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

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Recommendation on duplicate applications in mutual recognition and decentralised procedures

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1. INTRODUCTION

The applications for a marketing authorisation of veterinary medicinal products must be in accordance with the provisions of Directive 2001/82/EC (as amended), which also, applies to the duplicate applications for a marketing authorisation of veterinary medicinal products. Considering the absence of a guidance document for duplicate applications for veterinary medicinal products and due to the fact that the requests for duplicate marketing authorisations have increased steadily and this is a trend that is likely to continue in the future, the CMDv group agreed to address this issue.

2. AIM AND SCOPE

The aim of this CMDv guidance document is to facilitate and harmonise the regulatory issues for submission of duplicate applications – so called "duplicates" – in Mutual Recognition and Decentralised Procedures.

Likewise the purpose is to provide the competent national authorities of EU member states and applicants/MAHs with information regarding the administrative requirements for the submission of duplicate applications for veterinary medicinal products.

3. REFERENCES AND RELATED DOCUMENTS

- Directive 2001/82/EC as amended
- The Commission communication 98C 229/03
- HMA/CMDv/CMDv guidance - General Information on applications submission (see Transfer of information contained in Notice to Applicants/Volume 6A,Chapter 7 and CMDv GUI 22-30): http://www.hma.eu/51.html
- Notice to Applicants – Volume 6A Chapter 1- Marketing authorisations
- Notice to Applicants – Volume 6A chapter 2 – Mutual recognition procedure and decentralised procedure (November 2005)
- CMDh – document „Recommendations on Multiple/Duplicate Applications in Mutual Recognition and Decentralised Procedures"
- CMDv position on changing the Reference Member State: http://www.hma.eu/uploads/media/CMDv_POS_002_Changing_RMS.pdf
- Handling of duplicate marketing authorisations SANCO/D3/RSR/iv(2011)ddg1.d3. 1137738 http://ec.europa.eu/health/files/latest_news/2011_09_upd.pdf
- TIG-es guidance on e-submissions: http://esubmission.ema.europa.eu/

4. DEFINITION OF THE TERM DUPLICATE APPLICATION

A definition of a duplicate application does not exist in the Directive 2001/82/EC, as amended. A duplicate application is defined by reference to the initial application or marketing authorisation as follows (hereafter referred to as initial application/authorisation):

- Same dossier (copy of Part I, II, III and IV - the product name and the marketing authorisation holder are the only elements that may differ from the application or marketing authorisation referred to)
- Same legal basis according to Directive 2001/82/EC,as amended
- Different trade name
- Same,linked or different applicant/ MAH

5. GENERAL PRINCIPLES

- In line with the opinion of the European Commission, which is shared in all EU Member States, it is not legally acceptable for a Concerned Member State (CMS) to recognise more than once the marketing authorisation of a veterinary medicinal product granted by the Reference Member State (RMS)
- A duplicate application from the same applicant/MAH must therefore be submitted in the Reference Member State of the initial application/authorisation. Authorisation of this duplicate in another Member State should then be made via MRP or DCP
- All applications for a marketing authorisation must fulfil the requirements of Directive 2001/82/EC, as amended. Such requirement likewise applies for a duplicate application. Therefore, the dossier of a duplicate must be in compliance with the current legislation at the time of the duplicate application submission
- Applications for duplicates result in independent marketing authorisations, which can be varied independently. However, MAH are strongly advised to maintain the SPC, package insert and labels of the authorised duplicates harmonised, whenever possible
- A duplicate application cannot be submitted in respect of a marketing authorisation that has been withdrawn/revoked or that has been suspended, or that has ceased to be valid because of application of the sunset clause.

6. REQUIREMENTS ON THE DUPLICATE APPLICATION SUBMISSION

6.1. Update of the initial dossier before submission of the duplicate application

As a general rule, the same requirements apply to the duplicate applications as to the so-called initial applications to which the reference is made and these requirements are governed by the provisions of the Directive 2001/82 EC, as amended, and by Notice to Applicants issued by the European Commission.

Meeting this requirement automatically implies that the initial dossier must be in compliance with the Directive in force when an application for a duplicate is submitted.

Especially in cases where the older initial authorisations are being referred to this must be taken into account, and if necessary a variation must be submitted to update the initial authorisation (including revision to bring SPC, package insert and the labelling in line with current templates). Otherwise reference is not possible.

6.2. Requirements on dossier submission

a) When submitting a duplicate application (simultaneously or subsequently), the applicant shall indicate in **the cover letter** and in **the application**, as applicable:

i. That the submission concerns a duplicate;
ii. That the submitted dossier is identical to the dossier taken as reference (the initial application/marketing authorisation). The applicant/MAH is required to confirm the dossier identity through the declaration form (see Annex I of this document);
iii. If other duplicates are pending or submitted simultaneous. The applicant should indicate the procedure number(s), the RMS and the CMS and in case where there are several applicants, information, whether they are linked or not, shall be given as well.

b) The national requirements for the submission of dossiers, e.g number of copies, language of **the dossier,** other national requirements, and the requirements for electronic submission can be found in references in section 3 of this document.

7. VALIDATION OF DUPLICATE APPLICATIONS BY COMPETENT AUTHORITIES

NB Section 7 of this document does not apply in case of duplicate applications that are submitted in parallel with the initial marketing authorisation application (i.e. in cases where the application for the initial marketing authorisation is still pending).

The applicant should prepare the dossier in order to ensure a smooth validation of the application. In connection with the validation of the application for the duplicate marketing authorisation, the following elements should be checked by the competent authorities:

7.1. Application form

That the section 4.3 of the application form for a new marketing authorisation is filled in.

7.2. Validity of the initial marketing authorisation

That the initial marketing authorisation is valid at the time of the submission of the duplicate application.

7.3. Legal basis

That the legal basis is identical with initial application according to Directive 2001/82/EC,as amended, (e.g. full application, bibliographical, generic, hybrid etc).

7.4. Marketing authorisation dossier

- That the applicant submitted Part I,II,III and IV of the marketing authorisation dossier;

- That the duplicate application is the same to the product taken as reference (initial application or marketing authorisation) ;

- That both dossiers are the same in fact: the product name and the Marketing Authorisation Holder are thus the only elements that may differ from the application or marketing authorisation referred to.

7.5. Dossier identity confirmation

That the dossier identity is confirmed via declaration form submitted by the applicant/MAH (see Annex I of this document).

8. SUBMISSION SCENARIOS OF DUPLICATE APPLICATIONS IN FRAMEWORK OF MUTUAL RECOGNITION/DECENTRALISED PROCEDURE

If the same/linked/different applicants/MAHs wish to have several marketing authorisations for the same product in the Member State(s) of EEA, usually for purpose of co-marketing they may submit duplicate applications for marketing authorisations. The position given in this document applies regardless of the legal basis of the application (e.g. generic application, extension application etc.). However, the duplicate application must always have the same legal basis as the initial application/marketing authorisation.

Different situations may occur depending on whether the applicant/MAH is the same/linked/different and where the application is submitted.

8.1. The duplicate application is submitted in the Reference Member State

Irrespective of whether the applicants for the duplicates are the same/linked/different, the RMS will initiate independent MRPs/DCPs, characterised by different procedure numbers. The CMSs could be different in the initial application and in the duplicate application(s).
For purpose of consistency, the RMS should maintain the harmonisation of the product information (SPC, PL and labelling), whenever possible, between the duplicate(s) and the initial application.

8.2. The duplicate application is submitted in a Concerned Member State

The situation should be considered differently if the applicants/MAHs are the same/linked/different.

8.2.1. Applicants/MAHs are independent

A mutual recognition or decentralised procedure is finalised by the first MAH/applicant in several CMSs. In one of these CMSs, a duplicate application is submitted subsequently through the national (case 1) or decentralised procedure

(case 2). As the two applicants are different, a national/decentralised application is acceptable in any Member State. However, in the 1st case, if the second applicant wishes to have a marketing authorisation in another Member State(s), a mutual recognition procedure should be initiated.

8.2.2. Applicants/MAHs are the same/linked

A mutual recognition or decentralised procedure is started by the first MAH/applicant in several CMSs. In one of these CMSs, a duplicate application is submitted in parallel (or subsequently) to the initial application. As it is not acceptable to recognise more than once the marketing authorisation granted by the RMS and because the MAH are the same/linked, a parallel/subsequent duplicate application is invalid in any Member State. The MAH should either first obtain a duplicate marketing authorisation in the RMS, then apply for a mutual recognition of the duplicate approved in the RMS or initiate for the duplicate a decentralised procedure, where the RMS of the initial marketing authorisation is automatically the RMS for the duplicate application.

8.3. The duplicate application is submitted in Member States where the initial marketing authorisation was granted purely nationally before 1998

Before 1st January 1998, a MAH has obtained several national marketing authorisations for the same product in different Member States. Afterwards, if the same/linked MAH wishes to obtain an authorisation for a duplicate application in one of these Member States, different situations may occur:

The MAH can choose either to submit a national duplicate application (case 1) or to choose a RMS in order to obtain a duplicate marketing authorisation through a mutual recognition or decentralised procedure (case 2). However, in the 1st case, if the applicant wishes to have a marketing authorisation (for the same duplicate) in another Member State, then the mutual recognition procedure of the first duplicate has to be followed.

In case of a mixture of national and mutual recognition procedures granted before 1998, a national submission of the first duplicate application is still allowed in any Member State where a national marketing authorisation was granted or in the RMS of the MRP. However, if the applicant wishes to have a marketing authorisation (for the same duplicate) in another Member State, then the mutual recognition procedure of the first duplicate has to be followed.

Annex I

Declaration for duplicate applications – veterinary medicinal products

The duplicate application for the veterinary medicinal product:
Proposed name: Pharmaceutical form: Strength: MRP/DCP number (if applicable):
Definition of a duplicate application:
For practical purpose, a duplicate application is defined by reference to the initial application or marketing authorisation as follows: ➢ Same dossier (copy of Part I,II, III and IV*) ➢ Same legal basis according to Directive 2001/82/EC,as amended ➢ Different trade name ➢ Same,linked or different applicant/ MAH * That both dossiers are the same in fact: the product name and the Marketing Authorisation Holder are thus the only elements that may differ from the application or marketing authorisation referred to.
The application is a duplicate application to:
Product name: Pharmaceutical form: Strength: MA number (if applicable): MRP/DCP number (if applicable):
Confirmation of compliance with the current legislation
We confirm that the initial application/marketing authorisation referred to is in compliance with the current regulatory and scientific legislation requirements.
Dossier identity confirmation
We declare that the dossier supporting the submission of the duplicate application is the same with the dossier suppporting the initial application/marketing authorisation.
Signature

Name of company (MAH/applicant):	Date:
Person representing MAH/applicant (name, title):	E-mail address: