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

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BEST PRACTICE GUIDE

for

Processing of SPC, Labelling and Packaging provided in support of Mutual Recognition and Decentralised Applications

Edition 02

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1. INTRODUCTION

1.1. Under Article 32 Paragraph 4 of Directive 2001/82/EC[1] Member States involved in Mutual Recognition or Decentralised Procedures are now obliged to approve the assessment report and the product information i.e. summary of product characteristics, labelling and package leaflet. This Best Practice Guide provides information for applicants and Competent Authorities on the information required to help achieve this harmonisation.

2. AIM AND SCOPE

2.1. Applications using the Mutual Recognition or the Decentralised Procedure where the period of 90 days or second assessment phase begins after 31 October 2005 will be required to harmonise the product literature i.e. labelling and package leaflet. The purpose of this Best Practice Guide is to describe the processing of product information documents by the Reference Member State and Concerned Member States. This Best Practice Guide should be read in conjunction with the documentation listed in paragraph 3 below.

3. REFERENCES AND RELATED DOCUMENT

This Best Practice Guide should be read in conjunction with:

CMDv/001/005 Best Practice Guide for the Reference Member State

CMDv/BPG/001 Best Practice Guide for Veterinary Mutual Recognition Procedure

CMDv/BPG/002 Best Practice Guide for the Decentralised Procedure

CMDv Annotated QRD Template

Articles 58 to 61 of Directive 2001/82 cover the legislative requirements relating to labelling and package leaflet

Article 14 of Directive 2001/82 deals with the summary of product characteristics.

TIGes Guideline on the submission of electronic applications.

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[1] As amended by Directive 2001/28/EC

4. DESCRIPTION OF PROCEDURE

4.1. General Principles

4.1.1. The template for SPC and the agreed Quality of Review Documents Template (QRD) adapted for Mutual Recognition and Decentralised Procedures should be followed.

4.1.2. Additional information on labelling/package leaflet that may be required nationally in accordance with Directive 2001/82/EC, can be found in Section 10 of Chapter 7 of Volume 6A of the Notice to Applicants.

4.1.3 There is a requirement for package leaflets to be written in terms, which the general public will find easy to understand. Until such time as a veterinary specific readability guideline is available, the Guideline on the Readability of the Label and Package Leaflets of Medicinal Product covering the Human pharmaceutical sector may be useful. This guideline is available at http://ec.europa.eu/health/files/eudralex/vol-2/c/2009_01_12_readability_guideline_final_en.pdf

4.2. Definitions

4.2.1 Directive 2001/82/EC as amended by Directive 2004/28/EC (Title 1, Article1) provides the following definitions, which are used throughout this Best Practice Guide:

- The **immediate packaging** is the container or any other form of packaging that is in direct contact with the medicinal product.
- The **outer packaging** is the packaging into which is placed the immediate packaging.
- The **labelling** is the information on the immediate or outer packaging.
- **T**he **package leaflet** is a leaflet containing information for the user that accompanies the medicinal product.

4.2.2 For the purposes of this Best Practice Guide, the following additional definitions apply:

- The **product literature** refers to all the above components

- **A Mock-Up** is a copy of the flat artwork design in full colour, providing a replica of both the outer and immediate packaging, providing a three dimensional presentation of the label text of the medicinal product. It is generally referred to as a "paper copy" or "computer generated version". . This mock up may be presented in paper form and not necessarily in the material of the sales presentation.

4.3. General Requirements

4.3.1 As part of the assessment process to ensure that an application for a new marketing authorisation, a renewal or a variation to an existing marketing authorisation satisfies the criteria set out in the legislation, the SPC and product literature is assessed and authorised by national competent authorities according to legislative requirements.

4.3.2 The Marketing Authorisation Holder is legally the owner of and therefore responsible for the immediate packaging, any outer packaging, any package leaflet and SPC of an authorised veterinary medicinal product as set down in the marketing authorisation. The SPC and all product literature must be approved, and any subsequent changes to the text may only be made following approval by the Competent Authority in the Member State concerned according to national requirements.

4.4. Mutual Recognition: Submission and Approval of SPC and Product Literature

New Application

4.4.1 As part of the dossier submitted to the Concerned Member States the applicant should include in part 1B the proposed text of the SPC and all product literature in English, including the package leaflet if one is needed. Full colour mock-ups or black and white versions of the authorised product should also be submitted in accordance with national requirements.

4.4.2 Mock-ups should be submitted in hard copy. They may also be submitted in electronic format in accordance with national requirements as given in Chapter 7 of Vol 6A of the Notice to Applicants, and also in accordance with the TIGes Guidelines on electronic submissions.

It is strongly recommended that mock-ups using 3 times the English language should be submitted at the beginning of the procedure. This will help to minimise any potential problems with formatting the text on, and design of, the product literature in those Member States which require multi-lingual labelling at the end of the procedure.

4.4.3 Amended labelling texts and package leaflet texts in English are required at each time point during the procedure when a revised SPC is submitted (see Annex 1). However it will not be necessary to provide amended mock-ups at these times.

4.4.4 After the close of the procedure (Day 90) when acceptance of the product is notified, the applicant must provide the SPC and all product literature to all CMS, translated as required in accordance with national languages before the product may be marketed in the Member State concerned. Mock-Ups reflecting the changes made during the procedure, if any, will be provided in accordance with national requirements.

4.5. Decentralised Procedure: Submission and Approval of Product Information

4.5.1 The same principles detailed above will also apply to the Decentralised Procedure. However, on submission of the application only draft texts in English of the SPC and product literature are required (see Annex 2). If a full colour-mock up is available at this stage it should be submitted however black and white text layout would be sufficient.

4.5.2 After the close of the procedure when acceptance of the product is notified, the applicant must provide the SPC and all product literature to all CMS, translated as required in accordance with national languages before the product may be marketed in the Member State concerned. Mock-Ups reflecting the changes agreed during the procedure, if any, will be provided in accordance with national requirements.

4.6. Renewals

4.6.1 When applying for a renewal of an existing marketing authorisation, the current SPC and product literature including mock-ups should be supplied in order for the application to be validated. For products that are not marketed in a CMS the approved SPC and product literature text should be submitted.

4.7. Variations

4.7.1 When applying for a variation to an existing marketing authorisation, which affects the SPC or product literature, then the current mock-ups should be supplied, accompanied by drafts showing the proposed changes. Draft versions do not have to be presented in colour.

4.8. Multi Lingual Packs

4.8.1 Labels and package leaflets may contain other languages provided that the information given is identical to the agreed harmonised text and legibility is not compromised.

Annex 1

Mutual Recognition Procedure

Validation	Applicant submits: i) draft SPC and product literature text (in English). ii) mock-ups of the product as authorised by the RMS. iii) mock-ups 3x English.
Day 0	PROCEDURE STARTS
Day 65	Applicant provides responses to questions, revised draft SPC, revised product literature
Day 82	Applicant submits revised draft SPC and product literature, if necessary.
Day 87	Applicant submits final draft SPC, and product literature
Day 90	PROCEDURE ENDS. RMS circulates final agreed SPC and product literature
Mocks ups	Applicant provides mock-ups of product literature, appropriately translated, to RMS and CMS
Day 120	MA issued by MS. If final mock-ups have not been approved, the MA will be conditional on approval of mock-ups

Annex 2

Decentralised Procedure

Validation	Applicant submits product literature text (in English).
Day 0	PHASE 1 STARTS
Day 120	RMS sends assessment report, questions to applicant.
Day 0	PHASE 2 STARTS
Day 30 (150)	RMS sends out list of questions to the applicant
Day 50 (170)	Applicant provides responses to questions, revised draft SPC, revised product literature text, if necessary
Day 82 (202)	Applicant submits further draft SPC, revised product literature text if necessary
Day 88 (208)	Applicant submits final draft SPC and product literature
Day 90 (210)	PROCEDURE ENDS. RMS circulates final agreed SPC and product literature
Mocks ups	Applicant provides appropriately translated mock-ups of product literature, to RMS and CMS
Day 120 (240)	MA issued by MS. If final mock-ups have not been approved, the MA will be conditional on approval of mock ups