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Guide to information on human medicines evaluated by EMA

What the Agency publishes and when

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Table of contents

1. Introduction.....	3
2. Applications for centralised marketing authorisation	3
2.1. Medicines under initial evaluation	3
2.2. Positive opinions	3
2.3. Negative opinions.....	5
2.4. Re-examination of opinions.....	6
2.5. Withdrawal of initial marketing authorisation applications	6
3. Changes to centralised marketing authorisations.....	7
3.1. Extensions of indication	7
3.2. Other variations, annual re-assessments, renewals and line extensions.....	9
4. Withdrawal/expiry of centralised marketing authorisations.....	10
5. EU referrals.....	11
5.1. Article 20, 31 and 107i referrals.....	11
5.2. Article 13(2), 29(4) and 30 referrals.....	12
5.3. Article 5(3) opinions.....	13
5.4. Article 29 (Paediatrics) opinions	13
6. Other documents and procedures.....	14
6.1. Orphan designations	14
6.2. ATMP classification.....	14
6.3. Requests for PRIME eligibility	14
6.4. Paediatric investigation plans	15
6.5. Safety signals.....	15
6.6. Medicines under additional monitoring	15
6.7. Compassionate use.....	15
6.8. Shortages	16
6.9. Periodic safety update reports	16
6.10. Imposed non-interventional post-authorisation safety studies.....	16
6.11. Direct healthcare professional communications (DHPCs)	17
6.12. Medicines for use outside the EU (Article 58)	17
6.13. Ancillary medicinal substances	17
6.14. Agendas, minutes and reports of meetings of EMA’s scientific committees	18
6.15. Medical literature monitoring	18
7. Information on non-centrally authorised medicines.....	18
8. Coordination of information on medicines.....	19
Annex: Tabulated overview of EMA documents on human medicinal products	20

1. Introduction

The European Medicines Agency (EMA) publishes information on human medicinal products at various stages of their life cycle, from the early developmental stages through to EMA's evaluation of authorisation applications, post-authorisation changes, safety reviews and withdrawals of authorisation.

This guide describes the different types of information the Agency currently publishes for both centrally and non-centrally authorised medicines, as well as publication times and location on EMA's website. It aims to help stakeholders know what kind of information to expect on medicines undergoing evaluations and other regulatory procedures.

The information described in this document is presented in a tabulated format in the Annex.

Whilst reflecting the current practice, the guide is not intended to provide an exhaustive list of EMA publications, and EMA may at its discretion publish additional documents as appropriate. Other non-confidential documents held by EMA which are not published may be provided to stakeholders [upon request](#).

2. Applications for centralised marketing authorisation

2.1. Medicines under initial evaluation

A **list of new medicines that are under evaluation** for a centralised marketing authorisation by EMA's Committee for Medicinal Products for Human Use (CHMP) or the Committee for Advanced Therapies (CAT) is published each month on EMA's [medicines under evaluation page](#). It lists the international non-proprietary name (INN) and therapeutic area(s) of each medicine.

For orphan medicines, information on designated orphan medicinal products under evaluation for a centralised marketing authorisation, including the name of the applicant, is also available in the **monthly meeting reports** of the Committee for Orphan Medicinal Products (COMP) published on the [COMP page](#) (see Section 6.1).

2.2. Positive opinions

Initial publications at time of CHMP opinion

The CHMP gives opinions on centralised marketing authorisation applications at its monthly plenary meetings, which usually run from a Monday to a Thursday. If the CHMP gives a positive opinion recommending the authorisation of a medicine, a **summary of opinion** document is published in the [CHMP meeting highlights](#) on the Friday following the CHMP plenary meeting (see Table 1). This document can also be found using the [Medicines search page](#). The summary of opinion provides key information about the medicine, including the full recommended indication and its main benefits and risks.

For selected medicines that are likely to address an unmet medical need or represent an important innovation or change in clinical practice, a **dedicated press release** is published on [EMA's homepage](#) and also linked to the CHMP meeting highlights to inform the media and general public.

Table 1. Publications on outcomes of applications for initial marketing authorisation

	Initial publications	Full documentation
Withdrawal of application	Withdrawal Q&A plus withdrawal letter (Friday following next CHMP plenary)	Withdrawal public assessment report (within 3 months of receipt of withdrawal letter) Clinical study reports (about 5 months after receipt of withdrawal letter)
Positive CHMP opinion	Summary of opinion Press release (for selected products) (Friday following CHMP plenary)	New EPAR documents (2 weeks after EC decision) Medicine overview Product information List of all authorised presentations Public assessment report Summary of risk management plan Orphan maintenance or withdrawal assessment report (for orphan medicines) (2 weeks after EC decision) Clinical study reports (about 2 months after EC decision)
Negative CHMP opinion	Refusal Q&A (Friday following CHMP plenary)	Refusal public assessment report (2 weeks after EC decision) Clinical study reports (about 2 months after EC decision)

Full documentation published after European Commission's decision

Around 2 weeks after the European Commission's decision on the marketing authorisation of a new medicine, a comprehensive set of documents called the **European Public Assessment Report (EPAR)** is published on the medicine's page, which can be found using the [Medicines search page](#). The EPAR of each centrally authorised medicine comprises the following:

- the **medicine overview**, which is a lay-language document in a question-and-answer format explaining why the medicine is approved in the EU and its conditions of use. This overview, which appears in the top section of the medicine's page, is published in all official EU languages and its target audience is the general public;
- the approved **product information** (which comprises the summary of product characteristics or SmPC, the product labelling and the package leaflet), and a **list of all authorised presentations**. Both these documents are published in all official EU languages plus Icelandic and Norwegian, in the section 'Product information' of the medicine's page. The target audience of the SmPC is healthcare professionals, while the package leaflet is for patients;
- the **public assessment report** adopted by the CHMP with any divergent positions annexed to the report. Only information of a commercially confidential nature is redacted. The assessment report is published in the section 'Assessment history' of the medicine's page;
- the previously published summary of opinion, which can now be found in the section 'Assessment history' of the medicine's page (N.B. this summary is no longer listed under the category 'Summaries of opinion' in the Medicines search page).

A summary of the medicine's risk management plan (RMP) is also published. The RMP details important risks of the medicine, how these risks can be minimised, and how more information will be obtained about risks and uncertainties (missing information). The **summary of the RMP** is published on the medicine's page.

For medicines for which additional measures have been included in their risk management plan to reduce the risk of medication errors, a **communication on medication error prevention** is also published in all official EU languages on the medicine's page under the section 'Preventing medication errors', as well as on a dedicated page called [Recommendations on medication errors](#). The target audience includes patients and healthcare professionals.

For orphan designated medicines, an **orphan maintenance assessment report** (in case of maintenance of the orphan designation at the time of authorisation) or an **orphan designation withdrawal assessment report** (in case of withdrawal of the orphan designation) is published at the same time as the EPAR on the medicine's page in the section 'Assessment history', as well as in the medicine's orphan designation page in the section 'Review of designation' (see also Section 6.1). A medicine's orphan designation page can be found using the [Medicines search page](#).

About 2 months after the European Commission's decision, the **clinical study reports** submitted by the company in the marketing authorisation application are published on EMA's dedicated website on [clinical data](#). These reports are anonymised to prevent patients and professionals who participated in clinical trials from being identified, in order to comply with European legislation on personal data protection. In limited circumstances commercially confidential information may be redacted.

2.3. Negative opinions

Initial publications at time of CHMP opinion

If the CHMP gives a negative opinion on a marketing authorisation application, a **refusal questions-and-answers (Q&A)** document is published in the [CHMP meeting highlights](#) on the Friday following the CHMP plenary meeting (see Table 1). This Q&A document can also be found using the [Medicines search page](#). It provides basic information in lay language about the medicine and the reasons why it was not recommended for approval. Its target audience is the general public.

Full documentation published after European Commission's decision

Around 2 weeks after the European Commission's decision refusing the marketing authorisation, a **refusal EPAR** is published on the medicine's page, which can be found using the [Medicines search page](#). The refusal EPAR comprises:

- the previously published refusal Q&A and its translations in all official EU languages (N.B. this refusal Q&A is no longer listed in the category 'Summaries of opinion' on the Medicines search page);
- the **refusal public assessment report**, which is the assessment report as adopted by the CHMP. Only information of a commercially confidential nature is redacted. The assessment report is published in the section 'Assessment history' on the medicine's page.

About 2 months after the European Commission's decision, the **clinical study reports** submitted by the company in their marketing authorisation application are published on EMA's website on [clinical data](#).

2.4. Re-examination of opinions

Applicants may request a re-examination of a CHMP opinion no later than 15 days after receipt of the opinion. If a company requests a re-examination, the refusal Q&A is updated with a note on the start of the re-examination procedure, and this is also mentioned in the CHMP meeting highlights.

After the CHMP has re-examined its original opinion, a **re-examination Q&A** is published in the [CHMP meeting highlights](#) on the Friday following the CHMP plenary meeting where the re-examination was concluded. This re-examination Q&A can also be found using the [Medicines search page](#); it replaces the original refusal Q&A which remains linked to the CHMP meeting highlights where it was first published. The re-examination Q&A is written in lay language and its target audience is the general public.

If the outcome of the re-examination is negative (i.e. the CHMP maintains its negative opinion), a refusal EPAR is also published on the medicine's page around 2 weeks after the European Commission's decision refusing the marketing authorisation as described in Section 2.3 and will include both the original refusal Q&A and the re-examination Q&A.

If the outcome of the re-examination is positive, a summary of opinion document is published with the re-examination Q&A in the CHMP meeting highlights. Around 2 weeks after the European Commission's decision, the same set of EPAR documents described in Section 2.2 is published on the medicine's page and will include both the original refusal Q&A and the re-examination Q&A.

The public assessment report, which is published as part of the EPAR, covers both the initial assessment and the assessment done during the re-examination.

Most cases of re-examinations involve an applicant requesting a re-examination of a negative CHMP opinion. In some cases, an applicant may request a re-examination of a positive opinion if there are aspects of the opinion with which it does not agree. The publication practice in these cases is the same as for re-examinations of negative opinions: a note on start of the re-examination, an updated summary of opinion at the end of the re-examination (if outcome remains positive), and EPAR documents around 2 weeks after the European Commission's decision (unless the applicant withdraws its application).

2.5. Withdrawal of initial marketing authorisation applications

If an applicant withdraws its application for initial marketing authorisation, a **withdrawal Q&A** is published in the [CHMP meeting highlights](#) on the Friday following the [upcoming](#) CHMP plenary meeting (see Table 1). For applications withdrawn during a CHMP meeting, the Q&A is published on the Friday following the [next](#) CHMP meeting. The withdrawal Q&A is also published in the medicine's withdrawn application page, which can be found using the [Medicines search page](#).

The withdrawal Q&A contains information in lay language on the scientific assessment of the product up to the time of the withdrawal. Its target audience is the general public.

The application withdrawal is also mentioned in the corresponding CHMP agenda and/or meeting minutes.

EMA also publishes the **withdrawal letter** sent by the applicant, which is linked to the withdrawal Q&A and includes the reason for the withdrawal (in line with Article 11 of Regulation EC 726/2004). All personal contact information (addresses, emails, phone numbers and signatures) in the letter are redacted. The withdrawal letter is also published separately on the medicine's withdrawn application page in the section 'All documents'.

Within 3 months of receipt of the withdrawal letter, EMA publishes the **withdrawal public assessment report**, which is the last adopted CHMP assessment report available at time of withdrawal. All information of a commercially confidential nature is redacted. The assessment report is published in the section 'All documents' on the medicine's withdrawn application page. Translations of the withdrawal Q&A in all official EU languages are also published at the same time as the assessment report.

About 5 months after the receipt of the withdrawal letter, **clinical study reports** submitted by the company in their marketing authorisation application are published on EMA's website on [clinical data](#).

3. Changes to centralised marketing authorisations

3.1. Extensions of indication²

The documents published on the outcome of extension of indication applications closely mirror those published for initial authorisation applications, and are summarised in Table 2.

Positive opinions

If the CHMP gives a positive opinion on an extension of indication application, a **summary of opinion** is published in the [CHMP meeting highlights](#) on the Friday following the CHMP plenary meeting³. Until a decision from the European Commission has been issued, this document can also be found using the [Medicines search page](#). For selected extension of indications, a **dedicated press release** may also be published at the same time on [EMA's homepage](#) to inform the media and general public of important extensions of indication that address unmet medical needs.

Around 2 weeks after the European Commission's decision, the summary of opinion appears in the section 'Assessment history' of the medicine's page, which can be found using the [Medicines search page](#).

In this page updated documents related to the extension of indication are published. These include the updated **product information** and, if applicable, the **updated medicine overview and RMP summary**.

The **assessment report** related to the extension of indication as adopted by the CHMP is also published on the medicine's page in the section 'Assessment history'. All information of a commercially confidential nature is redacted and any divergent positions of CHMP members are annexed to the report.

A document called **procedural steps taken and scientific information after authorisation** is also published (in the section 'Assessment history') or updated if the document was already available. This document provides an overview of all the changes made to the marketing authorisation since the medicine's initial authorisation.

If the medicine was designated an orphan medicine, an **orphan maintenance assessment report** (in case of maintenance of the orphan designation at the time of authorisation) or an **orphan designation withdrawal assessment report** (in case of withdrawal of the orphan designation) related to the new indication is also published at the same time as the updated EPAR in the section 'Assessment history', as well as on the medicine's orphan designation page in the section 'Review of

² List of ongoing evaluations of extension of indication applications not currently published. EMA will publish such a list in the near future. Until then this information can be provided upon request.

³ Summaries of opinion for extensions of indications are not published for generic or biosimilar medicines.

designation' (see Section 6.1). A medicine's orphan designation page can be found using the [Medicines search page](#).

About 2 months after the European Commission's decision, the **clinical study reports** submitted by the company in their application are published on EMA's website on [clinical data](#).

Table 2. Publications on outcomes of applications for extensions of indication

	Initial publications	Full documentation
Withdrawal of application	Withdrawal Q&A plus withdrawal letter (Friday following next CHMP plenary)	Withdrawal public assessment report (within 3 months of receipt of withdrawal letter) Clinical study reports (about 5 months after receipt of withdrawal letter)
Positive CHMP opinion	Summary of opinion Press release (for selected products) (Friday following CHMP plenary)	New or updated EPAR documents (2 weeks after EC decision for extension of indications) Medicine overview Product information List of all authorised presentations Public assessment report Procedural steps document Summary of risk management plan Orphan maintenance/withdrawal assessment report (for orphan medicines) (2 weeks after EC decision for extension of indications) Clinical study reports (about 2 months after EC decision)
Negative CHMP opinion	Refusal Q&A (Friday following CHMP plenary)	Refusal public assessment report (4 to 5 weeks after CHMP opinion for extension of indications) Clinical study reports (about 2 months after EC decision)

Negative opinions

If the CHMP's opinion on an extension of indication application is negative, a **refusal Q&A** is published in the [CHMP meeting highlights](#) on the Friday following the CHMP plenary meeting. It can also be found using the [Medicines search page](#).

Around 4 to 5 weeks after the CHMP's negative opinion, the translations of the refusal Q&A in all official EU languages are published in the section 'Assessment history' of the medicine's page, which can be found using the [Medicines search page](#). The **refusal public assessment report** is also published on the same page in the section 'Assessment history' and the document **procedural steps taken and scientific information after authorisation** is also published, or updated if the document was already available.

About 2 months after the European Commission's decision, the **clinical study reports** submitted by the company in their application are published on EMA's website on [clinical data](#).

Re-examinations

If an applicant requests a re-examination of a negative opinion, the refusal Q&A is updated with a note on the start of the re-examination procedure and this is also mentioned in the [CHMP meeting highlights](#).

At the end of the re-examination, a **re-examination Q&A** is published in the [CHMP meeting highlights](#) on the Friday following the CHMP plenary meeting in which the re-examination was concluded.

If the outcome of the re-examination is negative, the same set of documents as for negative opinions described above are published around 2 weeks after the CHMP's opinion on the re-examination.

If the outcome of the re-examination is positive, a summary of opinion is published together with the re-examination Q&A in the [CHMP meeting highlights](#) on the Friday following the CHMP plenary. Around 2 weeks after the European Commission's decision, the summary of opinion and the re-examination Q&A are linked to the medicine's page, and the same set of documents as for positive opinions described above are published.

Withdrawn applications

If the applicant withdraws its application for an extension of indication, a **withdrawal Q&A**, **withdrawal letter**, **withdrawal public assessment report** and clinical study reports are published in the same way as for initial applications (see Section 2.5). The document **procedural steps taken and scientific information after authorisation** is also published, or updated if the document was already available, on the medicine's page.

Changes of scope during extensions of indication applications

There are cases where an applicant applies for an extension of indication but the extension of indication aspect is later removed from the application. The CHMP may then issue an opinion recommending changes to the product information that do not include the extension of indication initially applied for.

In such cases EMA publishes a **Q&A document** on the Friday following the CHMP plenary meeting on the medicine's page, explaining the scientific assessment of the extension of indication application up to the point it was removed. Around 2 weeks after the European Commission's decision, the updated **product information** is published on the same page in the section 'Product information'. The **public assessment report** is published in the section 'Assessment history', reflecting the initial scope applied for and the opinion finally granted. The document **procedural steps taken and scientific information after authorisation** is also published, or updated if the document was already available.

3.2. Other variations, annual re-assessments, renewals and line extensions

Publications at time of CHMP opinion

For some changes to the marketing authorisation (other than extensions of indication), EMA publishes a **summary of opinion** in the [CHMP meeting highlights](#) on the Friday following the CHMP plenary meeting. This document can also be found using the [Medicines search page](#). These include changes to contra-indications and changes that will significantly alter the way the medicine is used (i.e. new route of administration, switch of prescription status e.g. from prescription-only to OTC, moving from multiple doses to a single dose or vice versa, extension to use in combination).

If a change to the marketing authorisation is of major public health importance, EMA may also publish in the [CHMP meeting highlights](#) on the Friday following the CHMP plenary meeting a **public health communication** containing advice for patients and healthcare professionals.

Update of the EPAR

For variations that result in an updated **product information**, the medicine's EPAR is updated around 2 weeks after the European Commission's decision if an immediate decision is expected, or 4-5 weeks after the CHMP's opinion or notification when no immediate European Commission's decision is issued.

In addition to the updated product information, the EPAR update may include an updated **medicine overview** (if needed). The **procedural steps taken and scientific information after authorisation** is published or updated in all cases.

Finally, the EPAR update also includes the publication of the **public assessment report** for those changes that are considered to be of particular importance. In particular, public assessment reports are published for line extension applications (Annex I applications) when they contain new non-clinical or clinical data and are considered to be of particular importance, and for conditional marketing authorisations when they are switched to full authorisations.

Public assessment reports are also published for paediatric studies submitted under Article 46 of paediatric regulation (Regulation (EC) No 1901/2006).

All assessment reports are published in the section 'Assessment history' of the medicine's page with commercially confidential information redacted.

As with extension of indication applications, a CHMP evaluation of applications for other variations or line extensions may not result in a change to the marketing authorisation, either because the CHMP decided no change was needed (negative opinion) or the applicant withdrew its application. In such situations, there will usually be no EPAR update. However, EMA may decide to publish an assessment report if the outcome of the evaluation is considered to be of particular importance.

4. Withdrawal/expiry of centralised marketing authorisations

A marketing authorisation may be withdrawn at the request of a marketing authorisation holder if it no longer wishes to market a medicine or chooses not to renew its authorisation. In some cases, a marketing authorisation may expire because of the so-called 'sunset clause' that comes into force when a product has not been marketed in any EU country for three consecutive years.

In these instances, EMA publishes a **public statement** on the medicine's page at the time of the authorisation's expiry or the official withdrawal of the authorisation by the European Commission. The EPAR documents already published remain on the website but are watermarked to indicate that the medicine is no longer authorised.

The European Commission may also withdraw or suspend a medicine's authorisation when a medicine is deemed to have an unfavourable benefit-risk balance. Such withdrawals or suspensions usually take place within the context of an EU referral. Section 5 describes the documents EMA publishes for EU referrals. The EPAR documents for the medicines concerned are also watermarked as described above.

Medicines whose marketing authorisation has been withdrawn can be found using the [Medicines search page](#).

5. EU referrals

A [referral](#) is a procedure used to resolve issues such as concerns over the safety or benefits of a medicine or a class of medicines. The matter is 'referred' to EMA, so that it can make a recommendation for a harmonised position across the European Union. Information on referral procedures is published on a medicine's referral page, which can be found using the [Medicine search page](#).

The referrals described below are grouped according to the extent of information published about them.

5.1. Article 20, 31 and 107i referrals⁴

At the start of an Article 20, 31 or 107i referral, EMA publishes a **communication** on the start of referral in lay language to inform the general public of the reasons for the safety, efficacy or quality review (see Table 3). Depending on whether or not the referral is triggered on the basis of pharmacovigilance data, EMA's Pharmacovigilance Risk Assessment Committee (PRAC) or EMA's CHMP carries out the assessment, and the communication on the start is published on the Friday following the plenary meeting where the referral is initiated. The official **notification**, the draft **list of products** affected by the procedure (annex I), a **list of questions** intended for marketing authorisation holders, and a **timetable** for the referral are also published.

In addition, for Article 107i referrals EMA also publishes the **PRAC list of questions addressed to stakeholders** inviting stakeholders (e.g. healthcare professionals, patients' organisations and the general public) to submit data relevant to the procedure.

Once recommendations have been adopted, for those referrals that involve the PRAC, a lay-language **communication** is published on the Friday following the PRAC plenary meeting where the recommendations were adopted. If the medicines included in the review were all authorised through national procedures, the PRAC recommendations are then sent to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which adopts a final position. When the CMDh position is agreed by consensus, the position is directly implemented in all EU Member States. If, however, the CMDh position is agreed by majority it is sent to the European Commission, which issues a final decision applicable throughout the EU. For reviews that include centrally authorised medicines, the PRAC recommendations are sent to the CHMP, which adopts the Agency's final opinion.

On the Friday following the CHMP opinion or CMDh position, a further **communication** is published.

These communication documents are high-level summaries targeting the general public and may include dedicated sections for patients and healthcare professionals when relevant. The **text of the updated product information** (annex III) in English is also published at the same time. In addition, when there is a CMDh consensus position, EMA publishes a **timetable for implementation** of the CMDh position. The **public assessment report** is published around 1 week after the European Commission's decision or CMDh consensus position.

⁴ Article 20 of Regulation (EC) 726/2004; Article 31 of Directive 2001/83/EC; Article 107i of Directive 2001/83/EC.

Table 3. EMA publications for Article 20, 31 and 107i referrals

	Documents
Start of referral	Start of referral communication Notification List of questions Timetable Draft list of products (Friday following CHMP/PRAC plenary)
↓	
PRAC recommendation (if applicable)	Communication at time of PRAC recommendations (Friday following PRAC plenary)
↓	
CHMP opinion/CMDh position	Updated communication Text of updated product information Timetable for implementation of CMDh consensus position (Friday following CHMP/CMDh plenary)
↓	
EC decision (if applicable)	Public assessment report * (1 week after EC decision) Updated communication § Annexes § (around 4 weeks after EC decision)

* - If the CMDh position is agreed by consensus, there is no EC decision and the public assessment report is published 1 week after the CMDh consensus position.
§ - If the CMDh position is agreed by consensus, there is no EC decision and the updated public health communication and Annexes are published 8 weeks after the CMDh consensus position.

Finally, around 4 weeks after the European Commission’s decision is issued or 8 weeks after CMDh consensus position, the public health communication is updated saying that the review is now final, and translations in all official EU languages are also published together with relevant **annexes** in all official EU languages (containing, as applicable, the final list of medicines affected by the referral, the scientific conclusions, the text of the updated product information and the conditions of the marketing authorisation).

All the documents related to referral procedures are published on the medicine’s referral page. All the communications are also linked to the meeting highlights of the relevant committees, and some of them may also be published on [EMA’s homepage](#). For centrally authorised medicines, the referral page is linked to the medicine’s page and EPAR documents are updated as applicable (see Section 3.2).

5.2. Article 13(2), 29(4) and 30 referrals⁵

For Article 13(2), 29(4) and 30 referrals, assessment is carried out by the CHMP. The start of these referrals is made public in a table called **Start of Union reviews**, which is published as a link to the [CHMP meeting highlights](#) on the Friday after the CHMP plenary meeting where the referrals are initiated.

⁵ Article 13(2) of Regulation (EC) 1234/2008; Article 29(4) and Article 30 of Directive 2001/83/EC.

For Article 30 referrals, a **communication** on the start of referral, the official **notification**, the draft **list of products** affected by the procedure (annex I), a **list of questions** intended for marketing authorisation holders, and a **timetable** for the referral are also published on the Friday after the CHMP plenary meeting where the referrals are initiated.

On the Friday following the CHMP plenary where the CHMP assessment is concluded, EMA publishes a further **communication** in a Q&A format and, if applicable, the **text of the updated product information** (annex III) in English. The **public assessment report** is then published around 1 week after the European Commission's decision is issued.

Finally, around 4 weeks after the European Commission's decision, the Q&A in all official EU languages is published along with relevant **annexes** in all official EU languages (containing, as applicable, the list of medicines affected by the referral, the agency's scientific conclusions, the text of the updated product information and the conditions of the marketing authorisation).

All these documents are published on the medicine's referral page. In addition, the Q&A and the announcement of the start of Article 30 referrals are also linked to the [CHMP meeting highlights](#).

5.3. Article 5(3) opinions

In accordance with Article 5(3) of Regulation (EC) No 726/2004, the CHMP may at the request of EMA's Executive Director, the European Commission or an EU Member State draw up opinions on scientific matters related to the evaluation of a medicine or a group of medicines.

The start of an Article 5(3) review is made public in the table **Start of Union reviews**, which is published as a link to the [CHMP meeting highlights](#) on the Friday following the CHMP plenary meeting where the review is started.

The **public assessment report** is published on EMA's [Article 5\(3\) opinions page](#) 15 days after the CHMP opinion. For those reviews that are considered to be of public interest, a communication is also published. It will be published at the start and at the end of the review on the Friday following the CHMP plenary meeting, linked to the [CHMP meeting highlights](#).

5.4. Article 29 (Paediatrics) opinions

In accordance with Article 29 of Regulation (EC) No 1901/2006, the CHMP issues opinions on non-centrally authorised medicines concerning applications for new indications, pharmaceutical forms or routes of administration intended for children.

On the Friday following the CHMP plenary meeting where the CHMP opinion is issued, EMA publishes a **summary** of the CHMP conclusion on the medicine's referral page. The **public assessment report** is then published around 1 week after the European Commission's decision is issued. Finally, around 4 weeks after the European Commission's decision relevant **annexes** (containing, as applicable, the list of medicines affected by the referral, the agency's scientific conclusions, the text of the updated product information and the conditions of the marketing authorisation) are published in all official EU languages.

6. Other documents and procedures

6.1. Orphan designations

When EMA's Committee for Orphan Medicinal Products (COMP) has evaluated an application for orphan designation, a summary of the COMP's opinion (known as a **public summary of opinion on orphan designation**) is published on the medicine's orphan designation page around 4 weeks after the European Commission has issued a final decision. The medicine's orphan designation page can be found using the [Medicine search page](#). This public summary of opinion on orphan designation is written in lay language. It explains the rationale for the medicine's designation and provides basic information about the medicine and its stage of development.

Orphan designations are reviewed when an application for marketing authorisation or extension of indication application for an orphan medicine is successful. The COMP reviews the designation to determine whether the medicine still meets the necessary criteria and an **orphan maintenance assessment report** (in case of maintenance of the orphan designation) or an **orphan designation withdrawal assessment report** (in case of withdrawal of the orphan designation) is published at the same time as the EPAR on the medicine's page and on the medicine's orphan designation page, in the section 'Review of designation' (see also Section 2.2). In addition, the orphan designation can be further reviewed upon request of a Member State within the first 5 years of receipt of the marketing authorisation. In such cases, a new orphan maintenance or withdrawal assessment report will be published in the same place 6-8 weeks after COMP opinion.

6.2. ATMP classification

Companies can request a recommendation from EMA's Committee for Advanced Therapies (CAT) on whether a medicine they are developing is an advanced-therapy medicinal product (ATMP). The CAT has 60 days to issue its recommendation on ATMP classification, following which a summary (known as **summary of scientific recommendations on classification of advanced-therapy medicinal products**) is published on EMA's [advanced-therapy classification page](#). The summary includes a brief description of the product and its proposed indication and the CAT's conclusion on whether the product falls within the definition of any of the different types of ATMPs (gene therapy medicinal products, somatic cell therapy medicinal products or tissue engineered products).

6.3. Requests for PRIME eligibility

Companies can receive enhanced regulatory and scientific support from EMA for the development of their medicine through a scheme called [PRIME](#) (Priority Medicines). This scheme is for medicines addressing an unmet medical need and showing promising early results. Requests for PRIME eligibility are reviewed every month and the CHMP outcome is made available in the document **Recommendations on eligibility to PRIME scheme** published as part of the [CHMP Highlights](#). This document provides general information on medicines accepted in the scheme and those that were not considered eligible.

A list of all medicines that have been granted access to the PRIME scheme since its launch is also published on the [PRIME webpage](#) and updated every month. Products are removed from the list once a marketing authorisation application is submitted, or if they are withdrawn from the scheme or no longer meet the eligibility criteria.

6.4. Paediatric investigation plans

All applications for marketing authorisation for human medicines have to include the results of studies in children as described in an agreed [paediatric investigation plan](#) (PIP), unless the applicant has been granted a deferral or waiver. The requirement for a PIP also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorised.

EMA's Paediatric Committee (PDCO) is responsible for agreeing or refusing PIPs, deferrals and waivers. The **decisions on PIPs** and **waivers** are published 6-8 weeks after adoption on the medicine's PIP page, which can be found using the [Medicine search page](#).

Once an applicant has completed an agreed PIP, it may request EMA to perform a compliance check. Alternatively, compliance check is carried out as part of the validation of an application for a marketing authorisation or a change to an existing marketing authorisation. The medicine's PIP page is updated twice a year to indicate the outcome (positive or negative) of the compliance checks performed by EMA. In addition, the **PIP compliance statement** is published on the medicine's page around 2 weeks after the European Commission's decision if an immediate decision is expected, or 4-5 weeks after the CHMP's opinion or notification when no immediate European Commission's decision is issued.

6.5. Safety signals

A safety signal is information on a new or known adverse event that is potentially caused by a medicine that warrants further investigation. The PRAC assesses safety signals for both centrally and non-centrally authorised medicines and makes recommendations to the CHMP or CMDh. The recommendations are then published within a month of the PRAC plenary meetings on the page [PRAC recommendations on safety signals](#). In addition to publishing the **PRAC recommendations on signals**, EMA also publishes the document **new product information wording**. This document captures the proposed changes to the product information following the assessment of a signal and is translated into all official EU languages.

6.6. Medicines under additional monitoring

A medicine can be included in the list of medicines under additional monitoring (i.e. medicines that are monitored particularly closely) when it is approved for the first time or in certain cases during its life cycle. It remains under additional monitoring for five years or until the PRAC decides to remove it from the list. Every month, the PRAC reviews the **list of medicines under additional monitoring**, and the up-to-date list is published on the page [List of medicines under additional monitoring](#). The list contains the invented name and active substance of the medicine, the reason why the medicine is on the list, the name of the marketing authorisation holder, a link to the medicine's page (for centrally authorised medicines) and the date of inclusion in the list. The list is available in both a PDF and Excel format. Medicines undergoing additional monitoring can be found using the [Medicines search page](#).

6.7. Compassionate use

The CHMP can provide recommendations on how to administer, distribute and use certain medicines for compassionate use, although these recommendations do not create a legal framework and compassionate use programmes remain under the responsibility of individual Member States. After the CHMP opinion on a compassionate use, EMA publishes on the page [Compassionate use](#) a **Summary on**

compassionate use and a document called '**Conditions of use, conditions for distribution and patients targeted and conditions for safety monitoring**'.

A **public statement** is published on the compassionate use webpage when EMA has been informed by a company that a compassionate use programme has been terminated.

6.8. Shortages

EMA maintains a [Catalogue](#) on shortages of medicines that are likely to affect more than one EU Member State and where EMA has made specific recommendations to patients and healthcare professionals. Each catalogue entry includes information on the reason for the shortage, the countries affected as well as the recommendations for patients and healthcare professionals during the shortage. The information is updated when the shortage is resolved. Information on medicines' shortages can also be found using the [Medicines search page](#).

6.9. Periodic safety update reports

Periodic safety update reports (PSURs) are periodic reports on the benefit-risk balance of an active substance or combination of active substances contained in medicines authorised in the EU. PSURs are submitted by companies and evaluated by the PRAC and CHMP/CMDh at defined time points after a medicine's authorisation.

A single assessment of related PSURs (PSUSAs) is carried out for medicines containing the same active substance or combination of active substances, as included in the list of EU reference dates (EURD list published on the [PSUR page](#)).

PSUSAs for active substances found only in centrally authorised medicines will result in an update of relevant EPAR documents, as described in Section 3.2. In addition, when a PSUSA leads to a change to the product information, a document called **Scientific conclusions and grounds for the variation to the terms of the marketing authorisation** is always published on the medicine's page in the section 'Assessment history'.

Information on PSUSAs can be found using the [Medicines search page](#). If the PSUSA results in no change to the marketing authorisation (maintenance), the **List of medicines** that were assessed in the PSUSA is made available 1 week after the end of the procedure. For PSUSAs which result in changes to the marketing authorisation (i.e. a variation), EMA also publishes the **List of medicines** together with the **Scientific conclusions and grounds for the variation to the terms of the marketing authorisation** within 2 months of the conclusion of the PSUSA procedure. This latter document, which shows the changes made to the product information of the medicines concerned, is available in all official EU languages. An **Assessment report** is only published when changes are considered to be of significant clinical relevance.

6.10. Imposed non-interventional post-authorisation safety studies

Post-authorisation safety studies (PASS) are studies carried out after a medicine has been authorised in order to obtain further information on the medicine's safety, or to measure the effectiveness of risk-management measures. The PRAC assesses both the protocols and the final study results of all imposed non-interventional PASS.

All procedures to assess final results of imposed non-interventional PASS result in a change to the marketing authorisation (i.e. a variation).

The assessment of results from imposed non-interventional PASS for active substances found only in centrally authorised medicines will result in an update of relevant EPAR documents, as described in Section 3.2. A document called **Scientific conclusions, amendments to product information and implementation timetable** is also published on the medicine's page in the section 'Assessment history'.

The outcomes of assessments of imposed non-interventional PASS results for active substances found only in nationally authorised medicines are published on the page [Outcomes of imposed non-interventional post-authorisation safety studies](#) within 2 months of the conclusion of the procedure. EMA publishes on this page the **List of medicines** that were assessed in the PASS together with the **Scientific conclusions, amendments to product information and implementation timetable**. This latter document is available in all official EU languages. An **Assessment report** is only published when changes are considered to be of significant clinical relevance.

6.11. Direct healthcare professional communications (DHPCs)

A [DHPC](#) is a communication tool for delivering important safety information directly to individual healthcare professionals to inform them of the need to take certain actions or adapt their practices in relation to a medicine. A DHPC can be issued, for example, when a medicine has had its marketing authorisation suspended, withdrawn or revoked for safety reasons, or when there is an important change to the use of a medicine due to the restriction of an indication, a new contraindication, or a change in the recommended dose. It can be adopted, for example, in the context of a referral procedure or during the assessment of a safety signal or a PSUR.

DHPCs agreed at EU level are published on the EMA website at the time of their dissemination and can be found using the [medicine search page](#).

6.12. Medicines for use outside the EU (Article 58)

The CHMP evaluates applications for some medicines that are not intended for use in the EU, in accordance with Article 58 of Regulation (EC) No 726/2004. Medicines eligible for an Article 58 evaluation are those used to prevent or treat diseases of major public-health interest, including vaccines used in the WHO Expanded Programme on Immunization or for protection against a public-health priority disease, and medicines for WHO target diseases such as HIV/AIDS, malaria or tuberculosis.

Article 58 evaluations are part of EMA's co-operation with WHO. When the evaluation is complete, EMA publishes similar documents to those described in Section 2 and 3 on positive and negative opinions and withdrawals within 2 months of the CHMP's opinion. These documents are published in English only on a dedicated webpage for [Medicines for use outside the EU](#).

6.13. Ancillary medicinal substances

The CHMP evaluates applications for consultations on ancillary medicinal substances or ancillary human blood derivatives incorporated in a medical device, in accordance with Article 1(4) of Directive 93/42/EEC as amended and Article 1(4) of Directive 90/385/EEC as amended.

When the evaluation is completed and EMA has received confirmation from the notified body of the issuing of a CE mark for the medical device, EMA publishes the **Consultation public assessment report** on the page [CHMP opinions on consultation procedures](#). Publication of reports occurs around 2 weeks after receipt of this confirmation. The reports are only published for positive opinions.

When changes are made to an ancillary substance for which EMA has already given an opinion, in particular to its manufacturing process, EMA is consulted to confirm that quality and safety are maintained. This is called a post-consultation procedure with EMA. Around 2 weeks after finalisation of a post-consultation procedure, a document called **Procedural steps and scientific information after initial consultation** is published on the same page.

6.14. Agendas, minutes and reports of meetings of EMA's scientific committees

In addition to the documents focusing on individual medicines or groups of medicines, EMA publishes several documents on the activities of its scientific committees.

Agendas are published in advance of the meetings and list the medicines and other topics to be discussed. The **Minutes**, which are published after the meeting (usually the following month), contain information on the outcomes of procedures discussed or concluded by the committees, including those described above in sections 2 to 6 of this document.

For CHMP and PRAC, EMA also publishes **Meeting highlights** on the Friday following their monthly plenary meetings to highlight outcomes of major public interest.

For CAT, COMP and PDCO, EMA publishes **Monthly meeting reports** in the week following the committee's plenary meeting.

These documents can be found on the respective [Committee pages](#). The meeting highlights are also published on [EMA's homepage](#).

6.15. Medical literature monitoring

EMA monitors medical literature on a number of active substances. The objective is to identify suspected adverse reactions with medicines authorised in the EU and to enter the relevant information into the EudraVigilance database. The list of substance groups (chemical and herbal) which are subject to the monitoring activities by the Agency are published in the document **Medical literature monitoring: substance and herbal substance groups** which is available on the page on [Medical literature monitoring](#). The list is reviewed annually.

7. Information on non-centrally authorised medicines

Although most of the information published on EMA's website relates to centrally authorised medicines, EMA also publishes information on non-centrally authorised medicines, particularly on those medicines that are included in reviews by its scientific committees. Such reviews include the PRAC's review of safety signals (see Section 6.5), referral procedures (see Section 5) and PSUSAs (see Section 6.99).

A list of national medicine registers in the different Member States of the EU and European Economic Area (EEA) is available on the [EMA website](#). These contain information on medicines authorised in those countries, including links to the product information for healthcare professionals (SmPC) and the package leaflet for patients.

8. Coordination of information on medicines

It is important that adequate mechanisms are in place to ensure that accurate information reaches the EU public in a timely manner. This is especially relevant for information which might be sensitive or which may generate significant public interest.

Marketing authorisation holders, applicants and third parties are generally expected to refrain from making public announcements, which cannot be independently verified, on the expected outcomes of evaluations carried out by EMA's scientific committees until the committees have formally adopted their opinions (i.e. on the last day of the committee meeting).

Some committees (the CHMP and PRAC) make use of the so-called meeting highlights to communicate information considered to be of major public interest. Meeting highlights are usually published the day after a committee meeting ends. As a matter of good practice, marketing authorisation holders, applicants and third parties should wait until EMA communication is published before publishing their own communication related to the committee's outcome.

With regard to communication on safety, EMA has procedures for giving advance notice of their safety-related publications to national competent authorities in the EU, the European Commission and the concerned marketing authorisation holders. This is to ensure that the same message reaches all patients and healthcare professionals in the EU at the same time. Under EU legislation, marketing authorisation holders are also obliged to inform the Agency and relevant national competent authorities of their intention to publish information on the safety of medicines. This exchange and coordination of safety communication in the EU is described in [Good Pharmacovigilance Practice \(GVP\) Module XV](#).

Annex: Tabulated overview of EMA documents on human medicinal products

Table 1: Applications for centralised marketing authorisation: Medicines under initial evaluation

Type of document	Publication time
List of medicines that are under evaluation	Monthly
COMP monthly meeting reports (for orphan medicines)	Week following COMP plenary

Table 2: Applications for centralised marketing authorisation: Positive opinions

Type of document	Publication time	
Summary of opinion	Friday following CHMP plenary	
Dedicated press release (for selected medicines)	Friday following CHMP plenary	
EPAR	Medicine overview	2 weeks after EC decision
	Product information	
	List of all authorised presentations	
	Public assessment report	
Summary of risk management plan	2 weeks after EC decision	
Communication on medication error prevention (if applicable)	2 weeks after EC decision	
Orphan maintenance or withdrawal assessment report (for orphan medicines)	2 weeks after EC decision	

Table 3: Applications for centralised marketing authorisation: Negative opinions

Type of document	Publication time
Refusal Q&A	Friday following CHMP plenary
Refusal public assessment report	2 weeks after EC decision

Table 4: Applications for centralised marketing authorisation: Re-examination of opinions[§]

Type of document	Publication time
Re-examination Q&A (for both positive and negative outcomes)	Friday following CHMP plenary
Summary of opinion (for positive outcomes only)	Friday following CHMP plenary

[§] After EC decision, depending on the outcome of the re-examination, the same set of documents as for positive and negative opinions will also be published (see tables 2 and 3 above).

Table 5: Applications for centralised marketing authorisation: Withdrawal of applications

Type of document	Publication time
Withdrawal Q&A	Friday following upcoming CHMP plenary
Withdrawal letter	Friday following upcoming CHMP plenary
Withdrawal public assessment report	Within 3 months of receipt of withdrawal letter

Table 6: Changes to centralised marketing authorisations: Extensions of indication

Type of document	Publication time
Positive opinions	
Summary of opinion (excluding generics and biosimilars)	Friday following CHMP plenary
Dedicated press release (for selected extensions of indication)	Friday following CHMP plenary
Update of EPAR documents (product information, procedural steps document and, if applicable, medicine overview and list of all authorised presentations)	2 weeks after EC decision
Update of summary of risk management plan (if applicable)	2 weeks after EC decision
Orphan maintenance or withdrawal assessment report (if applicable)	2 weeks after EC decision
Public assessment report	2 weeks after EC decision
Negative opinions	
Refusal Q&A	Friday following CHMP plenary
Update of procedural steps document	4-5 weeks after CHMP opinion
Refusal public assessment report	4-5 weeks after CHMP opinion
Re-examinations[§]	
Re-examination Q&A (for both positive and negative outcomes)	Friday following CHMP plenary
Summary of opinion (for positive outcomes only)	Friday following CHMP plenary
Withdrawals	
Withdrawal Q&A	Friday following next CHMP plenary
Withdrawal letter	Friday following next CHMP plenary
Withdrawal public assessment report	Within 3 months of receipt of withdrawal letter
Update of procedural steps document	Within 3 months of receipt of withdrawal letter
Changes of scope during extension of indication applications	
Q&A for change in scope	Friday following CHMP plenary
Update of procedural steps document	2 weeks after EC decision
Updated product information	2 weeks after EC decision
Public assessment report	2 weeks after EC decision

§ After EC decision, depending on the outcome of the re-examination, the same set of documents as for positive or negative opinions on extension of indication will be published.

Table 7: Changes to centralised marketing authorisations: Other variations, annual re-assessments, renewals and line extensions

Type of document	Publication time
Summary of opinion for: <ul style="list-style-type: none"> • changes to contra-indications • changes that significantly alter the medicine’s use 	Friday following CHMP plenary
Public health communication (for selected changes of major public health importance)	Friday following CHMP plenary
Update of EPAR documents (product information, procedural steps document and, if applicable, medicine overview and list of all authorised presentations)	2 weeks after EC decision or 4-5 weeks after CHMP opinion/notification, as applicable
Public assessment reports (for those changes that are of particular importance) §	2 weeks after EC decision or 4-5 weeks after CHMP opinion/notification, as applicable

§ EMA may also publish reports for negative or withdrawn applications if evaluation is of particular importance.

Table 8: Withdrawal/expiry of centralised marketing authorisations

Type of document	Publication time
Public statement	At time of withdrawal or expiry of marketing authorisation
EPAR documents watermarked	At time of withdrawal or expiry of marketing authorisation

Table 9: EU referrals: Article 20, 31 and 107i referrals

Type of document	Publication time
Announcement of start of referral	Friday following PRAC or CHMP plenary where referral is started
Notification Draft list of medicines List of questions Timetable Rationale for Art. 107i procedure	Friday following PRAC or CHMP plenary where referral is started
PRAC list of questions addressed to stakeholders (for Art. 107i referrals)	Friday following PRAC plenary where referral is started
Communication on PRAC recommendation (when PRAC is involved)	Friday following PRAC plenary where PRAC recommendation is adopted
Updated communication	Friday following CHMP or CMDh plenary where CHMP opinion or CMDh position is adopted
Text of the updated product information in English	Friday following CHMP or CMDh plenary where CHMP opinion or CMDh position is adopted
Timetable for implementation of CMDh consensus position	Friday following CMDh plenary where CMDh consensus position is adopted
Public assessment report	1 week after EC decision or CMDh consensus position
Annexes	4 weeks after EC decision or 8 weeks after CMDh consensus position
Update of EPAR documents (product information, procedural steps document and, if applicable medicine overview and list of all authorised presentations) if CAPs are involved	2 weeks after EC decision

Table 10: EU referrals: Article 13(2), 29(4) and 30 referrals

Type of document	Publication time
Table 'Start of community reviews'	Friday following CHMP plenary where referral is started
Announcement of start of referral (for Article 30 referrals only)	Friday following CHMP plenary where referral is started
Notification Draft list of medicines List of questions Timetable (for Article 30 referrals only)	Friday following CHMP plenary where referral is started
Q&A document	Friday following CHMP plenary where CHMP opinion is adopted
Text of the updated product information in English (if applicable)	Friday following CHMP plenary where CHMP opinion is adopted
Public assessment report	1 week after EC decision
Annexes	4 weeks after EC decision

Table 11: EU referrals: Article 5(3) opinions

Type of document	Publication time
Table 'Start of community reviews'	Friday following CHMP plenary where referral is started
Press release (for selected opinions)	Friday following CHMP plenary where CHMP opinion is adopted
Public assessment report	15 days after CHMP opinion

Table 12: EU referrals: Article 29(Paediatrics) opinions

Type of document	Publication time
Summary of CHMP conclusions	Friday following CHMP plenary where CHMP opinion is adopted
Public assessment report	15 days after CHMP opinion

Table 13: Orphan designations

Type of document	Publication time
Public summary of opinion on orphan designation	4 weeks after EC decision on orphan designation
Orphan maintenance/withdrawal assessment report	2 weeks after EC decision
Orphan maintenance/withdrawal assessment report following Member State request	6-8 weeks after COMP opinion

Table 14: ATPM classification

Type of document	Publication time
Summary of scientific recommendations on classification of advanced-therapy medicinal products	After CAT conclusion

Table 15: Requests for PRIME eligibility

Type of document	Publication time
Recommendations on eligibility to PRIME scheme	After each CHMP meeting
List of products granted eligibility to PRIME	After each CHMP meeting

Table 16: Paediatric investigation plans

Type of document	Publication time
Decisions on PIPs and waivers	6-8 weeks after EMA decision
Compliance check outcome	Twice a year
Compliance statement	2 weeks after EC decision or 4-5 weeks after CHMP opinion/notification, as applicable

Table 17: Safety signals

Type of document	Publication time
PRAC recommendations on signals	Within a month of PRAC plenary
New product information wording (if applicable)	Within a month of PRAC plenary

Table 18: Medicines under additional monitoring

Type of document	Publication time
List of medicines under additional monitoring	Monthly

Table 19: Compassionate use

Type of document	Publication time
Summary of compassionate use	After CHMP opinion
Conditions of use, conditions for distribution and patients targeted and conditions for safety monitoring	After CHMP opinion
Dedicated press release (for selected opinions)	Friday following CHMP plenary
Public statement on end of compassionate use programme	Following notification from company

Table 20: Shortages

Type of document	Publication time
Shortages catalogue	At time of shortage and when shortage is resolved

Table 21: Periodic safety update reports

Type of document	Publication time
PSUSAs for active substances found only in centrally authorised medicines	
Update of EPAR documents (product information, procedural steps document and, if applicable, medicine overview and list of all authorised presentations)	2 weeks after EC decision
Document 'The scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation' (for PSUSAs that lead to changes to product information)	2 weeks after EC decision
Public assessment report (for PSUSAs that are of significant clinical relevance)	2 weeks after EC decision
PSUSAs for active substances found only in nationally authorised medicines	
List of medicines	Within 1 week or 2 months of conclusion of PSUSA (for maintenance or variation, respectively)
Scientific conclusions and grounds for variation to the terms of the marketing authorisations (if applicable)	Within 2 months after conclusion of PSUSA
Public assessment report (for PSURs that are of significant clinical relevance)	Within 2 months after conclusion of PSUSA

Table 22: Imposed non-interventional post-authorisation safety studies

Type of document	Publication time
PSUSAs for active substances found only in centrally authorised medicines	
Update of EPAR documents (product information, procedural steps document and, if applicable, medicine overview and list of all authorised presentations)	2 weeks after EC decision
Document 'Scientific conclusions, amendments to product information and implementation timetable'	2 weeks after EC decision
Public assessment report (for PASS that are of significant clinical relevance)	2 weeks after EC decision
PSUSAs for active substances found only in nationally authorised medicines	
List of medicines	Within 2 months after conclusion of PASS
Scientific conclusions, amendments to product information and implementation timetable'	Within 2 months after conclusion of PASS
Public assessment report (for PASS that are of significant clinical relevance)	Within 2 months after conclusion of PASS

Table 23: Direct healthcare professional communications (DHPCs)

Type of document	Publication time
DHPC	At the time of dissemination of the DHPC

Table 24: Medicines for use outside the EU (Article 58)

Type of document	Publication time
Same documents as for centrally authorised medicines (see tables 1 to 7)	Within 2 months of CHMP opinion

Table 25: Ancillary medicinal substances

Type of document	Publication time
Consultation public assessment report	2 weeks after notified body confirms issue of CE mark
Procedural steps and scientific information after initial consultation	2 weeks after finalisation of a post-consultation procedure

Table 26: Agendas, minutes and reports of meetings of EMA’s scientific committees

Type of document	Publication time
Committees agendas	Before start of Committee plenary
Committees minutes	After Committee plenary where minutes are adopted
CHMP meeting highlights	Friday following CHMP plenary
PRAC meeting highlights	Friday following PRAC plenary
CAT, COMP and PDCO monthly meeting reports	Week following Committee plenary

Table 27: Medical literature monitoring

Type of document	Publication time
Medical literature monitoring: substance and herbal substance groups	Annually

Table 28: Clinical data publication

Type of document	Publication
Clinical reports as per the Agency's policy on the publication of clinical data (Policy 0070)	Marketing authorisation applications, line extensions and extensions of indication:
	Within 60 days after EC decision and following publication of the EPAR
	Article 58 applications:
	Within 150 days after the CHMP opinion
Withdrawn applications:	Within 150 days after the receipt of the withdrawal letter