



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 June 2023
EMA/599977/2012 rev.2¹

Procedural advice on publication of information on withdrawals of applications for marketing authorisation and variations/extensions to marketing authorisations

¹ This document was updated in 05-2023 to align it with [Guide to information on human medicines evaluated by EMA](#)..

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us An agency of the European

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 Union



Table of contents

1. Introduction	3
2. Legal basis and scope.....	3
3. Withdrawn applications for new marketing authorisations and extensions of indication	3
4. Change of scope of variations initially involving an extension of indication	4
5. Other variations or extension of marketing authorisation applications ...	5
6. Table of withdrawal documents to be published.....	6
7. Annex	7
Withdrawal letter template.....	7

1. Introduction

This paper describes the publication of information on the withdrawals of marketing authorisation applications for human medicinal products and withdrawals of applications for variations/extensions to marketing authorisation. This paper should be read in conjunction with EMA's general guide to information published on human medicines.²

2. Legal basis and scope

The legal basis for the publication of information on the withdrawal of applications for marketing authorisation for human medicinal products is Article 11 of Regulation (EC) No 726/2004, which states that:

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 publicly accessible and shall publish the assessment report, if available, after deletion of all information of a commercially confidential nature.

In September 2006, on the basis of Article 80 of Regulation (EC) No 726/2004,³ EMA's Management Board extended the publication requirement to variation applications to extend the therapeutic indication as well as withdrawals of new and extension of indication applications that take place after a CHMP opinion has been adopted but before the European Commission has issued a decision.

This paper also covers the publication of documents following the withdrawal of applications for other variations and applications for extension of marketing authorisations.

In addition to the application withdrawals mentioned above, this paper also covers communication on the outcomes of variation applications in cases where the initial scope of a variation application included an extension of indication (see Section 4.). Although these cases are not strictly speaking withdrawals of application, similar levels of transparency are applied.

The deletion of commercially confidential information and personal data referred to in this paper is based HMA/EMA guidance adopted in March 2012.⁴

3. Withdrawn applications for new marketing authorisations and extensions of indication

Applicant's withdrawal letter

When an applicant seeks to withdraw an application for a marketing authorisation or extension of indication, it shall communicate the reasons for doing so to EMA.

A template for withdrawal letters to be used by applicants has been prepared by the EMA and, in line with Article 11 of Regulation (EC) No 726/2004, includes a section on the reasons for the withdrawal. EMA recommends that applicants use the template and may request an applicant to resend a letter where insufficient information is provided. A template for withdrawal letters is included in the Annex of

² <https://www.ema.europa.eu/en/medicines/what-we-publish-medicines-when>

³ 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."

⁴ <https://www.hma.eu/about-hma/transparency/guideline-for-transparency.html>

Procedural advice on publication of information on withdrawals of applications related to the marketing authorisation of human medicinal products
EMA/599977/2012

this document. The withdrawal letter should be dated and signed on the applicant's headed paper. Both Word and PDF formats are acceptable.

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

Question-and-answer (Q&A) document

A Q&A document will be published routinely following the withdrawal of new marketing authorisation applications and applications for an extension of indication.

The Q&A document contains information in lay language on the scientific assessment of the product up to the time of the withdrawal. Where the CHMP has adopted an assessment report, the Q&A reflects the latest CHMP position on the application.

The Q&A in English will be published on the day after the upcoming CHMP plenary meeting linked to the CHMP Meeting Highlights. For applications withdrawn during a CHMP meeting, the Q&A is published on the day following the next CHMP meeting. The Q&A documents are first published in English, with translations in other official EU languages to follow.

For duplicate applications, EMA will not publish a Q&A if only one of the applications is withdrawn.

Withdrawal assessment reports

Within 3 months of receipt of the withdrawal letter, EMA will publish the last adopted CHMP assessment report for all withdrawn applications for new marketing authorisation applications and extensions of indication.

Prior to publication of any assessment report, EMA will liaise with the applicant to delete all commercially confidential information and personal data.

Procedural steps document

Following the withdrawal of an application for an extension of indication, a document entitled 'Procedural steps taken and scientific information after authorisation' is published as part of the EPAR on the EMA website within 3 months of receipt of the withdrawal letter.

This document outlines the regulatory procedures that have taken place since the authorisation of the medicine.

Post-opinion withdrawals

If an applicant withdraws an application for a new marketing authorisation or an extension of indication after the CHMP has adopted the final positive or negative opinion and the European Commission has not issued a decision, EMA will publish the relevant withdrawal documents described above, stating that the withdrawal occurred post-opinion. The timing of the publication of these documents is the same as for pre-opinion withdrawals (see table 6.).

4. Change of scope of variations initially involving an extension of indication

For several years, EMA has been publishing specific communication on withdrawn extension of indication applications. In September 2011, this practice was extended to cases where the scope of the variation that initially included an extension of indication has been changed, resulting in a CHMP

opinion that does not cover the extension of indication initially applied for. Although these cases are not strictly speaking withdrawals of application, EMA considers that the same level of transparency that applies to withdrawn extensions of indication applications should apply to these variations.

In such cases EMA publishes a Q&A document on the day following the CHMP plenary meeting on the medicine's page, explaining the scientific assessment of the extension of indication application up to the point it was removed. Around 2 weeks after the European Commission's decision, the updated product information is published on the same page in the section 'Product information'. The public assessment report is published in the section 'Assessment history', reflecting the initial scope applied for and the opinion finally granted. The document procedural steps taken and scientific information after authorisation is also published or updated if the document was already available.

5. Other variations or extension of marketing authorisation applications

As with extension of indication applications, applicants may also withdraw applications for other variations, including applications for extension of marketing authorisation. In such situations, there will usually be no specific EMA publication. However, EMA may decide to publish an assessment report if the outcome of an evaluation is considered to be of particular importance.

EMA also reserves the right to publish the withdrawal letter and/or a Q&A document should it be in the public interest to do so.

6. Table of withdrawal documents to be published

Type of application	Documents published	Timing
Withdrawn applications for a new marketing	Q&A	Day after next CHMP meeting linked to the CHMP Meeting Highlights
	Withdrawal letter	Published together with the Q&A
	Assessment report	Within three months of receipt of withdrawal letter
Withdrawn extension of indication applications	Q&A	Day after next CHMP meeting linked to the CHMP Meeting Highlights
	Withdrawal letter	Published together with the Q&A
	Assessment report	Within three months of receipt of withdrawal letter
	Updated procedural steps document	At the time of the publication of the assessment report
Withdrawn extension of indication applications with subsequent change in scope (see section 4.)	Q&A	At the time of CHMP opinion
	Assessment report	Within two weeks of European Commission decision
	Updated procedural steps document	At the time of the publication of the assessment report
Other variations, including extensions	No specific document. EMA reserves the right to publish the assessment report, the withdrawal letter and/or a Q&A	

7. Annex

Withdrawal letter template

(< FROM Applicant ON HEADED PAPER >)

Date: <dd mm yyyy>

<CHMP Chairman>
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: Withdrawal of <Product Name>, (INN), strength(s), pharmaceutical form(s) -
<EMA/H/product No.> OR <EMA/H/product No./X or II/nn>

Dear <CHMP Chairman> ,

For the withdrawal of initial marketing authorisation applications

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)>, which was intended to be used for <applied for Applicant's proposed indication>.

OR

For the withdrawal of applications to extend the therapeutic indication and other applications for variations, including extensions

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

This withdrawal is based on the following reasons <Please state the reasons for the withdrawal. The following is included as possible examples, amongst others>:

<identification of major manufacturing issues>

<identification of major pre-clinical issue>

<identification of major clinical issues>

<identification of major GxP issues>

<feedback from the CHMP indicates that Committee will not be able to conclude that the benefits outweigh the risks on the basis of the data provided.>

<Company's marketing strategy>

Other: <please elaborate>

<Please provide any further detailed comment as appropriate>

<Provide information on the consequences of the withdrawal on ongoing clinical trials and compassionate use programme>

<Provide additional information on any future plan for development of the product>

We reserve the right to make further <Marketing Authorisation Application submissions at a future date in this or other therapeutic indication(s)> <variation>application for this Marketing Authorisation><extension of marketing authorisation application>.

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

Yours sincerely,

<Signature from the applicant>