Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary

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Packaging 'blue-box' requirements for products authorised via national, mutual recognition, ~~or~~ decentralised or centralised procedures

Additional information on labelling/package leaflet that may be required nationally in accordance with Articles 58 and 64 of Directive 2001/82/EC, as amended, is outlined below.

~~These requirements apply to products authorised via a national, mutual recognition or decentralised procedure only.~~

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AUSTRIA (AT)

Additional Requirements for the Labeling

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;
- "Apothekenpflichtig" = available only in pharmacies;
- If the supply is not restricted to pharmacies, this has to be declared appropiately.

Price

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

Identification

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

Comment [TG1]:

Additional Requirements for the Package Leaflet

For veterinary medicinal product containing prohibited substances in accordance with § 1 section 2 of the Austrian Anti-Doping Convention 2007, the following sentence has to be added:
"Die Anwendung des Arzneimittels [Bezeichnung des Arzneimittels einsetzen] kann bei Dopingkontrollen zu positiven Ergebnissen führen." (= The administration of the medicinal product may result in positive doping controls).

Identification

The marketing authorisation number "Z.Nr." is required in the package leaflet.

~~***Additional or deviating information for centralised authorised products***~~

~~**Price**~~

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

~~**Identification**~~

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

BELGIUM (BE)

Additional Requirements for the Labelling

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.

Identification

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

Comment [TG2]:

~~***Additional or deviating information for centralised authorised products***~~

~~**Identification**~~

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

BULGARIA (BG)

Additional Requirements for the Labelling and Package leaflet

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.

Comment [TG3]:

In the other cases Where the VMP can be sold without prescription the note **'Без лекарско предписание'** shall be placed on each primary and outer packaging of the VMP.

Comment [TG4]:

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'.**

Comment [TG5]:

~~***Additional or deviating information for centralised authorised products***~~

~~**None**~~

CROATIA (HR)

No Additional Requirements for the Labelling and Package Leaflet

No specific requirements.

Additional Requirements for the Package Leaflet

No specific requirements.

Comment [TG6]:

~~Additional or deviating information for centralised authorised products~~

~~None~~

CYPRUS (CY)

No Additional Requirements for the Labelling and Package Leaflet

No specific requirements.

Additional Requirements for the Package Leaflet

No specific requirements.

Additional or deviating information for centralised authorised products

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.

Comment [TG7]:

CZECH REPUBLIC (CZ)

Additional Requirements for the Labelling

Legal Status

The following words are specific for **categories of prescription**

- depending on category of veterinary medicinal products that **are subject to prescription:**

<Na předpis.> or <Veterinární léčivý přípravek je vydáván pouze na předpis.> *(Where this information is not included in the approved text for packaging according to the current veterinary product template)*

When the veterinary medicinal product is **only intended for administration by a veterinary surgeon**, the above mentioned sentence shall followed by the present statement:
<Pouze pro použití veterinárním lékařem.>

For specific veterinary medicinal product with **restricted prescription (narcotic and psychotropic substances)** according the national act No. 167/1998 Coll.

The picture shall be completed with blue strip if the substance is additionally classified in accordance with §13, section 1 of the above mention national act.

- depending of category of veterinary medicinal products that are **not subject to prescription:**

For veterinary medicinal products **available in pharmacy**:
<Bez předpisu.> or <Veterinární léčivý přípravek je vydáván bez předpisu.> *(Where this information is not included in the approved text for packaging according to the current veterinary product template)*

For specific veterinary medicinal products that are not subject to prescription and are **available in authorised merchants – petshops**:
<Vyhrazený veterinární léčivý přípravek.>

The following words (Indikační omezení = prudent use) are required for certain veterinary medicinal products containing **antimicrobial substances,** in accordance with national law. Concerning the veterinary medicinal products which are the subjects to prescription and which are **intended to be reserved for the treatment of severe infections and clinical conditions which have responded poorly, or are expected to**

respond poorly (refers to very acute cases when treatment must be initiated without bacteriological diagnosis), to first line treatment. Their use should be whenever possible based on results of susceptibility testing of target pathogens and on detection of resistance to other classes of antibiotics.

<Indikační omezení>

The following words shall be used for **homeopathic products:**
<Veterinární homeopatický léčivý přípravek>
When the veterinary **homeopathic product** is approved by the **simplified registration procedure**, the use text shall be as follows:
<Veterinární homeopatický léčivý přípravek bez schválených léčebných indikací>

Identification

There is no requirement for the EAN1 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.

Comment [TG8]:

Additional or deviating information for centralised authorised products

~~**None**~~

[1] European Article Number

DENMARK (DK)

Additional Requirements for the Labelling

Legal Status

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

Comment [TG9]:

Identification

The Nordic number is required on the outer labelling of all medicinal products, except radiopharmaceuticals, certain vitamins and mineral products, homeopathic, herbal and traditional herbal medicinal products. It may be written as “Vnr XX XX XX”.

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

Comment [TG10]:

Additional requirements (only for national, MR & DC products)

Other warnings to be included in the labelling are listed in section 29(1-3) and section 31(4-6) of the Danish executive order no 869 of 21 July 2011, as amended on labelling etc. of medicinal products (Danish title: Bekendtgørelse nr. 869 af 21. juli 2011, med senere ændringer, om mærkning m.m. af lægemidler).

Additional Requirements for the Package Leaflet (only for national, MR & DC products)

Section / Explanation	English translation	Danish text required in the package leaflet
Section 8, Dosage for each species, route(s) and method of administration	Please notice that your veterinarian may have prescribed the medicinal product for a different therapeutic indication and/or at a different dosage than stated in the package leaflet. Always follow the veterinarian's prescription and the instructions on the dosage label.	Vær opmærksom på, at dyrlægen kan have foreskrevet anden anvendelse eller dosering end angivet i denne information. Følg altid dyrlægens anvisning og oplysningerne på doseringsetiketten.
Section 6, Adverse reactions: - *After the sentence "If you notice any serious effects.."*	Side effects can thereby be reported to the Danish Health and Medicines Authority and the knowledge about side effects can be improved. The owner of the animal can also report side effects directly to the Danish Health and Medicines Authority. You can find guidance on the Danish Health and Medicines Authority's website (see Pharmacovigilance). www.sst.dk	Bivirkningerne kan dermed blive indberettet til Sundhedsstyrelsen, og viden om bivirkninger kan blive bedre. Dyrets ejer kan også indberette bivirkninger direkte til Sundhedsstyrelsen. De/du finder skema og vejledning under Bivirkninger på Sundhedsstyrelsens netsted. www.sst.dk

Field Code Changed

~~***Additional or deviating information for centralised authorised products***~~

Additional information (only for CP products):

Comment [TG11]:

Products containing inflammable material must bear the international warning symbol:

- 

ESTONIA (EE)

No Additional Requirements for the Labelling and Package Leaflet

No specific requirements.

Additional Requirements for the Package Leaflet

No specific requirements.

Comment [TG12]:

~~***Additional or deviating information for centralised authorised products***~~

~~**None**~~

FINLAND (FI)

Additional Requirements for the Labelling

Legal Status

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

Comment [TG13]:

Identification and Authenticity

The Nordic number is required on the label of all medicinal products, except radiopharmaceuticals and herbal remedies. It is written as “Vnr XX XX XX”.

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

Comment [TG14]:

Symbols and Pictograms

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

~~**Additional Requirements for the Package Leaflet**~~
~~**(only for national, MR & DC products)**~~

~~Advice regarding disposal of unused veterinary medicinal product should be in the package leaflet in both Finnish and Swedish versions.~~

~~(The unused product should be taken to a pharmacy or toxic waste disposal plant)~~

~~Finnish:~~

~~"Käyttämättä jäänyt valmiste toimitetaan hävitettäväksi apteekkiin tai ongelmajätelaitokselle"~~

~~In case of common pack for Finland/Sweden the words "För Finland:" should be added before the sentence in Swedish~~

~~"Oanvänt läkemedel levereras till apotek eller problemavfallsanstalt för oskadliggörande."~~

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FRANCE (FR)

Additional Requirements for the Labelling

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.
- "A NE DELIVRER QUE SUR ORDONNANCE DEVANT ETRE CONSERVEE PENDANT AU MOINS 5 ANS" for products intended for food producing animals.
- « VACCIN : DELIVRANCE SOUMISE A ORDONNANCE » for vaccines.
- « PRODUIT IMMUNOLOGIQUE : DELIVRANCE SOUMISE A ORDONNANCE » for immunological products other thna vaccines (sera for instance).

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, per lingual, 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 appropriate, the French MA number has to appear on the label.

~~***Additional or deviating information for centralised authorised products***~~

~~**None**~~

GERMANY (DE)

Additional Requirements for the Labelling

Legal Status

The legal status is required on the label:

- "apothekenpflichtig" = to appear in the case of medicinal products that are not subject to medical prescription but are only available in pharmacies or from veterinarians
- ~~"verschreibungspflichtig" = in case of veterinary medicinal products that are subject to medical prescription only~~
- "verschreibungspflichtig; Betäubungsmittel" in case of narcotics **(only for national, MR & DC products)**
- No separate statement is necessary in the case of products, which are neither prescription only nor pharmacy only.

Identification and Authenticity

- ~~The declaration of the constituents has to be stated in accordance with the declaration published by the German Federal Institute for Drugs and Medical Devices (BfArM).~~
- In respect of sera, the animal species from which they were obtained, in respect of vaccines, particulars of the host system serving the multiplication process of the virus shall be given. **(only for label & outer package)**
- A barcode is accepted on the label. A distribution number (PZN, i.e. Pharmazentralnummer) is accepted on the label.

Additional information:

- In case of samples the indication "unverkäufliches Muster" (sample – not for sale) is required. **(only for national, MR & DC products)**
- A special symbol concerning the recycling of the packaging material is accepted such as the "Grüne Punkt".

- ~~National waste disposal instructions, as appropriate, have to be stated.~~

Additional Requirements for the Package leaflet

(only for national, MR & DC products)

- ~~The heading "Gebrauchsinformation" (instructions for use) is required.~~

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Comment [TG15]:

Comment [TG16]:

- ~~The declaration of the constituents has to be stated in accordance with the declaration published by the German Federal Institute for Drugs and Medical Devices (BfArM).~~
- ~~National waste disposal instructions, as appropriate, have to be stated.~~
- Specific requirements in case of narcotics have to be stated.

~~Additional or deviating information for centralised authorised products~~

~~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 (EL)

Additional Requirements for the Labelling

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».

~~**Price**~~

~~On the outer package of the veterinary medicinal products the price should be written in Greek language <<ΣΥΝΙΣΤΩΜΕΝΗ ΑΙΑΝΙΚΗ ΤΙΜΗ ΠΩΛΗΣΗΣ….ΕΥΡΩ>> and in English language << SUGGESTED PRICE….EURO>>.~~

~~Additional or deviating information for centralised authorised products~~

~~**None**~~

HUNGARY (HU)

No Additional Requirements for the Labelling and Package Leaflet

No specific requirements.

Additional Requirements for the Package Leaflet

No specific requirements.

Comment [TG17]:

~~***Additional or deviating information for centralised authorised products***~~

~~**Legal status**~~

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

- ~~for medicinal product only available on medical prescription : **„állatorvosi rendelvényre”,**~~
- ~~for products available without prescription in pharmacy: **„Vény nélkül.** Az állatgyógyászati készítmények forgalmazására jogosultak forgalmazhatják.**”,**~~
- ~~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.~~

ICELAND (IS)

Additional Requirements for the Labelling

Identification

The Nordic Article Number is required on the outer package of all veterinary medicinal products except radiopharmaceuticals, homeopathics and herbal remedies. It is written as “Vnr xx xx xx”.

A barcode is accepted on the package but not required.

Comment [TG18]:

~~***Additional or deviating information for centralised authorised products***~~

~~**None**~~

IRELAND (IE)

The following requirements are in addition to those of Directive 2001/82/EC as amended and the QRD templates.

Immediate packaging	Outer packaging	Package Leaflet
Legal status		
Abbreviation for route of sale and supply, as appropriate: VPO VPO-1 POM POM(E) PS LM CAM	Abbreviation for route of sale and supply, as appropriate: VPO VPO-1 POM POM(E) PS LM CAM	Abbreviation for route of sale and supply and explanatory phrase, as appropriate: VPO Veterinary Practitioner Only VPO-1 Veterinary Practitioner Only POM Prescription Only Medicine POM(E) Prescription Only Medicine (Exempt) PS Pharmacy Only LM Licensed Merchant CAM Companion Animal Medicine
Identification - nationally authorised products		
*Veterinary Product Authorisation (VPA) number	*Veterinary Product Authorisation (VPA) number	*Veterinary Product Authorisation (VPA) number
~~***Identification - centrally authorised products***~~		
~~No additional requirements~~		
Other requirements		
		For nationally authorised immunological products only: If a product is classified as LM the following warning is required 'Prior to first time use on a farm, it is strongly recommended that the advice of a veterinary practitioner is sought'.

~~*Note: Whilst VPA number is included on this list, exceptionally, in justified cases, it may be omitted.~~

Comment [TG19]:

Comment [TG20]:

Additional or deviating information for centralised authorised products

Legal status

1. An animal remedy designated for veterinary practitioner use only may be designated by the following symbols: **VPO** or **VPO 1**

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 (IT)

Additional Requirements for the Labelling

Legal Status

For products "subject to prescription":

- When the veterinary medicinal product contains an active substance of the pharmacological groups listed in article 2, letters c) and h) of the **D.M. 28/07/2009:**

  "Da vendersi soltanto dietro presentazione di ricetta medico-veterinaria in triplice copia non ripetibile" or "Medicinale veterinario soggetto a ricetta.... (veterinary prescription to be decided, on a case by case basis), secondo D.P.R. 309/90 e successive modifiche, tabella II ...." (with the correct letter specified by the Italian authority on a case by case basis according to "Decreto Presidente della Repubblica 9 ottobre 1990, n. 309" as amended).

  followed by:

  "La somministrazione e detenzione del medicinale deve essere effettuata esclusivamente dal medico veterinario."

- When the veterinary medicinal product **contains** an active substance of the pharmacological groups listed in art. 2 of the **D.M. 28/07/2009:**

  "La somministrazione del medicinale deve essere effettuata esclusivamente dal medico veterinario. "

  The veterinary prescription to be decided according to articles 75 and 76 of **D. Lgs. n. 193, 06/04/2006.**

- When the veterinary medicinal product is intended for food producing animals, according to **D. Lgs. n. 193, 06/04/2006, art. 76**:

  "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 or companion animals, according to **D. Lgs. n. 193, 06/04/2006, art. 75**:

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

- or, only for a veterinary medicinal product intended for companion animals, according to **D. Lgs. n. 193, 06/04/2006, art. 76, section 6**:

  "Da vendersi dietro presentazione di ricetta medico-veterinaria ripetibile" (to be sold with a renewable vet. med. prescription)

- In the case of a veterinary medicinal product authorized without prescription.

  "Medicinale veterinario senza obbligo di ricetta medico veterinaria"

For veterinary medicinal product containing psychotropic substances, the following sentence has to be specified:

"Medicinale veterinario soggetto a ricetta.... (veterinary prescription to be decided, on a case by case basis), secondo D.P.R. 309/90 e successive modifiche, tabella II ...." (with the correct letter specified by the Italian authority on a case by case basis according to "Decreto Presidente della Repubblica 9 ottobre 1990, n. 309" as amended).

Identification

The national identification number (N.I.N.) and the barcode (DM 17/12/2007) are required in the label.

Any other information according to D. Lgs. n. 193, 06/04/2006, articles 30 or 58, section 5, published in the "Supplemento ordinario alla Gazzetta Ufficiale" n. 121, 26/05/2006 is required, where applicable.

Additional or deviating information for centralised authorised products

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").

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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.

Comment [TG21]:

LATVIA (LV)

Additional Requirements for the Package leaflet

~~Conditions or r~~Restrictions regarding supply ~~and use if applicable~~ must be mentioned in Section 15.

Additional or deviating information for centralised authorised products

~~**None**~~

Legal Status

1. For immunologicals, general anesthetics, narcotic analgesics, psychotropics and for specific products which have special precautions for use or they can cause potential hazard to human or animal health:
   "**Izplatīšanai tikai praktizējošam veterinārārstam.**"
   (For supply only to veterinary practitioner).

2. For all veterinary medicinal products: restrictions regarding supply must be mentioned under Section 15 of Package leaflet.

LIECHTENSTEIN (LI)

No Additional Requirements for the Labelling and Package Leaflet

No specific requirements.

Additional Requirements for the Package Leaflet

No specific requirements.

Comment [TG22]:

~~***Additional or deviating information for centralised authorised products***~~

~~**None**~~

LITHUANIA (LT)

No Additional Requirements for the Labelling and Package Leaflet

No specific requirements.

Additional Requirements for the Package Leaflet

No specific requirements.

Comment [TG23]:

~~Additional or deviating information for centralised authorised products~~

~~None~~

LUXEMBOURG (LU)

No Additional Requirements for the Labelling and Package Leaflet

No specific requirements.

Additional Requirements for the Package Leaflet

No specific requirements.

Comment [TG24]:

~~Additional or deviating information for centralised authorised products~~

~~None~~

MALTA (MT)

No Additional Requirements for the Labelling and Package Leaflet

No specific requirements.

Additional Requirements for the Package Leaflet

No specific requirements.

Comment [TG25]:

~~***Additional or deviating information for centralised authorised products***~~

~~**None**~~

NETHERLANDS (THE) (NL)

Additional Requirements for the Labelling

Legal Status

UDD – (Uitsluitend door dierenartsen toe te dienen – administration only by veterinarian), or

UDA – (Op recept van dierenarts, af te leveren door de dierenarts of apotheker – prescription by veterinarian, for supply by veterinarian or pharmacist), or

URA – (Op recept van dierenarts, af te leveren door de dierenarts, apotheker of vergunninghouder – prescription by veterinarian, for supply by veterinarian, pharmacist or licensed retailer), or

VRIJ – (Freely available without prescription in pharmacies, pet shops and by licensed retailers)

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Identification

The national identification number is required on the label.

~~***Additional or deviating information for centralised authorised products***~~

~~**None**~~

NORWAY (NO)

Additional Requirements for the Labelling

Legal status:
There are no additional requirements

Comment [TG26]:

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.

Comment [TG27]:

Additional warnings:

Products containing inflammable material must bear the international warning symbol:

- Brannfarlig + symbol 

- English translation: Inflammable + symbol 

Comment [TG28]:

POLAND (PL)

Additional Requirements for the Labelling

Legal Status

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

- **Legal status regarding categories of administration:**

  Wydawany z przepisu lekarza - Rp = available on prescription only

  Wydawany bez przepisu lekarza - OTC = available without prescription

- **Legal status regarding distribution/dispensing:**

  Do podawania wyłącznie przez lekarza weterynarii = Administration by the veterinary surgeon only

  Do podawania pod nadzorem lekarza weterynarii = Administration by the veterinary surgeon or under their direct responsibility

  Do podawania przez właściciela lub opiekuna zwierzęcia = Administration by the owner or animal keeper

The description of the legal status must be exactly the same as in the Marketing License

(= Pozwolenie na dopuszczenie do obrotu)

Identification and Authenticity

The EAN code is required on the label.

Additional or deviating information for centralised authorised products

~~**None**~~

PORTUGAL (PT)

A - ITEMS MANDATORY FOR PHARMACOLOGICALS

IMMEDIATE LABEL (≥ 50 ML) AND OUTER PACKAGING

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 a responsabilidade directa do médico-veterinário" (to be administered under the responsability of a veterinarian).

2. Veterinary Medicinal 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 autorizadas de fabrico de alimentos medicamentosos para animais".

Formatted: English (U.S.)

OUTER PACKAGING

1. "MVG" for generic veterinary medicinal products.

B - ITEMS MANDATORY FOR IMMUNOLOGICALS

IMMEDIATE LABEL (≥ 50 ML) AND OUTER PACKAGING

The following sentences are mandatory unless authorized otherwise:

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

   or,

2. "Só pode ser administrado sob a responsabilidade directa do médico-veterinário" (to be administered under the responsability of a veterinarian).
3. Name/address of the local representative/distributor.

PACKAGE LEAFLET

1. Name/address of the local representative/distributor.

C - ITEMS MANDATORY FOR PHARMACOLOGICALS AND IMMUNOLOGICALS

IMMEDIATE LABEL (≥ 50 ML) AND OUTER PACKAGING

1. The legal status is required in the blue box, if not mentioned elsewhere on the label.

Comment [TG29]:

2. If considered necessary, 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. AIM nº (Portuguese MA number).
4. "Manter fora da vista e do alcance 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, or in bold and upper case.

IMMEDIATE LABEL OF SMALL CONTAINERS (< 50 ML)

(Small immediate packaging units are defined as containers sized up to and including 50 ml, for greater containers full information is required):

Withdrawal period

AIM nº (Portuguese MA number)

Additional or deviating information for centralised authorised products

(Harmonisation is proposed, but the proposalwas not send)

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 (RO)

Additional Requirements for the Labelling

Price

There is no requirements for the price to appear on the label and package leaflet

Reimbursement

There is no requirement for the reimbursement conditions to appear on the label.

Comment [TG30]:

Legal Status

The legal statutus is required to be expressed on the label for prescription-only products.

Comment [TG31]:

The following mentions must appear in the boxed area:

For medicinal products supplied in pharmacy based on veterinary prescriptions:

- Se elibereaza pe baza de prescriptie medicala : **PRF =**available with prescription

- Se elibereaza pe baza de prescriptie medicala speciala cu timbru sec: **PTS=** available with special prescription /stamp

- Se elibereaza fara prescriptie medicala : **OTC =** available without prescription

Symbols or pictograms

Medicinal products containing inflammable material must bear the international warning symbol:-

If veterinary medicinal product contains a narcotic or psychotropic substance indicate a follows:

- **Produsul medicinal veterinar contine o substanta narcotica** (Veterinary product contains a narcotic substance.)
- **Produsul medicinal veterinar contine o substanta psihotropa** (Veterinary product contains a psychotropic substance.)

Identification

Veterinary Product Authorisation (VPA) number on the label .
In justified cases VPA may be omitted
Barcodes are accepted on the label, but are not required.

Comment [TG32]:

Additional or deviating information for centralised authorised products

Comment [TG33]:

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 (SK)

Additional Requirements for the Labelling

~~**Identification**~~

~~The EAN bar codes are accepted when they are put on the label.~~

~~**Additional information**~~

~~Recycling symbols are accepted.~~

~~***Additional or deviating information for centralised authorised products***~~

~~(Agreement on harmonisation)~~

Legal status

For specific veterinary medicinal products with restricted prescription (**narcotic and psychotropic substances**) according the national act No. 362/2011 Coll:
<VETERINÁRNY LIEK OBSAHUJE OMAMNÚ LÁTKU.>
or
<VETERINÁRNY LIEK OBSAHUJE PSYCHOTROPNÚ LÁTKU.>

For **homeopathic** veterinary products shall be used the following words:
<HOMEOPATICKÝ VETERINÁRNY LIEK. >

When the homeopathic veterinary product is approved by the simplified authorisation procedure shall be used he following words:
<HOMEOPATICKÝ VETERINÁRNY LIEK BEZ SCHVÁLENÝCH TERAPEUTICKÝCH INDIKÁCIÍ. >

When the homeopathic veterinary product was not pharmacologically, toxicological and clinical tested shall be used the following words:
< VETERINÁRNY LIEK NEBOL KLINICKY SKÚŠANÝ. >

For the **radioactive veterinary** medicinal product shall be used the international symbol for radioactivity and the quantity of radioactivity.

Identification

The GTIN bar codes are accepted when they are put on the label

Additional information

Recycling symbols are accepted

Package leaflet

Where veterinary medicinal product is subject to prescription:

< Na veterinárne použitie - Výdaj len na veterinárny lekársky predpis>

SLOVENIA (SI)

No Additional Requirements for the Labelling and Package Leaflet

No specific requirements.

Additional Requirements for the Package Leaflet

No specific requirements.

Comment [TG34]:

~~***Additional or deviating information for centralised authorised products***~~

~~**None**~~

SPAIN (ES)

Additional Requirements for the Labelling

The following requirements for outer packaging of veterinary medicines are according to *Real Decreto 1246/2008, de 18 de julio, por el que se regula el procedimiento de autorización, registro y farmacovigilancia de los medicamentos veterinarios fabricados industrialmente* .

Legal status:

The medicinal product may only be supplied in accordance **with a prescription** (legends and pictograms), including **controlled drugs** (psicotropics according to Annex I or II of RD 2829/1977):

- Supplied with a prescription*: Dispensación con receta veterinaria* ○
- Supplied with a prescription for narcotics: *Dispensación con receta de estupefacientes* ●
- Supplied with a prescription for psicotropics*: Dispensación con receta de psicótropos* ◐ anexo I del RD 2829/1977
- Supplied with a prescription for psicotropics*: Dispensación con receta de psicótropos* ◑ anexo II del RD 2829/1977

Requirements of preservation:

- Preservation in a fridge*: Conservación en frigorífico* ✱
- Preservation in a freezer *Conservación en congelador* ✱✱

Further information

- The medicinal product may only be administered by a surgeon:

  Administración exclusiva por el veterinario **AV**
- In all medicinal products for veterinary use: *"USO VETERINARIO"*.
- In the particular case of medicinal premixes for feed: *"Premezclas medicamentosas para piensos"*.
- National code number (*Código Nacional*) is granted for every authorised format of all medicinal products and required on the outer packaging. It is written as *C.N. XXXXXX.X*. in the main face on the upper right corner. "
- In cases requiring a prescription symbol or "AV" should be included on a dedicated place of the outer package, upper right corner, outside the blue-box.

~~***Additional or deviating information for centralised authorised products***~~

~~**None**~~

SWEDEN (SE)

Additional Requirements for the Labelling

Price

There is no requirement for the price to appear on the label.

Reimbursement

There are no reimbursement conditions to appear on the label.

Legal status

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

Comment [TG35]:

Identification and authenticity

The Nordic number is required on the label of all medicinal products, except radiopharmaceuticals and herbal remedies. It is written as “Vnr XX XX XX”.
A bar code is accepted on the label but not required.

Comment [TG36]:

Additional requirements regarding OTC for Labels and the Package Leaflet

As the Legal status may differ between MS there is a need for the possibility to make additional amendments as adequate for the legal status.

~~***Additional or deviating information for centralised authorised products***~~

Additional information (only for CP products):

Comment [TG37]:

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

UNITED KINGDOM (UK)

Additional Requirements for the Labelling

Legal Status

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 Veterinarian 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 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.

Comment [TG38]:

Additional Information

'Keep out of reach of children' – if not included elsewhere on product literature

Comment [TG39]:

'Keep the container in the outer carton'

~~***Additional or deviating information for centralised authorised products***~~

~~None~~