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SCIENCE MEDICINES HEALTH

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Procedure Management and Business Support

Questions & answers on Article 30 referral procedures

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

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



Table of contents

Initiation of Article 30 referral	4
1. What is the legal basis for an Article 30 referral procedure?.....	4
2. In which situations can an Article 30 referral procedure be initiated?	4
3. Who can initiate an Article 30 referral procedure?	5
4. Can regulatory submissions continue during an Article 30 referral procedure?	5
5. Which medicinal products can be involved in an Article 30 referral procedure?	5
6. Should the marketing authorisation holder/applicant identify a contact person to communicate with the Agency during the Article 30 referral procedure?.....	6
7. When and how will the Article 30 referral procedure be announced?	6
8. How will the marketing authorisation holder be informed about the start of the Article 30 referral procedure?	6
9. Does the marketing authorisation holder have to pay a fee?.....	7
10. Who can submit data to be considered during the Article 30 referral procedure?	7
11. How will data be gathered during the Article 30 referral procedure?	7
12. Who will perform the assessment?	7
13. How are the rapporteur and co-rapporteur appointed?.....	8
During the assessment	8
14. How shall I present my answers?	8
15. How and to whom shall I submit my answers?.....	9
16. How will my data be assessed?	11
17. What is the timetable for the assessment by the CHMP?	12
18. Will I receive the CHMP (co-)rapporteur's assessment report(s)?	14
19. Do I need to submit readability testing of the package leaflet	14
20. Will I have the possibility to present my views in front of the CHMP and how is it organised?	14
21. What should I do if my product is withdrawn or transferred to another marketing authorisation holder?.....	15
22. What should I do if the name of my product changes or if the name or address of the marketing authorisation holder changes?	15
Committee for Medicinal Products for Human Use (CHMP) opinion	15
23. When will the CHMP opinion be issued?.....	15
24. What could be the opinion of CHMP?	15
25. How is the CHMP opinion structured?.....	16
26. When is the CHMP opinion published?.....	16
27. Will I receive the CHMP opinion?.....	17
28. When and how can I request a re-examination of the CHMP opinion?	17

29. When do I have to submit translations?	17
30. What happens after the final opinion of the CHMP on the Article 30 referral procedure?	18
31. Will there be any publication in relation to the Article 30 referral procedure after the Commission Decision?	18

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 Community 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 submitted in 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 \(CMDh\)](#), 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 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 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 he intends 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 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 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?

To facilitate the exchange of information prior to the start and during the procedure, the marketing authorisation holder (MAH)/applicant should inform the Agency of the designated contact person 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. In this case it must inform the procedure manager identified in the letter notifying the procedure initiation.

All documentation concerning the Article 30 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/applicant 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 relevant revised letter of representation.

All documentation concerning the Article 30 referral procedure will be sent to the contact person only.

7. When and how will the Article 30 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 concerns under consideration.

Reference:

[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?

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

The letter notifying the marketing authorisation holder (MAH) 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. 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. the procedure was not triggered by the MAH) adopted by the Committee for Medicinal Products for Human Use (CHMP).

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

Fees are only payable for referral procedures under Article 30 of Directive 2001/83/EC which have been initiated by the marketing authorisation holder (MAH).

References:

[Fees payable to the European Medicines Agency](#)

[Council Regulation \(EC\) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products](#)

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

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

This is an opportunity given to the MAH to 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 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.

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 marketing authorisation holder presents their explanations to the CHMP, an opinion will be issued by the CHMP, in any case, applicable to all marketing authorisations concerned by the procedure.

11. How will data be gathered during the Article 30 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 17](#)).

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 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 rapporteur and co-rapporteur(s) 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 30 referral procedure is 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.

If the procedure was triggered by a Member State (MS), the CHMP member of that MS will be appointed as Rapporteur, if not the rapporteurship will be opened to all members, as will the co-rapporteurship.

The CHMP Chairperson will endeavour to apply the criteria of best available expertise to be taken into account 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 answers?

Marketing authorisation holder(s) (MAHs) are requested to submit to the Agency and all Committee for Medicinal Products for Human Use (CHMP) members all available evidence to support the Article 30 referral procedure.

Referral procedures triggered by a Member State or the European Commission

The MAHs 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. 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.
- 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;

- o the rationale 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.

Referral procedures triggered by a marketing authorisation holder

- In these referrals, the procedure starts with the evaluation of the data submitted by the MAH.

It is left to the MAH'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 published list of questions/ list of outstanding issues numbering). A listing of all studies (pre-clinical, clinical, post-marketing studies, etc.) and literature referred to in the responses is also strongly recommended.

Published data can be presented as supportive documentation in response to a specific question if no other data is available.

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](#)).

Reference:

[CMDh annotated QRD template for MRP/DCP](#)

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

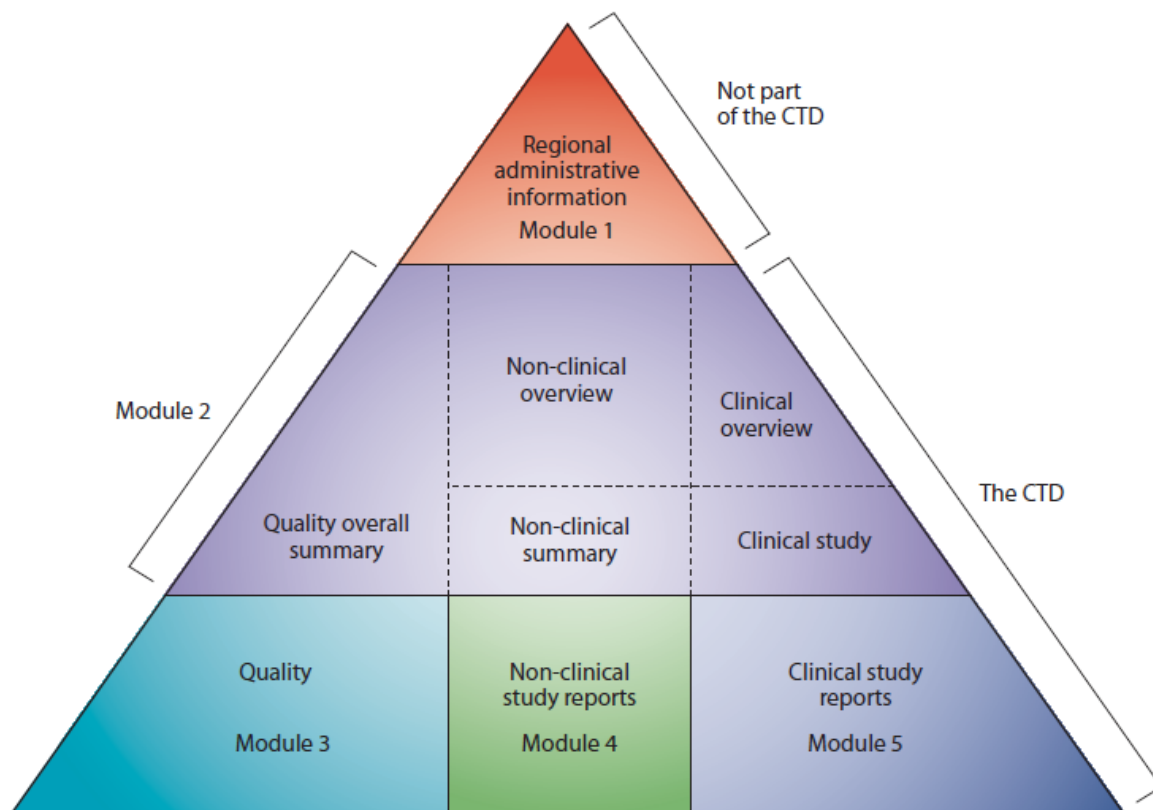
Responses from the marketing authorisation holder (MAH) should be submitted to the Agency within the timeline specified in timetable enclosed to the letter notifying the MAH of the procedure initiation.

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.

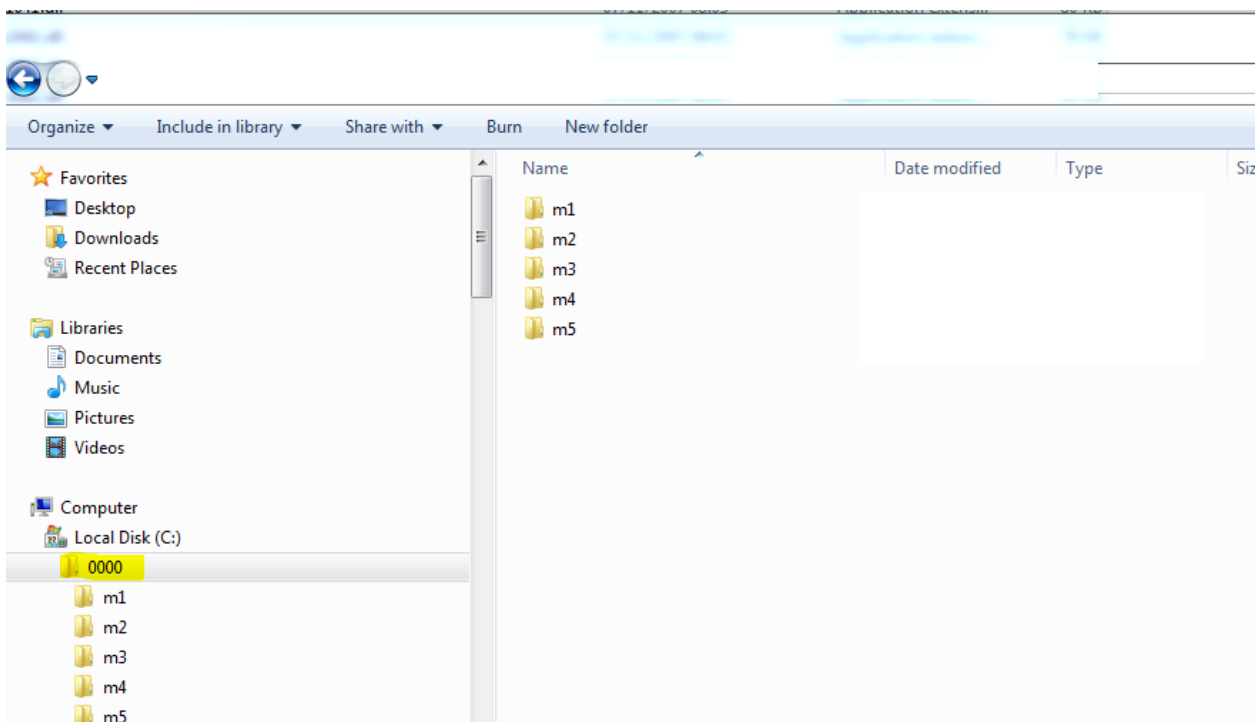
For all types of submissions, responses should be presented in the modular format.

Recommended folder structure:

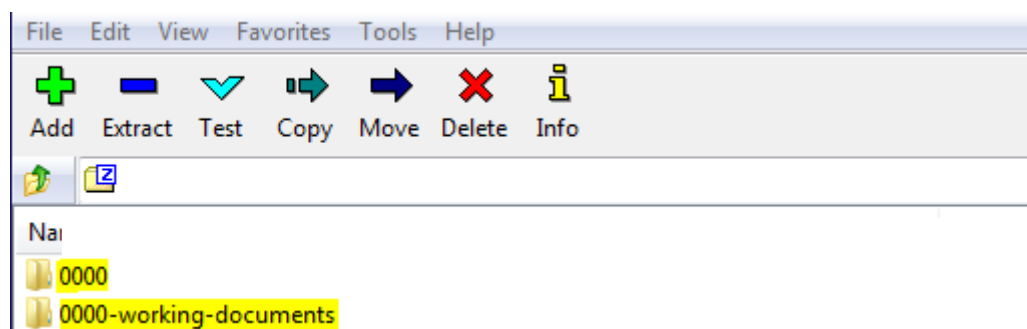


Documentation can be included in respective modules following the CTD location as referenced in the above folder structure – e.g. as following:

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) are 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 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 procedure when triggered by a Member State (MS) or the European Commission (EC) is as follows:

Article 30 referral initiated by a Member State or the European Commission - <i>Timetable for the assessment</i>		Day
Notification of a referral to the CHMP/Agency Secretariat		Day 0
Discussion at the first meeting of the CHMP following receipt of the notification: <ul style="list-style-type: none"> • Appointment/confirmation of the (co-)rapporteur(s) • Discussion of the question(s) referred • Adoption of the CHMP list of questions (LoQ) to be addressed by the marketing authorisation holder (MAH)/applicant and timetable 		Day 1
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 procedural timetables		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 CHMP (co-)rapporteur's assessment reports and proposed SmPC/labelling/PL, if applicable		Day 25
Discussion at the CHMP meeting: <ul style="list-style-type: none"> • 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 		Day 30
Preparation and submission of written and/or of oral explanations if applicable		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

Article 30 referral initiated by a Member State or the European Commission - <i>Timetable for the assessment</i>	Day
	Day 31
Discussion at the CHMP meeting: <ul style="list-style-type: none"> Adoption of the CHMP opinion (with annexes as per Article 32 of Directive 2001/83/EC) 	Day 60

The timetable for the procedure when triggered by a MAH is as follows:

Article 30 referral initiated by a MAH - <i>Timetable for the assessment</i>	Day
Notification of a referral to the CHMP/Agency Secretariat	Day 0
Agency to liaise with MAH to ensure that the relevant documentation is submitted to the CHMP/Agency secretariat	
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): <ul style="list-style-type: none"> Appointment of the (co-)rapporteurs and 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 report(s) 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 report(s) and proposed SmPC/labelling/PL, if applicable	Day 25
Discussion at the CHMP meeting: <ul style="list-style-type: none"> 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 explanations by the MAH in response to the CHMP list of questions	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'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: <ul style="list-style-type: none"> Adoption of the CHMP opinion (with annexes as per Article 32 of Directive 	Day 60

Article 30 referral initiated by a MAH - <i>Timetable for the assessment</i>	Day
2001/83/EC).	

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

The CHMP may extend the time limit of 60 days to 150 days (which will include clock-stops) to allow for the assessment of further data provided as answers 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 up to one month will apply. For an extension of the clock-stop adopted by the 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 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. 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 Community 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 in front of the CHMP and how is it 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)/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 attend an oral explanation. In such a case, the MAH/applicant 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](#).

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

If the marketing authorisation (MA) for a nationally authorised product 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 Member 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.

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

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. 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

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.

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 summary of the product characteristic (SmPC) 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 safety/efficacy 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 concerned CHMP members will be appended to the opinion.

25. How is the CHMP 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/applications concerned, including the names of all identified products 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 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?

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 and with the 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 31](#)).

Reference:

27. 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.

28. 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 is sent to the European Commission (EC) for the initiation of the decision-making process.

Re-examination

If within 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 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 (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 detailed grounds and adopt a final opinion.

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

29. 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, if applicable¹) of the following annexes to the Committee for Medicinal Products for Human Use (CHMP) opinion:

- listing of nationally authorised products (including via the mutual recognition/decentralised procedures) concerned by the procedure;

¹ If authorised in Iceland and Norway

- 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 [here](#).

30. What happens after the final opinion of the CHMP on the Article 30 referral procedure?

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/applicant.

Detailed information on the decision-making process can be found [here](#).

The [Co-ordination Group for Mutual Recognition and Decentralised Procedures \(CMDh\)](#) recommendation for implementation of Commission Decisions can be found [here](#).

31. Will there be any publication in relation to the Article 30 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 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](#)