EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Mandate, objectives and rules of procedure for the Medicine 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 medicinal products **for human use** considered as critical to address a given 'public health emergency'[2] or other 'major events'[3] 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.

According to the Medicines Shortages Steering Group (MSSG) rules of procedure, the MSSG 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 Points of Contact (SPOCs) related to shortages from National Competent Authorities (NCAs) for medicinal products (hereafter referred to as 'Medicine Shortages SPOC Working Party' or 'the working party').

The Medicine Shortages SPOC Working Party (formerly known as 'EU SPOC Network') was initially set up in 2019, as a deliverable of the joint HMA-EMA taskforce on the availability of authorised medicines (TF-AAM), to improve information-sharing on shortages and availability issues of medicines (of both human and veterinary use) between Member States, EMA and the European Commission. The legal mandate formalises the establishment of the EU SPOC Network as the Medicine Shortages SPOC Working Party. Although Regulation (EU) 2022/123 does not apply to veterinary medicines, the working party will continue their information-sharing activities for medicinal products **for veterinary use.**

The MSSG may consult its working party on any issue related to shortages of medicines. The tasks identified by the MSSG should be included in the work plan of the working party to be adopted by the MSSG. The Medicine Shortages SPOC Working Party is therefore established to provide recommendations to the MSSG on all matters relating to monitoring and management of shortages and

[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
[3] '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.

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availability issues in peace-time and during 'public health emergencies' and 'major events', and to perform the tasks described under section 2.

2. Mandate and objectives

The Medicine Shortages SPOC Working Party is established to provide recommendations to the MSSG on all matters relating directly or indirectly to shortages or availability issues of medicinal products (for both human and veterinary use) during 'public health emergencies', 'major events' and under normal circumstances including, but not limited to, the tasks defined below:

Responsibilities under 'Public health emergencies' and 'major events' (only medicinal products for human use)

a) Monitor any event that is likely to lead to a 'major event' or a 'public health emergency';

b) Report in a timely manner to the Agency on any event including an "actual" or "potential" shortage of a medicinal product in a given Member State that is likely to lead to a 'major event' or a 'public health emergency', based on the agreed reporting criteria;

c) At the request of the MSSG, and within 6 months after the entry into force of the Regulation, develop a list with the main 'therapeutic groups' of medicinal products for ensuring emergency care, surgeries and intensive care, with a view to inform the preparation of the critical medicines lists, to respond to a 'public health emergency' or 'major event';

d) At the request of the MSSG, and using the defined/ agreed list of main therapeutic groups as a basis, develop 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') to be adopted by the MSSG. The lists shall be updated whenever necessary until the 'major event' has been sufficiently addressed, or until the end of the 'public health emergency';

e) Submit to the Agency estimated data on volume of demand including demand forecasts of medicinal products included on the lists referred above ('critical medicines lists'), based on the set of information required and adopted by the MSSG 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;

f) Gather relevant information and data, including on stock levels or on any logistical challenges in the wholesale supply chain, from wholesale distributors and other legal entities and persons authorised or entitled to supply the public with medicinal products included on the critical medicines lists, where necessary to fulfil reporting obligations set out above;

g) Where Member States are in possession of any additional information on volume of sales and volumes of prescriptions, including data based on Article 23a of Directive 2001/83/EC, which provides evidence of a potential or actual shortage of a medicinal product included on the critical medicines lists, they shall immediately provide such information to the MSSG;

h) 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 MSSG 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 MSSG.

Additional responsibilities under normal circumstances (medicinal products for human and veterinary use)

i) Report to the Agency a critical shortage of a medicinal product in a given Member State based on the agreed reporting criteria;

j) For critical shortages as identified in i), and following the request of an individual Member State, report to the Agency the availability of alternative medicinal products, which could help mitigate shortages in that same or other affected EU/EEA countries;

k) At the request of the Committees/Co-ordination Groups for the Mutual recognition and Decentralised procedure and working parties/working groups, provision of information on general and product specific matters related to shortages or availability issues;

l) Provide support to the preparation, review and update of guidance documents at the request of TF-AAM;

m) Setting up of drafting groups;

n) Focus and catalyst for regulatory training on shortages or availability issues in the European Medicines Regulatory Network (EMRN). Contribution to shortages related workshops and training;

o) Advice to the European Commission on shortage related issues;

p) International cooperation on shortage related matters.

3. Composition and rules of participation

The Medicine Shortages SPOC Working Party is comprised of single points of contacts for shortages from national competent authorities for medicinal products.

All EU/EEA NCAs are invited to nominate one expert to be member of the working party (one member per NCA).

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.

A member may 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 SPOC WP meetings.

The Chairperson of the working party is the EMA Head of Supply and Availability of Medicines and Devices Service. 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 Medicine Shortages SPOC Working Party shall meet up to 11 times per year (virtually or face-to-face) in accordance with the adopted work plan. The dates of the meetings shall be included in the work plan of 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 approximately 6 times a year per topic or in the margins of plenary meetings to complement the Medicine Shortages SPOC Working Party working procedures.

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 Medicine 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 Medicine 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 Medicine Shortages SPOC Working Party with that of other relevant Committees/Working Parties of the Agency;
- Report on the activities of the Medicine Shortages SPOC Working Party to the MSSG 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

- The Medicine 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 Medicine 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 MSSG or relevant Committee for adoption.
- When considered appropriate by the Medicine Shortages SPOC Working Party, oral presentations by pharmaceutical companies can be made during working party meetings on matters directly related to the activities of the working party.
- The Medicine Shortages SPOC Working Party shall prepare an annual work plan for adoption by the MSSG, which shall include topics identified in accordance with point 2 above and any specific tasks identified by the MSSG. The work plan shall be regularly reviewed and updated as necessary with the agreement of the MSSG.
- The chairperson and rotating vice-chairperson will be invited to attend plenary MSSG meetings to report on the activities of the working party and ensure liaison with the work of the MSSG.
- The mandate of the Medicine Shortages SPOC Working Party shall be agreed by the MSSG. 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 Medicine 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 Medicine Shortages SPOC Working Party and experts shall not have any direct interests in 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 Medicine Shortages SPOC Working Party and experts involved in working party activities.

6.7. Code of conduct

Members of the Medicine 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 Medicine Shortages SPOC Working Party.

Proceedings undertaken by the Medicine Shortages SPOC Working Party shall be transparent. The rules of procedure and the work plan 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 Medicine Shortages SPOC Working Party;
- Prepare and co-ordinate the work of the Medicine 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 Medicine Shortages SPOC Working Party, MSSG and other concerned scientific committees/ working parties;

- Ensure adequate co-ordination of the work carried out within the Medicine Shortages SPOC Working Party, the MSSG, 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 MSSG recommendations relevant to the Medicine 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 Medicine Shortages SPOC Working Party.

6.10. Contacts with interested parties

During 'Public health emergencies' and 'major events'

Meetings with interested parties are held by the MSSG, as foreseen in the legislation.

Under normal circumstances

Where relevant, the Medicine Shortages SPOC Working Party will establish contacts, on an advisory basis, with parties concerned with the use of medicinal products, in particular patient organisations, healthcare professionals' associations or other interested parties. Draft guidelines and general regulatory developments will be subject to public consultation of all interested parties (industry, health care professionals, patients/consumers or other). The working party may also meet with interested parties to discuss general matters or specific shortage issues. The Medicine Shortages SPOC Working Party shall neither conduct any deliberations nor reach any formal decisions in the presence of interested parties.

Before any consultation session, interested party representatives and working party members will communicate to the EMA Secretariat the points they would like to be discussed, so that an agenda of the session can be prepared for agreement by the Medicine Shortages SPOC Working Party Chairperson and circulated by the EMA Secretariat.

6.11. General Provisions

The members of the Medicine 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 Medicine 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 Medicine Shortages SPOC Working Party.