

**CMDv BPG-017**

**BEST PRACTICE GUIDE**

**for**

**the submission of high quality national translations**

**for veterinary medicines**

**Edition number : 00**

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## 1. INTRODUCTION

### *New Applications: DCP and MRP*

The *Best Practice Guide for Veterinary Decentralised Procedure* (DCP) and the *Best Practice Guide for Veterinary Mutual Recognition Procedures* (MRP) of the Co-ordination Group for Mutual Recognition and Decentralised Procedures (CMDv) states that:

- the MAH should send the national translations within **5 days** of the procedure ending.

### *Variations*

The *CMDv Best Practice Guides for variations* states that:

- for type IA, type IB and type II variations the MAH should send the national translations within **10 days** of the procedure ending.

The applicant must submit **high quality national translations** of the product information (*product information = SPC + Labelling + PL*), and mock-ups when required, in accordance with the timelines described in the Best Practice Guides mentioned above. For DCP/MRP marketing authorisation applications the high quality national translations shall be submitted **within 5 days after the end of the procedure**. A product cannot be approved and placed on the market until high quality national translation(s) has been deemed acceptable by the NCA.

MSs may only introduce linguistic changes to the product information and must ensure the national version of the product information is a faithful translation of the final harmonised position (this guidance document does not cover the blue box requirements for each MS).

The applicant should also be aware that translating does not equal a word-to-word translation from one language to another. It is therefore of crucial importance, that the translation is made by a person who has professional knowledge of the field and whose mother tongue should preferably be the target language (avoiding the use of machine translations).

## 2. AIM AND SCOPE

This document aims to improve the quality of translations of the agreed product information submitted during the national implementation phase of the procedures. It provides information about criteria defined to ensure the high quality, clarity, consistency and coherence of the product information translations.

This document also intends to ensure and facilitate the compliance with the timelines by all parties involved to comply with the established legal timeframe for the national phase and to avoid delay in the market access of the veterinary medicinal products.

This guidance should be read together with the:

- CMDv Best Practice Guide for the Veterinary Decentralised Procedure
- CMDv Best Practice Guide for the Veterinary Mutual Recognition Procedure
- CMDv Best Practice Guide For Renewals
- CMDv Best Practice Guide For Type IA Variations
- CMDv Best Practice Guide For Type IB Variations

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- CMDv Best Practice Guide For Type II Variations
- National guidance on language specific conditions

There is a requirement for package leaflets to be written in terms, which the general public will find easy to understand.

### 3. CRITERIA TAKEN IN ACCOUNT FOR LINGUISTIC REVIEW OF THE PRODUCT INFORMATION

In accordance with the guidance established in the *CMDv Best Practice Guides for Veterinary Medicinal Products (please see list above in section 1)*, the applicant must submit high quality translations of the final agreed versions of the product information.

To guarantee the quality of the product information translation, the applicant should check all crucial issues ensuring their compliance, namely a complete national translation with **clear wording**. Specific attention should be given to spelling, punctuation and other grammatical aspects taking also into account the extent of editorial and stylistic changes, particularly with the rephrasing of the texts ensuring that the meaning of the information is clear and comprehensible and in agreement with the final harmonised product information.

A correct user friendly translation of the PL is just as important as a high quality medically correct translation of the SPC. This will often not be achieved by a literal translation of the English text.

**The proposed product information should take into account the following points:**

***a) Compliance of the translation with the final agreed product information***

The applicant must ensure a faithful translation of the final agreed product information approved at the end of the European phase of the procedure, avoiding omissions and/or addition of sentences, terms or paragraphs.

***b) Use of QRD vet template, country specific national language version***

The submitted translations must ensure that the latest approved QRDvet/CMDv veterinary template version and its appendixes are used. Therefore, the applicant should not use different titles, subtitles and sentences from those stated on current QRDvet/CMDv veterinary template and its appendixes.

The current QRDvet/CMDv veterinary template *including implementation plans* are available at the [EMA\\_QRD\\_website](http://www.ema.europa.eu/ema/pressroom/pressroom_content.cfm?id=EMEA_P010101) and at the CMDv pages at HMAs website <http://www.hma.eu/166.html>.

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### **c) User-friendly terms for the Package Leaflet**

**NEW** *New wording in the QRDvet/CMDv template [Version 8, 10/2012]*

"The package leaflet must be easily readable for the healthcare professionals, farmers **and** animal owners."

The package leaflet should reflect the terminology the user is likely to be familiar with.

References:

- Instructions preceding the leaflet section in the [annotated template](#).
- Article 61 in Directive 2001/82/EC, amended by Directive 2004/28/EC.

### **d) Tables of non-standard abbreviations**

Tables of [non-standard abbreviations](#) should be applied. Please refer to the EMA QRD website.

### **e) Compilation of QRD decisions on stylistic matters in product information**

A [compilation of QRD decisions](#) on stylistic matters in product information should be adhered to. Please refer to the EMA QRD website.

### **f) Differences between QRDvet/CMDv veterinary template**

Please refer to the [annotated template](#) for the sections of the QRDvet/CMDv veterinary template which are not identical for the centralised procedure versus DCP/MRP.

### **g) Use of the appropriate scientific terminology**

The scientific terms used in the translation of the product information should be carefully checked. Therefore, the applicant should use appropriate scientific terminology and take into account that if a standard statement is used in the English text, a standard translation should be used, namely:

- 1) In all sections where reference is made to the pharmaceutical form, the standard term according to the EDQM should be used (current version of the *Standard Terms – European Pharmacopoeia*).
- 2) The information in the SPC, Section 6.4 "Special precautions for storage" should comply with the Storage condition statements (available in the QRDvet/CMDv veterinary template).
- 3) The information regarding Batch number and Expiry date should comply with Appendix IV of the QRDvet/CMDv veterinary template.
- 4) With regard to the active substances and excipients, their naming should always follow the INN or European Pharmacopoeia terminology *in national language*, where applicable.
- 5) In all sections where reference is made to the routes of administration and primary packages, the standard terms in accordance with the EDQM should be used (current version of the *Standard Terms – European Pharmacopoeia*).

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***h) Consistency of terminology with other veterinary medicinal products (innovator, generic or class-similar medicinal products) already approved***

The applicant should take into account the terminology already approved by the NCA for the reference veterinary medicinal product or a veterinary medicinal product with the same active substance or from the same therapeutic class.

Additionally, it should be noted that for generic applications to centrally authorised products the applicant shall use the national wording from the centrally approved product in all relevant sections of the SPC and PL, provided that the final English product information follows the wording from the centrally approved product.

Furthermore, generics implementing the wording of an article 34 Commission Decision for the innovator product should comply with the national translation published in the [Community Register](#).

Where the existence of usage patent(s) leads to differences in the product information compared to the reference medicinal product, this should be indicated accordingly when submitting the national translations.

***i) National blue-box requirements***

The applicant must ensure that all national blue box requirements are taken into account. The requirements are stated in the document "[Packaging 'blue-box' requirements for products authorised via national, mutual recognition or decentralised procedures](#)", published at the HMA website,

## **4. PROCESS OF REVIEWING THE TRANSLATIONS**

### **4.1. Submission**

The applicant must submit, to all MS involved in the procedure, high quality national translations of the SPC, Labelling and PL (and mock-ups if necessary), according to the *CMDv Best Practice Guides* for Veterinary Medicinal Products listed in section 1 above.

Final DCP/MRP English texts circulated by the RMS and not the texts from the earlier phases of the procedure must be used for the national translations.

Marketing authorisation applicants or marketing authorisation holders are advised to take into account the criteria defined above in Section 3. Any deviation to the principles identified should be avoided.

Where combined labels in more than one Member State are being sought, this should have been considered during the application procedure as a space restriction might exist and a solution has to be sought in trying to fulfil the legal requirements for harmonisation, the national legal requirements and the safe use of veterinary medicinal products. The submission of mock-ups during the application procedure reflecting the maximum number of intended languages to be included on multilingual packs (or a minimum 3 x EN) can facilitate this process. If a combined label for more than one MS is intended, the applicant should have sought agreement

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on the invented name of the product with the CMS(s) affected, as early as possible in the application procedure. The applicant should liaise with the NCAs concerned by the combined packaging and communicate all comments received from NCAs. Please refer to Q&A N. 130/2011 regarding "[Changes to the invented name during mutual recognition or decentralised procedures](#)".

## **4.2. National implementation**

### *MRP and DCP:*

The National Competent Authority (NCA) of each member state (MS) shall adopt, for new applications, extensions and renewals, a national decision **30 days** after the RMS closes the procedure, subject to submission of acceptable translations.

### *Type IA variations:*

Competent authorities should implement the decision nationally within:

- Two months in the case of a variation(s) that does not require immediate notification or
- Six months if the variation(s) does require immediate notification.

### *Type IB variations:*

The national competent authorities should implement the decision nationally within 6 months after acceptance.

### *Type II variations:*

The national competent authorities should implement the decision nationally within 2 months after acceptance.

## **4.3. In case of non-acceptability**

In case the quality of the national translations is not acceptable, the NCA will inform the applicant of the identified deficiencies and request the applicant to address these and resubmit updated national translations. The NCA can preferably send an electronic version of a Word document with tracked changes.