EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

3 April 2017
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QRD template 'Particulars to appear on the immediate package – combined label and package leaflet' for veterinary medicinal products authorised via the centralised (CP), mutual recognition (MRP) and decentralised procedures (DCP)

Draft

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Comments should be provided using this template. The completed comments form should be sent to qrd@ema.europa.eu

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - <u>COMBINED LABEL AND PACKAGE LEAFLET</u>

{NATURE/TYPE}

- *This template caters for the situation where applicants intend not to print a package leaflet and propose to accommodate all labelling + package leaflet information on the immediate packaging, which is foreseen by Art. 61(1) of Directive 2001/82/EC: "The inclusion of a package leaflet in the packaging of veterinary medicinal products shall be obligatory unless all the information required by this Article can be conveyed on the immediate packaging and the outer packaging".*
- *The combined label-leaflet template can only be used when **all** the printed information is **directly visible** on the immediate container and cannot be used if a fold-out or concertina format is proposed.*
- *Sections 1 to 17 relates to information according to package leaflet requirements. Sections 18 to 22 relates to additional information as per labelling requirements and which are not covered by sections 1 to 17.*
- *All information shall be clearly displayed on the printed label. Information given in sections 2, 4, 5, 9 and 19 must be displayed on the main panel and in the same field of vision as these are important items for correct and safe identification, avoidance of mix-ups of the veterinary medicinal product and child safety. Advice and warnings <u>crucial</u> for correct use of the veterinary medicinal product given in sections 11 and 14 as well as route of administration as given in section 10 shall also be included in the main field of vision when applicable.*
- *Boxed headings are provided to help applicants when completing the template; they should remain in the opinion/decision annexes. However, they are not to appear in the final printed packaging materials (mock-ups/specimens).*
- *The headings numbers are not to be printed on mock-ups and on the final printed material. These are only included in the template to facilitate navigation.*

1. Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release , if different

[Name or corporate name and permanent address or registered place of business of the marketing authorisation holder and of the manufacturer responsible for batch release and, where appropriate, of the representative of the marketing authorisation holder – see also section 15.]

[Including town, postal code (if available) and country name in the language of the text (Telephone Fax numbers, e-mail addresses may be included (no websites or e-mails linking to websites allowed).]

[For MRP/DCP: To be completed nationally.]

<<u>Marketing authorisation holder <and manufacturer responsible for batch release:></u>

<<u>Manufacturer responsible for batch release</u>:>

2. Name of the veterinary medicinal product

[Name of the veterinary medicinal product followed by strength (if applicable) and pharmaceutical form. The common name shall appear if the product contains only one active substance and its name is an invented name.]
[Target species: according to the target species CTL on the EUTCT website http://eutct.ema.europa.eu/eutct/displayWelcome.do]

{(Invented) name of veterinary medicinal product <strength> pharmaceutical form <target species>}
{active substance(s)}

3. Statement of the active substance (s) and other ingredients

[Qualitative and quantitative composition in terms of the active substances and constituents of the excipient, knowledge of which is essential for proper administration of the veterinary medicinal product. Include information on the description of the pharmaceutical form. Also, include information on the appearance of the product before reconstitution/dilution, if applicable.]

4. Pharmaceutical form

Pharmaceutical form according to the full "Standard terms" published by the Council of Europe. If the pharmaceutical form is already mentioned following the name of the product, it should be repeated here in grey shading (i.e. it will appear in the template text but NOT on the mock-ups and on the final printed materials) e.g. Oral solution.]

5. Package size

[By weight, by volume or by number of doses of the veterinary medicinal product (i.e. package size, including a reference to any ancillary items included in the pack such as needles, swabs; content of bottle etc.).]
[A short statement should be used to describe the package size:
e.g.
"10 ml"(not "10 ml vial")
"10 x 50 ml" (not "10 vials with 50 ml of solution for injection")]

[In case of a combined text covering different package-sizes of the same strength, further package-size(s) should be included in grey shading.
e.g.
28 tablets
56 tablets
100 tablets]

6. Indication(s)

[Indication(s) in the target species should be stated here, using understandable language.
A short section describing clearly the benefits of the veterinary medicinal product and the purpose of the treatment should be stated here, using understandable language, in order to provide a good balance between information on the benefits of the product and its risks.]

7. Contraindications

[Include information under section 4.3 of the SPC, if applicable.]

8. Adverse reactions

[All adverse reactions displayed during the course of one treatment should be ranked in "frequency groupings" with the most frequently occurring reactions listed first.]

[If frequencies of adverse reactions are included, the following statements should also be included at the end of the section.]

<The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).>

[Close this section with:] If you notice any side effects, even those not already listed in this label or you think that the medicine has not worked, please inform your veterinary surgeon.

[For MRP/DCP only:
The following statement may also be added <Alternatively you can report via your national reporting system {national system details}.>*]*

9. Target species

[According to the target species CTL on the EUTCT website http://eutct.ema.europa.eu/eutct/displayWelcome.do]

[Include any sub-categories.]

10. Dosage for each species, route(s) and method of administration

[Method of administration: directions for proper use of the veterinary medicinal product.]

[Route of administration: According to "Standard terms" published by the Council of Europe. See also QRD reference document "Tables of non-standard abbreviations".]

11. Advice on correct administration

[Directions for proper use by healthcare professionals, farmer or animal owner; including practical details such as mixing instructions. A description of appearance after reconstitution, if applicable.]

[Where appropriate, warning against certain visible signs of deterioration.]
<Do not use {name} if you notice {description of the visible signs of deterioration}.>

12. Withdrawal period(s)

[As it appears in the SPC.]
[Not applicable for non-food producing animals. Present by species and/or food components.]

<Withdrawal period(s):>
[If withdrawal period is not applicable, the template heading should be deleted and the section should be left blank.]

13. Special storage precautions

<Do not store above <25°C> <30°C>.> or
<Store below <25°C> <30°C>.>
<Store in a refrigerator (2°C - 8°C).>
<Store and transport refrigerated (2°C - 8°C).>*
<Store in a freezer {temperature range}.>
<Store and transport frozen {temperature range}.>**
<Do not <refrigerate> <or> <freeze>.>
<Protect from frost.>***
<Store in the original <container><package>>

<Keep the {container}**** tightly closed>

<in order to protect from <light> <and> <moisture>.>

<Protect from light.>
<Store in a dry place>
<Protect from direct sunlight.>

<This veterinary medicinal product does not require any special storage conditions.>
<This veterinary medicinal product does not require any special temperature storage conditions.>*****

[The stability data generated at 25°C/60 % RH (acc) should be taken into account when deciding whether or not transport under refrigeration is necessary. The statement should only be used in exceptional cases.*
*** This statement should be used only when critical.*
**** E.g. for containers to be stored on a farm.*
***** The actual name of the container should be used (e.g. bottle, blister, etc.).*
******Depending on the pharmaceutical form and the properties of the product, there may be a risk of deterioration due to physical changes if subjected to low temperatures. Low temperatures may also have an effect on the packaging in certain cases. An additional statement may be necessary to take account of this possibility.]*

Do not use this veterinary medicinal product after the expiry date which is stated on the <label> <bottle> <...> <after {abbreviation used for expiry date}>. *[Where a specific abbreviation for Expiry date is used on the labelling, it should be mentioned here.]* <The expiry date refers to the last day of that month.>

14. Special warning(s)

[Warnings from relevant sections 4.4, 4.5, 4.7, 4.8, 4.10 and 6.2 from the SPC should be included as appropriate in user-friendly wording.]
[Sub-headings should be used in this section to list warnings and precautions. For certain veterinary medicinal product not all sub-headings may be relevant, in this case the heading should not be included.]

[For warning on accidental self-administration, etc. include statement as it appears in the SPC.]

<None.>

<Special warnings for each target species:>

<Special precautions for use in animals:>

<Special precautions to be taken by the person administering the veterinary medicinal product to animals:>

[If the veterinary medicinal product contains mineral oil, the warnings in the SPC should be repeated here.]

<Pregnancy:>

<Lactation:>

<Pregnancy and lactation:>

<Lay:>

<Fertility:>

<Interaction with other medicinal products and other forms of interaction:>

<Overdose (symptoms, emergency procedures, antidotes):>

<Incompatibilities:>

15. Special precautions for the disposal of unused product or waste materials, if any

[Include information from section 6.6 of the SPC in user-friendly wording.]
[For MRP/DCP only: additional national requirements may apply in some Member States and can be included here.]

<Medicines should not be disposed of via wastewater <or household waste>.>
<Ask your <veterinary surgeon> <or> <pharmacist> how to dispose of medicines no longer required. These measures should help to protect the environment.>

16. Date on which the label was last approved

[Leave blank in case of first authorisation. Item to be completed by the marketing authorisation holder at time of printing the label. Date of approval of latest variation or transfer changing the label, e.g. the latest Commission Decision amending the marketing authorisation, implementation date of Urgent Safety Restriction or date of EMA notification amending the annexes to the marketing authorisation.]
[The date must be stated only in figures <DD/MM/YYYY>.]

[For MRP/DCP: To be completed in accordance with national requirements after conclusion of the MR phase.]

[For veterinary medicinal products authorised via the centralised procedure, the following reference to the European Medicines Agency website should be included:]
Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/ *[Not applicable for MRP/ DCP.]*

<17. Other information>

[For MRP/DCP: Relevant additional text if necessary.]

[Information about pharmacological or immunological properties could be included here.]

[All package sizes must be listed here.]

[If applicable, add:] <Not all pack sizes may be marketed.>

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>

- *[Listing of local representatives is not a requirement, but where used they must be stated for all Member States but if included in the product information annexes, the full list for all Member States must be stated [not applicable for MRP/DCP]. However, a representative may be designated for more than one country and may also be the MAH where no other local representative is indicated. In cases where the same representative is designated for more than one country, the representative's details may be listed only once below the names of the countries concerned.*
- *In the **printed** package leaflet, only the concerned local representative can be mentioned provided the whole list has been included in the product information annexes [not applicable for MRP/DCP].*
- *Where a local representative is located outside the country concerned and where an address is given, the country name must be included in the address of the local representative and must be given in the language(s) of the country for which the local representative is designated.*
- *ISO country codes* may be used to replace the full name of the country heading. ISO codes together with the respective names of EU/EEA countries can be found at the following web site: http://publications.eu.int/code/en/en-370101.htm*
- *In order to save space in the printed package leaflet, local representatives may be presented sequentially rather than in a tabulated format. In case of multi-lingual leaflets, the list of local representatives can be printed only once at the end of the printed leaflet.*
- *The local representative may be indicated by name, telephone number and E-mail address (optional) only. Postal address may be added space permitting. Website addresses or E-mails linking to websites are not allowed.*
- *For Belgium and Finland addresses may appear in two languages, respectively Dutch/French and Finnish/Swedish.*
- *For Greece and Cyprus, the address must appear in Greek.*

Telephone numbers: international dialling code followed by the area code and telephone number, e.g. EMA Tel: + 44-(0)20 7418 8400.]

[except for the United Kingdom, for which UK is recommended (instead of the ISO code GB)]

België/Belgique/Belgien
{Nom/Naam/Name}
<{Adresse/Adres/Anschrift }
BE-0000 {Localité/Stad/Stadt}>
Tél/Tel: + {N° de téléphone/Telefoonnummer/ Telefonnummer}
<{E-mail}>

Република България
{Наименование}
<{Адрес}
BG {Град} {Пощенски код}>
Тел: + 359 {Телефонен номер}
<{E-mail}>

Lietuva
{pavadinimas}
<{adresas}
LT {pašto indeksas} {miestas}>
Tel: +370{telefono numeris}
<{E-mail}>

Luxembourg/Luxemburg
{Nom}
<{Adresse}
L-0000 {Localité/Stadt}>
Tél/Tel: + {N° de téléphone/Telefonnummer}
<{E-mail}>

Česká republika
{Název}
<{Adresa}
CZ {město}>
Tel: +{telefonní číslo}
<{E-mail}>

Danmark
{Navn}
<{Adresse}
DK-0000 {by}>
Tlf: + {Telefonnummer}
<{E-mail}>

Deutschland
{Name}
<{Anschrift}
DE-00000 {Stadt}>
Tel: + {Telefonnummer}
<{E-mail}>

Eesti
(Nimi)
<(Aadress)
EE - (Postiindeks) (Linn)>
Tel: +(Telefoninumber)
<{E-mail}>

Ελλάδα
{Όνομα}
<{Διεύθυνση}
EL-000 00 {πόλη}>
Τηλ: + {Αριθμός τηλεφώνου}
<{E-mail}>

España
{Nombre}
<{Dirección}
ES-00000 {Ciudad}>
Tel: + {Teléfono}
<{E-mail}>

France
{Nom}
<{Adresse}
FR-00000 {Localité}>
Tél: + {Numéro de téléphone}
<{E-mail}>

Magyarország
{Név}
<{Cím}
HU-0000 {Város}>
Tel.: + {Telefonszám}
<{E-mail}>

Malta
{Isem}
<{Indirizz}
MT-0000 {Belt/Raħal}>
Tel: + {Numru tat-telefon}
<{E-mail}>

Nederland
{Naam}
<{Adres}
NL-0000 XX {stad}>
Tel: + {Telefoonnummer}
<{E-mail}>

Norge
{Navn}
<{Adresse}
N-0000 {poststed}>
Tlf: + {Telefonnummer}
<{E-mail}>

Österreich
{Name}
<{Anschrift}
A-00000 {Stadt}>
Tel: + {Telefonnummer}
<{E-mail}>

Polska
{Nazwa/ Nazwisko:}
<{Adres:}
PL – 00 000{Miasto:}>
Tel.: + {Numer telefonu:}
<{E-mail}>

Portugal
{Nome}
<{Morada}
PT-0000–000 {Cidade}>
Tel: + {Número de telefone}
<{E-mail}>

Hrvatska
{Ime}
<{Adresa}
{Poštanski broj} {grad}>
Tel: + {Telefonski broj}
<{e-mail}>

Ireland
{Name}
<{Address}
IE - {Town} {Code for Dublin}>
Tel: + {Telephone number}
<{E-mail}>

Ísland
{Nafn}
<{Heimilisfang}
IS-000 {Borg/Bær}>
Sími: + {Símanúmer}
<{Netfang}>

Italia
{Nome}
<{Indirizzo}
IT-00000 {Località}>
Tel: + {Numero di telefono}>
<{E-mail}>

Κύπρος
{Όνομα}
<{Διεύθυνση}
CY-000 00 {πόλη}>
Τηλ: + {Αριθμός τηλεφώνου}
<{E-mail}>

Latvija
{Nosaukums}
<{Adrese}
{Pilsēta}, LV{Pasta indekss }>
Tel: + {Telefona numurs}
<{E-mail}>

România
{Nume}
<{Adresă}
{Oraş} {Cod poştal} – RO>
Tel: + {Număr de telefon}
<{E-mail}>

Slovenija
{Ime}
<{Naslov}
SI-0000 {Mesto}>
Tel: + {telefonska številka}
<{E-mail}>

Slovenská republika
{Meno}
<{Adresa}
SK-000 00 {Mesto}>
Tel: + {Telefónne číslo}
<{E-mail}>

Suomi/Finland
{Nimi/Namn}
<{Osoite/Adress}
FI-00000 {Postitoimipaikka/Stad}>
Puh/Tel: + {Puhelinnumero/Telefonnummer}
<{E-mail}>

Sverige
{Namn}
<{Adress}
SE-000 00 {Stad}>
Tel: + {Telefonnummer}
<{E-mail}>

United Kingdom
{Name}
<{Address}
{Town} {Postal code} – UK>
Tel: + {Telephone number}
<{E-mail}>

18. The words "For animal treatment only" and conditions or restrictions regarding supply and use, if applicable

For animal treatment only. <To be supplied only on veterinary prescription.>

[For prohibition on manufacture, import, possession, sale, supply and/or use include statement as it appears in the SPC.]

<Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.> *[For premixes for medicated feeding stuff.]*

19. The words "Keep out of the sight and reach of children"

Keep out of the sight and reach of children.

20. Expiry date

[For terms on Batch number and Expiry date see Appendix IV on the European Medicines Agency website http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2014/08/WC500170559.pdf

[The expiry date should be taken to mean the last day of that month. Expiry dates should be expressed with the month given as 2 digits or 3 characters and the year as 4 digits. e.g.:02-2007, Feb 2007]

<EXP {month/year}>

<Once <broached> <opened> <diluted> <reconstituted> <use by…> <use within…><use immediately.>>

[Where applicable, shelf life after reconstitution, dilution or after first opening the container.]
<Shelf life after first opening the container: …..>
<Shelf life after <dilution> <reconstitution> according to directions: …..>
<Shelf life after incorporation into meal or pelleted feed: ….>

21. Marketing authorisation number(s)

[Item to be completed by the marketing authorisation holder once the marketing authorisation has been granted.]
[In case of a combined labelling text covering different package-sizes of the same strength, the respective package-size should be included in grey shading after the corresponding EU Sub-Number and listed on a separate line.
e.g.
EU/0/00/000/001 28 tablets
EU/0/00/000/002 56 tablets
EU/0/00/000/003 100 tablets]

EU/0/00/000/000

[For MRP/DCP only: Number allocated by the Member State. To be completed in accordance with national requirements after conclusion of the MR phase.]

22. Manufacturer's batch number

[For terms on Batch number and Expiry date see Appendix IV on the European Medicines Agency website http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2014/08/WC500170559.pdf

<Batch> <Lot> <BN> {number}