EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Methodology for the establishment of lists of "main therapeutic groups" in crisis preparedness and of the lists of "critical medicines[1]" in the context of a major event and/or public health emergency

Contents

[1] Critical medicines as referred to in Article 6 of Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

1. General considerations

Regulation (EU) 2022/123[2] provides the European Medicines Agency ('EMA' or 'the Agency') with a framework to monitor and mitigate potential and actual shortages of medicinal products for human use considered as critical to address a given 'public health emergency'[3] or other 'major events'[4] which may have a serious impact on public health. It also foresees the continuous monitoring of any events which may lead to a major event or a public health emergency, and which may affect the supply, quality, safety and efficacy of medicinal products.

In the context of the new regulatory framework to detect, monitor and mitigate/prevent medicine shortages, according to Article 6(1) of Regulation (EU) 2022/123 the Executive Steering Group on Shortages and Safety of Medicinal Products (hereafter described as 'the Medicines Shortages Steering Group' or 'MSSG') shall establish a list with the **"main therapeutic groups" (MTGs)** of medicinal products that are necessary for emergency care, surgeries and intensive care, within 6 months after the entry into force of the Regulation (i.e. 2 August 2022), in order to inform the preparation of the critical medicines lists to respond to a 'public health emergency' or 'major event'.

Moreover, the MSSG shall – according to Article 6 (2 & 3) - adopt lists of authorised **medicinal products considered as critical** during the major event ('the major event critical medicines list') as well as during the public health emergency ('the public health emergency critical medicines list'). The lists shall be updated whenever necessary until the 'major event' has been sufficiently addressed, or until the end of the 'public health emergency'.

This document describes the methodology for the establishment of such lists by the MSSG.

2. Establishment and Review of list of "main therapeutic groups" (MTGs) of medicinal products

2.1. Scope and implementation

As per Article 6(1) of Regulation (EU) 2022/123 the list of MTGs should include the main therapeutic groups of medicinal products that are necessary for intensive care (IC), emergency care (EC) and, surgical care (SC).

The MSSG will define the MTGs of medicinal products and may decide at a later stage to include specific INNs in each therapeutic group.

The list of MTGs serves as the basis for the list of the major event critical medicines list (MECM) and the public health emergency critical medicines list (PHECM) and shall be established by 2 August 2022 and updated annually, and whenever necessary.

[2] EUR-Lex - L:2022:020:TOC - EN - EUR-Lex (europa.eu)

[3] 'public health emergency' means a public health emergency recognised by the European Commission in accordance with Decision No 1082/2013/EU

[4] 'major event' means an event which is likely to pose a serious risk to public health in relation to medicinal products in more than one Member State. Such an event concerns a deadly threat or otherwise serious threat to health of biological, chemical, environmental or other origin or incident that can affect the supply, demand or quality, safety, and efficacy of medicinal products. Such an event may lead to shortages of medicinal products in more than one Member State and necessitates urgent coordination at Union level in order to ensure a high level of human health protection.

2.2. Data Sources and inclusion criteria

In the drafting procedure the Agency may consider collecting data from public available sources e.g. clinical practice guidelines/recommendations, WHO list of priority medicines for COVID-19 pandemic[5].

For the establishment of the MTGs the pharmacological or therapeutic subgroups will be specified and if appropriate the chemical subgroups[6].

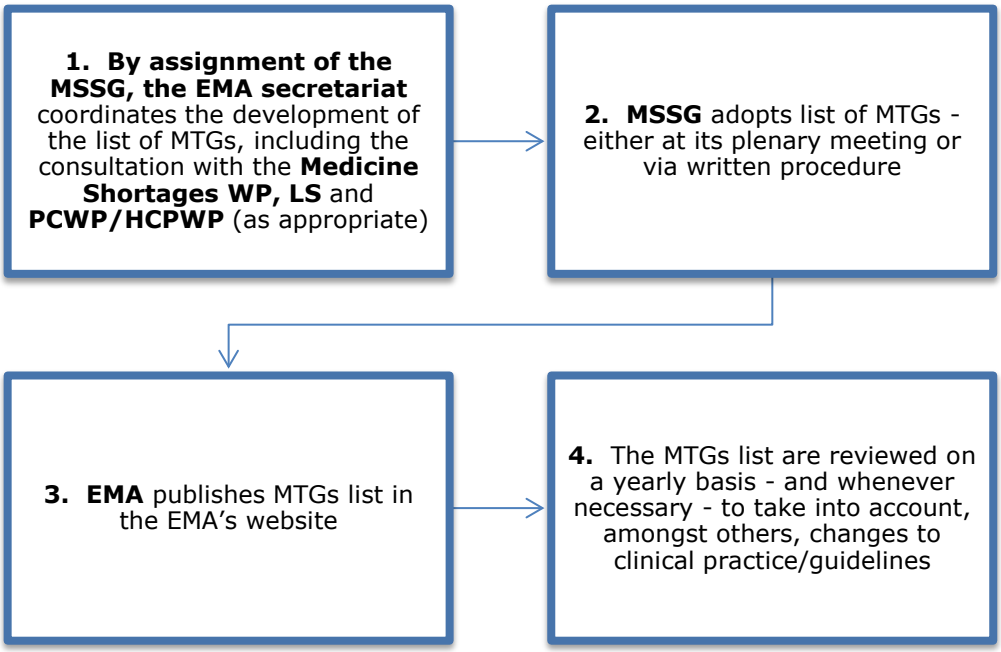
2.3. High level methodology

The Agency shall coordinate the development of the list, which shall then be adopted by the MSSG. During the drafting of the list of MTGs, by assignment of the MSSG the EMA secretariat shall engage with the Medicine Shortages SPOC Working Party (WP) and may engage with the Agency's Patients' and Consumers' Working Party ('PCWP') and Healthcare Professionals' Working Party ('HCPWP') through the MSSG representatives.

Learned Societies (LS)[7] may be invited to review the list during the development as appropriate, to gather their feedback based on their clinical fields of expertise.

If specific medical devices need to be considered the Executive Steering Group on Shortages of Medical Devices (MDSSG) will be consulted.

A description of the high-level methodology to establish the list of MTGs is schematized below:



[5] http://www.wcoomd.org/-/media/wco/public/global/pdf/topics/nomenclature/covid_19/prioritization-medicines-list-during-covid_19-_v9_wco_en.pdf?la=en
[6] The ATC classification system may be used (https://www.who.int/tools/atc-ddd-toolkit/atc-classification)
[7] European Society of Intensive Care Medicine (ESICM); European Society for Emergency Medicine (EuSEM); European Surgical Association (ESA); European Society of Paediatric and Neonatal Intensive Care (ESPNIC); European Paediatric Surgeons' Association (EUPSA)

3. Establishment and Review of lists of critical medicines as defined in Article 6 (2 & 3) of Regulation (EU) 2022/123

The MSSG should establish in the context of a major event or a public health emergency a list or lists of critical medicines, as follows:

- the major event critical medicines (MECM) list
- the public health emergency critical medicines (PHECM) list

The methodology for the drafting and adoption of such lists is defined below.

3.1. Scope and implementation

The MECM and PHECM[8] lists should focus exclusively on authorised medicinal products which require close monitoring during either the ME or PHE. Active substances from the list of "main therapeutic groups" may be included in the MECM or PHECM lists, as appropriate.

The MECM list should be established immediately following the recognition of a major event, which is likely to pose a serious risk to public health in relation to medicinal products in more than one Member State.

On the other hand, the PHECM list should be established as soon as a public health emergency is recognised by the European Commission in accordance with Decision No 1082/2013/EU.

3.2. Data Sources and inclusion criteria

By assignment of the MSSG, the EMA secretariat coordinates the drafting procedure. In the drafting procedure the MSSG shall use as a basis to establish the lists of critical medicines, the medicinal products identified by the Medicines shortages SPOC WP. Individual clinical practice knowledge from Member States will be considered by the Medicines shortages SPOC WP when identifying medicines requiring close monitoring.

The MECM or PHECM lists should include information on the authorised routes of administration, pharmaceutical forms and strengths or concentrations of active substances. If clinically relevant, the specific combination of active substances may be specified. It is not envisaged that for the purpose of the publication of the lists specific pack sizes are identified, but volume (e.g. for parenteral products) could be relevant.

Subject to the total number of medicines selected by the Medicines Shortages SPOC WP members, inclusion criteria may be applied when drawing up the consolidated MECM or PHECM lists, taking into consideration the number of MSs selecting the same medicines, the demand for the medicinal products or other criteria.

From 2023 the creation of the lists may be supported by a programme of drug utilisation studies coordinated by the Agency. These studies will leverage DARWIN EU, as well as any other real-world evidence contracts available to the Agency.

8 To illustrate an example - a PHECM list in the context of COVID-19 pandemic would consist of the following product categories: hospital ICU medicines, outpatient respiratory therapies, COVID-19 vaccines and therapeutics.

3.3. High level methodology

By assignment of the MSSG the EMA secretariat shall coordinate the development of the MECM and PHECM lists. Immediately following the recognition of a "major event" or "public health emergency" respectively, EMA shall consult the Medicines Shortages SPOC WP to support the development of the lists. In particular the Medicines Shortages SPOC WP should support the identification of the relevant medicinal products subject to close monitoring during the ME or PHE.

During the drafting of the MECM or PHECM lists, the Agency may engage with relevant stakeholders (e.g. PCWP and HCPWP). Industry Trade Associations may be invited to review the lists after their development, as appropriate.

A MSSG Working Group (WG)[9] may be set up to support the continuous review of the lists. The WG will be responsible for the continuous monitoring and review of the lists, in line with latest clinical practice knowledge and evolution of the event/emergency.

Following that consultation, the MSSG shall adopt a list of medicinal products considered critical during the ME or PHE (i.e. MECM or PHECM lists). For the public health emergency critical medicines list, the MSSG shall liaise – in parallel – with the ETF to review the lists before the adoption of the PHECM list.

The MSSG shall update the MECM or PHECM lists, whenever necessary, ie:

I. until the "major event" has been sufficiently addressed, i.e. as soon as it has been confirmed that the assistance of the MSSG is no longer needed[10];

II. until the termination of the recognition of the "public health emergency".

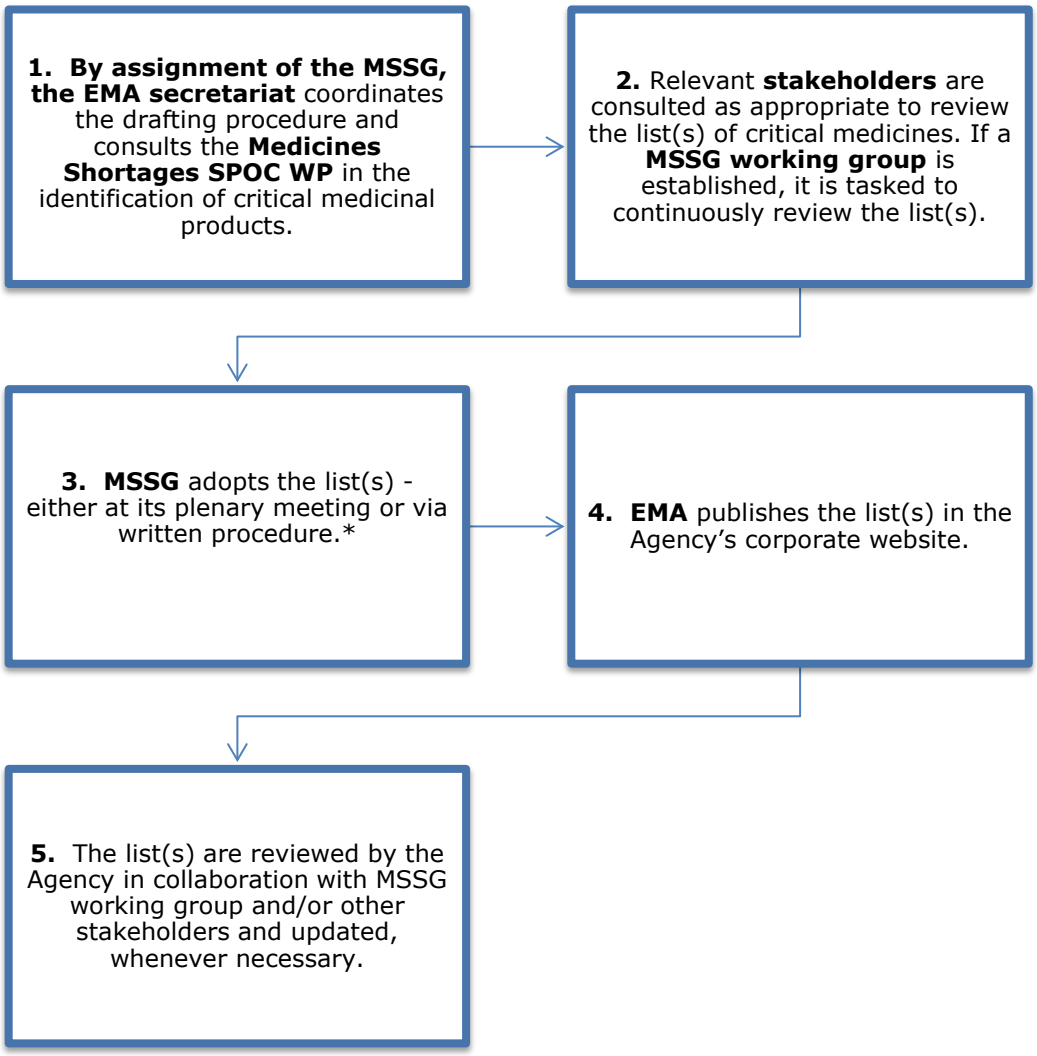
Any requests for changes to the lists by stakeholders will be reviewed by the Agency as per the established methodology, as needed.

Following the adoption of critical medicines lists, the Agency shall immediately publish those lists and any updates to those lists, including the termination of the crisis, on its web portal.

[9] The composition of the MSSG Working group (WG) may include: Members of the ETF (only for PHEs); Members of the MSSG or nominated experts; Experts from Learned Societies; Members of the Medicines Shortages SPOC WP; WHO specialists

[10] The MSSG shall inform the Commission and the Executive Director of the Agency once the MSSG considers that the major event has been sufficiently addressed and considers that its assistance is no longer needed.
On the basis of the information or on its own initiative, the Commission or the Executive Director may confirm that the major event has been sufficiently addressed and therefore that the assistance of the MSSG is no longer needed.

A description of the high-level procedure to establish the lists of critical medicines (for ME or PHEs) is schematized below:



*prior to adoption, ***ETF*** *shall be consulted within the review process, and before adopting the final PHECM list*