17 January 2023
EMA/244151/2020

EMA transparency measures for medicines addressing public health emergencies

1. Introduction

This document describes what information EMA publishes in relation to the development, evaluation and supervision of medicinal products for a public health emergency.[1]

Providing a global overview of EMA's activities in the context of a public health emergency will not only keep the public informed but will also be useful to individual medicines developers who can take advantage of incentives and programmes aimed at speeding up the development and regulatory evaluation of medicines.

In many cases, the transparency measures described in this document mirror standard procedures already in place for all medicines. However, in other cases, the measures go beyond standard procedures due to the high level of public interest expected around medicinal products that address or have the potential to address a public health emergency.

The transparency measures also include those required by Regulation (EU) 2022/123 extending EMA's mandate with respect to public health emergencies.

2. Information to be published

In the context of a public health emergency, EMA publishes information on the following:[2]

- therapeutic groups of medicines for emergency care, surgery and intensive care
- critical medicines with potential to address a public health emergency
- shortages of critical medicines
- promising medicines with the potential to address a public health emergency

[1] A situation of public health emergency recognised by the Commission in accordance with Article 12(1) of Decision No 1082/2013/EU.

[2] When EMA publishes information about a public health emergency, it may also update the dedicated webpage(s) for the public health emergency as well as the 'Latest Updates' web feed.

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- statements from EMA's Emergency Task Force (ETF)
- EMA recommendations on compassionate use or use of unauthorised medicines
- medicines for which EMA has provided guidance to developers
- start of evaluations of medicines with the potential to address a public health emergency
- withdrawals from rolling review or withdrawals of marketing authorisation applications
- EMA opinions on marketing authorisation applications
- European Commission decisions at the time of initial marketing authorisation
- post-authorisation procedures
- withdrawal/expiration of marketing authorisations

2.1. Therapeutic groups of medicines for emergency care, surgery and intensive care

EMA has published a list of the main therapeutic groups of medicinal products that are necessary for emergency care, surgeries and intensive care.[3,4] EMA updates this list as necessary.

2.2. Critical medicines with the potential to address a public health emergency

Following the declaration of a public health emergency, EMA will publish a list of medicines critical to addressing a public health emergency[5] taking into account the published list of the main therapeutic groups of medicinal products that are necessary for emergency care, surgeries and intensive care mentioned above. EMA will update the list of critical medicines as necessary.

2.3. Shortages of critical medicines

EMA will publish information on shortages of medicines critical to addressing a public health emergency in cases where the Agency has assessed the shortage and has provided recommendations to healthcare professionals and patients.[6]

The publication of information on shortages of critical medicines will complement information in EMA's current shortages catalogue.

2.4. Promising medicines with the potential to address a public health emergency

EMA will publish a list of medicines that the ETF considers to have potential to address the public health emergency[7] and for which it has reviewed available scientific data.[8] The published list will be updated as necessary.

[3] List referred to in Article 6 (1) of Regulation (EU) 2022/123

[4] https://www.ema.europa.eu/en/documents/other/list-main-therapeutic-groups-mtgs-crisis-preparedness_en.pdf

[5] In accordance with Article 6 (5) of Regulation (EU) 2022/123

[6] In accordance with Article 6 (6) of Regulation (EU) 2022/123

[7] In accordance with Article 15(9) of Regulation (EU) 2022/123

[8] List referred to in Article 19 of Regulation (EU) 2022/123 for products under review referred to in Article 18(1) of Regulation (EU) 2002/123

2.5. Statements from EMA's Emergency Task Force (ETF)

During a public health emergency, the ETF may issue recommendations on the use of any authorised or unauthorised medicines. EMA will publish statements on these recommendations and may also publish a press release to accompany the statements.

2.6. EMA recommendations on compassionate use or use of unauthorised medicines

In cases where EMA's Committee for Medicinal Products for Human Use (CHMP) provides a recommendation on compassionate use or the use of an unauthorised medicine during a public health emergency,[9] EMA publishes the following:

- a press release
- the CHMP's assessment report
- a document or documents detailing the conditions of use, conditions for distribution and patients targeted and conditions for safety monitoring.

2.7. Medicines for which EMA has provided guidance to developers

During a public health emergency, EMA will consider publishing a list of medicines for which EMA has given advice, along with information on the stage of development (e.g. clinical or nonclinical phase) when the advice was given. The table will be updated regularly.

2.8. Start of evaluations of medicines with the potential to address a public health emergency

At the start of an evaluation of a medicine with the potential to address a public health emergency (which could be the start of a rolling review or the start of a marketing authorisation application review), EMA publishes a press release.[10]

While rolling reviews and evaluations of applications are underway, EMA may consider interim communication to update the public should the need arise.

2.9. Withdrawals from rolling review or withdrawals of marketing authorisation applications

Should a developer withdraw from a rolling review or withdraw an application for marketing authorisation, EMA publishes a withdrawal questions-and-answers document and the applicant's withdrawal letter, with the option of a press release.

EMA will also publish the CHMP list of questions (for rolling reviews) and assessment report (for applications), if these documents have been adopted, as soon as possible and within 3 months of the receipt of the withdrawal letter. The list of questions or the withdrawal assessment report that EMA publishes will be the last one adopted by the CHMP at time of withdrawal with information of a commercially confidential nature redacted and personal data anonymised.

[9] In accordance with Article 18(4) of Regulation (EU) 2022/123

[10] With respect to sections 2.8 to 2.11, EMA provides similar level of transparency for initial extensions of indication and initial marketing authorisations aimed at addressing a public health emergency.

The documents described above will be published on a dedicated 'withdrawal' page in line with standard practice.

When applicable, clinical data supporting the application will be published, where possible within two months of the withdrawal.[11]

2.10. EMA opinions on marketing authorisation applications[12,13]

In the event of a **positive EMA opinion** on a marketing authorisation application, EMA publishes on the date of the opinion:

- a dedicated press release
- a summary of opinion
- the CHMP approved product information in English pending the issuance of the EC decision.

If the CHMP issues a **negative opinion**, EMA publishes on the date of the opinion a refusal questions-and-answers document, with the option of a press release. Clinical data supporting the application will also be published, where possible within two months of the negative opinion.[14]

2.11. European Commission decisions at the time of marketing authorisation

In line with standard procedures following the issuance of an EC decision granting a marketing authorisation, EMA publishes on the medicines webpage:

- the public assessment report in an expedited manner
- an updated medicine overview in an expedited manner
- the risk management plan as soon as possible in accordance with Article 17 (2d) Regulation (EU) 2022/123.[15]

Clinical data supporting the application, where possible within two months of the marketing authorisation.

The medicine overview and product information are translated into all official EU languages. As procedure for European Commission decision will be expedited, translations may not be available at the time of publication, in which case only the English version will be published. Translations will be added as soon as they are ready.

For refused applications, EMA will publish a refusal EPAR, including the public assessment report.

[11] In accordance with Article 17 (2c) Regulation (EU) 2022/123.

[12] This also covers medicines previously authorised for other conditions which EMA has assessed for the public health emergency

[13] For public health emergencies, CHMP opinions could be issued outside of a regular plenary meeting, in which case the initial communication will not be linked to the CHMP Meeting Highlights.

[14] In accordance with Article 17 (2c) Regulation (EU) 2022/123.

[15] The RMP may not be ready at the time of the initial EPAR publication as EMA will need to work the MAH on appropriate redactions.

2.12. Post-authorisation procedures

This section describes EMA publication practices about post-authorisation procedures for medicines addressing a public health emergency.[16]

2.12.1. Major variations, including extensions of indication

The outcomes of major regulatory procedures to change the use of medicines already authorised to address a public health emergency (e.g. to add paediatric indications and boosters for vaccines or to extend indications for therapeutics) or introduce major modifications to the product (e.g. changes to the strain included in a vaccine) will be communicated through an update on the relevant webpages for public health emergency and/or the dedicated pages for the products concerned.

In the event of a **positive EMA opinion** on an extension of indication, EMA will publish:

- a dedicated press release or a statement in the CHMP Meeting Highlights, depending on the nature of the extension.
- a summary of opinion and the CHMP approved product information in English pending the issuance of the EC decision.
- the public assessment report in an expedited manner.
- an updated medicines overview in an expedited manner.
- clinical data supporting the application for the extension of indication, where possible within two months of the marketing authorisation.

If the CHMP issues **a negative opinion**, EMA should publish a refusal questions-and-answers document as usual, with the option of a press release.

Should the applicant **withdraw its application**, EMA should publish a withdrawal questions-and-answers document as usual, with the option of a press release.

For both **negative and positive opinions**, EMA will publish the assessment report. For **withdrawals,** EMA will publish a withdrawal assessment report if the CHMP has adopted one. The withdrawal public assessment report will be the last adopted CHMP assessment report available at time of withdrawal. All information of a commercially confidential nature as well as personal data will be redacted.

Clinical data supporting the application for the extension of indication will also be published, where possible within two months of the negative opinion or the withdrawal.

2.12.2. Other (type II) variations related to safety or efficacy, PSURs, variations linked to PASS results, renewals (including conversion to full marketing authorisation) and line extensions[17]

When one of these variation procedures concludes, EMA will:

- publish a press release if the variation is judged to be of major public health importance.

[16] For some medicines that attract high public interest (e.g. COVID-19 vaccines), in addition to what is described in this section, EMA publishes a table on their medicine page with information on all the major changes that have occurred since authorisations. These include extensions of indications, the approval of new manufacturing site and the extension of shelf-lives.

[17] Whenever the line extensions contain clinical data the assessment report will be published.

- publish an update on the page of the public health emergency as well as web updates if deemed necessary (published documents).
- publish a summary of opinion and the CHMP approved product information in English pending the issuance of the EC decision, if the variation is judged to be of major public health importance.
- publish the assessment report on clinical aspects and expedite publication if the variation is judged to be of major public health importance. This is likely to be the case if it is linked to a significant change to the product information.
- update the relevant medicine overview. EMA will expedite the publication if the variation is judged to be of major public health importance.
- publish any submitted clinical data supporting the regulatory procedure[18], where possible within two months of the marketing authorisation.

2.12.3. Referral procedures

For referral procedures, EMA will:

- publish relevant documents in line with standard procedures.
- expedite publication of the relevant assessment report.
- publish any submitted clinical data supporting the regulatory procedure, where possible within two months of the marketing authorisation.

2.12.4. Safety signal procedures

For safety signal procedures, EMA will:

- announce the start and finalisation of the signal procedure in the PRAC highlights.
- consider a stand-alone public health communication if the signal evaluation concludes with a recommendation for a significant change to the product information.
- publish an assessment report if the outcome of the signal evaluation is judged to be of major public health importance, for example, if it leads to a significant change to the product information.

2.12.5. Other post-authorisation procedures

For other types of procedures, EMA will follow standard procedures. More information is available in EMA's Guide to Information Published on Human Medicines.

2.12.6. Withdrawal/expiration of marketing authorisations

If a marketing authorisation holder requests the withdrawal of a marketing authorisation or allows the validity of the authorisation to expire, EMA will:

- publish a public statement in line with standard procedures.
- publish press release as needed.

[18] For PSUR clinical data will not be published because it is out of the scope of Policy 70.

3. Other publications

Safety Updates

If there are regular safety updates (apart from PSURs), EMA will publish the outcome on its website during the week after the relevant PRAC plenary meeting.

List of medicines subject to additional monitoring

Publication in line with standard procedures.

Risk management plans and subsequent updates

In accordance with Regulation (EU) 2022/123, it is proposed that EMA publishes the risk management plans for medicines that address the public health emergency and republishes the documents when there are updates.