EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 September 2025
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Procedural advice on publication of information on withdrawals of marketing authorisation and variation applications for veterinary medicinal products

* This procedural advice replaces the CVMP Reflection paper on publication of withdrawals of marketing authorisation applications for veterinary medicinal products (EMEA/CVMP/425558/2006-Rev.1).

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1. Introduction

This document defines the scope, content and format of the documents to be published by the European Medicines Agency in connection with the withdrawal of an application for marketing authorisation or variation to the terms of a marketing authorisation for a centralised veterinary medicinal product by the applicant/marketing authorisation holder, taking into account commercially confidential information and the different stages of the evaluation procedure.

2. Legal basis and scope

Article 32(1) of Regulation (EU) 2019/6 indicates that "*an applicant may withdraw the application for marketing authorisation submitted to a competent authority or the Agency, as applicable, at any time before the decision referred to in Article 44, 47, 49, 52 or 53 has been taken*". In case an applicant withdraws the application for a marketing authorisation before the examination of the application has been completed, the applicant shall communicate the reasons for doing so to the competent authority or the Agency (Article 32(2) of Regulation (EU) 2019/6).

Article 32(3) of Regulation (EU) 2019/6 obliges the Agency to publish information on withdrawn applications:

"The competent authority or the Agency, as applicable, shall make publicly available the information that the application has been withdrawn, together with the report or the opinion, as applicable, if already drawn up, after deletion of any commercially confidential information."

Publication will occur for all withdrawals of applications for marketing authorisation made between Day 1 of the procedure (in accordance with the timetable for the procedure) and before the decision to grant or refuse the marketing authorisation is taken by the European Commission.

In addition, on the basis of Article 80[†] of Regulation (EC) No 726/2004, the EMA Management Board decided at its September 2006 meeting, in the context of a further strengthening of the transparency of EMA processes and with a view to maintaining consistency on related processes, to extend the publication of information to withdrawals of variation applications for new indications. By analogy in the veterinary sector, this would apply to the variations requiring assessment (VRAs) listed below.

In this context, publication will also occur for all withdrawals of applications for variations to marketing authorisations made between Day 1 of the procedure (in accordance with the timetable for the procedure) and before the decision to amend the marketing authorisation or reject the variation referred to in Article 67(2) of Regulation (EU) 2019/6 has been taken by the European Commission, for the following VRAs:

- All variations listed in chapter I of the guidance on the classification of VRAs[‡] concerning changes of active substance(s), strength, pharmaceutical form, route of administration or food producing target species;
- Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one (G.I.7.a);

[†] 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*."

[‡] Guidance on the details of the classification of variations requiring assessment according to Article 62 of Regulation (EU) 2019/6 for veterinary medicinal products and on the documentation to be submitted pursuant to those variations (EMA/CMDv/7381/2021)

- Variations concerning a change to or addition of a non-food producing target species (G.I.10);
- Other variations than those listed above if the outcome of the evaluation is considered to be of particular importance for the public.

3. Documents to be made available to the public and timelines

The following documents refer to withdrawals of both marketing authorisation applications and variation applications (VRA classifications referred to in section 2 of this document):

- Announcement of the withdrawal in the CVMP meeting highlights;
- 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.

As soon as the Agency receives the withdrawal letter from the applicant, the CVMP is informed and the information is included in the CVMP meeting highlights of the CVMP meeting following the receipt of the letter of withdrawal.

The withdrawal letter from the applicant and the WEPAR, if applicable, are published at a later stage, but normally within 3 months after the withdrawal announcement.

4. Structure and content of the documents to be published

4.1. Applicant's withdrawal letter

The Agency 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 another. The template letter is included in Annex 1 of this document. The letter should be provided to the Agency electronically (both Word and PDF formats are acceptable) and should be dated and signed on the applicant's digital letterhead. The Agency may request an applicant to resend a letter where insufficient information is provided.

Withdrawal letters will be published on the EMA website with all personal data and contact information (addresses, emails, phone numbers, names and signatures) blanked out.

4.2. Withdrawal European Public Assessment Report (WEPAR)

The WEPAR will provide the views of the CVMP on the application at the stage at which it was withdrawn. In the WEPAR document, the main concerns raised by the CVMP during assessment will be clearly stated and explained.

A WEPAR will be prepared for withdrawals after Day 120 (List of Questions) for marketing authorisation applications and for withdrawals after Day 60 (List of Questions) for the variation applications referred to in section 2. The WEPAR will be based on the assessment report(s) available depending on the stage of the procedure.

It is reasonable for the WEPAR to be published normally within 3 months after the published announcement of the withdrawal, reflecting the time necessary for the Agency to prepare the WEPAR,

the company to identify commercially confidential information and for the Agency to finalise the document prior to publication.

The draft WEPAR will be sent to the applicant who will usually be asked to make proposals for the deletion of commercially confidential information within 10 working days. It should, however, be noted that it is the Agency's decision whether or not to accept the deletions of text proposed by the applicant. Deletion of commercially confidential information can be accepted provided that the company gives a proper justification. The rapporteurs for the procedure are consulted in the process of preparing and finalising the WEPAR.

The applicant will be provided with the final WEPAR for information purposes prior to its publication.

5. Timetable for the publication of documents depending on the stage of the procedure at the time of 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 marketing authorisation and relevant variation applications for withdrawals made:

a. Prior to the adoption of the list of questions (i.e. between day 1 and day 120 for marketing authorisation applications and between day 1 and day 60 for variation applications):

The withdrawal will be announced in the next CVMP meeting highlights, which will state as follows:

The Committee was informed of the formal notification from <applicant/MAH> of their decision to withdraw the application for a <marketing authorisation> <variation requiring assessment> for <product name> during the initial phase of the evaluation and before the CVMP could finalise a list of questions to be addressed to the applicant. No CVMP withdrawal assessment report will be produced in line with standard process for a withdrawal at this timepoint.

The withdrawal letter from the applicant will not be published.

b. After adoption of the list of questions and before the adoption of the CVMP opinion:

The withdrawal will be announced in the next CVMP meeting highlights, which will state as follows:

The Committee was informed of the formal notification from <applicant/MAH> of their decision to withdraw the application for a <marketing authorisation> <variation requiring assessment> for <product name>. More information about this application and the current state of the scientific assessment at the time of the withdrawal will be made available in a public assessment report. The document, together with the withdrawal letter from the applicant will be published on the Agency's website in due course.

In addition to the announcement in the CVMP meeting highlights, the withdrawal letter and a WEPAR will be published normally within 3 months.

c. After the opinion is adopted by the CVMP and before the Commission Decision is issued:

In addition to the announcement in the CVMP meeting highlights, the withdrawal letter and a WEPAR will be published normally within 3 months.

d. During a re-examination process:

In addition to the announcement in the CVMP meeting highlights, the withdrawal letter and a WEPAR will be published normally within 3 months.

6. Annex 1: withdrawal letter template

<On applicant/marketing authorisation holder digital letterhead>

Date: <dd mmmm yyyy>

Veterinary Medicines Division
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: Withdrawal of *<product name, strength(s), pharmaceutical form, target species>*: *<EMEA/V/C/product No./0000> <EMEA/V/C/product No./VRA/nn> <EMA/VRA/nn>*

Dear Madam/Sir,

For the withdrawal of a marketing authorisation application

I would like to inform you that, at this time, *<applicant's name>* has taken the decision to withdraw the application for marketing authorisation for *<product name>*, *<(INN), strength(s), pharmaceutical form(s), target species>*, which was intended to be used for *<applicant's proposed indication>*.

For the withdrawal of a variation requiring assessment

I would like to inform you that, at this time, *<MAH name>* has taken the decision to withdraw the application for a variation requiring assessment for *<product name>*, concerning *<include the variation classification and precise scope proposed>*.

For all withdrawals

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 issues>*
- *<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.

For applications withdrawn after the adoption of the list of questions

I agree for this letter to be published on EMA's corporate website.

Yours faithfully,

<Signature from the applicant>[§]*,*

[§] Personal details appearing on the withdrawal letter will be blanked out prior to publication on the EMA corporate website