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Human Medicines Division

Questions & answers on Article 20 non-pharmacovigilance procedures

This guidance document addresses a number of questions which stakeholders, in particular marketing authorisation holders (MAHs), may have on an Article 20 non-pharmacovigilance procedure. It provides an overview of the European Medicines Agency's (the Agency) practical and operational aspects with regards to the handling of Article 20 non-pharmacovigilance 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 must in all cases comply with the requirements of EU legislation.

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Initiation of an Article 20 non-pharmacovigilance procedure

1. What is the legal basis for an Article 20 non-pharmacovigilance procedure?

An Article 20 non-pharmacovigilance procedure follows the provisions of Article 20 of Regulation (EC) No 726/2004.

It applies when the procedure is initiated as a result of the evaluation of data that do not relate to pharmacovigilance activities of medicinal product(s)[1] authorised via the centralised procedure only.

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

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

2. In which situations can an Article 20 non-pharmacovigilance procedure be initiated? Rev. Jul 2026

An Article 20 non-pharmacovigilance procedure should be initiated in case the supervisory authorities or the competent authorities of a Member State (MS) are of the opinion that the manufacturer or importer established within the Union territory is no longer fulfilling the obligations laid down in Title IV of Directive 2001/83/EC, or where a MS or the European Commission (EC) considers that one of the measures envisaged under title IX (Pharmacovigilance) or XI (Supervision and sanctions) of Directive 2001/83/EC must be applied for centrally authorised medicinal products (CAPs), or where the Committee for Medicinal Products for Human Use (CHMP) has delivered an opinion to that effect in accordance with Article 5 of Regulation (EC) No 726/2004, as a result of the evaluation of data that do not relate to pharmacovigilance, for example data relating to the quality or efficacy of a CAP(s).

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 Community code relating to medicinal products for human use

3. Who can initiate an Article 20 non-pharmacovigilance procedure?

An Article 20 non-pharmacovigilance procedure can only be initiated by the European Commission (EC), in view of considerations from a Member State (MS), the EC or the Committee for Medicinal Products for Human Use (CHMP) (please refer to Question 2). A marketing authorisation holder (MAH) cannot trigger this procedure.

[1] When the procedure is initiated as a result of the evaluation of data relating to the pharmacovigilance activities of centrally authorised medicinal product(s), an Article 20 pharmacovigilance procedure will apply, and in such cases the matter should be referred to the Pharmacovigilance Risk Assessment Committee (PRAC). Please refer to the Q&A: Article 20 pharmacovigilance procedures.

The EC refers the matter to the Agency, by circulating a notification to the Agency and to all Member States (MSs), requesting an opinion by the CHMP.

The notification will identify the concern including a detailed explanation of the issue raised and the need for any regulatory action to be considered.

The notification will be publicly available at the start of the procedure (please refer to Question 6).

4. Can a Member State take regulatory action on a centrally authorised medicinal product?

A Member State (MS) may on its own initiative or at the European Commission's (EC) request, where urgent action is considered essential to protect public health, suspend the use of a centrally authorised medicinal product in its territory, until a definitive decision is adopted.

When it does so on its own initiative, the MS should inform the EC and the Agency of the reasons for its action no later than the next working day following the suspension.

The Agency will inform all other MSs without delay, and the EC will immediately initiate an Article 20 procedure, if not already ongoing.

5. Which medicinal products can be involved in an Article 20 non-pharmacovigilance procedure?

An Article 20 non-pharmacovigilance procedure is initiated where only centrally authorised medicinal products (CAPs) are concerned by the issue.

The 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). The CAPs concerned by the scope will be involved in the procedure.

If the concern referred relates to a range of medicinal products or a therapeutic class involving not only CAPs but also nationally authorised medicinal products (including products authorised via the mutual recognition and decentralised procedures), then an Article 31 non-pharmacovigilance referral[2], will be initiated including all products affected.

6. When and how will an Article 20 non-pharmacovigilance procedure be announced?

Following receipt of the notification initiating the Article 20 procedure, 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 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 issue under consideration, the product(s) concerned 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;

[2] Please refer to the Q&A: Article 31 non-pharmacovigilance referral procedures.

- notification triggering the procedure;
- list(s) of questions and timetable adopted by the CHMP.

The announcement on the Agency's website will also be linked to the European public assessment report (EPAR) of the centrally authorised medicinal product(s) concerned by the Article 20 non-pharmacovigilance procedure.

References:

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

7. How will marketing authorisation holder(s) be informed about the start of the Article 20 non-pharmacovigilance procedure? Rev. Jul 2026

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

In addition, all marketing authorisation holder(s) (MAHs) concerned by the Article 20 non-pharmacovigilance procedure will be informed via IRIS by the Agency.

This communication on the procedure initiation in IRIS will include:

- the name and contact details of the EMA procedure lead from the referral procedures service that will be the primary contact point for this procedure only. The EMA product lead for the centrally authorised product will remain assigned to this product and should be copied in all correspondence regarding the Article 20 non-pharmacovigilance procedure;
- 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 should continuously check the Agency's website for any relevant updates (please refer to Question 27 and Question 31).

References:

IRIS: Access

8. Should marketing authorisation holders identify a contact person to communicate with the Agency during the Article 20 non-pharmacovigilance procedure? Rev. Jul 2026

The marketing authorisation holder's (MAH) designated contact person for each centrally authorised product concerned by the procedure will, by default, be the contact person and will receive all the correspondence from the Agency regarding the Article 20 non-pharmacovigilance procedure.

MAHs may, if they wish, designate a different contact person for the Article 20 non-pharmacovigilance procedure. Throughout the procedure, MAHs 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 this case they should inform the EMA procedure lead and procedure assistant.

All documentation concerning the Article 20 non-pharmacovigilance procedure will be shared by EMA via the IRIS platform. The making available of any documents by EMA in IRIS to the contact person will be considered to constitute effective receipt by the MAH *inter alia* for the purposes of calculating the procedural timelines.

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

9. Can marketing authorisation holders involved in the procedure form groups of companies?

The marketing authorisation holders (MAHs) 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.

10. Do marketing authorisation holders have to pay a fee? Rev. Jul 2026

The Agency will levy a fee for a non-pharmacovigilance procedure under Article 20 of Regulation (EC) 726/2004.

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

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

The marketing authorisation holder(s) (MAHs) concerned by an Article 20 procedure will be requested to submit information relevant for the assessment of the concern.

The MAHs 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 15 and Question 17.

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

12. How will data be gathered during the procedure?

The concern triggering the Article 20 non-pharmacovigilance procedure 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(s) of questions/list of outstanding issues, 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).

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 6).

Notwithstanding the above, the CHMP may also collect additional data through a further list of outstanding issues or in an oral explanation in accordance with an extended timetable, which will be made publicly available (please refer to Question 19 and Question 21).

13. Who will perform the assessment?

The assessment of data within the Article 20 non-pharmacovigilance procedure is carried out by 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.

14. How are the CHMP rapporteur and CHMP co-rapporteur appointed? Rev. Jul 2026

The Committee for Medicinal Products for Human Use (CHMP) (co-)rapporteurs for an Article 20 non-pharmacovigilance procedure are appointed by the CHMP Chairperson from amongst its members or alternates (hereafter referred to as CHMP members).

The CHMP (co-)rapporteurs already nominated for the centrally authorised medicinal products (CAPs) are appointed in priority. In case the procedure is not product specific, the CHMP Chairperson may advise to open rapporteurship to all CHMP members.

In case of an Article 20 procedure concerning several medicinal products belonging to the same therapeutic class or where several issues are to be assessed, a lead rapporteur and several co-rapporteurs could be appointed.

The CHMP Chairperson will endeavour to apply the criteria of best available expertise for the appointment of the CHMP (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

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

Marketing authorisation holder(s) (MAHs) should submit to the Agency all available evidence to support the assessment of the matter relating to the procedure in response to the List of Questions and as per the timelines published on the Article 20 non-pharmacovigilance procedure page.

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

- The data should be presented in electronic format in accordance with the electronic Common Technical Document (eCTD) 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. Please note that supportive data to the responses submitted (e.g. study reports, literature data) are expected to be provided together with a summary of those data as per the modular structure of the eCTD 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, risk management plan, direct healthcare professional letter and communication plan).

In case some questions (e.g. on a specific pharmaceutical form) are not applicable/relevant to all medicinal product(s) concerned by the procedure, or to the product(s) of the represented group, the response should be "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 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. Moreover, in general it is not expected that individual submissions by the MAHs will include commercially confidential information.

It should be noted that the MAHs cannot use the information and data from other MAHs 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 17). Submission of responses for centrally authorised products should follow the dossier requirements for centrally authorised products (CAPs) (please refer to Question 17).

In case MAHs formed a group (please refer to Question 9), the cover letter accompanying the single consolidated response and/or request for oral explanation should clearly identify the parties responsible for the submission/request.

16. Should I submit revised product information?

In case the responses to the Committee for Medicinal Products for Human Use (CHMP) require changes to the product information, the marketing authorisation holder(s) (MAHs) must submit the revised product information annexes as part of the responses. Only the English language version (highlighted version) of a relevant example of the full set of product information annexes (i.e. Annex I, II, IIIA and IIIB) is required during the assessment.

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

Responses from marketing authorisation holder(s) (MAH) should be submitted within the timeline specified on the procedure page.

All submissions should be sent via the eSubmission Gateway or the 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 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.

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

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 for the Article 20 procedure.

References:

Dossier requirements for centrally authorised products (CAPs)

eSubmission website

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

EMA Service Desk portal

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

Submissions from marketing authorisation holder(s) (MAHs) are directly available in the common repository to the Committee for Medicinal Products for Human Use (CHMP) (co-)rapporteurs to be considered for assessment.

All information gathered will be assessed within an agreed timeframe as published on the Article 20 non-pharmacovigilance procedure page. The assessment report(s) prepared by the CHMP (co-)rapporteur will reflect all data submitted and considered 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 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.

19. What is the timetable for the assessment by the Committee for Medicinal Products for Human Use? 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 20 non-pharmacovigilance procedure – *Timetable for the assessment*	Active day
Notification of an article 20 non-pharmacovigilance procedure to the CHMP/Agency	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 CHMP (co-)rapporteurs	Day 1

Article 20 non-pharmacovigilance procedure – *Timetable for the assessment*	Active day
• Adoption of the CHMP list of questions (LoQ) to be addressed by the marketing authorisation holder(s) (MAHs) and timetable	
Preparation and submission of written explanations by the MAH(s) 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 MAH(s)' written responses	Day 20
Comments in writing from CHMP members on the (co-)rapporteurs' assessment report(s)	Day 25
Discussion at the CHMP meeting: • Adoption of the 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 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 above timetable reflects a fictional example where, the CHMP conducts its assessment and adopts an opinion after a single round of assessment, in 30 days. However, depending on the urgency, the complexity and amount of data to assess the CHMP may agree on a shorter or longer timetable.

The CHMP may also extend the time limits to allow for the assessment of further data provided as responses to the CHMP list of outstanding issues, 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 should send a justified request to the Agency for agreement by the CHMP. The letter specifying the length of the requested extension should be addressed to the CHMP Chairperson, signed and sent electronically to the EMA procedure lead. In preparing the justification, the MAH should consider the 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 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 MAH(s).

References:

Timetable: Non-safety referrals

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

All marketing authorisation holder(s) with medicinal products included in the scope of the Article 20 non-pharmacovigilance procedure will be provided with the Committee for Medicinal Products for Human Use (CHMP) (co-)rapporteur's assessment report(s) via the IRIS platform.

21. 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 holder(s) (MAHs). In such a case the MAH(s) will be duly informed in advance of the issues to be addressed during the oral explanation.

The MAH(s) may also request to the CHMP to present their views in an oral explanation. In such a case, the MAH(s) 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 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 MAH(s) can provide the oral explanation on their own behalf or on behalf of a group of MAHs.

References:

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

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

If during the procedure, the marketing authorisation (MA) is withdrawn or transferred, the former marketing authorisation holder (MAH) should inform the EMA procedure lead, and the appropriate procedure should be followed.

References:

Notifying a change of marketing status

Transfer of marketing authorisation: questions and answers

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

If during the procedure, the name of a medicinal product (CAP) is changed, or the name and/or address of a marketing authorisation holder (MAH) changes, or if the contact person changes, the marketing authorisation holder (MAH) should inform the EMA procedure lead and procedure assistant, 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

Committee for Medicinal Products for Human Use (CHMP) opinion

24. When will the Committee for Medicinal Products for Human Use opinion be issued? Rev. Jul 2026

The Committee for Medicinal Products for Human Use (CHMP) will issue an opinion on the concern referred under Article 20 in accordance with the adopted timetable. The CHMP may extend the initial timetable to take into account the views of the marketing authorisation holder(s), or when an ad-hoc expert group meeting/ scientific advisory group (SAG) meeting is needed.

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

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

The Committee for Medicinal Products for Human Use (CHMP) opinion on the Article 20 non-pharmacovigilance procedure shall include any or a combination of the following:

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

b) the MAH(s) should be subject to certain conditions (in case of maintenance or variation);

c) the 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.

Where the CHMP recommends that the MA(s) should be subject to certain conditions, these 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)

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

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

- a cover page in which the opinion adopted is outlined together with the voting outcome of the CHMP;

- the list of the medicinal products concerned i.e. Annex A for each product;
- the scientific grounds and explanation for the CHMP opinion;
- the revised product information (in English only) with agreed wording included in the relevant sections of the summary of product characteristics, the labelling and/or package leaflet, if applicable;
- the conditions or restrictions imposed to the marketing authorisation for the safe and effective use of the medicinal product, if applicable;
- the conditions for lifting the suspension of the marketing authorisation(s), if applicable;
- the CHMP member(s)'s 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.

27. When will the CHMP opinion be published? Rev. Jul 2026

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 revised 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

28. Will I receive the CHMP opinion?

The marketing authorisation holder(s) of medicinal products concerned and identified at the start of the procedure will receive the Committee for Medicinal Products for Human Use (CHMP) opinion during the week following its adoption**.**

29. When do I have to submit the translations?

The marketing authorisation holder(s) of centrally authorised products involved in the procedure will have to provide the full product information in all EU languages by Day +5 (i.e. 5 days after adoption of the opinion) to the Member States' contact points for linguistic check and copied to the Agency. Member States may send linguistic comments until Day +19. The MAH(s) should send the translations amended accordingly together with the completed QRD form 2 to the Agency by Day +25.

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)

30. What happens after the adoption of the Committee for Medicinal Products for Human Use opinion? Rev. Jul 2026

After the adoption of the Committee for Medicinal Products for Human Use (CHMP) opinion, the Agency together with the concerned marketing authorisation holder(s) (MAHs) 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 MAH(s).

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

References:

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

31. Will there be any publication in relation to the Article 20 non-pharmacovigilance procedure 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. In addition, this page will be linked to the European public assessment report (EPAR) of the centrally authorised medicinal product(s) concerned by the Article 20 procedure and as relevant, to the page with the corresponding direct health care professional communication.

References:

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