15 July 2026
EMA/457319/2016/Rev.1
Human Medicines Division

Questions & answers on Article 30 referral procedures

This guidance document addresses a number of questions which stakeholders, in particular the marketing authorisation holders (MAHs)/applicants, may have on Article 30 referral procedures. It provides an overview of the European Medicines Agency's (the Agency) practical and operational aspects with regards to the handling of Article 30 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/applicants must in all cases comply with the requirements of EU legislation.

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Initiation of Article 30 referral

1. What is the legal basis for an Article 30 referral procedure?

An Article 30 "harmonisation" referral procedure follows the provisions of Article 30 of Directive 2001/83/EC.

It applies when divergent decisions have been adopted by the Member States (MSs) concerning the authorisation of a nationally authorised medicinal product, in order to promote harmonisation of authorisations. It also applies when divergent decisions have been adopted by MSs concerning the suspension or revocation of a medicinal product.

The procedure for an Article 30 referral procedure is laid down in Articles 32, 33 and 34 of Directive 2001/83/EC.

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

2. In which situations can an Article 30 referral procedure be initiated?

An Article 30(1) referral procedure may be initiated when divergent decisions have been adopted by Member States (MSs) concerning the authorisation (e.g. different indications, posology, contraindications or warnings), suspension or revocation of a particular medicinal product. This procedure can be initiated by a MS, the European Commission (EC) or a marketing authorisation holder (MAH)/applicant where divergent decisions have been taken for an application by two or more MSs.

An Article 30(2) referral procedure may be initiated for the same reasons in order to promote harmonisation of authorisations for medicinal products authorised in the European Union (EU). A list of products proposed for harmonisation is drafted each year by the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), taking into account the proposals from all MSs, and forwarded to European Commission (EC). The Article 30(2) referral procedure may then be initiated for products on this list by the EC or a MS, in agreement with the Agency and taking into account the views of interested parties.

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

3. Who can initiate an Article 30 referral procedure?

An Article 30 referral procedure can be initiated by the national competent authorities (NCAs) in Member States (MSs), the European Commission (EC) or by the marketing authorisation holder (MAH)/applicant.

The initiator of the referral procedure refers the matter to the Committee for Medicinal Products for Human Use (CHMP) by circulating a notification form to the Agency, all MSs and the EC.

The notification form will identify the areas of divergence amongst the national decisions and the question(s) sent to the CHMP for consideration.

The MAH/applicant can request a pre-referral meeting with the Agency; this is particularly advisable in case they intend to initiate a referral under Article 30(1).

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 regulatory submissions continue during an Article 30 referral procedure?

Any variation(s) submitted but not approved (pending) should be mentioned at the pre-referral stage as well as in the referral submission, informing the Agency and (co-)rapporteurs. Submitted variations will be taken into account during the referral only if approved in at least one Member State (MS) (including Iceland and Norway).

Although the Article 30 referral is independent from any paediatric submission or paediatric work sharing exercises, Periodic Safety Update Report (PSUR) submissions and annual re-assessments, these should be highlighted clearly at the pre-referral stage as well as in the marketing authorisation holder's (MAH) submission(s).

5. Which medicinal products can be involved in an Article 30 referral procedure?

For Article 30 referral procedures, only the concerned medicinal product for which divergent decisions have been adopted in Member States (MSs) concerning its authorisation, suspension or revocation shall be included.

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

Parallel Article 30 referral may be considered for medicinal products that include different salt forms or pharmaceutical alternatives that may have an impact on bioavailability/administration schedules, or where single active substances and their fixed combinations are being considered.

6. Should the marketing authorisation holder/applicant identify a contact person to communicate with the Agency during the Article 30 referral procedure? Rev. Jul 2026

To facilitate the exchange of information prior to the start and during the procedure, the marketing authorisation holder (MAH)/applicant should designate a contact person that will receive all correspondence from the Agency for the Article 30 referral procedure.

The MAH/applicant may, if they wish, be represented by another party (e.g. a consultant), who will be the contact person for the 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/applicant 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 should inform the Agency's procedure lead and procedure assistant.

All documentation concerning the Article 30 referral procedure will be shared by EMA via the IRIS platform. The contact details of the person should be clearly stated (name, address, phone and fax number and email address) in the letter of representation. The making available of any documents by EMA in IRIS to the contact person will be considered to constitute effective receipt by the MAH/applicant *inter alia* for the purposes of calculating the procedural timelines.

All communication with the Agency concerning the Article 30 referral procedure should be channelled via the contact person only.

References:

IRIS: Access

7. When and how will the Article 30 referral procedure be announced?

Following receipt of the notification initiating the Article 30 referral procedure, the divergent decisions previously adopted by Member States and referred to the Agency for harmonisation 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 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 concerns 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 30 referral procedure? Rev. Jul 2026

Following the Committee for Medicinal Products for Human Use (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 (MAH)/applicant will be informed via the IRIS platform by the Agency. The MAH/applicant 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. It will be sent to the MAH together with the notification triggering the procedure, the timetable and the list of questions (if applicable, i.e. unless the procedure was triggered by the MAH) adopted by the CHMP.

The Agency may release updated information on the website during the procedure and therefore the MAH/applicant should continuously check the Agency's website for any relevant updates (please refer to Question 26 and Question 31).

9. Does the marketing authorisation holder have to pay a fee? Rev. Jul 2026

The Agency will levy a fee for a referral procedure under Article 30 of Directive 2001/83/EC.

For more information on fees to be paid, applicable fee reductions and payment process, please refer to the Fee Q&A in Annex I, section 6, on the Fees payable to the European Medicines Agency page.

References:

Fees payable to the European Medicines Agency

10. Who can submit data to be considered during the Article 30 referral procedure?

The marketing authorisation holder (MAH)/applicant will be requested to submit information relevant for the assessment.

The MAH/applicant can present written or oral explanations to the Committee for Medicinal Products for Human Use (CHMP) within a time limit(s) as specified in the procedure timetable, and before an opinion is issued by the CHMP.

In the case where divergent decisions have been adopted by the Member States (MSs) concerning the authorisation of a medicinal product, the MAH should also submit a proposal for a harmonised summary of product characteristics (SmPC), labelling and package leaflet (PL) within the time limit(s) as specified in the procedure timetable.

For detailed information on how and when to submit data please refer to Question 8, Question 14 and Question 17.

Whether the marketing authorisation holder/applicant presents explanations to the CHMP or not, an opinion applicable to all marketing authorisations/applications concerned by the procedure will be issued by the CHMP.

11. How will data be gathered during the Article 30 referral procedure? Rev. Jul 2026

At the start of the procedure the data considered to be necessary for the assessment will be identified and requested by the Committee for Medicinal Products for Human Use (CHMP) in the format of a list of questions. The CHMP will also agree on a deadline for the marketing authorisation holder (MAH)/applicant to submit responses as indicated in the timetable (please refer to Question 8, Question 14 and Question 17).

Where the MAH/applicant initiated the procedure, it is left to their discretion to submit the relevant documentation necessary for the evaluation of the divergences and justify the proposed harmonisation. At the start of the procedure the data submitted will be assessed by CHMP.

The CHMP may also collect additional data through a list of questions/list of outstanding issues and/or in an oral explanation in accordance with an extended timetable.

12. Who will perform the assessment?

The assessment of data within the Article 30 referral procedure is the responsibility of the Committee for Medicinal Products for Human Use (CHMP). At the start of the procedure, the CHMP appoints a CHMP rapporteur and CHMP co-rapporteur(s) 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? Rev. Jul 2026

The Committee for Medicinal Products for Human Use (CHMP) (co-)rapporteurs for an Article 30 referral procedure are appointed by the CHMP Chairperson from amongst the members or alternates (hereafter referred to as CHMP members), approximately 3 months before the start of the Article 30 referral procedure.

The CHMP Chairperson will endeavour to apply the criteria of best available expertise for the appointment of the (co-)rapporteurs for each procedure.

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?

Marketing authorisation holder(s) (MAHs)/applicants are requested to submit to the Agency all available evidence to support the Article 30 referral procedure.

In cases where the referral procedure is triggered by a Member State or the European Commission, the MAHs/applicants 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 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/CHMP list of outstanding issues. Please note that supportive data to the responses submitted (e.g. study reports, literature data, risk management plan) 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 (see also next bullet).
- If the procedure was triggered to resolve divergences in the product information (e.g. different indications, posology, contraindications or warnings), the MAH should provide:

- a proposal of harmonised Summary of product characteristics, labelling and package leaflet (in Word format);
- a description the divergences across Member States for each section of the Summary of Product Characteristics;
- the rational with supportive evidence for the proposed harmonised wording. When applicable, this should include a justification, supported by evidence as to why it is considered appropriate not to include wording currently existing in a MS in the harmonised PI.

In cases where the referral procedure is triggered by the marketing authorisation holder/applicant, the procedure starts with the evaluation of the data submitted by the MAH/applicant. It is left to the MAH/applicant's discretion to submit the relevant documentation necessary for the evaluation of the matter referred to justify the proposed harmonised product information, with a particular focus on the resolution of divergences. The same principles as described above are recommended to be followed. This should be accompanied by an expert report/overviews, which have been updated to reflect the current regulatory status.

In all cases, data submitted should be accompanied by an overall summary of its content and should make reference to the specific CHMP question being addressed (as per CHMP list of questions/ list of outstanding issues numbering). A listing of all studies (e.g. pre-clinical, clinical, post-marketing studies) and literature referred to in the responses is also strongly recommended.

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

References:

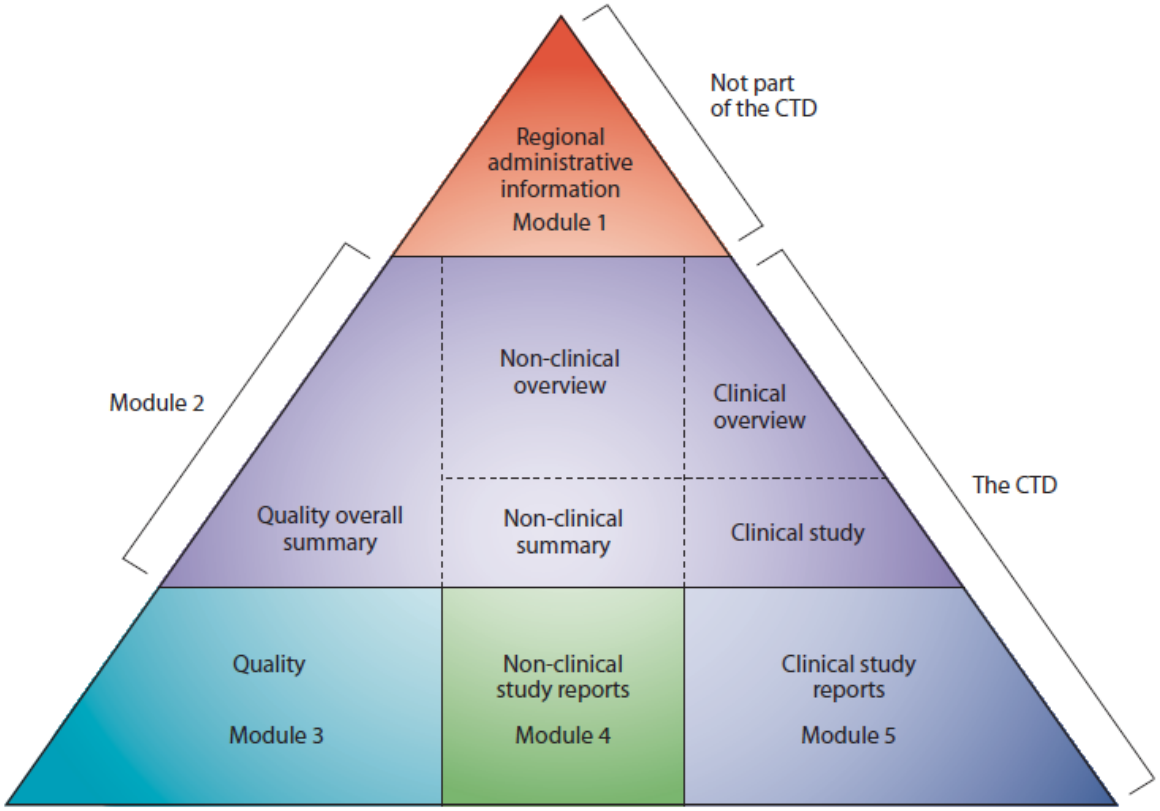
CMDh annotated QRD template for MRP/DCP

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

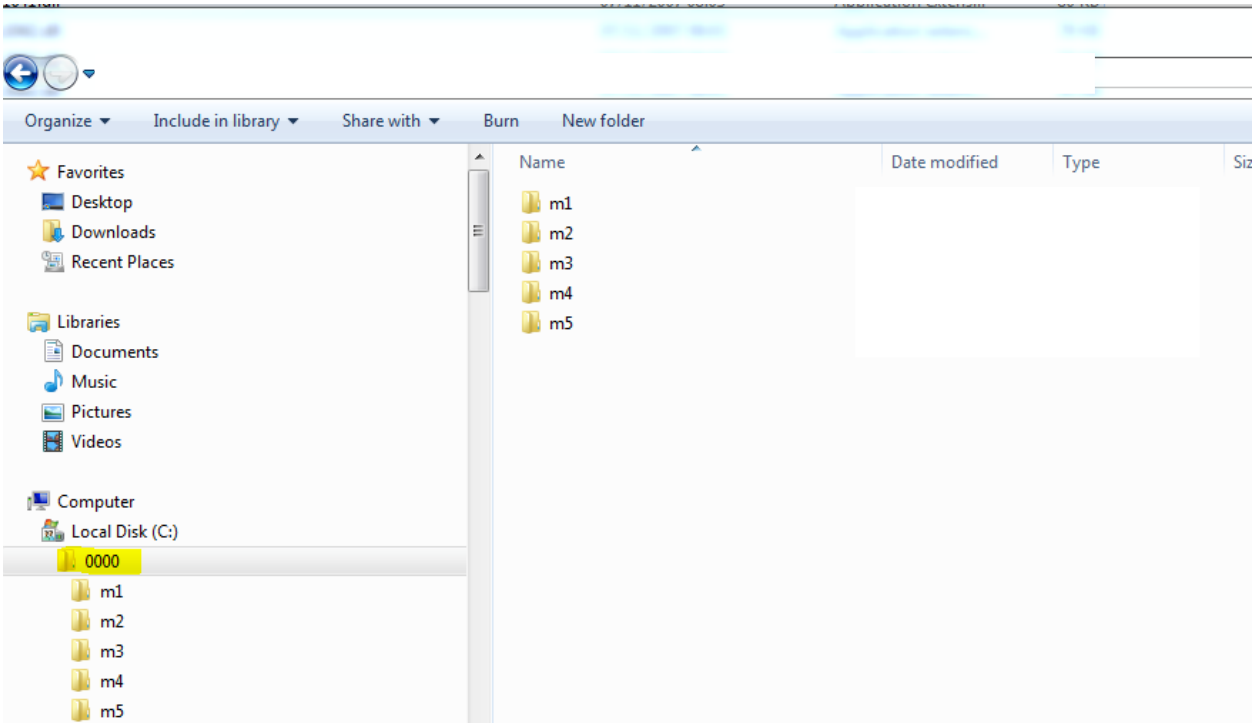
Responses from the marketing authorisation holder (MAH)/applicant should be submitted within the timelines specified in the timetable enclosed to the letter notifying the MAH/applicant of the procedure initiation.

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.

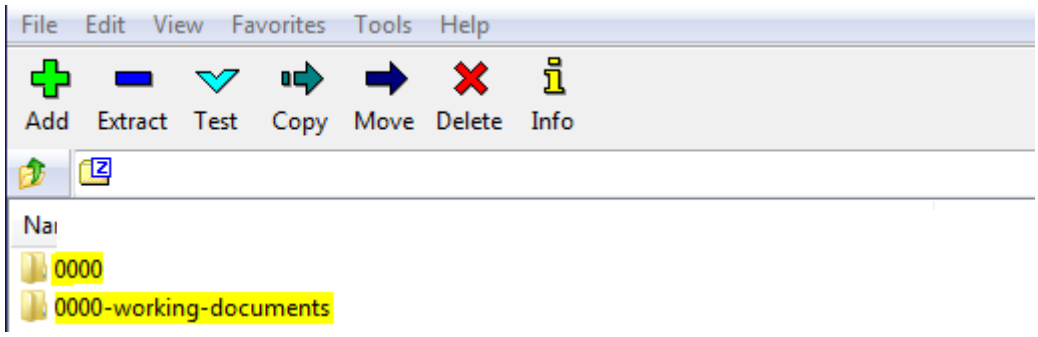
For all types of submissions, responses should be presented in the modular format:



Documentation can be included in respective modules following the CTD location as referenced in the above folder structure, further, 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:



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 for 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)/applicant are directly available 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 procedure when triggered by a Member State (MS) or the European Commission (EC) are as follows:

Article 30 referral initiated by a Member State or the European Commission - *Timetable for the assessment*	Day
Notification of a referral to the CHMP/Agency	Day 0
Discussion at the first meeting of the CHMP following receipt of the notification: • Appointment/confirmation of the (co-)rapporteur(s)	Day 1

Article 30 referral initiated by a Member State or the European Commission - *Timetable for the assessment*	Day
• Discussion of the divergence(s) referred • Adoption of the CHMP list of questions (LoQ) to be addressed by the marketing authorisation holder (MAH)/applicant and timetable	
Preparation and submission of written explanations by the MAH/applicant in response to the CHMP list of questions	Clock Stop
Re-start of the procedure in accordance with the published submission dates	Clock re-start
Circulation of the CHMP (co-)rapporteur's assessment report(s) on the MAH's/applicant 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 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 CHMP opinion (ends here)	Day 30
If the CHMP adopted a LoOI: • Preparation and submission of written and/or of oral explanations if applicable	Clock Stop
Re-start of the procedure following submission of written responses in accordance with the published submission dates or at the time of oral explanations	Clock re-start Day 31
Discussion at the CHMP meeting: • Adoption of the CHMP opinion	Day 60

The timelines for the procedure when triggered by a MAH/applicant are as follows:

Article 30 referral initiated by a MAH/applicant - *Timetable for the assessment*	Day
Notification of a referral to the CHMP/Agency Agency to liaise with MAH/applicant to ensure that the relevant documentation is submitted to the CHMP/Agency	Day 0
Discussion at the first CHMP meeting following receipt of the notification (provided that the relevant documentation has been submitted by the MAH/applicant in advance): • Appointment/confirmation of the (co-)rapporteurs and • Discussion of the divergence(s) referred	Day 1

Article 30 referral initiated by a MAH/applicant - *Timetable for the assessment*	Day
• Adoption of the timetable for the assessment of the documentation already submitted to the CHMP/Agency (no CHMP list of questions is adopted)	
Circulation of the CHMP (co-)rapporteur's assessment report(s) on the MAH/applicant'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 report(s) 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	Day 30
Preparation and submission of written responses to the CHMP list of questions by the MAH/applicant	Clock Stop
Re-start of the procedure in accordance with the procedural timetables	Clock re-start Day 31
Circulation of the CHMP (co-)rapporteur's assessment report(s) on the MAH/applicant's written responses and the proposed SmPC/labelling/PL, if applicable	Day 51
Comments in writing from CHMP members on the CHMP (co)-rapporteurs assessment report(s) 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.

The CHMP may extend the time limit up to 150 active days (interrupted by clock-stops) to allow for the assessment of further data provided as responses to the CHMP list of outstanding issues, or in an oral explanation, or in cases where the CHMP requires input from experts to support the CHMP opinion.

As a general rule, a clock-stop of one or two months will apply. For an extension of the clock-stop adopted by the CHMP, the MAH/applicant 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/applicant 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)/applicant will be provided with the Committee for Medicinal Products for Human Use (CHMP) (co-)rapporteur's assessment report(s) via the IRIS platform.

19. Do I need to submit readability testing of the package leaflet?

In compliance with article 59(3) of Directive 2001/83/EC (consultation with target patient groups), data should be submitted and assessed to ensure compliance of the package leaflet (PL) with the summary of product characteristics (SmPC), and also to ensure that the way in which the information is set out in the document is accessible to the reader, easy to read (readability) and easy to navigate.

During an Article 30 referral, it is recommended that the results of the consultation with target patient groups are submitted with the responses to the list of outstanding issues (LoOI).

A full user consultation may not be necessary in every case, and a "bridging study" may be prepared to support the PL, where justified.

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 Guideline on the readability of the labelling and package leaflet of medicinal products

20. Will I have the possibility to present my views orally to the CHMP and how is it 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)/applicant. The MAH/applicant will be duly informed in advance of the issues to be addressed during an oral explanation.

The MAH/applicant may also make a request to the CHMP to present their views in an oral explanation. In such a case, the MAH/applicant 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

21. What should I do if my medicinal 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.

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

If the name of a nationally authorised product or if the name and/or address of a marketing authorisation holder (MAH) changes during the referral procedure, the marketing authorisation holder (MAH) should inform the Agency. Following official confirmation of the change, the Agency will inform the MAH that the change has been noted.

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

Committee for Medicinal Products for Human Use (CHMP) opinion

23. 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 30 within 60 days of the start date of the procedure. The CHMP may extend that period up to 150 days, to take into account all available data as well as any issues addressed by the marketing authorisation holder (MAH) during an oral explanation and/or input from experts (if any) before issuing an opinion (please refer to Question 17).

The CHMP opinion will usually be adopted on the last day of the CHMP's plenary meeting.

24. What could be the opinion of CHMP?

The Committee for Medicinal Products for Human Use (CHMP) opinion on an Article 30 referral procedure may be that:

a) the product information as proposed by the applicant should be amended, or the marketing authorisation(s) (MA(s)) should be varied, as applicable;

b) the MA(s) should be subject to certain conditions;

c) the application does not satisfy the criteria for authorisation, or the MA(s) should be suspended or revoked, as applicable.

Where the product information is to be amended, the CHMP opinion will include the entire revised harmonised product information texts (i.e. summary of product characteristics (SmPC), labelling or package leaflet (PL)).

Where the MA should be subject to certain conditions or is to be suspended with condition(s) for lifting the suspension of the marketing authorisation(s), these can include, but are not limited to, requesting the marketing authorisation holder to conduct a post-authorisation study. The assessment of the fulfilment of the condition(s) to the marketing authorisation(s) will be the responsibility of the Member States, under the lead of the reference Member State (RMS) unless otherwise stated.

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

25. How is the CHMP opinion structured? Rev. Jul 2026

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 list of the medicinal products and applications authorised nationally including via the mutual recognition/decentralised procedures, their respective marketing authorisation holders (MAHs)/applicants in each Member State;
- the scientific grounds and explanations for the CHMP opinion;
- the harmonised summary of product characteristics (SmPC) and/or the labelling or package leaflet (PL), if applicable;
- the conditions or restrictions imposed on the marketing authorisation(s), if applicable;
- the conditions for lifting the suspension of 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;
- the Direct Healthcare Professional Communication (DHPC) and communication plan as agreed by CHMP, if applicable.

26. When is the CHMP opinion published?

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, 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 31).

References:

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

27. 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.

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

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.

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.

The Agency will levy a fee for the re-examination of 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 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 the 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 30 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
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, 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 is 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.

References:

Fees payable to the European Medicines Agency

29. 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 harmonised summary of product characteristics (SmPC) and/or the labelling and/or package leaflet (PL), if applicable

The Agency will contact the MAH/applicant 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 the CHMP opinion can be found on the page the 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)

30. What happens after the adoption of the final opinion of the CHMP on the Article 30 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)/applicant, the CHMP opinion is considered final.

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 28).

Following the adoption of the 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).

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

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/applicant.

Detailed information on the decision-making process can be found in the chapter 6 of the volume 2A of the notice to applicants.

The Co-ordination 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

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

31. Will there be any publication in relation to the Article 30 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 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