EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committees and Quality Assurance

Questions & Answers on the consultation procedure to the European Medicines Agency by notified bodies on an ancillary medicinal substance or an ancillary human blood derivative incorporated in a medical device

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Table of contents

1. Initial consultation

1.1. How and when should I submit "a letter of intent" for an initial consultation on an ancillary medicinal substance/ancillary human blood derivative incorporated in a medical device? Rev. July 2023

Please notify the Agency of the intention to submit an application for an initial consultation on an ancillary medicinal substance by sending "a letter of intent" at least 6 months before the expected date of submission. Details on the content of the letter can be found in section 4.1 of the European Medicines Agency recommendation on the procedural aspects and dossier requirements for the consultation of the European Medicines Agency by a notified body on an ancillary medicinal substance or an ancillary human blood derivative incorporated in a medical device or active implantable medical device.
Please send "the letter of intent" by raising a ticket via EMA Service Desk, selecting the tab "Business Services", category "Human Regulatory". The subcategory to be selected is "Pre-Submission Phase - Human", followed by the sub-option: "Letter of Intent Request". "The letter of intent" should be submitted at least 10 days prior to a CHMP meeting to ensure timely inclusion in the CHMP agenda. Please do not send any documents to individual email addresses within the Agency.
After submitting your "letter of intent", you will receive a unique product identifier (UPI) for your product. Please use the UPI for all future correspondence with the Agency.
If you do not have an EMA Account, please create it via the EMA Account Management portal. For further information or guidance about how to create an EMA Account reference the guidance "Create an EMA Account".

1.2. How and when are the Rapporteurs appointed? Rev. March 2021

Following receipt of "the letter of intent", the Agency will trigger the appointment of a Rapporteur, Co-Rapporteur and Peer Reviewer (if applicable) by CHMP. The Rapporteurs are usually appointed at the next or subsequent CHMP meeting. The applicant will be informed of the outcome.

1.3. How and when should I submit an application for an initial consultation on an ancillary medicinal substance/ancillary human blood derivative incorporated in a medical device? Rev. March 2021

The eSubmission Gateway and the eSubmission Web Client are mandatory submission channels for the submission of applications to EMA (including Supplementary information requested during validation).

The eSubmission Gateway and the eSubmission Web Client are electronic submission channels that allow the applicants to submit documents supporting all types of applications to the Agency securely over the internet in structured and non-structured formats.

Links and detailed information on the systems required:

1. eSubmission Gateway Web Client and eSubmission Gateway web client: Guidance for applicants.

2. xml Delivery File and Guidance for submissions using xml delivery files (refer to section *4.8. Create delivery file for Medical Devices*).

Information on how to register to eSubmission Gateway and detailed guidance for all submission types can be found on the eSubmission website.

All submissions sent to EMA via eSubmission Gateway/Web Client will be considered delivered to all National Competent Authorities representatives, alternates and experts of the scientific committees.

There should be no additional copies of submissions sent directly to the NCAs on CD/DVD or via CESP as this might lead to validation issues and cause delays. All EMA submissions should be sent via EMA eSubmission Gateway/Web Client only.

For technical issues with the submissions visit the EMA Service Desk portal.

Detailed requirements for submissions, and the contact details of the CHMP members and alternates, are available at Dossier requirements for referral, ASMF and NAP submissions (PASS107, Workshare, Signal Detection procedures) and ancillary medicinal substances in a medical device.

Submissions should follow the published deadlines for submission (Initial (Full) Marketing Authorisation application assessment timetables).

In order to facilitate the registration of the submission, applicants are required to fill in all the submission attributes through the eSubmission delivery file.

1.4. What are the data and format requirements for the application dossier? Rev. March 2021

Please refer to Appendix 1 of the guideline European Medicines Agency recommendation on the procedural aspects and dossier requirements for the consultation of the European Medicines Agency by a notified body on an ancillary medicinal substance or an ancillary human blood derivative incorporated in a medical device or active implantable medical device.

1.5. How will the application for an initial consultation on an ancillary medicinal substance/ancillary human blood derivative incorporated in a medical device be validated? Rev. March 2021

Please refer to question "How are initial Marketing Authorisation Applications validated at the EMA?" in the European Medicines Agency's pre-authorisation procedural advice for users of the centralised procedure.

2. Post-consultation:

2.1. How and when should I submit my type IA, IB or type II variation for an ancillary medicinal substance or ancillary human blood derivative incorporated in the medical device? Rev. March 2021

The eSubmission Gateway and the eSubmission Web Client are mandatory submission channels for the submission of applications to EMA (including Supplementary information requested during validation). Please see question ***1.3. How and when should I submit the application for an initial consultation on an ancillary medicinal substance/ancillary human blood derivative incorporated in a medical device?***

Type IA, IB or type II variations for an ancillary medicinal substance or ancillary human blood derivative should be classified and evaluated by analogy to the variations regulation (Commission Regulation (EC) 1234/2008).

There are no recommended submission dates for IA/IB variations. For type II variations please refer to procedural timetables for the submission dates.

2.2. How should I present my type IA, IB or type II variation? Rev. March 2021

The following documents should be included in type IA, IB or type II applications, as specified in the variations guideline:

Cover letter (for groupings, include a short overview of the nature of the changes). There is no standard template to be used.

Procedure number. The procedure number will be assigned by EMA only upon receipt of an application. For further details please refer to EMA pre-submission guidance "How is an EMA Application/Procedure Number attributed?"

The completed application form.

Relevant documentation as per variations classification guideline.

For type II variations, update or addendum to quality, non-clinical and clinical critical summaries (or expert reports), as relevant, should be included in section 2 of the dossier.

If applicable, the revised labelling in EN.

3. Fees

3.1. What fee do I have to pay for consultation on ancillary substances including blood derivatives incorporated in medical devices? Rev. March 2021

For information on the fees applicable to applications for marketing authorisation and to variations, please refer to fees payable to the European Medicines Agency.

The specific fees applicable to consultation procedures on an ancillary medicinal substance or an ancillary human blood derivative incorporated in a medical device can be found in the 'Rules for the implementation of Council Regulation (EC) No 297/95 on fees payable to the European Medicines Agency and other measures' and in the 'Explanatory note on fees payable to the European Medicines Agency'. As envisaged in said Rules and Explanatory note, although the notified body requests the consultation from the EMA, the medical device manufacturer is responsible to pay the fees for this consultation directly to EMA.