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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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 or in an active implantable medical device? New Dec 2015

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 of intent can be found in section 4.1 of the European Medicines Agency guideline on an Ancillary Medicinal Substance/Ancillary Human Blood Derivative.

Please send the letter of intent to pa-bus@ema.europa.eu, using the Agency’s secure email system, Eudralink. 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 letters of intent or applications to individual email addresses within the Agency.

If you do not have a Eudralink account, please contact eudralink@ema.europa.eu to set one up.

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.

1.2. How and when are the Rapporteurs appointed? New Dec 2015

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. To whom should I submit the application for an initial consultation on an ancillary medicinal substance/ancillary human blood derivative incorporated in a medical device or in an active implantable medical device? New Dec 2015

Please submit your initial application to the Agency in parallel to the appointed Rapporteur, Co-Rapporteur and Peer Reviewer (if applicable). For instructions on how to submit, please see question 1.4. How should I submit the application for an initial consultation on an ancillary medicinal substance/ancillary human blood derivative incorporated in a medical device or in an active implantable medical device?

Detailed requirements for submissions can be found in Dossier requirements for referral, ASMF and NAP submissions (PASS107, Workshare, Signal Detection procedures) and ancillary medicinal substances in medical device.

Every submission should include a cover letter (see question 1.5. What information should be provided in the cover letter accompanying the application?).

Supplementary information requested during validation should be provided to EMA, the Rapporteur, Co-Rapporteur and Peer Reviewer (if applicable).

After receipt of the Agency’s letter confirming the start of procedure, the applicant should immediately send the final documentation for the procedure to each of the other CHMP members and alternates.
1.4. How should I submit the application for an initial consultation on an ancillary medicinal substance/ancillary human blood derivative incorporated in a medical device or in an active implantable medical device? New Dec 2015

The eSubmission Gateway and the eSubmission Web Client are strongly recommended for the submission of applications to EMA.

Information on how to register and connect can be found on the eSubmission website. Please contact esubmission@ema.europa.eu for detailed information on the required naming convention and file formats before submitting your application.

For submissions to CHMP Rapporteur, Co-Rapporteur, Peer Reviewer and CHMP members the Common European Submission Platform (CESP) should be used. For CHMP members (including Rapporteurs) with no access to CESP, the documentation should be sent on CD or DVD (Blu-ray discs are not acceptable).

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. Please also refer to the CESP website for further details.

Please indicate the Agency's unique product identifier (UPI) provided for your product clearly on the cover letter. Please note that the application should reach the Agency, Rapporteur, Co-Rapporteur and Peer Reviewer before or on the day of the published deadlines for submission (see Initial (Full) Marketing Authorisation Application).

1.5. What information should be provided in the cover letter accompanying the application? New Dec 2015

A cover letter should always accompany any submission to the Agency and CHMP members. A summary table should be incorporated in the cover letter of each submission (see explanatory notes in the template). For consultation procedures the applicant should fill in the following sections of the summary table: 1-3, 5–8 and 11.

1.6. What are the data and format requirements for the application dossier? New Dec 2015

Please refer to Appendix 1 of the guideline European Medicines Agency guideline on an Ancillary Medicinal Substance/Ancillary Human Blood Derivative.

1.7. How will the application for an initial consultation on an ancillary medicinal substance/ancillary human blood derivative incorporated in a medical device or in an active implantable medical device be validated? New Dec 2015

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. **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? New Dec 2015**

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? New Dec 2015**

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). The cover letter should contain the summary table to facilitate submission and registration. See question 1.5, What information should be provided in the cover letter accompanying the application?

- **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.

2.3. **To whom should I send my type IA, IB or type II variation? New Dec 2015**

Please submit your type IA, IB or type II variation to the Agency in parallel to the appointed Rapporteur and Co-Rapporteur. For instructions on how to submit your application, please see question 1.4, How should I submit the application for an initial consultation on an Ancillary Medicinal Substance/Ancillary Human Blood Derivative incorporated in a medical device or in an active implantable medical device?

Every submission should include a cover letter (see question 1.5, What information should be provided in the cover letter accompanying the application?).

Supplementary information requested during validation should be provided to EMA, the Rapporteur and the Co-Rapporteur.
Type IA variations:

After receipt of the Agency's acknowledgment of receipt and review of outcome (i.e. notification) of the Type IA variation, the applicant should immediately send the final documentation for this procedure to each of the other CHMP members and alternates.

Type IB and type II variations:

After receipt of confirmation of the start of the procedure from EMA, the applicant should send the documentation to each of the other CHMP members and alternates. Please do not resend the same package to the CHMP Rapporteur, Co-Rapporteur or EMA.

3. Fees

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

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

The specific fees applicable to consultation procedures can be found in the Explanatory note on fees payable to the European Medicines Agency.