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Procedure Management and Business Support

Questions & answers on Article 13 referral procedures

This guidance document addresses a number of questions which stakeholders, in particular the marketing authorisation holders (MAHs)/applicants, may have on Article 13 referral procedures. It provides an overview of the European medicines Agency's ('the Agency') practical and operational aspects with regards to handling of Article 13 referral procedures.

This integrated version has been created for printing purposes only. Please refer to the individual questions & answers as published in the referral procedures guidance to access the hyperlinked information.

Question & answers are being updated continuously, and will be marked by 'NEW' or 'Rev.' with the relevant date upon publication.

Note:

It should be highlighted that this document has been produced for guidance only, and should be read in conjunction with "The rules governing Medicinal Products in the European Union, Volume 2A, chapter 3, Notice to applicants".

MAHs/applicants must in all cases comply with the requirement of EU legislation.

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Initiation of Article 13 referral procedure

1. What is the legal basis for an Article 13 referral procedure?

An Article 13 referral procedure follows the provisions of Article 13(1) of Regulation (EC) No 1234/2008.

It applies when during the coordination group procedure, the Member States fail to reach an agreement under the mutual recognition procedure on a major variation of Type II or on a worksharing variation procedure, on the grounds of a potential serious risk to public health.

The procedure for an Article 13 referral is laid down in Articles 29(3), (4) and (5) of Directive 2001/83/EC for which the procedure under Articles 32, 33 and 34 of Directive 2001/83/EC is applied.

References:

Commission Regulation 1234/2008

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

Notice to Applicants, volume 2A Procedures for marketing authorisation, Chapter 3 Union Referral Procedures

Guideline on the definition of a potential serious risk to public health in the context of Article 29(1) and (2) of Directive 2001/83/EC

2. In which situations can an Article 13 referral procedure be initiated?

An Article 13 referral procedure should be initiated on the grounds of potential serious risks to public health, where no agreement has been reached by the Member States during the 60-day co-ordination group procedure carried out by the Co-ordination Group for Mutual Recognition and Decentralised Procedures (CMDh) to:

- Recognise the decision on a major variation of Type II within 30 days, by reference to Article 10(4) of Commission Regulation (EC) No 1234/2008 or;
- Approve an opinion on a worksharing variation procedure within 30 days, by reference to point (b) of Article 20(8) of Commission Regulation (EC) No 1234/2008.

The reasons for the disagreement can relate to aspects arising during the assessment which may affect the summary of product characteristics (SmPC), the labelling or the package leaflet (PL) prepared by the reference Member State (RMS) in the context of a major type II variation or a worksharing variation procedure of marketing authorisations(s). In such a case the RMS will refer the matter to the Agency.

A potential serious risk to public health concern can only be raised by the concerned Member States (CMS) in case of a positive assessment by the RMS.

For the definition of 'potential serious risk to public health', the Commission has adopted a guideline and annex of examples (please refer to guideline on the definition of a potential serious risk to public health and annex).

References:

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

Notice to Applicants, volume 2A Procedures for marketing authorisation, Chapter 3 Union Referral Procedures

3. Who can initiate an Article 13 referral procedure?

An Article 13 referral procedure must be initiated by the reference Member State (RMS) when its assessment is positive but that Member States do not reach agreement in the co-ordination group procedure on the grounds of a 'potential serious risk to public health'.

The RMS shall provide the notification form for a referral procedure to the Committee for Medicinal Products for Human Use (CHMP)/Agency, which will include a detailed statement of the matter(s) on which the Member States concerned have been unable to reach agreement and the reasons for the disagreement based on potential serious risk to public health grounds.

References:

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

Notice to Applicants, volume 2A Procedures for marketing authorisation, Chapter 3 Union Referral Procedures

4. Can the variation application be withdrawn before the initiation or during an Article 13 referral procedure?

After potential serious risk to public health has been raised in accordance with Article 13 of Commission Regulation (EC) No 1234/2008 by a concerned Member State, a withdrawal of the variation application in some of the Member States will not stop the matter from being discussed within the Co-ordination Group for Mutual Recognition and Decentralised Procedures (CMDh) and, eventually, from a referral procedure being initiated.

The referral procedure can only be stopped if the MAH withdraws the variation application in the European Economic Area (EEA) Member States.

5. Which medicinal products can be involved in an Article 13 referral procedure?

For Article 13 referral procedures, only the concerned medicinal product for which a variation to national marketing authorisation has been applied for (under the mutual recognition procedure or a worksharing procedure) may be involved.

The marketing authorisation holder (MAH) will be requested to provide a list of the (invented) names of the medicinal product, the name of the MAH to whom the product is authorised, the strength(s), pharmaceutical form(s), route of administration(s), content (as applicable) in the respective Member States (MSs). This will be checked with the national competent authorities (NCAs) of the MSs.

6. Should the marketing authorisation holder identify a contact person to communicate with the Agency during the Article 13 referral procedure?

To facilitate the exchange of information prior to the start and during the procedure, the marketing authorisation holder (MAH) should confirm the designated contact person for the Article 13 referral procedure.

The MAH may if they wish, be represented by another party (e.g. a consultant), who will be the contact person for the procedure. In this case it must inform the procedure manager identified in the letter notifying the procedure initiation.

All documentation concerning the Article 13 referral procedure will be sent to the contact person only. The contact details of the person should be clearly stated (name, address, phone and fax number and email address) in the letter of representation.

It is the responsibility of the MAH to notify the Agency of any change that might affect the validity of the letter of representation as soon as possible (e.g. in case of a change of the contact person), and to provide a revised letter of representation.

All documentation concerning the Article 13 referral procedure will be sent to the contact person only.

7. When and how will the start of the Article 13 referral procedure be announced?

A brief summary of the issue will be discussed at the upcoming Committee for Medicinal Products for Human Use (CHMP) plenary meeting and will be included in the agenda published at the beginning of the meeting.

The start of the procedure will be announced as part of the CHMP meeting highlights, which will be published on the next working day following the CHMP meeting during which the matter is considered.

The announcement will specify the concern under consideration.

Reference:

Guide to information on human medicines evaluated by EMA

8. How will the marketing authorisation holders or applicants be informed about the start of the Article 13 referral procedure?

The public announcement on the Agency's website will include information related to the start of procedure.

The letter notifying the marketing authorisation holder(s) (MAHs)/applicants of the procedure initiation will include:

- the name and contact details of the Agency's dedicated procedure manager who will be the primary contact point during the procedure, and the e-mail address of the product-shared mailbox, which should always be copied in all correspondence with the Agency;
- the notification triggering the procedure;
- the timetable and the list of questions (if applicable) adopted by the Committee for Medicinal Products for Human Use (CHMP).

9. Does the marketing authorisation holder have to pay a fee?

No fees are payable for referral procedures under Article 13 of Commission Regulation (EC) No 1234/2008.

10. Who can submit data to be considered during the Article 13 referral procedure?

As soon as the marketing authorisation holder (MAH) is informed that the matter concerning a potential serious risk to public health has been referred to the Agency, the MAH must forward to the Agency a copy of the variation application submitted to the competent authorities of the Member States concerned, as referred to in Article 10(1) and (3) or 20(3) and (6) of Commission Regulation (EC) No 1234/2008.

During the Article 13 procedure, the MAH will in most cases be requested to submit further information relevant for the assessment, in response to a list of question adopted by the Committee for Medicinal Products for Human Use (CHMP).

This is an opportunity for the MAH to present written or oral explanations to the (CHMP) within a time limit(s) as specified in the procedure timetable before an opinion is issued by the CHMP.

The MAH will be informed of the start of the procedure and during the procedure on how and when to submit data (please refer to Questions 8, 11 and 14).

Regardless of whether or not the MAH present their explanations to the CHMP, an opinion will be issued by the CHMP, applicable to the MAH concerned by the procedure.

11. How will data be gathered during the Article 13 referral procedure?

At the start of the procedure the data considered to be necessary for the assessment will be identified in a list of questions for submission within the specified deadline as indicated in the timetable (please refer to Question 8, 14 and 15).

In certain cases, the procedure may begin with the assessment of the data already submitted to the competent authorities of the Member States concerned, as referred to in Articles 10(1) and (3) or 20(3) and (6) of Commission Regulation (EC) No 1234/2008.

The Committee for Medicinal Products for Human Use (CHMP) may also collect additional data through a list of outstanding issues and/or in an oral explanation.

12. Who will perform the assessment?

The assessment of data within the Article 13 referral procedure is the responsibility of the Committee for Medicinal Products for Human Use (CHMP). At the start of the procedure, the CHMP Chairperson appoints a rapporteur and (co-)rapporteur who will perform the assessment of all data collected within the agreed timelines.

The assessment of all the available data will result in the CHMP adopting an opinion on the issue reviewed.

13. How are the rapporteur and co-rapporteur appointed?

The Committee for Medicinal Products for Human Use (CHMP) (co-)rapporteurs for an Article 13 referral procedure is appointed by the CHMP Chairperson from amongst the members or alternates, as soon as the Article 13 referral procedure has been triggered by the reference Member State (RMS).

The CHMP Chairperson will appoint (co-)rapporteurs to represent the RMS and the objecting concerned Member State.

Reference:

Procedural Advice on CHMP/CAT/PRAC Rapporteur/Co-Rapporteur appointment principles, objective criteria and methodology in accordance with Article 62(1) of Regulation (EC) No 726/2004

During the assessment

14. How shall I present my answers?

The marketing authorisation holder (MAH) is requested to submit to the Agency and all Committee for Medicinal Products for Human Use (CHMP) members all available evidence to support the Article 13 referral procedure.

Referrals procedures starting with a list of questions (LoQ)

For these referrals, the MAH should submit their responses to the list of questions (LoQ) as follows:

- The data should be presented electronically according to the electronic Common Technical Document (eCTD)/CTD format and accompanied by a signed cover letter and a written summary of each question.
- The cover letter must make clear reference to the procedure number and the Agency's Procedure Manager should always be put in copy. A cover letter template can be found here.
- The written summary answering each question should follow the numbering as per the CHMP list of questions/CHMP list of outstanding issues. Please note that supportive data to the responses submitted (e.g. new analyses, study reports, literature data) are expected to be provided together with a summary of those data as per the modular structure of the CTD format.

It is left to the MAH's discretion to submit the relevant documentation necessary for the evaluation of the matter referred.

Referral procedures starting with the assessment of the data already available

- In these referral procedures, the evaluation starts with the data which has already been made available by the MAH at the start of the procedure (please refer to Question 10).

It should be noted that the responsibility for the quality of the submitted documentation lies with the MAH and is crucial to the overall assessment. All submissions are expected to be submitted in English and electronically only (please refer to Question 15).

15. How and to whom shall I submit my answers?

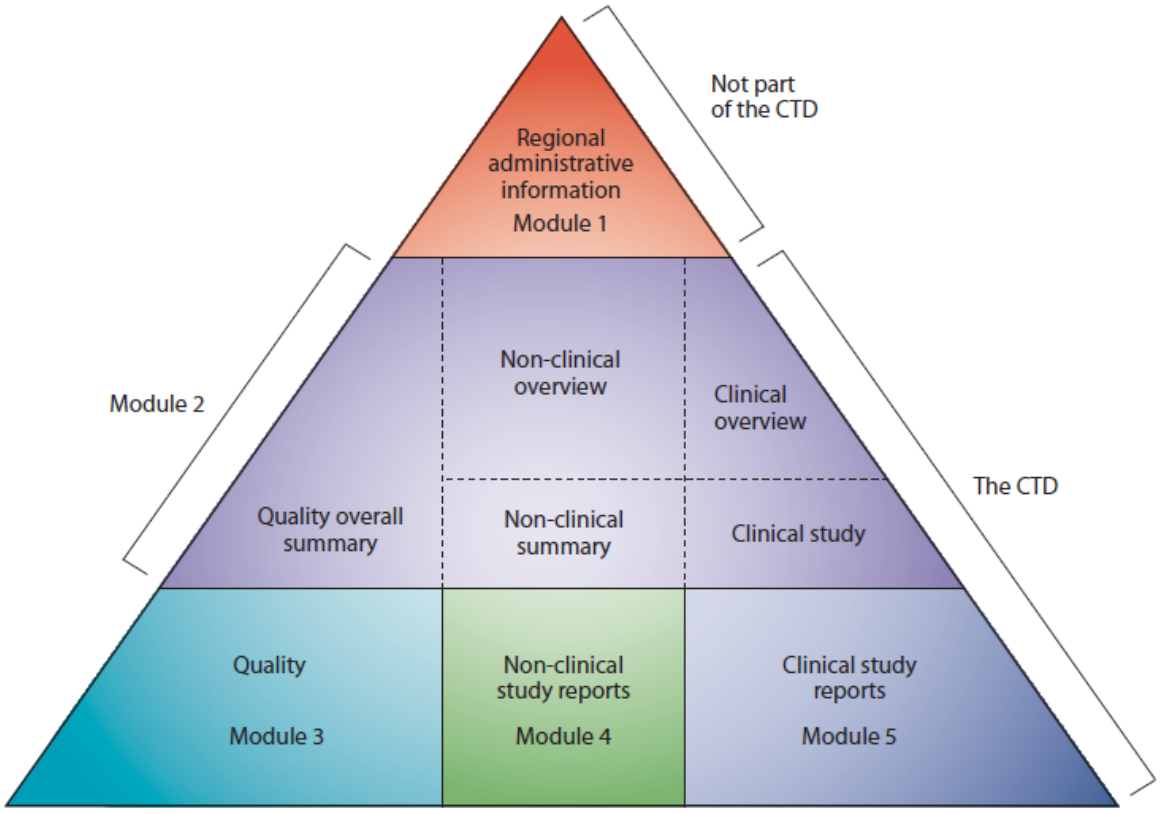
Responses from the marketing authorisation holder (MAH) should be submitted to the Agency within the timeline specified in timetable enclosed to the letter notifying the MAH of the procedure initiation.

All submissions for referral procedures should be sent via the eSubmission Gateway or eSubmission Web Client. These portals send automated acknowledgement of receipt of submission, or of failed submission if an error occurred. The Agency no longer accepts submissions on CD-ROM or DVD.

Please note that submissions for nationally authorised products (NAPs), are not available via the Common Repository and should be sent separately to each NCA. For all referral submissions related to NAPs, the Agency strongly recommends using the electronic Common Technical Document (eCTD) or Non-eCTD electronic Submissions (Nees) formats.

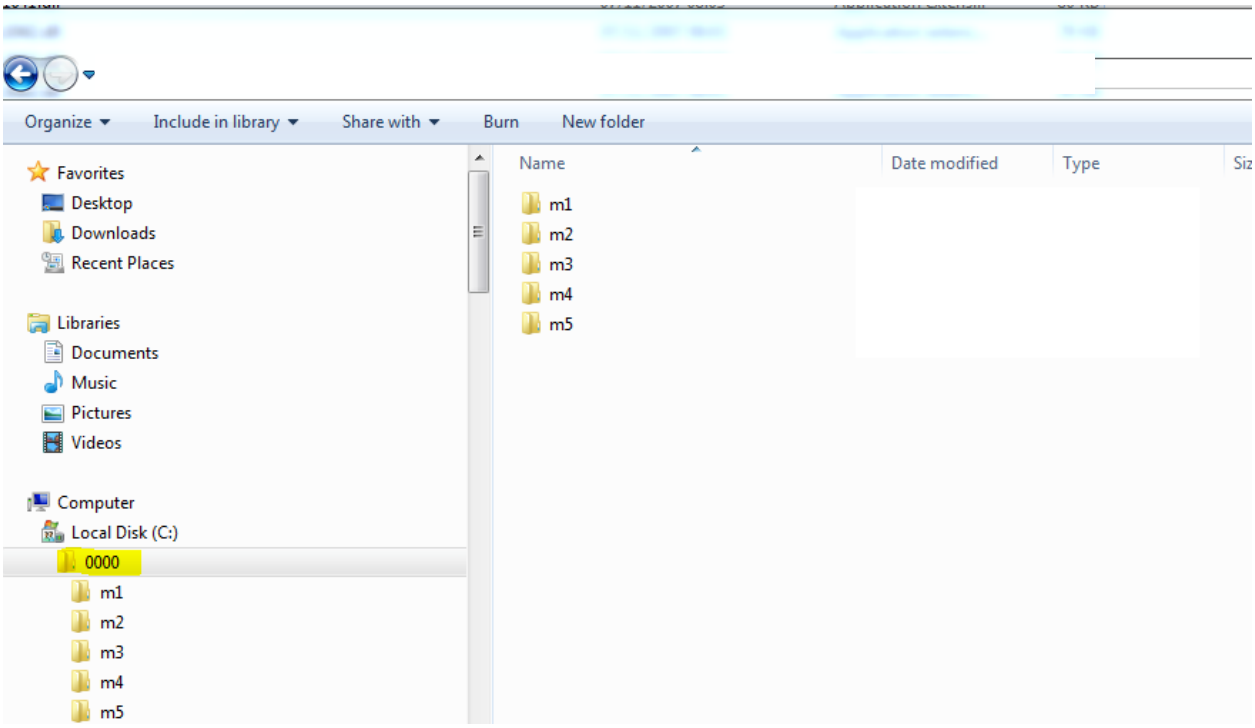
For all types of submissions, responses should be presented in the modular format.

Recommended folder structure:

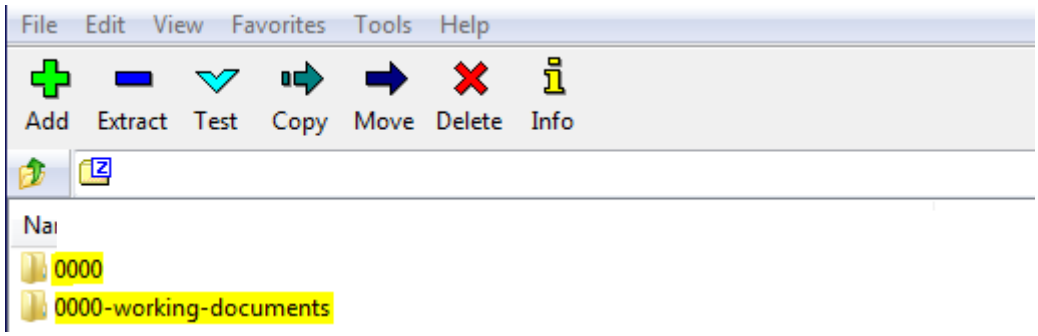


Documentation can be included in respective modules following the CTD location as referenced in the above folder structure – e.g. as following:

Root folder should be 4 digits (between 0000-9999), e.g. submission 0000 as below:



Any working documents (for example: documents in Word format) should be outside the root submission folder, e.g. as following:



More information on the required naming conventions and file formats can be found in detailed examples of filenames for different application types and in the eSubmission gateway web client - guidance for applicants. For more information please refer to eSubmission website.

There is no need to send any separate paper cover letters for these submissions, as the cover letter will be in the relevant part of eCTD/CTD module 1 in PDF format.

Should you have any questions regarding your submission, please contact us via email: REFERRALsubmission@ema.europa.eu, for any technical issues contact eSubmission@ema.europa.eu.

16. How will my data be assessed?

Submissions from the marketing authorisation holder (MAH) should be provided directly to the Committee for Medicinal Products for Human Use (CHMP) (co-)rapporteurs to be considered in their assessment.

All information gathered will be assessed within an agreed timeframe (please refer to Question 17). The assessment report(s) prepared by the CHMP (co-)rapporteurs will reflect all data reviewed and considered relevant for the assessment.

The CHMP may in some cases require input from individual experts to advise it on specific questions in relation to the assessment.

The CHMP (co-)rapporteur's assessment report(s) will be circulated to the CHMP members for comments.

17. What is the timetable for the assessment by the CHMP?

Please note that the timelines below are provided for guidance purposes only and they refer to active days, which correspond to the time the Committee for Medicinal Products for Human Use (CHMP) takes to assess the data provided.

The timetable for the Article 13 referral procedure is as follows:

Article 13 referral procedure starting with a list of questions (LoQ) - *Timetable for the assessment*	Day
Notification of a referral procedure to the CHMP/Agency Secretariat	Day 0
Discussion at the first meeting of the CHMP following receipt of the notification: • Appointment of the (co-)rapporteurs • Discussion of the question(s) referred • Adoption of a CHMP list of questions (LoQ) to be addressed by the marketing authorisation holder (MAH) or applicants and timetable	Day 1
Preparation and submission of written explanations by the MAH in response to the CHMP list of questions	Clock Stop
Re-start of the procedure following submission of written explanations (in accordance with procedural timetables)	Clock re-start
Circulation of the CHMP (co-)rapporteur's assessment report(s) on the MAH's written responses and the proposed SmPC/labelling/PL, if applicable	Day 20
Comments in writing from CHMP members on the CHMP (co-)rapporteur's assessment reports and proposed SmPC/labelling/PL, if applicable	Day 25
Discussion at the CHMP meeting: • Adoption of a CHMP list of outstanding issues (LoOI) to be answered in writing and/or in an oral explanation and timetable for the rest of the procedure, or • Adoption of a CHMP opinion (with annexes as per Article 32 of Directive 2001/83/EC)	Day 30

If the CHMP adopts a LoOI:

Preparation and submission of written and/or of oral explanations the MAH in response to the CHMP list of questions	Clock Stop
Re-start of the procedure following submission of written explanations (in accordance with the procedural timetables) or at the time of oral explanations	Clock re-start Day 31

Circulation of the CHMP (co-)rapporteur's assessment report(s) on the MAH's written responses and the proposed SmPC/labelling/PL, if applicable	Day 51
Comments in writing from CHMP members on the CHMP (co-)rapporteur's assessment reports and proposed SmPC/labelling/PL, if applicable	Day 55
Discussion at the CHMP meeting • Adoption of a CHMP opinion (with annexes as per Article 32 of Directive 2001/83/EC).	Day 60

Alternatively, an Article 13 starting with the assessment of the data already available may also be considered following the first discussion at CHMP, and the timetable in such a situation is as follows:

Article 13 referral procedure starting with the assessment of the data already available - *Timetable for the assessment*	Day
Notification of a referral procedure to the CHMP/Agency Secretariat Submission of the relevant documentation by the MAH to the CHMP/Agency secretariat	Day 0
Discussion at the first meeting of the CHMP following receipt of the notification (provided that the relevant documentation has been submitted by the MAH in advance of the start of the procedure): • Appointment of the (co-)rapporteurs • Discussion of the question(s) referred • Adoption of the timetable for the assessment of the documentation already submitted to the CHMP/Agency secretariat (no CHMP list of questions is adopted)	Day 1
Circulation of the CHMP (co-)rapporteur's assessment reports on the MAH's submitted documentation and the proposed SmPC/labelling/PL, if applicable	Day 20
Comments in writing from CHMP members on the CHMP (co-)rapporteur's assessment reports and proposed SmPC/labelling/PL, if applicable	Day 25
Discussion at the CHMP meeting: • Adoption of a CHMP list of questions (LoQ) to be answered in writing and/or in an oral explanation and timetable, or • Adoption of the CHMP opinion (with annexes as per Article 32 of Directive 2001/83/EC)	Day 30

If the CHMP adopts a LoQ:

Preparation and submission of written explanations by the MAH in response to the CHMP list of questions	Clock Stop
Re-start of the procedure following submission of written explanations (in accordance with the procedural timetables)	Clock re-start Day 31

Circulation of the CHMP (co-)rapporteur's assessment report(s) on the MAH's/appli written responses and the proposed SmPC/labelling/PL, if applicable	Day 51
Comments in writing from CHMP members on the CHMP (co-)rapporteur's assessment reports and proposed SmPC/labelling/PL, if applicable	Day 55
Discussion at the CHMP meeting: • Adoption of the CHMP opinion (with annexes as per Article 32 of Directive 2001/83/EC)	Day 60

The dates to be followed in accordance to the above timetable for each month can be found in the following link procedural timetables.

As a general rule, a clock-stop of up to one month will apply. For an extension of the clock-stop, the MAH should send a justified request to the Agency for agreement by the CHMP. The letter specifying the length of the requested extension should be addressed to the CHMP Chairperson, signed and sent electronically to the EMA procedure manager. In preparing the justification, the MAH should consider the issue under consideration and the impact the extension may have. The CHMP will consider the request, and if agreed, an extended timetable may be adopted.

18. Will I receive the CHMP (co-)rapporteur's assessment report(s)?

The marketing authorisation holder (MAH) will be provided with the Committee for Medicinal Products for Human Use (CHMP) (co-)rapporteur's assessment report(s) electronically via Eudralink.

19. Will I have the possibility to present my views in front of the CHMP and how is this organised?

The Committee for Medicinal Products for Human Use (CHMP) may decide whether there are issues that also need to be addressed orally by the marketing authorisation holder (MAH). The MAH will be duly informed in advance of the issues to be addressed during an oral explanation.

The MAH may also make a request to the CHMP to attend an oral explanation. In such a case, the MAH should send a written request to the CHMP stating the reason(s) and specifying the issue(s) to be addressed during the oral explanation. The CHMP will take due account of the request and will decide whether the oral explanation should be held.

The oral explanation should take place during the assessment phase and after the receipt of the CHMP (co-)rapporteur's assessment report(s). Further detailed information on organisational aspects of the oral explanation can be found here.

20. What should I do if my product is withdrawn or transferred to another marketing authorisation holder?

If the marketing authorisation (MA) is withdrawn or transferred during the referral procedure, the former marketing authorisation holder (MAH) should inform the Agency. The Agency will then liaise with the national competent authority (NCA) of the Members State (MS) concerned.

Following confirmation by the NCA of the withdrawal of the MA, the Agency will inform the former MAH that the specific product will no longer be included in the ongoing referral procedure.

Following confirmation by the NCA of the transfer of a MA, the Agency will inform the transferee that they are included in the referral procedure, and will request the submission of an updated letter of representation.

21. What should I do if the name of my product changes or if the name or address of the marketing authorisation holder / applicant changes?

If the name of the product or the name and/or address of a marketing authorisation holder (MAH) changes during the referral procedure, the MAH should inform the Agency. The Agency will then liaise with the national competent authority (NCA) of the Member State (MS) concerned. Following confirmation by the NCA of the change, the Agency will inform the MAH that the change has been noted.

Committee for Medicinal Products for Human Use (CHMP) opinion

22. When will the CHMP opinion be issued?

The Committee for Medicinal Products for Human Use (CHMP) will issue an opinion on the matter referred under Article 13 at the conclusion within 60 days of the start date of the procedure. The CHMP opinion will usually be adopted on the last day of the CHMP's plenary meeting.

23. What could be the opinion of the Committee for Medicinal Products for Human Use?

The Committee for Medicinal Products for Human Use (CHMP) opinion on an Article 13 referral procedure may be that:

a) the marketing authorisations (MA) should be maintained or varied, and/or;

b) the MA should be subject to certain conditions.

In the case of a positive outcome of the referral procedure resulting in the variation of the MA, an amended summary of product characteristics (SmPC), labelling and the package leaflet (PL) will be annexed to the CHMP opinion, if applicable. It is also possible that the assessment of the CHMP concludes that no modifications of the final versions of the summary of product characteristics, labelling and package leaflet achieved during the coordination group procedure are needed, in which case the CHMP opinion shall reflect that conclusion.

In cases where the assessment of the CHMP is restricted to limited parts of the SmPC, labelling and PL, only those parts which were subject to amendment during the referral procedure will be annexed to the CHMP opinion, together with a statement that for the remaining parts, the summary of product characteristics, labelling and package leaflet are the final versions achieved during the coordination group procedure.

Where the MA should be subject to certain conditions, these will be clearly stated in the CHMP opinion. Conditions to the MA can include, but are not limited to, requesting the marketing authorisation holder to conduct a post-authorisation study and/or a non-interventional study. The assessment of the fulfilment of the condition(s) will be the responsibility of the Member States, coordinated by the reference Member State unless otherwise stated.

The CHMP opinion can be adopted by consensus or by majority vote. In the event of an adoption by majority vote, the divergent positions of the relevant CHMP members will be appended to the opinion.

24. How is the Committee for Medicinal Products for Human Use opinion structured?

The Committee for Medicinal Products for Human Use (CHMP) opinion will include:

- a cover page in which the adopted opinion is outlined together with the voting outcome of CHMP;
- a listing of all products concerned; including the names of all identified products involved in the procedure, their respective marketing authorisation holders (MAHs) in each Member State;
- the scientific grounds and explanations for the CHMP opinion;
- the summary of product characteristics and/or the labelling or package leaflet, or those parts which were subject to amendment during the referral procedure, if applicable;
- the conditions or restrictions imposed on the marketing authorisation(s), if applicable;
- the CHMP members' divergent views, in case the opinion is adopted by majority;
- the CHMP assessment report on the evaluation of all the data submitted and the conclusion of the CHMP that led to the adoption of the opinion.

25. When is the Committee for Medicinal Products for Human Use opinion published?

A brief outcome of the Committee for Medicinal Products for Human Use (CHMP) opinion will be included in the CHMP meeting highlights that are released on the Friday of the CHMP plenary meeting week, together with a summary of the CHMP conclusions in the format of a Question & Answers document, together with adopted product information, if applicable.

The CHMP opinion will be published on the procedure webpage following the adoption of the European Commission Decision (please refer to Question 30).

Reference:

Guide to information on human medicines evaluated by EMA

26. Will I receive the CHMP opinion?

The designated contact person representing the marketing authorisation holder (MAH) (please refer to Question 6) identified at the start of the procedure, will receive the Committee for Medicinal Products for Human Use (CHMP) opinion and assessment report during the week following the adoption of the CHMP opinion.

27. When and how can I request a re-examination of the CHMP opinion?

The marketing authorisation holder (MAH)/applicant may, within 15 calendar days of the receipt of the Committee for Medicinal Products for Human Use (CHMP) opinion, notify the Agency in writing of its intention to request a re-examination of the CHMP opinion.

After these 15 calendar days, if the MAH/applicant has not requested a re-examination, the CHMP opinion is considered final and will be sent to the European Commission (EC) for the initiation of the decision-making process.

Re-examination

If, within the 15 days after the receipt of the CHMP Opinion, the MAH/applicant has notified the Agency in writing of its intention to request a re-examination of the CHMP opinion, the Agency will inform the CHMP of the letter of intent received.

The detailed grounds for the re-examination requested should be sent to the Agency within 60 calendar days of receipt of the CHMP opinion. The detailed grounds submitted will determine the scope of the re-examination procedure and may encompass all aspects set out in the CHMP opinion or only certain aspects of it. However, no new data can be presented at this stage of the procedure.

The re-examination procedure will only deal with the aspects of the CHMP opinion identified by the MAH/applicant in the detailed grounds for re-examination. The MAH/applicant may request that the CHMP consults a scientific advisory group (SAG) or ad-hoc expert group during the re-examination procedure. In such a case, this request should be made as early as possible, and should be no later than the submission date of the detailed grounds.

New rapporteurs will be appointed for the re-examination, and within 60 calendar days of receipt of the detailed grounds for re-examination, the CHMP will conclude its assessment of the detailed grounds and adopts a final opinion.

The CHMP final opinion following re-examination will be sent to the EC for the initiation of the decision-making process.

28. When do I have to submit translations?

The marketing authorisation holder (MAH) will have to provide translations in all EU languages (including Icelandic and Norwegian) of the following annexes to the Committee for Medicinal Products for Human Use (CHMP) opinion:

- listing of nationally authorised products concerned by the procedure;
- the harmonised summary of product characteristics (SmPC) and/or the labelling and/or package leaflet (PL), if applicable.

The Agency will contact the MAH as early as possible to ensure the smooth running of the process. The translations will have to be provided to the Member States contact points for linguistic check by Day +5 (i.e. 5 days after adoption of the opinion) and copied to the Agency. Member states may send linguistic comments until Day +19. The MAH should send the translations amended accordingly together with the completed QRD form 2 to the Agency by Day +22.

Detailed information on the translation process of CHMP opinion can be found here.

29. What happens after the final opinion of the CHMP on the Article 13 referral procedure?

Following the adoption of the Committee for Medicinal Products for Human Use (CHMP), the Agency together with the marketing authorisation holder (MAH) and national competent authorities (NCAs) in the Member States (MSs) will finalise the translations and will send these to the European Commission (EC).

The EC will then start the decision-making process leading to the adoption of a binding decision addressed to the MSs and notified to the MAH.

Detailed information on the decision-making process can be found here.

The Coordination Group for Mutual Recognition and Decentralised Procedures (CMDh) recommendation for implementation of Commission Decisions can be found here.

30. Will there be any publication in relation to the Article 13 referral procedure after the Commission Decision?

Around one week following the adoption of the European Commission (EC) decision, the Committee for Medicinal Products for Human Use (CHMP) assessment report, in English only, will be published on the procedure webpage. Within four weeks of the adoption of the EC decision, the CHMP opinion with its annexes and the Question & Answers document in all EU languages will also be published on the procedure webpage on the Agency's website, which will be updated to reflect the date of the EC decision.

Reference:

Guide to information on human medicines evaluated by EMA