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Human Medicines Division

Questions & answers on Article 13 referral procedures

This guidance document addresses a number of questions which stakeholders, in particular the marketing authorisation holders (MAHs), 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.

Hyperlinks to the documents, websites or pages listed as reference under specific questions can be found on the page:

Referral procedures: Regulatory and procedural guidance | European Medicines Agency (EMA)

Updates to these question and answers 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 must in all cases comply with the requirements of EU legislation.

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Table of contents

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:

Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Union 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 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 (PSRPH), where no agreement is 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 – Human (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 constituting PSRPH and 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 PSRPH concern can only be raised by the concerned Member States (CMS) in case of a positive assessment by the RMS.

The Commission has adopted a guideline on the definition of 'potential serious risk to public health' including examples in an annex.

References:

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Union 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 Directive 2001/83/EC

Annex to the Guideline on the definition of a potential serious risk to public health in the context of Directive 2001/83/EC

3. Who can initiate an Article 13 referral procedure?

An Article 13 referral procedure shall be initiated by the reference Member State (RMS) when its assessment is positive and at least one Member State does not agree with that assessment 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. It will include a detailed statement of the matter(s) on which the Member States concerned disagree and the reasons why, 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 Union 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 – Human (CMDh) and, eventually, from a referral procedure being initiated.

The referral procedure can only be stopped if the marketing authorisation holder (MAH) withdraws the variation application in all 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 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). The accuracy of this list 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? Rev. Jul 2026

To facilitate the exchange of information prior to the start and during the procedure, the marketing authorisation holder (MAH) should designate a contact person that will receive all correspondence from the Agency for the Article 13 referral procedure.

The contact person should be registered in IRIS prior to the start of procedure to receive the information at the start of procedure.

Guidance on how to register and how to use the IRIS platform is available on the dedicated IRIS website.

Throughout the procedure, the MAH can change the "submission contact" (the person who will receive by default all communications for the procedure, also known as "portal contact") in IRIS. In these cases, they inform the Agency's procedure lead and procedure assistant.

All documentation concerning the Article 13 referral procedure will be shared by EMA via the IRIS platform. The making available of any documents by EMA in IRIS to the contact person will be considered to constitute effective receipt by the MAH *inter alia* for the purposes of calculating the procedural timelines.

All communications with the Agency should be channelled via the contact person only.

References:

IRIS: Access

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

Following receipt of the notification initiating the Article 13 referral procedure, the issues referred to the Agency on the grounds of potential serious risk(s) to public health will be discussed at the upcoming Committee for Medicinal Products for Human Use (CHMP) plenary meeting and a brief summary will be included in the agenda published at the beginning of that 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 issues under consideration and will be published on the Agency's website on a page created specifically for the procedure.

References:

What EMA publishes and when - Guide to information on human medicines evaluated by EMA

8. How will the marketing authorisation holder be informed about the start of the Article 13 referral procedure? Rev. Jul 2026

Following the CHMP meeting, a public announcement on the Agency's website will include information related to the start of procedure.

In addition, the concerned marketing authorisation holder(s) (MAHs) will be informed electronically via the IRIS platform by the Agency. The MAH must be registered in IRIS to receive communications from EMA throughout the procedure.

This communication on the procedure initiation will include:

- the name and contact details of the EMA procedure lead who will be the contact point throughout the procedure, and the address of the procedure mailbox, which should 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).

  The Agency may release updated information on the website during the procedure and therefore the MAH should continuously check the Agency's website for any relevant updates (please refer to Question 25 and Question 30).

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 concerned Member States, as referred to in Article 10(1) and (3) or 20(3) and (6) of Commission Regulation (EC) No 1234/2008, as relevant.

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

The MAH can then present written or oral explanations to the CHMP within a time limit as specified in the procedure timetable, and before an opinion is issued by the CHMP.

For detailed information on how and when to submit data please refer to Question 8, Question 11 and Question 14.

Whether the MAH present written or oral explanations to the CHMP or not, an opinion applicable to the marketing authorisations concerned by the procedure will be issued by the CHMP.

11. How will data be gathered during the Article 13 referral procedure? Rev. Jul 2026

At the start of the procedure the Committee for Medicinal Products for Human Use (CHMP) will decide whether additional data is needed to that already submitted to the competent authorities of the Member States concerned.

Accordingly, the MAH will be requested to submit additional data, in response to a list of questions, within the deadline indicated in the timetable (please refer to Question 8, Question 14 and Question

15). Alternatively, the procedure will 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.

Notwithstanding the above, the CHMP may also collect additional data through further questions to the MAH to be addressed in writing 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 CHMP rapporteur and CHMP (co-)rapporteur who will perform the assessment of all data collected within the agreed timelines.

The CHMP assessment will conclude with the issuance of 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 are appointed by the CHMP Chairperson from amongst the members or alternates, upon the initiation of the Article 13 referral procedure.

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

References:

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 responses? Rev. Jul 2026

The marketing authorisation holder (MAH) is requested to submit to the Agency all available evidence to support the Article 13 referral procedure (please refer to Question 11).

In cases where the CHMP adopts a list of questions (LoQ), the MAH should submit their responses 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 the response to each question.
- The cover letter must make clear reference to the procedure number, and the EMA procedure lead should always be put in copy.
- The written summary of the response to each question should follow the numbering as per the CHMP list of questions, and (if applicable) the 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.

- Additional copies of certain documents are required in Word format as "working documents" outside the eCTD structure to facilitate the preparation of the assessment reports. This includes the written responses to all questions, and where applicable documents to be reviewed (e.g. the product information).

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

In cases where no LoQ is adopted, 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).

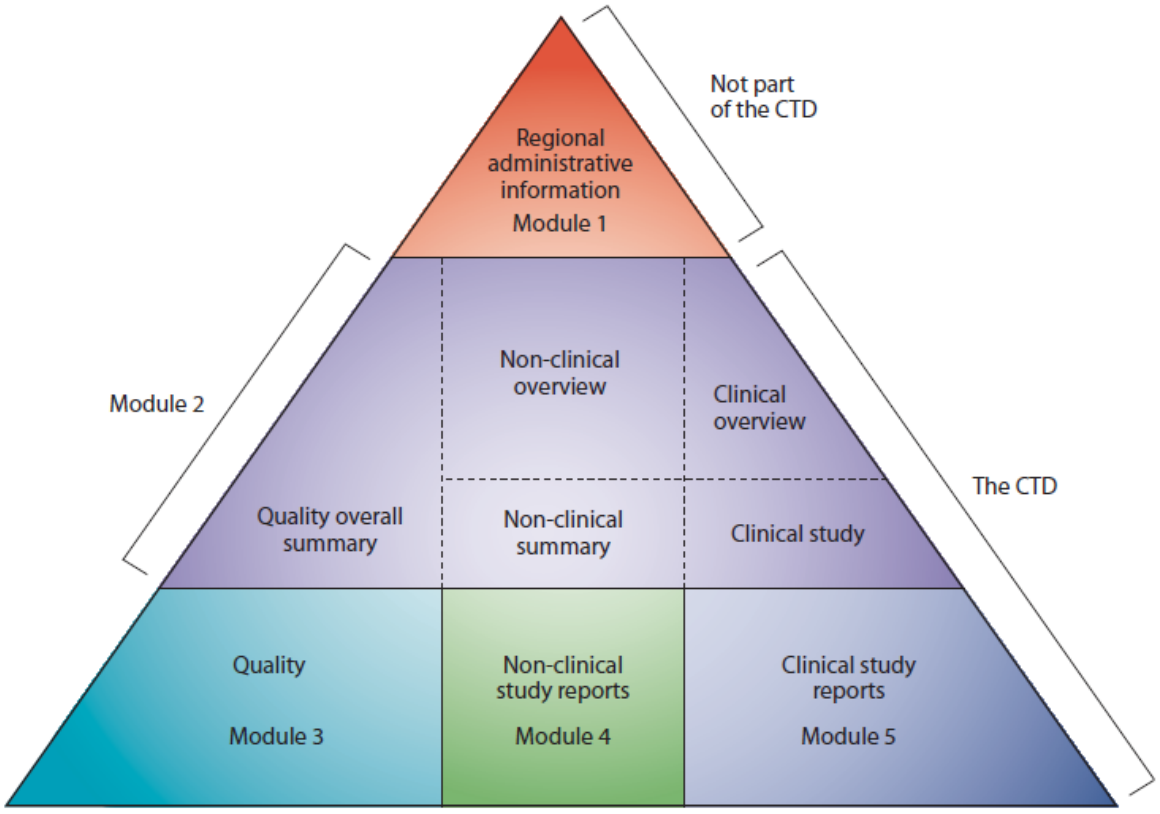
It should be noted that the responsibility for the quality of the submitted documentation lies with the MAH and is crucial to the overall assessment. All submissions are expected to be submitted in English and electronically only (please refer to Question 15).

15. How and to whom shall I submit my responses? Rev. Jul 2026

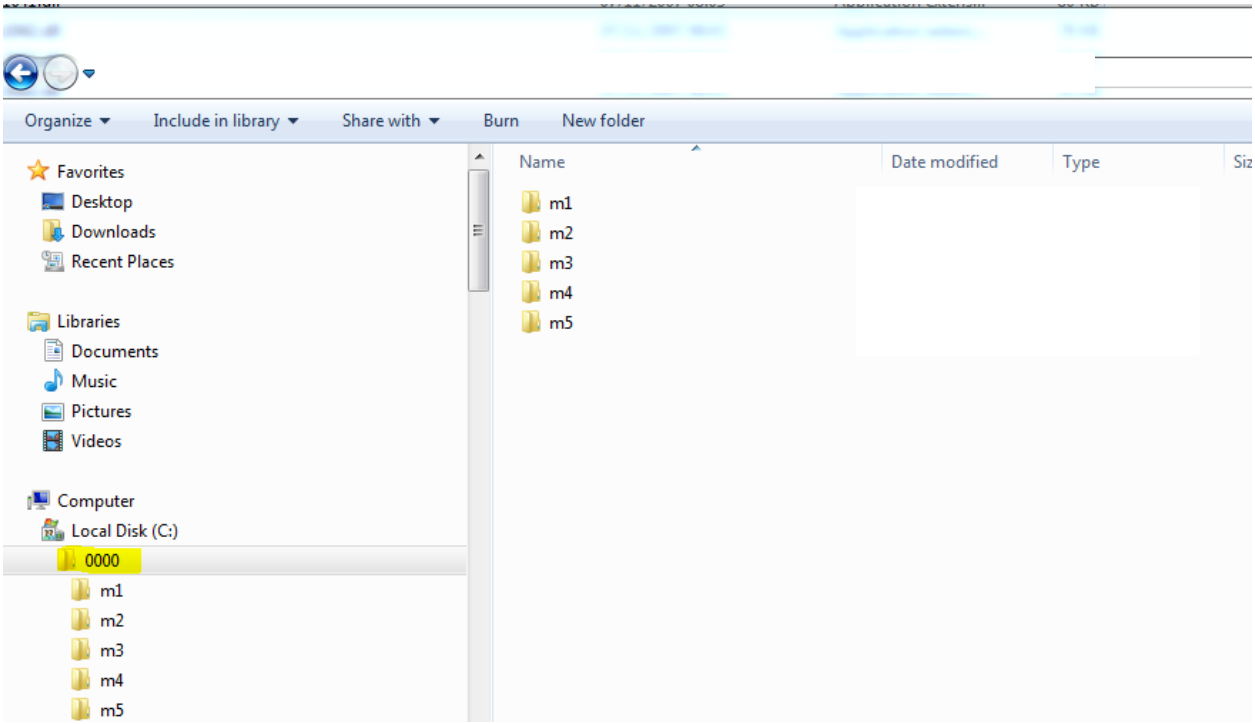
Responses from the marketing authorisation holder (MAH) should be submitted within the timelines specified in the timetable enclosed to the letter notifying the MAH of the procedure initiation.

All submissions for referral procedures should be sent via the eSubmission Gateway or eSubmission Web Client using XML delivery files. Upon successful submission these portals send automated acknowledgement of receipt. Where no such acknowledgement is received, it must be assumed that the submission failed. Responses submitted via these portals are available in the common repository and will be considered delivered to all Committee members and alternates.

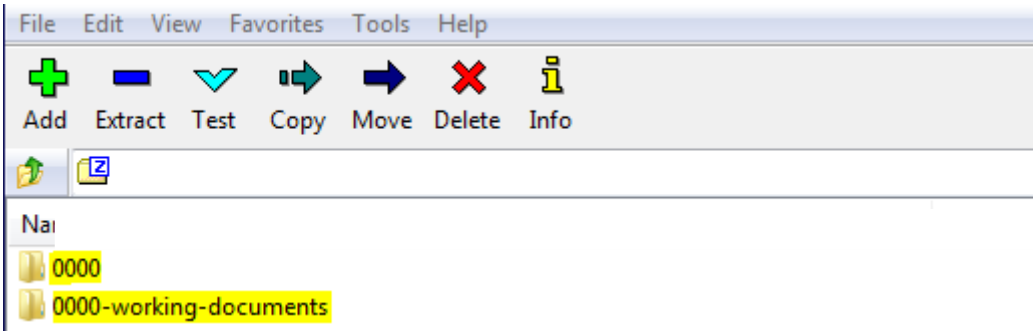
For all types of submissions, responses should be presented in the modular format:



Documentation can be included in respective modules following the CTD location as referenced in the recommended folder structure, further, the root folder should be 4 digits (between 0000-9999), e.g. submission 0000 as below:



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



For technical issues regarding your submission, visit the EMA Service Desk portal. Should you have any other questions regarding your submission, please contact the EMA procedure assistant.

References:

Dossier requirements to referral procedures and nationally authorised products

eSubmission website

XML delivery files use for all submissions via the eSubmission Gateway and the eSubmission Gateway Web Client

EMA Service Desk portal

16. How will my data be assessed? Rev. Jul 2026

Submissions from the marketing authorisation holder (MAH) are directly available in the in the common repository to the Committee for Medicinal Products for Human Use (CHMP) (co-)rapporteurs for 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 (co-)rapporteur's assessment report(s) will be circulated to the CHMP members for comments.

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

17. What is the timetable for the assessment by the CHMP? Rev. Jul 2026

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 timelines for the Article 13 referral procedure are 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 Submission of the relevant documentation by the MAH to the Agency	Day 0
Discussion at the first meeting of the CHMP following receipt of the notification: • Appointment of the (co-)rapporteurs • Discussion of the issue(s) referred • Adoption of a CHMP list of questions (LoQ) to be addressed by the marketing authorisation holder (MAH) 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 responses (in accordance with published submission dates)	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 (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	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 responses (in accordance with the published submission dates) 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	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 timelines 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 Submission of the relevant documentation by the MAH to the Agency	Day 0
Discussion at the first meeting of the CHMP following receipt of the notification: • Appointment of the (co-)rapporteurs • Discussion of the issue(s) referred • Adoption of the timetable for the assessment of the documentation already submitted to the CHMP/Agency (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	Day 30

If the CHMP adopts a LoQ:

Preparation and submission of responses to the CHMP list of questions by the MAH	Clock Stop

Re-start of the procedure following submission of written explanations (in accordance with the published submission dates)	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 the CHMP opinion	Day 60

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

As a general rule, a clock-stop of one or two months will apply. For an extension of the clock-stop adopted by CHMP, 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 lead. 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 will be adopted.

References:

Timetable: Non-safety referrals

18. Will I receive the CHMP (co-)rapporteur's assessment report(s)? Rev. Jul 2026

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 the IRIS platform.

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

The Committee for Medicinal Products for Human Use (CHMP) may decide that issues 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 present their views in an oral explanation. In such a case, the MAH should send to the EMA procedure lead a request addressed 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.

Oral explanation(s) 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 in the published guidance documents.

References:

Guidance to applicants /Marketing Authorisation Holders (MAHs) on oral explanations at EMA

20. What should I do if my product is withdrawn or transferred to another marketing authorisation holder? Rev. Jul 2026

If the marketing authorisation (MA) is withdrawn during the referral procedure, the former marketing authorisation holder (MAH) should update the Article 57 database without delay and inform the referral procedure lead. Following official confirmation of the withdrawal, the Agency will inform the former MAH that the specific MA will no longer be included in the ongoing referral procedure.

If the MA is transferred during the referral procedure, both the former and the new MAH should update the Article 57 database without delay. The new MAH should provide a copy of the transfer decision of the relevant competent authority to the referral procedure lead. It should also provide to the procedure lead information on the new contact person for the procedure (please refer to Question 6). Following receipt of the transfer decision, the Agency will inform the former MAH that they are no longer included in the referral procedure, in relation to the MA transferred.

21. What should I do if the name of my product changes or if the name or address of the marketing authorisation holder changes? Rev. Jul 2026

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. Following official confirmation by the NCA of the change, the Agency will inform the MAH that the change has been noted.

If the contact person changes, the MAH should update the "submission contact", also known as "portal contact", accordingly in IRIS and inform the EMA procedure lead and procedure assistant.

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 within 60 days of the start of the procedure (please refer to Question 17). The CHMP opinion will usually be adopted on the last day of the CHMP plenary meeting.

23. What could be the opinion of the Committee for Medicinal Products for Human Use? Rev. Jul 2026

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 product information (PI) 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 version of PI 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 PI 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 of the PI the final version is that 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 to implement risk minimisation measures. 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 opinion adopted is outlined together with the voting outcome of CHMP;
- a list of the medicinal products involved in the procedure and 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 performed and the conclusion of the CHMP that led to the adoption of the opinion, based on all the data gathered.

25. When is the Committee for Medicinal Products for Human Use opinion published? Rev. Jul 2026

The next working day following the plenary meeting, the Agency will publish a communication summarising the Committee for Medicinal Products for Human Use (CHMP) opinion in the format of a Question & Answers document and, if applicable, the amendments to be applied to the product information.

In addition, the outcome of the CHMP opinion will be included in the CHMP meeting highlights that are released on the same day.

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

References:

What EMA publishes and when - Guide to information on human medicines evaluated by EMA

26. Will I receive the CHMP opinion? Rev. Jul 2026

The marketing authorisation holder (MAH) (please refer to Question 6), will receive the Committee for Medicinal Products for Human Use (CHMP) opinion via the IRIS platform during the week following its adoption.

27. When and how can I request a re-examination of the CHMP opinion? Rev. Jul 2026

The marketing authorisation holder (MAH) 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.

When such communication is received, the Agency will inform the CHMP accordingly.

The detailed grounds for the re-examination requested should be sent to the Agency within 60 calendar days of receipt of the CHMP opinion. In case these deadlines are not respected, the request for re-examination is considered inadmissible and the opinion becomes final and is sent to the European Commission (EC).

The start of a re-examination procedure will be mentioned in the Question & Answers document summarising the initial CHMP opinion.

No fees are payable for re-examination of Article 13 referral procedures.

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 in the detailed grounds for re-examination. The MAH may request that the CHMP consults a scientific advisory group (SAG) or ad-hoc expert group during the re-examination procedure. Such request should be made as early as possible, and no later than the submission of the detailed grounds.

New (co-)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 said grounds and adopt a final opinion.

The MAH is recommended to contact the procedure lead and discuss the most appropriate dates for submission of the notice for the request and grounds for re-examination, within the legal timeframe taking into account, as far as possible, Committee meeting scheduled dates, including potential consultations with SAG/AHEG. Please note that the timelines below are provided for guidance purposes only:

Article 13 referral procedure – *Timetable for the re-examination assessment*	Day
Receipt by EMA of MAH's letter of intent to request a re-examination	-
Receipt by EMA of MAH's detailed grounds for the request of re-examination	Day 0
Next calendar day	Day 1
Circulation of the CHMP (co-)rapporteur's assessment report(s) on the MAH's detailed grounds for the re-examination request	Day 30

Article 13 referral procedure – *Timetable for the re-examination assessment*	Day
Comments in writing from CHMP members on the (co-)rapporteur's assessment report(s)	Day 40
Discussion at the CHMP meeting and adoption of CHMP opinion	Day 60

At the end of the re-examination procedure, the Question & Answers document summarising the initial CHMP opinion and, if applicable, the amendments to be applied to the product information, will be revised to reflect the outcome of the re-examination procedure and will be published next working day following the plenary meeting. In addition, the outcome of the CHMP opinion will be included in the CHMP meeting highlights that are released on the same day.

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

In case of withdrawal of the request for re-examination, the initial CHMP opinion will immediately become the final opinion.

28. When do I have to submit translations? Rev. Jul 2026

The marketing authorisation holder (MAH) will have to provide translations of the following annexes to the Committee for Medicinal Products for Human Use (CHMP) opinion in all EU languages (including Icelandic and Norwegian, if applicable[1]):

- The product information or those parts which were subject to amendment during the referral procedure, 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 on the page Referral procedures: Regulatory and procedural guidance.

References:

Submission of Day +25/235 final product information annexes (human and veterinary) – QRD Form 2

Practical information on translations for referral procedures (human)

29. What happens after the adoption of the final opinion of the CHMP on the Article 13 referral procedure? Rev. Jul 2026

When no request for re-examination of the Committee for Medicinal Products for Human Use (CHMP) opinion has been received 15 calendar days following its receipt by the marketing authorisation holder (MAH), the CHMP opinion is considered final.

[1] If the product is authorised in Iceland and/or Norway

When a re-examination procedure is initiated, the CHMP will adopt a final opinion within 60 calendar days of receipt of the detailed grounds for re-examination (please refer to Question 27).

Following the adoption of the Committee for Medicinal Products for Human Use (CHMP) opinion, 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 in chapter 6 of the volume 2A of the Notice to Applicants.

The Coordination Group for Mutual Recognition and Decentralised Procedures (CMDh) recommendation for implementation of Commission Decisions can be found in the published CMDh Procedural Guidance.

References:

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

Notice to Applicants, Volume 2A, Procedures for marketing authorisation, Chapter 6 Decision Making Procedure for the adoption of Commission Decisions

CMDh Recommendation for implementation of Commission Decisions or CMDh agreements following Union referral procedures where the marketing authorisation is maintained or varied

CMDh questions & answers post referrals phase

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

The Committee for Medicinal Products for Human Use (CHMP) assessment report will be published on the procedure page, in English only, around one week following the adoption of the European Commission (EC) decision. Within four weeks of the adoption of the EC decision, the CHMP opinion with its annexes in all EU languages will be published on the procedure page. The page will also be updated to reflect the date of the EC decision.

References:

What EMA publishes and when - Guide to information on human medicines evaluated by EMA