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European Medicines Agency

Mandate, objectives and rules of procedure for the Medical Device Shortages SPOC Working Party

1. General considerations

Regulation (EU) 2022/123[1] provides the European Medicines Agency ('EMA' or 'the Agency') with a framework to monitor and mitigate potential and actual shortages of medical devices considered as critical to address a given 'public health emergency'[2].

According to the Medical Device Shortages Steering Group (MDSSG) rules of procedure, the MDSSG shall be supported in its work by a working party and shall establish procedures relating to the working party. The Working Party should be comprised of Single Point of Contact (SPOCs) related to shortages from National Competent Authorities (NCAs) for medical devices (hereafter referred to as 'Medical Device Shortages SPOC Working Party', MD SPOC WP, or 'the working party').

The MDSSG may consult its working party on any issue related to shortages of medical devices. The MD SPOC WP is therefore established to provide recommendations to the MDSSG on all matters relating to monitoring and management of shortages and availability issues during 'public health emergencies', and to perform the tasks described under section 2.

2. Mandate and objectives

The MD SPOC WP is established to provide recommendations to the MDSSG on all matters relating directly or indirectly to shortages or availability issues of medical devices during 'public health emergencies' including, but not limited to, the tasks defined below:

Responsibilities under 'Public health emergencies'

a) At the request of the MDSSG, immediately following the recognition of a public health emergency, support the MDSSG with the establishment of a list of categories of critical medical devices which the MDSSG considers to be critical during the public health emergency ('public health emergency critical medical devices list')

b) To the extent possible, gather relevant information on critical medical devices and related manufacturers from Eudamed, once fully functional, or other available sources. Until Eudamed is

[1] https://www.europarl.europa.eu/meetdocs/2014_2019/plmrep/COMMITTEES/ENVI/DV/2021/11-29/EMA_Mandate-agreed_text_EN.pdf
[2] 'public health emergency' means a public health emergency recognised by the European Commission in accordance with Decision No 1082/2013/EU

fully functional, gather information from national databases or other available sources. As appropriate, gather information from importers and distributors. The lists shall be updated whenever necessary until the end of the 'public health emergency';

c) Submit to the Agency estimated data on volume of demand including demand forecasts of medical devices included on the list referred above ('public health emergency critical devices lists'), based on the set of information required and adopted by the MDSSG and using the reporting methods and system established. In the demand data submissions, existence of any commercially confidential information (CCI) should be indicated; in addition, where information cannot be provided or if there are delays in providing such data this should be indicated to the Agency;

d) Gather relevant information and data, including on stock levels or on any logistical challenges in the wholesale supply chain, from manufacturers of medical devices and their authorised representatives, health care providers, importers, and distributors, as applicable, and notified bodies on medical devices included on the public health emergency critical devices where necessary to fulfil reporting obligations set out above;

e) Where Member States are in possession of any additional information on available and estimated data on volume of demand and demand forecasts for medical devices, which provides evidence of a potential or actual shortage of a medical device included on the critical devices lists, they shall immediately provide such information to the MDSSG;

f) To take into account - in the respective Member State - any recommendations and guidelines and coordinate their actions related to any measures taken at Union-level, as well as to inform the MDSSG of any measures taken and report on the results of those measures, including information on the resolution of the potential or actual shortage. Where an alternative course of action related to any recommendations/guidelines has been taken at national level, the Member States where such alternative course of action occurred, shall share, in a timely manner, the reasons for doing so with the MDSSG.

3. Composition and rules of participation

The Medical Device Shortages SPOC Working Party shall consist of representatives of the national competent authorities responsible for shortage monitoring and management of medical devices, who shall be the single points of contact in relation to shortages of medical devices.

All EU/EEA NCAs are invited to nominate one expert and one alternate to be members of the working party per NCA. These members and alternates should have complimentary knowledge to ensure that both medical device and in vitro diagnostic related topics can be discussed.

A member may in addition nominate an alternate to participate in those exceptional cases where he/she is unable to attend a meeting. Whenever possible, any given member should be replaced by the same person (alternate) in order to maintain continuity. The member shall inform the EMA secretariat at the latest one week in advance of the meetings if he/she will be replaced by the alternate. Alternates are encouraged to attend all MD SPOC WP meetings.

Membership of the working party implies a commitment to participate actively in the work of the working party and to attend the meetings of the working party regularly.

The Chairperson of the working party is the EMA Head of Supply and Availability of Medicines and Devices Workstream. A member of the working party acts as vice-chairperson.

Representatives of the European Commission may attend meetings of the working party.

Members who want to bring additional experts should notify the EMA Secretariat in advance of the meeting, subject to the agreement of the EMA Chairperson.

Meeting documentation will be distributed to an agreed list of recipients drawn up and maintained by the EMA Secretariat with the agreement of the EMA Chairperson.

Members from EMA's Scientific Committees and/or their working parties may participate with the agreement of the EMA Chairperson.

Observers from non-EEA countries may participate with the agreement of the EMA Chairperson.

Observers from accession countries and Mutual Recognition Agreement (MRA) partners may have standing invitations to participate in certain working parties' meetings.

Specific confidentiality rules will apply to observers.

4. Meeting frequency

The Medical Device Shortages SPOC Working Party shall meet (virtually or face-to-face) during a declared public health emergency. The dates of the meetings shall be communicated to the working party.

Ad-hoc meetings can be convened, when needed, with the agreement of the EMA Chairperson.

Drafting Group meetings may be convened on specific topics or in the margins of plenary meetings to complement the Medical Device Shortages SPOC Working Party working procedures as needed, during a public health emergency. In the absence of a declared public health emergency, the working party will remain dormant unless other ongoing activities are required by the MDSSG.

5. Duration of activity

Not applicable.

6. Rules of procedure

6.1. Responsibilities of chairperson and vice-chairperson

The chairperson, and in his/her absence the vice-chairperson, is responsible for the efficient conduct of the business of the working party and shall in particular:

- Plan the work of the Medical Device Shortages SPOC Working Party together with the EMA Secretariat;
- Monitor, together with the EMA Secretariat, that the rules of procedure are respected;
- Ensure that at the beginning of each meeting any potential conflict of interest is declared regarding any particular item to be discussed by the working party and, especially for virtual meetings, that all experts attending the meeting have declared their presence;
- Aim to achieve consensus on issues discussed by the working party;
- Ensure, together with the Medical Device Shortages SPOC Working Party and the EMA Secretariat, the regulatory and scientific consistency of the working party's recommendations;
- Co-ordinate together with the EMA Secretariat the work of the Medical Device Shortages SPOC Working Party with that of other relevant Committees/Working Parties of the Agency;

- Report on the activities of the Medical Device Shortages SPOC Working Party to the MDSSG and Committees as appropriate.

The vice-chairperson will deputise for the chairperson when the latter is unable to chair either all or part of the working party meeting. On such occasions the chairperson will seek the agreement of the vice-chairperson as early as possible, prior to the meeting and the EMA Secretariat shall be informed immediately.

6.2. Chairperson and rotating vice-chairperson

Meetings will be chaired by a representative of EMA, the Head of Supply and Availability of Medicines and Devices Service, who is the Chairperson of the working party.

The vice-chairperson will rotate taking into account the presidency of the Council of the EU, which rotates among the EU member states every 6 months. During a 6-month period, the NCA SPOC of the EU country who presides the Council of the EU, will deputise for the EMA chairperson to ensure the continuity of the working party's work.

6.3. Organisation of meetings and reporting arrangements

- During a declared public health emergency, the Medical Device Shortages SPOC Working Party shall meet regularly in virtual format, where members and experts participate through a remote connection. Face-to-face meetings shall take place at least once every year.
- The meetings will be held and minuted in English.
- The draft agenda and minutes for every meeting shall be circulated, together with the related documents, by the EMA Secretariat, in consultation with the chairperson, before the meeting and no later than 1 week before plenary meeting takes place.
- When a member of the Medical Device Shortages SPOC Working Party is unable to participate in a meeting, part of meeting, or discussion topic due to a conflict of interest, he/she must inform the EMA Secretariat in advance in writing.
- Any recommendation from the working party shall be transmitted to the MDSSG for adoption.
- When considered appropriate by the Medical Device Shortages SPOC Working Party, oral presentations by relevant economic operators (medical device manufacturers, importers, distributors, authorized representatives) and/or pharmaceutical companies can be made during working party meetings on matters directly related to the activities of the working party.
- The chairperson and rotating vice-chairperson will be invited to attend plenary MDSSG meetings to report on the activities of the working party and ensure liaison with the work of the MDSSG.
- The mandate of the Medical Device Shortages SPOC Working Party shall be agreed by the MDSSG. It shall be reviewed where and when needed.

6.4. Drafting groups

When further consideration is required in order to prepare proposals on specific topics, the Medical Device Shortages SPOC Working Party may convene drafting groups constituting of members of the working party or experts, as appropriate.

Drafting groups will report to the working party in direct line.

6.5. Participation of experts in meetings

When necessary, the working party may invite experts in specific scientific or technical fields. Such experts shall have proven experience in their field of expertise and be included in the European experts list. Where appropriate, members from patient organisations or health care professionals may act as experts. The names of these experts shall be notified to the EMA Secretariat before the meeting which they are due to attend.

6.6. Guarantees of independence

The members of the Medical Device Shortages SPOC Working Party and experts shall not have any direct interests in a medical device company or the pharmaceutical industry, which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of interests. The Declarations of Interests of the working party's members and experts shall be made available on the Agency's website.

Members of the working party and experts attending these meetings shall declare at the beginning of each meeting any specific interest, which has not yet been declared or which could be considered to be prejudicial to their independence with respect to the points of the agenda. These declarations shall be recorded in the minutes of the meeting.

The specific provisions for handling Declarations of Interests and confidentiality undertakings as defined in the European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts (EMA/626261/2014) are applicable to members of the Medical Device Shortages SPOC Working Party and experts involved in working party activities.

6.7. Code of conduct

Members of the Medical Device Shortages SPOC Working Party and experts involved in working party's activities shall abide by the principles set out in the 'EMA Code of Conduct' (EMA/385894/2012).

6.8. Transparency

The Agency shall, via a dedicated space on its website and other appropriate means, in conjunction with national competent authorities, inform the public and interest groups in a timely manner with regard to the work of the Medical Device Shortages SPOC Working Party.

Proceedings undertaken by the Medical Device Shortages SPOC Working Party shall be transparent. The rules of procedure shall be documented and made publicly available on the dedicated space on the Agency website.

6.9. EMA Secretariat

Under the authority of the Executive Director, the EMA Secretariat shall provide technical, scientific and administrative support to the working party. This includes the following:

- Provide technical and scientific support to the NCA SPOCs;
- Provide legal, regulatory and scientific support to the Medical Device Shortages SPOC Working Party;
- Prepare and co-ordinate the work of the Medical Device Shortages SPOC Working Party in consultation with the EMA Chairperson;

- Organise meetings of the working party ensuring timely circulation of meeting documents;
- Facilitate the necessary contacts between the Medical Device Shortages SPOC Working Party, MDSSG and other concerned scientific committees/ working parties;
- Ensure adequate co-ordination of the work carried out within the Medical Device Shortages SPOC Working Party, the MDSSG, the EMA scientific committees and other concerned working parties ;
- Contribute to the overall quality assurance and assurance of scientific and regulatory consistency of the documents/recommendations of the working party in cooperation with the chairperson or vice-chairperson, as appropriate;
- Prepare the agenda, minutes of the working party meetings in consultation with the EMA Chairperson;
- Communicate when necessary any MDSSG recommendations relevant to the Medical Device Shortages SPOC Working Party to interested parties;

The Executive Director of the Agency, members of the EMA Secretariat and representatives of the European Commission may attend all meetings of the Medical Device Shortages SPOC Working Party.

6.10. General Provisions

The members of the Medical Device Shortages SPOC Working Party as well as observers and all experts shall be bound, even after the cessation of their duties, not to disclose any information, which, by its nature, must be covered by professional secrecy.

When participating in international or other fora on behalf of the Medical Device Shortages SPOC Working Party, members shall ensure that the views expressed are those of the working party.

When participating in international or other fora not specifically on behalf of the working party, members shall make clear that the views expressed are their own views and not those of the Medical Device Shortages SPOC Working Party.