDANT AU MOINS 5 ANS” for products intended for food producing animals with a withdrawal period.

The information that the product is a veterinary medicine has to be mentioned as “USAGE VETERINAIRE” written in dark ink in the same red background rectangle.

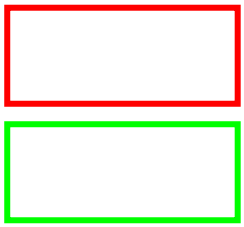
For medicinal products containing an active substance subject to a special regulation in France (narcotic, psychotropic or so called “substances vénéneuses”), it must be added:

- In the red background rectangle “ RESPECTER LES DOSES PRESCRITES” and, if the medicinal products is to be administered by a route different than nasal, oral, perlingual, sublingual, rectal, vaginal, urethral or by injection, “NE PAS FAIRE AVALER”.
- Above the red background rectangle

  - an empty (white) rectangle with a red border for List I substances

  or

  - an empty (white) rectangle with a green border for List II substances



Identification

If available, the marketing code (“CIP code”) and/or the barcode have to appear on the label.

GERMANY

Legal status

The legal status is required on the label:

"apothekenpflichtig" = to appear in the boxed area in the case of medicinal products that are not subject to medical prescription but are only available in pharmacies or from veterinarians

No separate statement is necessary in the case of products, which are neither prescription only nor pharmacy only.

Identification

A barcode is accepted on the label. A distribution number (Pharmazentralnummer) is accepted on the label.

Additional information:

A special symbol concerning the recycling of the packaging material is accepted such as the "Grüne Punkt: "

GREECE

Legal status

Veterinary medicinal products subject to a special prescription (narcotics) must have a letter/code assigned by the Ministry of Health and Welfare with a special colour (read/green) according to the classification and the following text must appear on the label:

1. Products belonging to list B must mention in red letters:

   «Β, χορηγείται με ειδική συνταγή Ναρκωτικών».

2. Products belonging to the exceptions of list B must mention in green letters:

   «ΒΣ, χορηγείται με απλή συνταγή Ναρκωτικών».

3. Products belonging to list Γ must mention in red letters:

   «Γ, χορηγείται με ειδική συνταγή Ναρκωτικών».

4. Products belonging to the exceptions of list Γ must mention in green letters:

   «ΤΣ, χορηγείται με απλή συνταγή Ναρκωτικών».

5. Products belonging to list Δ must mention in green letters:

   «Δ, χορηγείται με συνταγή του Ν. 1729/98».

HUNGARY

Legal status

The legal status is shown in the blue box area as follows:

- for medicinal product only available on medical prescription : **„állatorvosi vényre",**
- for products available without prescription in pharmacy: **„vény nélkül, engedélyezett forgalmazóknál",**
- for products available without prescription, but not only in pharmacy: **„szabadon forgalmazható".**

Identification

Information for the identification and authenticity are not required on the label. Bar codes are accepted on the label, but are not required.

IRELAND

Legal status

1. An animal remedy designated for veterinary surgeon use may be designated by the following symbol: **VSO**

2. An animal remedy designated for prescription only sale may be designated by the following symbol: **POM**

3. An animal remedy designated for prescription only exempt sale may be designated by the following symbol: **POM (E)**

4. An animal remedy designated for pharmacy only sale may be designated by the following symbol: **PS**

5. An animal remedy designated for sale by a licensed merchant may be designated by the following symbol: **LM**

6. An animal remedy designated for sale by a companion animal medicines seller may be designated by the following symbol: **CAM**

ITALY

Legal status

For products "subject to prescription":

- when the veterinary medicinal product is intended for food producing animals with a withdrawal period of more than 0 days:
  "Da vendersi dietro presentazione di ricetta medico-veterinaria in triplice copia non ripetibile"
  (to be sold only with three copies of a non-renewable vet. med. prescription)
- when the veterinary medicinal product is intended for food-producing animals with no withdrawal period or companion animals:

  "da vendersi dietro presentazione di ricetta medico-veterinaria non ripetibile" (to be sold only with a non-renewable vet. med. prescription) or
- "da vendersi dietro presentazione di ricetta medico-veterinaria in copia unica ripetibile" (to be sold with a renewable vet. med. prescription)

For veterinary medicinal product containing psychotropic substances, the following sentence has to be specified:
"Prodotto soggetto alla disciplina del D.P.R. 309/90, tabella n...." (with the correct number specified by the Italian authority on a case by case basis according to "Decreto Presidente della Repubblica 9 ottobre 1990, n. 309").

Identification

The national identification number is required in the label. Barcodes are accepted as well as any other information about risk hazards, but not required.

LATVIA

Legal status

The legal status is required to be expressed in the boxed area as shown if the veterinary medicinal product is available as prescription only.

Pret RECEPTI

Identification

Marketing authorisation number serves for the identification of the product.

LITHUANIA

Legal status

The legal status is shown in the blue box area as follows.
For all veterinary medicinal products the following text is necessary: „**Tik veterinariniam naudojimui**“ (for veterinary use).

In addition the following text is necessary:

- for medicinal product only available on medical prescription: **„Parduodama su receptu”,**
- for products available for veterinarians only: **„Parduodama tik veterinarijos gydytojui”,**

Identification

A bar code is accepted on the label but not required.
National marketing authorisation number: RV XXXX/XXXX/X

LUXEMBOURG

There are no additional requirements.

MALTA

There are no additional requirements.

THE NETHERLANDS

Legal status

UDD (Uitsluitend door Dierenarts – administration only by veterinarian) or
UDA (Uitsluitend aan Dierenarts afleveren – prescription is needed but administration may be done by someone else than a veterinarian)

Identification

The national identification number is required in the label.

POLAND

Legal status

The following are the specific requirements for the expression of the legal status in the boxed area:
Do stosowania wyłącznie przez lekarza weterynarii = to be used by veterinary surgeon only
Wydawany na podstawie recepty (Rp.). = available on prescription only
Wydawany bez wystawiania recepty = available without prescription
The description of the legal status must be exactly the same as in the Marketing License
(= Pozwolenie na dopuszczenie do obrotu)

Identification

The EAN code is not required on the label.

PORTUGAL

Items mandatory for both pharmacologicals and immunologicals

1. The legal status is required in the blue box, if not mentioned elsewhere on the label
2. If applicable, specific statements, symbols or safety warnings concerning the handling/administration/storage/disposal of the veterinary medicinal product may be required on the label as, for example:

A INJECÇÃO ACIDENTAL É PERIGOSA - ANTES DE UTILIZAR LEIA O FOLHETO INFORMATIVO. (accidental injection is dangerous – Read the package leaflet before use)

3. Identification

   The national code of the veterinary medicinal product (*N° de Código Nacional*) is required on the label. A barcode is accepted.

4. "Manter fora do alcance e da vista das crianças" (Keep out of reach and sight of children) if not mentioned elsewhere on the label
5. The expression "Uso Veterinário" must be stated in an entirely green boxed area.

Specific items for pharmacologicals to be also included

1. If applicable, specific statements concerning the administration and/or availability of the veterinary medicinal product may be required on the label as one of the following:

- *"Só pode ser administrado pelo médico-veterinário"* (administered by a veterinarian only)
- "Só pode ser administrado sob controlo do médico veterinário" (to be administered under the responsability of a veterinarian)

2. Products for external use should state "Uso externo" in a entirely red boxed area on the label.
3. Medicated premixes: "*Só pode ser vendido a unidades de fabrico de alimentos compostos para animais"*

Specific items for IVMP – Immunological Veterinary Medicinal Products to be also included

1. The following sentences are mandatory unless authorised otherwise:

"Só pode ser administrado pelo médico veterinário" (to be administered by the veterinarian only)

or

"Só pode ser administrado sob controlo do médico veterinário" (to be administered under the responsability of a veterinarian)

2. Name/address of the local representative/distributor

ROMANIA

Legal Status

The legal statutus is required to be expressed on the label for **prescription-only** medicinal products (POM) as bellow:

- For medicinal products supplied in pharmacy based on veterinary prescription: „Se elibereaza numai pe baza de prescriptie medicala – **P-RF“**
- For medicinal products (narcotics) supplied in pharmacy based on special veterinary prescriptions: „Se elibereaza pe baza de prescriptie medicala speciala – **P-TS“**

Identification

A bar code is accepted on the label but is not required.

Additional information:

Medicinal products containing inflammable material must bear the international warning symbol.

A special symbol concerning the recycling of the packaging material is accepted.

SLOVAK REPUBLIC

Legal Status

There is no requirement for the legal status to appear on the label.

Identification

The EAN code is required.

SLOVENIA

There are no additional requirements.

SPAIN

Price

The price of supply to the public must be mentioned on the labelling as "PVP"(Precio de venta al Público)

Additional information:

The symbol “❄” for products which must be stored between 2-8° C.

SWEDEN

Legal status

There is no requirement for the legal status to appear on the label.

Identification

The Nordic number is required on the outer label of all medicinal products, except radiopharmaceuticals, certain vitamins and mineral products, homeopathic and herbal remedies. It is written as "Vnr XX XX XX".

A barcode is accepted on the label but not required.

Additional information:

- Products containing inflammable material must bear the international warning symbol:- 

UNITED KINGDOM

Legal status

The legal status is required to be expressed in the boxed area as one of the following: -

1. The medicinal product may only be supplied in accordance **with a prescription:**

POM-V

Medicines may only be prescribed by a registered veterinary surgeon for an animal under his care. The prescription may be dispensed by any registered veterinary surgeon or registered pharmacist.

POM-VPS

Medicines which can be prescribed and supplied by a Veterinary Surgeon, Pharmacist or a registered Suitably Qualified Person (SQP) or it may be supplied separately by one of the above in accordance with a written prescription from that person.

2. The medicinal product may be sold or supplied **without a prescription**:

NFA-VPS

Medicines which can be supplied without a prescription by a Veterinary Surgeon, Pharmacist or a Suitably Qualified Person (SQP).

AVM-GSL

Medicines which may be supplied by any retailer. Products which do not require specific advice concerning their method of use, and do not pose minimal safety risks.

3. Controlled Drug (CD):

Medicinal products considered to be dangerous and likely to be subject to abuse. Additional precautions in respect of storage and supply are required. These products are also **POM-V.**

CD, followed by Sch 2 or Sch 3 as appropriate

Identification
Information for the identification and authenticity are not required on the label. Barcodes are accepted on the label, but are not required.

Additional Information

‘Keep out of reach of children’

‘Keep the container in the outer carton’

EFTA COUNTRIES

ICELAND

Legal status

There is no requirement for the legal status to appear on the label.

Identification

The Nordic number is required on the label of all medicinal products except for radiopharmaceuticals and herbal remedies. It is written as "Vnr XX XX XX". A barcode is accepted on the label but not required.

Additional warnings:

Products containing inflammable material must bear the international warning symbol:- 

NORWAY

Legal status

There is no requirement for the legal status to appear on the label.

Identification

The Nordic number is required on the outer label of all medicinal products except for radiopharmaceuticals, homeopathics and herbal remedies. It is written as "Vnr XX XX XX". A barcode is accepted on the label but not required.

Additional warnings:

Products containing inflammable material must bear the international warning symbol:-