European Medicines Agency
Veterinary Medicines and Inspections

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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE (CVMP)

REFLECTION PAPER ON PUBLICATION OF WITHDRAWALS OF MARKETING AUTHORISATION APPLICATIONS FOR VETERINARY MEDICINAL PRODUCTS

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REFLECTION PAPER

Publication of Withdrawals of Marketing Authorisation Applications for Veterinary Medicinal Products

1. INTRODUCTION

This document defines the scope, content and format of the documents to be published by EMEA in connection with the withdrawal of an application for a centralised veterinary product by the MAH/Applicant, taking into account commercially confidential data and the different stages of the evaluation procedure.

2. LEGAL BASIS AND SCOPE

Article 36 of Regulation (EC) No. 726/2004, obliges the EMEA to publish information on withdrawn applications:
"If an applicant withdraws an application for a Marketing Authorisation submitted to the Agency before an opinion has been given on the application, the applicant shall communicate its reasons for doing so to the Agency. The Agency shall make this information accessible and shall publish the assessment report, if available, after deletion of commercially confidential information".

Publication of the withdrawal of an application includes the initial Marketing Authorisation Applications as well as applications for extensions of Marketing Authorisations as set out in Annex II to Regulation (EC) No 1085/2003.

Publication will occur for all withdrawals made between Day 1 of the procedure (in accordance with the timetable for the procedure) and before the opinion is adopted by the CVMP).

In addition, on the basis of Article 80 of Regulation (EC) No 726/2004[1], the EMEA Management Board decided at its September 2006 meeting, in the context of a further strengthening of the transparency of EMEA processes and with a view to maintaining consistency on related processes, to extend the publication of information to the following cases:

- Withdrawals occurring between the Opinion and the Commission Decision,
- Withdrawals of applications for new indications (Type II variations).

By analogy in the veterinary sector, this would apply to new indications and to changes to or additions of a non-food target species (Type II variations).

3. DOCUMENTS TO BE MADE AVAILABLE TO THE PUBLIC AND TIMELINES

- The withdrawal will be announced in the CVMP Press Release in case of initial Marketing Authorisation Applications, applications for new indications and changes to or additions of non-food target species (Type II variations) as well as applications for extensions of marketing authorisations as set out in Annex II to Regulation (EC) No 1085/2003 e.g. new strength, new pharmaceutical form, new route of administration, addition of a food-producing target species etc.

[1] Article 80 of Regulation (EC) No 726/2004: *"To ensure an appropriate level of transparency, the Management Board, on the basis of a proposal by the Executive Director and in agreement with the Commission, shall adopt rules to ensure the availability to the public of regulatory, scientific or technical information concerning the authorisation or supervision of medicinal products which is not of a confidential nature."*

- The withdrawal letter from the applicant

- A Withdrawal European Public Assessment Report (WEPAR)

Depending on the stage of the procedure when the applicant withdraws the application, some or all of the above-mentioned documents will be published.

For withdrawals of initial Marketing Authorisation Applications, application for new indications and changes to or additions of non-food target species (Type II variations) as well as Annex II applications, as soon as the Agency receives the withdrawal letter, the CVMP is informed and the information is included in the CVMP Press Release of a CVMP meeting following the receipt of the letter of withdrawal by the EMEA.

The withdrawal letter from the applicant and the WEPAR will be published at a later stage after deletion of commercially confidential information from the assessment report(s), but normally within 2-3 months after the announcement.

Other post-authorisation changes will only be made public if considered relevant, and published as part of the EPAR of the product (module 8 "Steps taken after authorisation").

4. STRUCTURE AND CONTENT OF THE DOCUMENTS TO BE PUBLISHED

Applicant's withdrawal letter:

The EMEA recommends the use of a template letter in order to make sure that the level of information provided by the applicants is similar from one withdrawal to the other one. The template letter is included in Annex 1 of this document. The signed letter should be provided to the EMEA as hard copy and electronically.

Withdrawal Public Assessment Report (WEPAR)

The WEPAR will provide the views of the CVMP on the application at the stage at which it was withdrawn.

A WEPAR will be provided for withdrawals after Day 120 (List of Questions) of a procedure for initial Marketing Authorisation Applications, for extension applications of marketing authorisations as set out in Annex II to Regulation (EC) No 1085/2003 and for Type II variation applications for new indications and to changes to or additions of a non-food target species.

It is reasonable for the WEPAR update to be published within 2 - 3 months after the announcement of the withdrawal, reflecting the time necessary for the company to delete commercially confidential information and for the EMEA to finalise the document prior to publication.

The draft WEPAR will be sent to the applicant who will usually be asked to verify the deletion of commercially confidential information within 10 working days (See Principles to be applied for the Deletion of Commercially Confidential Information for the Disclosure of EMEA Documents - EMEA/45422/2006). It should, however, be noted that it is the EMEA's responsibility whether or not to accept further proposed deletions of text.

The objective is to publish the WEPAR not later than 2–3 months after the published announcement of the withdrawal. Deletion of commercially confidential information will be accepted provided that the company gives a proper justification.

After deletion of any commercially confidential information, the CVMP will have the opportunity to comment on the WEPAR. However, the EMEA will ultimately decide on the final text.

In this document the main concerns raised by the CVMP will be clearly highlighted. The applicant will be provided with the adopted WEPAR for information purposes prior to its publication.

5. TIMETABLE FOR THE PUBLICATION OF DOCUMENTS DEPENDING OF THE STAGE OF THE PROCEDURE AT THE TIME OF THE WITHDRAWAL

Taking into account that any joint assessment report adopted by the CVMP, irrespective of the stage of the procedure, is considered to be the CVMP assessment report, the following timetable applies for withdrawals made:

- **Prior to the adoption of the List of Questions (i.e. between day 1 and before day 120):**

The withdrawal letter will be published and also announced in the next CVMP Press release, which will state as follows:
The applicant… withdrew its application for a <new product / extension> application at day…. during the initial phase of the evaluation before the CVMP could finalise a List of Questions to be addressed to the applicant. No CVMP withdrawal assessment report is available.

- **After adoption of the List of Questions and before the adoption of the CVMP opinion:**

In addition to the announcement in the CVMP press release, the withdrawal letter and a WEPAR will be published within 2-3 months.

- **After the Opinion is adopted by the CVMP and before the Commission Decision is issued**

In addition to the announcement in the CVMP press release, the withdrawal letter and a WEPAR will be published within 2-3 months.

- **During a re-examination process:**

In addition to the announcement in the CVMP press release, the withdrawal letter and a WEPAR will be published within 2-3 months.

- **Annex II and Type II variation applications for new indications and changes to or additions of non-food target species**

In addition to the announcement in the CVMP press release, the withdrawal letter and a WEPAR will be published within 2-3 months.

Also, module 8 (“Steps taken after authorisation”) of the EPAR of the product will be amended accordingly.

6. ELEMENTS TO BE CONSIDERED FOR THE PREPARATION OF THE WEPAR

The WEPAR will be based on the assessment report(s) available depending on the status of the application. The applicant will be asked prior to publication to justify removal of confidential aspects.

7. STARTING DATE OF THE IMPLEMENTATION

Implementation is from 20 November 2005 (the entry into force of Title 3 of Regulation (EC) No. 726/2004) and only for applications withdrawn from that day onwards.

ANNEX 1 – Withdrawal letter template

(< FROM APPLICANT/ MARKETING AUTHORISATION HOLDER HEADED PAPER >)

Date: <dd mmmm yyyy>

Veterinary Medicines and Inspections Unit
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Subject: Withdrawal of <Product name, strength(s), pharmaceutical form, target species> : New indication- **<EMEA/V/product No.>** OR **<EMEA/V/product No./X or II/nn>**

Dear Sirs,

For the withdrawal of an initial marketing authorisation application

I would like to inform you that, at this point of time, *<Applicant's name>* has taken the decision to withdraw the application for Marketing Authorisation of *<Product Name>, <(INN), strength(s), pharmaceutical form(s), target species>*, which was intended to be used for *<applied for Applicant's proposed indication>*.

OR

For the withdrawal of a Type II variation/Annex II application linked to an extension of the authorisation of a medicinal product already authorised

I would like to inform you that, at this point in time, *<MAH name>* has taken the decision to withdraw the application for *<a new indication> <a change to the marketing authorisation>* for *<name of the product>, <to add <a <strength><pharmaceutical form>target species>* in the *< indication>*.

This withdrawal is based on the following reasons *<the following is included as possible examples, amongst others>*:

- *<identification of major manufacturing issues>*
- *<identification of major <target animal>, <user>, <consumer>, <environmental> <safety issue>*
- *<identification of major efficacy issues>*
- *<identification of major GxP issues>*
- *<the CVMP considers that the data provided do not allow the committee to conclude on a positive benefit risk balance>*
- *<Company's marketing strategy>*
- Other*: <please elaborate>*

<Please provide any further detailed comment as appropriate>
<Provide additional information on any future plan for development of the product>

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s)/target species, if applicable.

I agree for this letter to be published on the EMEA website.

Yours faithfully,

<Signature from the Applicant>[2],

[2] Personal details appearing on the withdrawal letter will be blanked out prior to EMEA publication