EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Methodology for the establishment of the "public health emergency critical medical devices[1] list"

Contents

[1] 'Medical device' means **a medical device** as defined in Article 2, point (1), of Regulation (EU) 2017/745 or **an *in vitro* diagnostic medical device** as defined in Article 2, point (2), of Regulation (EU) 2017/746, **and includes accessories for such devices** within the meaning of Article 2, point (2), of Regulation (EU) 2017/745, and Article 2, point (4), of Regulation (EU) 2017/746, respectively

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1. General considerations

Regulation (EU) 2022/123[2] of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency (the 'Agency') in crisis preparedness and management for medicinal products and medical devices lays down the procedures for coordinating and managing the impact of public health emergencies[3] on medical devices at Union level.

Long-term structures will be established within the Agency to ensure a solid and effective monitoring of shortages of medical devices that can occur during a public health emergency and coordination of the management of those shortages, as well as increased and early dialogue with the medical devices industry and healthcare professionals to prevent and mitigate those shortages.

The Regulation foresees the establishment of the Executive Steering Group on Shortages of Medical Devices, the so-called 'Medical Device Shortages Steering Group (MDSSG)' within the Agency.

The Executive Steering Group on Shortages of Medical Devices, among others, will:

- coordinate urgent actions within the Union in relation to the management of supply and demand issues of medical devices (in the context of a PHE);
- establish **lists of critical medical devices in the case of a public health emergency** ('public health emergency critical devices list').

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

2. Establishment and Review of the public health emergency critical medical devices list(s) as defined in Article 22 (1 & 2) of Regulation (EU) 2022/123

In the context of a public health emergency the MDSSG shall establish a list or lists of categories of critical medical devices which it considers to be critical during the public health emergency (**public health emergency critical devices list' (PHECD list)**).

Immediately following the recognition of a public health emergency, the MDSSG shall consult the working party referred to in Article 21(5), which is further referred to as Medical Devices Shortages SPOC WP (MD SPOC WP). Immediately following this consultation, the MDSSG shall adopt the specific public health emergency critical devices list.

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

2.1. Scope and implementation

The PHECD list(s) shall focus on **CE-marked medical devices** which will require close monitoring during the PHE[4].

Devices such as investigational devices, devices for performance studies, devices undergoing conformity assessment and devices manufactured and used only within health institutions established in the Union according to Article 5.5. of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 are

[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 Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health

[4] This may involve devices for which an exception or derogation has been granted in accordance with Regulation (EU) 2017/745 or Regulation (EU) 2017/746, devices undergoing conformity assessment and devices incorporated in combination products.

out of scope of the PHECD list and will be included in the list to be drawn up by HERA under a PHE (Council Regulation (EU) 2022/2372 Art. 7.1).

The PHECD list(s) should be established as soon as a public health emergency is recognised by the European Commission in accordance with Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health[5].

Article 22(1) defines that the MDSSG shall adopt a list of categories of critical medical devices. Where applicable the European Medical Device Nomenclature (EMDN) will be used as a basis to define the respective categories of critical medical devices. The applicable/ appropriate term will be selected from appropriate level of the hierarchy structure of the EMDN. Additional specifications, functionalities or restrictions may need also to be included for specific critical medical devices.

Even if it is not envisaged that data on individual devices will be collected, this may be applicable for specific products or product combinations.

2.2. Data Sources and inclusion criteria

By assignment of the MDSSG, the EMA secretariat coordinates the drafting procedure. In the drafting procedure the MDSSG shall use the categories of critical medical devices identified by the MD SPOC WP as a basis to establish the public health emergency critical devices list. The 'catalogue of critical medical countermeasures (MCM) required to improve EU preparedness and response to serious cross-border health threats', established by DG HERA, shall be used as a basis to establish the **public health emergency critical devices list'.** Other data sources, e.g. the list of essential medical devices published by WHO and national lists will also be considered.

Individual clinical practice knowledge from Member States will be considered by the MD SPOC WP when identifying medical devices requiring close monitoring. Learned Societies (LS)[6] and existing Expert panels may be invited to review the list during the development as appropriate, to gather their feedback based on their clinical fields of expertise.

To the extent possible, relevant information relating to the defined/listed critical medical devices and the related manufacturers and authorised representatives will be gathered from Eudamed, once it is fully functional. Information will also be gathered from importers and distributors, as appropriate.

Until Eudamed is fully functional, information will be gathered from national databases or other available sources. After Eudamed is fully functional data may continue to be collected from national databases or other available sources, if needed. This data may relate to the details regarding distributors, as there is no obligation for distributors to register in Eudamed.

2.3. The PHECD list(s)

The PHECD list should include information identifying the category of medical device, the intended purpose, and where necessary, specific characteristics of the category of medical device. If clinically relevant, further specifications may be included on the listing, for example the combination of different medical devices and accessories may need to be specified in particular scenarios.

[5] Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (Text with EEA relevance

[6] LS may include, amongst others, 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); European Respiratory Society (ERS)

Every effort will be made by the MD SPOC WP members to ensure that the defined list reflects the clinical need while ensuring that a pragmatic and practical approach is taken so as to ensure that the list is useful, usable and manageable.

Subject to the total number of devices selected by the MD SPOC WP members, inclusion criteria may be applied when drawing up the consolidated PHECD lists, taking into consideration the number of MSs selecting similar devices, the demand for the devices, or other criteria.

The creation of the lists may be supported by the Data Analysis and Real-World Interrogation Network (DARWIN EU), as well as any other real-world evidence available to the Agency.

2.4. High level methodology

By assignment of the MDSSG the EMA secretariat shall coordinate the development of the PHECD list(s). Immediately following the recognition of a "public health emergency", EMA shall consult the MD SPOC WP to support the development of the list. In particular the MD SPOC WP should support the identification of the critical medical devices subject to close monitoring during the PHE.

A MDSSG Working Group (WG)[7] may be established to contribute to the selection of critical medical devices and support the continuous monitoring and review of the list in line with latest clinical practice knowledge and evolution of the public health emergency. During the drafting of the PHECD list, the Agency may engage with relevant stakeholders (e.g. PCWP and HCPWP). The MCM list from DG HERA and the list of essential medical devices from the WHO will also be considered, amongst other data sources, for the identification of critical medical devices.

European industry Trade Associations and European Associations for Notified Bodies may be invited to review the list(s) after their development, as appropriate.

Following these consultations, the MDSSG shall adopt a list of medical devices considered critical during the PHE (**'public health emergency critical devices list'**).

The MDSSG shall update the PHECD list(s), whenever necessary 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 in collaboration with MDSSG working group as per the established methodology, as needed.

Following the adoption of the **public health emergency critical devices list(s)**, the Agency shall immediately publish those lists and any updates to those lists, including the termination of the public health emergency, on its web portal.

[7] The composition of the MDSSG working group (WG) may include: Members of the ETF; Members of DG SANTE; Members of the MDCG; Members of the MDSSG or nominated experts; Members of the MD SPOC WP; Experts from Learned Societies; Members of the Medicines Shortages SPOC WP; WHO specialists, Members of DG HERA and the HERA Advisory Forum and additional relevant clinical and medical device experts.

A description of the high-level procedure to establish the lists of critical medical devices is schematized below: