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Human Medicines Division

Questions & answers on Article 31 non-pharmacovigilance referral procedures

This guidance document addresses a number of questions which stakeholders, in particular the marketing authorisation holders (MAHs)/applicants, may have on an Article 31 non-pharmacovigilance referral procedure. It provides an overview of the European Medicines Agency's (the Agency) practical and operational aspects with regards to the handling of Article 31 non-pharmacovigilance 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 questions 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 an Article 31 non-pharmacovigilance referral

1. What is the legal basis of an Article 31 non-pharmacovigilance referral?

An Article 31 non-pharmacovigilance referral follows the provisions of Article 31 of Directive 2001/83/EC.

It applies where the interests of the European Union are involved, and when the procedure is initiated as a result of the evaluation of data other than data relating to the pharmacovigilance[1] of authorised medicinal product(s) or application(s).

The procedure for an Article 31 non-pharmacovigilance referral 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 31 non-pharmacovigilance referral be initiated?

An Article 31 non-pharmacovigilance referral procedure should be initiated where the interests of the Union are involved and as a result of the evaluation of data that do not relate to pharmacovigilance activities, for example data relating to the quality and/or efficacy of an authorised medicinal product(s) or application(s)[1]. In such cases the matter will be referred to the Committee for Medicinal Products for Human Use (CHMP).

The term 'interest of the Union' refers particularly to the interests of public health related to medicinal products in the Union (for example in light of concerns related to the quality and efficacy of a medicinal product) and to the free movement of products within the Union.

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 31 non-pharmacovigilance referral?

An Article 31 non-pharmacovigilance referral procedure can be initiated by the competent authorities in the Member States (MSs), the European Commission (EC) or by the marketing authorisation holders (MAHs) and/or applicants.

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

[1] When the procedure is initiated as a result of the evaluation of data relating to the pharmacovigilance activities of authorised medicinal product(s), the procedure for an Article 31 pharmacovigilance referral will apply, and in such cases the matter should be referred to the Pharmacovigilance Risk Assessment Committee (PRAC). Please refer to the Questions & Answers on Article 31 pharmacovigilance referrals.

The notification will identify the concern and question(s) referred to the CHMP for consideration. The notification will also include a detailed explanation of the issue raised and should address how the Union interests are involved.

Only the MS concerned or the EC can identify the question. Therefore, in advance of initiating a referral under this Article, the MAH/applicant should contact a MS or the EC with a request to assess and confirm the Union interest. The MAH/applicant can include in the scope of the referral only its own product, with justification of potential extension to others.

The notification will be publicly available at the start of the procedure (please refer to Question 8).

4. Can a Member State take regulatory action during an Article 31 non-pharmacovigilance referral?

A Member State (MS) may, where urgent action is necessary to protect public health, suspend the marketing authorisation at any stage of the procedure, and prohibit the use of the medicinal product concerned on its territory until a definitive decision is adopted.

In this case, the MS informs the European Commission (EC), the Agency and all other MSs, no later than the following working day, of the reasons for its action.

5. Which medicinal products can be involved in an Article 31 non-pharmacovigilance referral?

All medicinal products affected by the concern referred and with a valid marketing authorisation (MA) in the European Economic Area (EEA) will be included in the Article 31 non-pharmacovigilance referral. This includes all medicinal products concerned by the issue, regardless of whether the MA was granted nationally (including via the mutual recognition and decentralised procedures) or via the centralised procedure. MA applications in the EEA may also be included. However, in case the issue concerns only centrally authorised medicinal products (CAPs), the procedure under Article 20 of Regulation (EC) No 726/2004[2] is initiated instead.

The referral procedure may concern a specific medicinal product, all medicinal products containing the same active substance (range of medicinal products) or all medicinal products belonging to the same therapeutic class (several active substances concerned).

The marketing authorisation holders (MAHs)/applicants cannot choose whether or not to include their medicinal products in an Article 31 non-pharmacovigilance referral procedure. The inclusion of their medicinal products depends on the scope of the procedure that is defined by the concerns raised in the notification.

References:

Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

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

[2] Please refer to the Questions & Answers on Article 20 non-Pharmacovigilance procedures.

6. How are the medicinal products identified to be part of an Article 31 non-pharmacovigilance referral? Rev. Jan 2017

The Agency, with input from the competent authorities of the Member States (MSs) within the European Economic Area (EEA) as necessary, will identify the authorised medicinal products or the applications concerned by the procedure. Whenever possible, all authorised medicinal products concerned are identified using information from the Article 57 database. This will take place at the start of the procedure and a draft list of the medicinal products identified will be publicly available on the Agency's website on the specific procedure page (please refer to Question 8).

If it is concluded that the issue also concerns other medicinal product(s) (e.g. range of medicinal products, a therapeutic class) than the ones covered by the notification, the Agency can extend the scope of the procedure.

From a procedural viewpoint, only those medicinal products identified at the start of the procedure will be covered by its scope. However, to the extent that other medicinal products affected by the concern but not identified at start of procedure are authorised in the EEA, or subject to future authorisations by the MSs, the concerned MSs should take due consideration of the scientific conclusions of the procedure and apply them to these products.

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

7. What happens if the medicinal product/application involved is only authorised in one Member State? Rev. Jan 2017

Upon receipt of the notification, the Agency, based on the information collected from the Article 57 database and, as necessary, in consultation with the national competent authorities (NCAs) of the Member States (MSs) within the European Economic Area (EEA), will identify in which MS(s) the concerned medicinal product(s)/application(s) is/are authorised.

If it is concluded that the scope of the procedure concerns medicinal product(s) authorised/application(s) in only one MS and the interest of the EU is not involved, an Article 31 non-pharmacovigilance referral procedure will not be initiated, and the concern will be handled by the MS concerned.

8. When and how will an Article 31 non-pharmacovigilance referral be announced?

Following receipt of the notification initiating the Article 31 referral procedure, the issue 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 concern under consideration and will include the publication of the following documents on the Agency's website on a page created specifically for the procedure:

- announcement of the start of the procedure;

- notification triggering the procedure;
- draft list of concerned medicinal products/active substance and MAHs/applicants;
- list(s) of questions and timetable adopted by the CHMP.

References:

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

9. How will the marketing authorisation holders/applicants be informed of the start of the Article 31 non-pharmacovigilance referral? Rev. Jul 2026

Whenever possible and when the regulatory contact point for the marketing authorisation holder (MAH)/applicant can be identified, MAHs will be informed on the Wednesday before the CHMP meeting of new non-pharmacovigilance Article 31 procedures that the CHMP will consider the following week. This communication will be provided for information only.

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

In addition, all MAHs/applicants of (a) product(s) concerned by the Article 31 non-pharmacovigilance referral identified in the published product list will be informed via the IRIS platform by the Agency. MAHs/applicants must be registered in IRIS to receive communications from EMA throughout the procedure. Guidance on how to register and how to use the IRIS platform is available on the dedicated IRIS website.

This communication on the procedure initiation to the MAHs/applicants 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;
- links to the Agency's page where the relevant documentation is available.

The Agency may release updated information on the website during the procedure and therefore MAHs/applicants should continuously check the Agency's website for any relevant updates (please refer to Question 29 and Question 34).

References:

IRIS: Access

10. Should marketing authorisation holders/applicants identify a contact person to communicate with the Agency during the Article 31 non-pharmacovigilance referral? Rev. Jul 2026

The regulatory contact point identified by the marketing authorisation holder (MAH) in the Eudravigilance registration system will, by default, be the contact person and will receive all correspondence from the Agency regarding the Article 31 non-pharmacovigilance procedure. In cases where the concerned products or applications cannot be identified using information in the Article 57 database, the Agency will liaise with the National Competent Authorities to identify the concerned products and corresponding contact person.

These contact persons should be registered in IRIS, prior to the start of procedure, to receive the information at the start of procedure. Throughout the procedure, MAHs/applicants 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 31 non-pharmacovigilance referral 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/applicant *inter alia* for the purposes of calculating the procedural timelines.

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

11. Can marketing authorisation holders/applicants involved in the procedure form groups of companies?

The marketing authorisation holders (MAHs)/applicants can form a group for the purpose of the procedure (irrespective of group/company affiliation) in order to provide a single consolidated response and/or oral explanations to the questions raised by the Committee for Medicinal Products for Human Use (CHMP) during the procedure. In this case, the cover letter accompanying the single consolidated response and/or request for oral explanation should clearly identify the parties responsible for the submission/request.

12. What happens if centrally authorised products are involved in the procedure?

If a centrally authorised product (CAP) is involved in an Article 31 non-pharmacovigilance referral, the marketing authorisation holder (MAH) will be notified by the Agency of the start of the procedure as will be all the other concerned MAHs/applicants (please refer to Question 9). The announcement on the Agency's website will also be linked to the EPAR page of the product.

13. Do marketing authorisation holders/applicants have to pay a fee? Rev. Jul 2026

The Agency will levy a fee for a non-pharmacovigilance referral under Article 31 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

14. Who can submit data to be considered for this procedure?

The marketing authorisation holders (MAHs)/applicants concerned by an Article 31 non-pharmacovigilance referral procedure will be requested to submit information relevant for the assessment of the concern.

The MAHs/applicants can present written or oral explanations to the Committee for Medicinal Products for Human Use (CHMP) within the 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 18 and Question 19.

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

15. How will data be gathered during the procedure?

The concern triggering the Article 31 non-pharmacovigilance referral will be substantiated by additional data that could be requested by the Committee for Medicinal Products for Human Use (CHMP) in the format of a list of questions, comments on the scientific background supporting the triggering of the procedure or by using data sources available to the Agency and/or to the national competent authorities (NCAs) of the Member States (MSs).

This data may be gathered from several different sources (e.g. from concerned marketing authorisation holders (MAHs), healthcare professionals, patients' organisations, Eudravigilance data, data available to the NCAs).

The need for specific data to be collected is identified by the CHMP at the start of the procedure.

The data to be considered for the assessment will have to be submitted within the specified deadline as published in the announcement of the start of the procedure (please refer to Question 8).

Notwithstanding the above, the CHMP may also collect additional data through further lists of outstanding issues and/or an oral explanation in accordance with an extended timetable, which will be made publicly available (please refer to Question 21 and Question 23).

16. Who will perform the assessment?

The assessment of data within the Article 31 non-pharmacovigilance referral 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(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.

17. 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 31 non-pharmacovigilance referral are appointed by the CHMP Chairperson from amongst its members or alternates (hereafter referred to as CHMP members).

In case of an Article 31 non-pharmacovigilance referral concerning several active substances belonging to the same therapeutic class, or where several issues are to be assessed, a lead rapporteur and several (co-)rapporteurs may be appointed.

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

18. How shall I present my responses? Rev. Jul 2026

Marketing authorisation holders (MAHs)/applicants should submit to the Agency all available evidence to support the assessment of the impact of the concern being reviewed in the procedure in response to the list of questions and as per the timelines published on the Article 31 non-pharmacovigilance procedure page.

MAHs of medicinal products concerned by the referral should submit their responses as follows:

- The data should be presented in electronic format 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 CHMP list of outstanding issues (if applicable). 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 (e.g. the product information, direct healthcare professional letter and communication plan).

In case some questions (e.g. on a specific pharmaceutical form) are not applicable/relevant to all the medicinal products concerned by the procedure, or to the medicinal product(s) of the represented group, the response should be stated as "not applicable" with a short explanation.

In case changes to the product information are proposed in response to the CHMP, only amendments directly related to the scope of the procedure should be proposed. Any other amendments to the product information should be applied for in separate dedicated procedures.

It should be noted that the responsibility for the quality of the submitted documentation lies with the MAHs/applicants and is crucial to the overall assessment. The data presented in the submissions should be intended exclusively for the purposes of the concerned procedure. The information and data contained in the individual submissions will be assessed and reflected in the assessment reports related to the concerned procedure. As a general rule, such information and data will not be redacted from the assessment reports with respect to individual products prior to sharing them with all concerned MAHs/applicants. Moreover, in general it is not expected that individual submissions by the MAHs/applicants will include commercially confidential information.

It should be noted that the MAHs/applicants cannot use the information and data from other MAHs/applicants contained in the assessment reports for any other purposes than those related to the concerned procedure.

All submissions are expected to be submitted in English and electronically only (please refer to Question 19). Submission of responses concerning the Article 31 non-Pharmacovigilance referral with regards to centrally authorised products (CAPs) should follow the requirements for post-authorisation procedures for CAPs (e.g. submission via e-CTD).

In case MAH(s)/applicants formed a group (please refer to Question 11), the cover letter accompanying the single consolidated response and/or request for oral explanation should clearly identify the parties responsible for the submission/request.

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

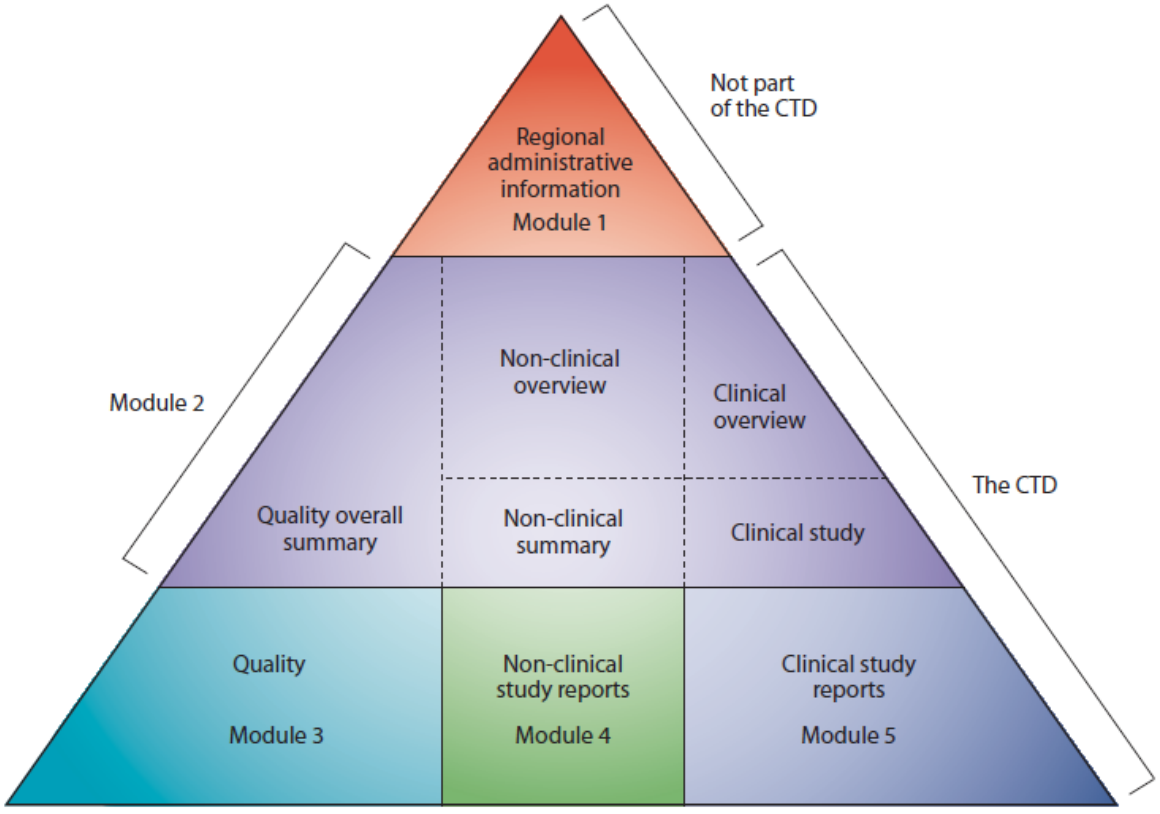
Responses from the marketing authorisation holders (MAHs)/applicants should be submitted within the timeline specified on the procedure page.

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 for nationally authorised products (NAPs) and for centrally authorised products (CAPs) submitted via these portals are available in the common repository and will be considered delivered to all Committee members and alternates.

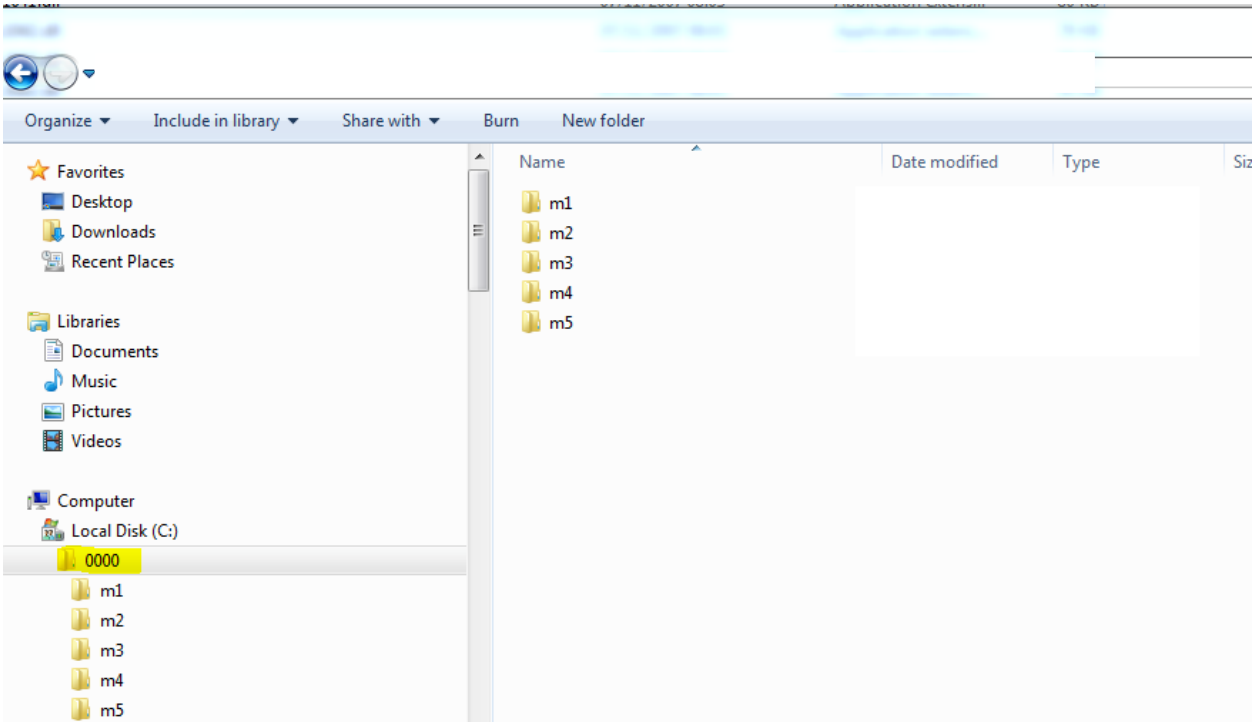
For advanced therapy medicinal products (ATMPs), additional submission requirements apply, please refer to the dossier requirements for centrally authorised products (CAPs).

For referral submissions related to CAPs, responses should always be submitted individually as the next sequence in each CAP product lifecycle. It is not possible to submit a standalone joint eCTD for the CAPs concerned. However, for submissions related to NAPs, if the documentation is common to several medicinal products and/or MAHs, a single joint eCTD should be submitted. Additional copies of the same eCTD should not be submitted.

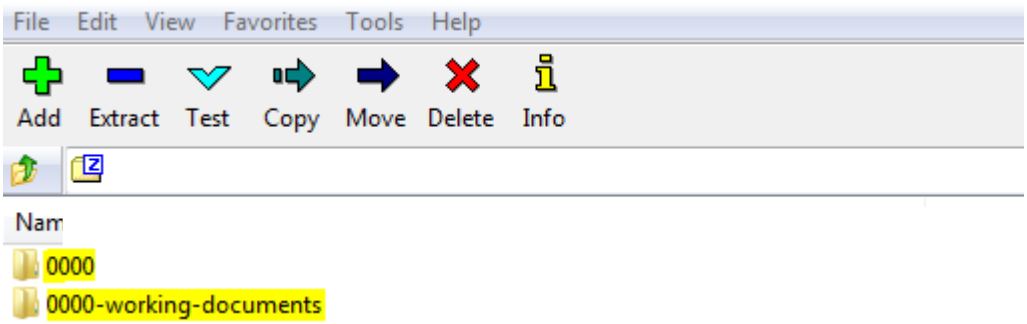
For all types of submissions, responses should be presented in the modular format:



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



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

References:

Dossier requirements for centrally authorised products

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

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

Submissions from the marketing authorisation holders (MAHs) 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 as published on the Article 31 non-pharmacovigilance referral webpage. The assessment report(s) prepared by the CHMP (co-)rapporteurs will reflect all data submitted and considered relevant for the review.

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

The CHMP may in some cases seek advice from experts on specific questions in relation to the assessment at a scientific advisory group meeting or an ad-hoc expert group meeting.

21. 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 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 following a 30 day assessment period are as follows:

Article 31 non-pharmacovigilance referral – *Timetable for the assessment*	Active day
Notification of a referral to the CHMP/Agency secretariat	Day 0
Discussion at the first CHMP meeting following receipt of the notification: • Discussion of the question(s) referred and whether an oral explanation(s) should be held • Appointment of the CHMP (Co-)rapporteurs • Adoption of the CHMP list of questions (LoQ) to be addressed by the marketing authorisation holders (MAHs)/applicants and timetable	Day 1
Preparation and submission of written explanations by the MAHs/applicants in response to the CHMP list of questions	Clock Stop
Re-start of the procedure following submission of the responses in accordance with published submission dates	Clock re-start
Circulation of the CHMP (co-)rapporteur's assessment report(s) on the MAHs'/applicants' written responses	Day 20
Comments in writing from CHMP members on the (co-)rapporteur's assessment report(s)	Day 25
Discussion at the CHMP meeting: • Adoption of CHMP opinion, or • Adoption of CHMP list of outstanding issues (LoOI) to be answered in writing and/or in an oral explanation, and timetable for the next assessment period of the procedure	Day 30

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

The CHMP may extend the time limit up to 150 active days to allow for the assessment of further data provided as responses to the CHMP list of outstanding issues, in an oral explanation, or in case the CHMP requires input from a scientific advisory group (SAG) or from an ad-hoc expert group 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 seriousness and urgency of the issue under consideration and the impact the extension may have on public health. The CHMP will consider the request, and if agreed, an extended timetable will be adopted. All MAHs/applicants involved in the procedure, will be informed of the CHMP outcome.

The CHMP assessment of responses to the list of outstanding issues will take up to 30 or, in exceptional cases, 60 days depending on the complexity and amount of data provided by the MAHs/applicants.

References:

Timetable: Non-safety referrals

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

All marketing authorisation holder(s) (MAHs)/applicants with medicinal products included in the scope of the Article 31 non-pharmacovigilance referral will be provided with the Committee for Medicinal Products for Human Use (CHMP) (co-)rapporteur's assessment report(s) electronically via the IRIS platform.

23. Will I have the possibility to present my views orally to 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 holders (MAHs)/applicants. In such a case the MAHs/applicants will be duly informed in advance of the issues to be addressed during the oral explanation.

The MAHs/applicants may also request to the CHMP to present their views in an oral explanation. In such a case, the MAHs/applicants 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. In such a case, the CHMP will take due account of the request and will decide whether the oral explanation will 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.

The MAHs/applicants can provide the oral explanation on their own behalf or on behalf of a group of MAHs/applicants.

References:

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

If the marketing authorisation (MA) for a concerned product is transferred during the referral, both the former and the new marketing authorisation holder (MAH) should update the Article 57 database without delay.

For nationally authorised products (including via mutual recognition and decentralised procedures), the new MAH should provide a copy of the transfer decision of the relevant competent authority and, if relevant, information on the new contact person, to the EMA procedure lead (please refer to Question 10).

Following receipt of the transfer decision, the Agency will inform the former MAH that they are no longer included in the Article 31 non-pharmacovigilance referral procedure, in relation to the MA transferred.

For a centrally authorised product (CAP), if during the referral procedure the MA is transferred, the former marketing authorisation holder should inform the Agency and the appropriate procedure should be followed.

If the application is transferred, the new applicant should provide the official confirmation to the EMA procedure lead.

The product list published at the start of the procedure (please refer to Question 8) will be updated accordingly and republished on the Agency's website on the specific procedure page.

References:

Transfer of marketing authorisation: questions and answers

25. What should I do if the name of my medicinal product changes, if the name or address of the MAH/applicant changes or if my contact person changes, or if my product/application is withdrawn? Rev. Jul 2026

If during the referral procedure, the name of a nationally authorised product (including via mutual recognition and decentralised products) changes or if the name and/or address of a marketing authorisation holder (MAH) changes, or if the marketing authorisation (MA) is withdrawn, the marketing authorisation holder (MAH) should update the Article 57 database without delay and inform the referral procedure lead. Following confirmation of the change, the Agency will inform the MAH that the change has been noted.

If the Article 57 database is updated within 30 days of the start of the procedure, these changes will be included in the revised products list that will be published at day 30. If such changes occur with regards to applications or applicants, the referral procedure lead should also be informed.

After day 30 the products list will not be subject to any changes except in case of transfer of a MA or application (please refer to Question 24).

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 and procedure assistant.

For a centrally authorised product (CAP), if during the referral procedure, the name of the product or the name and/or address of the MAH changes, or if the contact person changes, or if the MA is

withdrawn, the MAH should inform the EMA procedure lead and the appropriate procedure should be followed.

References:

Changing the (invented) name of a centrally authorised medicine: questions and answers

Notifying EMA of changes to contact persons

Notifying a change of marketing status

Committee for Medicinal Products for Human Use (CHMP) opinion

26. 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 31 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(s) (MAHs) during an oral explanation and/or in case input from experts (if any) is needed before issuing an opinion.

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

27. What could be the outcome of the opinion of CHMP? Rev. Jul 2026

The CHMP opinion on the matter (non-pharmacovigilance) referred under Article 31 shall include any or a combination of the following:

a) the application(s) do(es) (not) satisfy the criteria for authorisation;

b) the marketing authorisation(s) (MAs) should be maintained or varied;

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

d) MA(s) should be suspended or revoked.

Where the opinion is for the MA(s) to be varied, including changes to the information in the summary of the product characteristics (SmPC), labelling and/or package leaflet (PL), the opinion will include the suggested wording of such amendments.

With regards to point c), the opinion will specify any condition or restrictions to which the MA should be subject. Conditions for the safe and effective use of the medicinal product(s) can include, but are not limited to, requesting the marketing authorisation holder(s) to conduct a post-authorisation study.

The CHMP opinion can be adopted by consensus or by majority vote. In the event of adoption by majority, the divergent positions of the concerned CHMP members and the grounds on which they are based will be appended to the opinion issued by the CHMP.

The CHMP may also recommend the dissemination of a direct healthcare professional communication (DHPC) to inform individual healthcare professionals directly of the outcome of the review in line with an agreed communication plan.

References:

Post-authorisation efficacy studies (PAES): questions and answers

Direct healthcare professional communications (DHPC)

28. 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/applications, active substances and marketing authorisation holders (MAHs)/applicants for all identified concerned products authorised nationally (including via the mutual recognition/decentralised procedures). In case centrally authorised products (CAPs) are involved their respective Annexes A, including this information, will be attached;
- the scientific grounds and explanation for the CHMP opinion;
- the wording (in English only) to be included in the relevant sections of the summary of product characteristics (SmPC), the labelling and/or package leaflet (PL), if applicable (only for products authorised nationally including via the mutual recognition/decentralised procedures);
- the revised product information with agreed wording included in the relevant sections of the SmPC, the labelling and/or PL, if applicable (only for centrally authorised products);
- the conditions or restrictions imposed to the marketing authorisation(s) for the safe and effective use of the medicinal product(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 data gathered;
- the Direct Healthcare Professional Communication (DHPC) and communication plan as agreed by CHMP, if applicable.

29. When is the CHMP opinion published?

The next working day following the plenary meeting, the Agency will publish a communication including a summary of the Committee for Medicinal Products for Human Use (CHMP) opinion and targeted information for healthcare professional and patients 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 34).

References:

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

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

The marketing authorisation holder(s)/applicants of products concerned by the scope of the procedure and identified at the start of the procedure will receive the CHMP opinion via the IRIS platform during the week following its adoption.

31. When and how can I request a re-examination of the CHMP opinion on the Article 31 non-pharmacovigilance referral? Rev. Jul 2026

A concerned 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).

Regardless of whether re-examination request(s) are received from some or all concerned MAHs/applicants, the CHMP opinion will be considered under review and will be submitted to the EC only upon the final adoption following the re-examination (unless all requests for re-examination are withdrawn, as discussed further below).

In case several concerned MAHs/applicants notify the Agency of their intention to request a re-examination of the CHMP opinion, the re-examination will start after the receipt of all detailed grounds for the requested re-examination.

The start of a re-examination procedure will be mentioned in the communication 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/applicant 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 MAHs/applicants are 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 31 non-pharmacovigilance referral – *Timetable for the re-examination assessment*	Day
Receipt by EMA of MAH/applicants' letter of intent to request a re-examination	-
Receipt by EMA of MAH/applicants' detailed grounds for the request of re-examination	Day 0

Article 31 non-pharmacovigilance referral – *Timetable for the re-examination assessment*	Day
Next calendar day	Day 1
Circulation of the CHMP (co-)rapporteur's assessment report(s) on the MAH/applicants' 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 communication 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 is sent to the EC.

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

References:

Fees payable to the European Medicines Agency

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

The marketing authorisation holder(s) (MAHs)/applicants of medicinal products authorised nationally (including via the mutual recognition or decentralised procedures) will have to provide translations in all EU languages (including Icelandic and Norwegian, if applicable[3]) of the following annexe to the Committee for Medicinal Products for Human Use (CHMP) opinion:

- The wording to be included in the relevant sections of the summary of product characteristics, the labelling and/or package leaflet, if applicable.

Only one translation per EU language is required, therefore the MAHs/applicants actively involved in the procedure will be presented with a proposal for worksharing for the translation process. Not all MAHs/applicants may be involved in the translation process. MAHs/applicants that have not been contacted to participate in the worksharing process will be provided the set of translations at a later stage.

The Agency will contact the MAHs/applicants as early as possible to ensure the smooth running of the worksharing process. The translations will have to be provided to the Member States (MSs) 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/applicant should send the translations amended accordingly together with the completed QRD form 2 to the Agency by Day +22.

[3] If authorised in Iceland and Norway

The MAHs of centrally authorised products (CAPs) involved in the procedure will have to provide the full product information in all EU languages within the same timeframe (i.e. 5 days after adoption of the opinion) to the MSs contact points for linguistic check and copied to the Agency.

Detailed information on the translation process of the 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)

33. What happens after the adoption of the final opinion of the CHMP on the Article 31 non-pharmacovigilance referral? 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 31).

After the final opinion of the Committee for Medicinal Products for Human Use (CHMP), the Agency together with the concerned marketing authorisation holder(s) (MAHs)/applicants 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 either to the MAHs/applicants or to MSs and notified to the MAHs/applicants, depending on whether the decision concerns centrally authorised products (CAPs) or nationally authorised products (including via the mutual recognition and decentralised procedures), respectively.

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

The MAHs of CAPs need to submit an eCTD closing sequence with the final documents within 15 days following the EC decision.

For NAPs, the 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

34. Will there be any publication in relation to the Article 31 non-pharmacovigilance referral after the Commission Decision?

The Committee for Medicinal Products for Human Use (CHMP) assessment report will be published on the procedure page 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:

Guide to information on human medicines evaluated by EMA