7 April 2022
EMA/41493/2022

Executive Steering Group on Shortages and Safety of Medicinal Products

Rules of Procedure

1. General Considerations

Regulation (EU) 2022/123[1] provides a framework for activities to be deployed by the Agency in preparation for and during public health emergencies and other major events to enhance the Union's capacity to react quickly, efficiently, and in a coordinated manner to such emergencies (hereinafter referred to as "the Regulation"). It foresees a reinforced role for EMA in crisis preparedness and management for medicinal products and medical devices. The Regulation builds on experience from the COVID-19 pandemic and on *ad hoc* solutions established during the pandemic such as the *EU Executive Steering Group on shortages caused by major events*[2], as well as the management of previous major events in the context of the established incident management plan. As part of the incident management plan, the Incident Review Network (IRN) for medicines for human use was developed. This structure is used to continuously monitor events and new information, to review their public health impact and to take the necessary routine measures to remedy the situation. The IRN will continue its activities taking into account the new management structure of the Executive Steering Group on Shortages and Safety of Medicinal Products (Medicines Shortages Steering Group-MSSG) established by this Regulation. This means that IRN activities linked to the proactive incident management will continue; while the reactive incident management will be replaced by the MSSG.

One of the objectives of the Regulation is to monitor and mitigate potential and actual shortages of medicinal products considered critical in order to address a given public health emergency or other major event(s) which may have a serious impact on public health. For this purpose, an executive steering group, the MSSG, is established within the Agency to ensure a robust response to major events and/or public health emergencies, and to coordinate urgent actions within the Union in relation to the supply of medicinal products.

The operational phase of the work of the MSSG provided for in this Regulation will be triggered by the recognition of a public health emergency or the recognition of a major event.

Article 2 of the Regulation defines "major event" as 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

[1] 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
[2] EU Executive Steering Group on shortages caused by major events

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.

A "Public health emergency" is defined as a public health emergency recognised by the European Commission in accordance with Decision No 1082/2013/EU[3]

2. Roles and responsibilities

The role of the MSSG is to ensure a robust response to major events/public health emergencies, and to coordinate urgent actions within the Union in relation to the management of issues relating to the supply of medicinal products or those related to the quality, safety and efficacy of medicinal products.

The mandate of the MSSG is to fulfil the tasks referred to in Article 4(3), Article 4(4) and Articles 5 to 8 of the Regulation.

The MSSG may consult with the Committee for Medicinal Products for Veterinary Use (CVMP) whenever necessary to deal with public health emergencies and major events related to zoonoses or diseases affecting only animals that have or may have a major impact on human health, or where the use of active ingredients of veterinary medicinal products may be useful to address the public health emergency or the major event, or otherwise whenever necessary. For major events and/or public health emergencies the MSSG may consult the EMA scientific Committees, their working parties, other expert groups including the Emergency Task Force (ETF) and/or the CMDx.

The monitoring of the safety, quality and efficacy issues will be carried out using current systems already in place such as the Quality Defect Rapid Alert System (RAS) or the Pharmacovigilance Rapid Alert (RA) and Non-Urgent Information (NUI) Systems. Where the EMA considers that an actual or imminent major event needs to be addressed, this will be escalated to the MSSG, via the IRN or the EU Medicine Shortages Single Point of Contact (SPOC) Working Party, for a positive opinion of the MSSG, Commission's recognition of the major event and trigger of actions foreseen in the Regulation. The European Commission or at least one Member State may also raise the issue of concern to the MSSG on their own initiative.

[3] DECISION No 1082/2013/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC

The Executive Steering Group on Shortages and Safety of Medicinal Products

Having regard to Article 3(1) of Regulation (EC) No 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

Having received a favourable opinion from the Commission and the Management Board of the Agency on the basis of Article 3(5) of Regulation (EC) No 2022/123;

Adopts the following rules of procedure:

COMPOSITION

Article 1 - Members

1. The MSSG is composed of a representative of the Agency, a representative of the Commission and one representative per Member State.
2. The representative appointed by Member States are eligible to vote and should be able to make decisions on behalf of that Member State in a timely manner, even during the meeting.
3. The MSSG includes one observer of each EEA-EFTA state.
4. A representative of the Agency's Patients' and Consumers' Working Party ('PCWP') and a representative of the Agency's Healthcare Professionals' Working Party ('HCPWP') may attend meetings of the MSSG as observers.
5. Members and observers shall be appointed for a term of 3 years, which may be renewed.

Article 2 – (Co)-Chairs

1. The MSSG shall be co-chaired by the Agency and by a representative of a Member State elected by and amongst its members for a period of three years, renewable once.
2. The Co-Chairs are responsible for:
    - the efficient conduct of the business of the MSSG;
    - 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 item to be discussed by the MSSG;
    - decide when a vote is necessary.
3. Nominations for Co-Chair shall be submitted in writing to the EMA secretariat no later than the start of the MSSG meeting at which the election is to take place.
4. Candidates shall submit a brief résumé in support of their candidature at the time of the nomination.
5. The election shall be by absolute majority of the MSSG members and by secret ballot. At each round, the candidate(s) with the lowest number of favourable votes shall withdraw. If there is a tie amongst the candidates with the lowest number of votes, all tied candidates are eliminated, and a further voting round is organised with the remaining candidate(s) only. In the case of a tie when only two candidates remain, a new voting round is organised with these two remaining candidates. If, during the new round, the candidate with the highest number of votes does not get an absolute majority, a further voting round is organised with this candidate only. If there is only one

(remaining) candidate, she/he needs favourable votes from more than half of the total number of MSSG members eligible to vote, to be elected Co-Chair, as the case may be. If the remaining candidate(s) do(es) not get an absolute majority, the election is annulled, and a new election is convened for the next scheduled meeting of the MSSG following the same procedure as stated.

Article 3 –Participation of experts and observers in meetings

1. Members may be accompanied by experts in specific scientific or technical fields.
2. When necessary, the MSSG may invite experts from the European expert list in specific scientific or technical fields, as appropriate.
3. The chairperson and vice-Chair of the Medicine Shortages SPOC Working Party will be invited to attend the plenary meetings of the MSSG to report on its activities.
4. The Co-Chairs may, on their own initiative, or following a request from one or more members, invite the following representatives to meetings of the MSSG, as observers and to provide expert advice:
    - representatives of national competent authorities for medicinal products for veterinary use;
    - representatives of other relevant competent authorities and third parties, including representatives of medicinal product interest groups;
    - representatives of marketing authorisation holders, wholesale distributors, any other appropriate actors in the pharmaceutical supply chain;
    - representatives of healthcare professionals' associations and patients and consumers organisations.
5. Representatives from EMA scientific Committees, their working parties, other expert groups including the ETF and the CMDh may be invited to attend meetings and provide expert input as needed.
6. Observers from international organisations and/or non-EU regulatory authorities may be invited to attend specific parts of meetings if deemed necessary. Before attending the meeting those observers will sign a confidentiality undertaking form.
7. The decision to invite the aforementioned additional participants is taken by the Co-Chairs, following consultation with the members through the EMA secretariat.
8. The names of additional experts and observers shall be notified to the EMA Secretariat before the meeting.
9. All experts participating in meetings shall have proven experience in their field of expertise and be included in the European expert list. This is also applicable for any experts attending a meeting virtually via telephone/web links.

Article 4 – Recommendations

1. The quorum required for the adoption of recommendations by the MSSG shall be reached when an absolute majority of the members of the MSSG is present (i.e. more than half of the total number of members eligible to vote), either directly (in person or remotely) or by nominated proxy.

2. A member of the MSSG, may represent only one other member, when this member is unable to participate in a meeting. The member that is being represented shall inform the MSSG Secretariat in advance.

3. Whenever possible, recommendations of the MSSG shall be taken by consensus. If such a consensus cannot be reached, the recommendation will be adopted if supported by an absolute majority of the members of the MSSG (i.e. favourable votes by more than half of the total number of MSSG members eligible to vote). Divergent views shall be recorded.

4. The votes shall be positive or negative (unless the provision concerning the conflicts of interest is applied).

5. In the event of no absolute majority position in favour of the recommendation, the MSSG's opinion is deemed to be negative.

Article 5 – Organisation of meetings and reporting arrangements

1. The MSSG shall meet regularly and in addition, whenever the situation requires, either in person or remotely, in preparation for or during a public health emergency, major event or following a request for assistance referred to in Article 4(3) of the Regulation.

2. Meetings may have to be convened at short notice depending on the urgency of the matter and will preferably be held as virtual meetings.

3. In case of extreme urgency, it will be possible to request the opinion of the MSSG via written procedure. In these cases, the opinion shall be submitted by the EMA Secretariat to the MSSG for adoption by written procedure within a specified time period for replies, to be established in agreement with the Co-Chairs according to the urgency.

4. In agreement with the Co-Chairs, joint meetings of the Medicines and Medical Devices Steering Shortages Group may be held.

5. The meetings will be held and minuted in English.

6. The draft agenda and minutes for every meeting shall be circulated, together with the related documents, by the EMA Secretariat, in consultation with the Co-Chairs, before the meeting. For meetings planned in advance, the MSSG Secretariat will circulate the information a few days ahead of the meeting, for urgent ad-hoc meetings the information will be circulated as soon as possible. Minutes may be approved via written procedure.

7. When a member of the MSSG 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.

8. When considered appropriate by MSSG, oral presentations by pharmaceutical companies can be made during meetings.

9. In order to cope with situations of emergency, possibly coupled with the activation of the Agency's Business Continuity Plan in compliance with internal guidelines, the following rules shall apply:

    9.1. In case of in-person meetings, members who are prevented from participating in person, can participate through a remote connection.

    9.2. Members connected remotely can cast their votes remotely. In case a member of the MSSG temporarily faces difficulties to connect remotely, it is acceptable that his/her vote is cast via email to be sent before the voting is closed. In this latter scenario, the email must

clearly indicate the member who is casting the vote and the matter that is being voted upon, as well as the vote cast (against or in favour).

For transparency reasons, the vote cast by email shall be brought immediately to the attention of the Co-Chairs and other members of the MSSG.

Article 6 – Working parties

1. Where the major event or public health emergency may lead to shortages of medicinal products in more than one Member State, the MSSG shall be supported in its work by a working party comprised of single points of contact related to shortages from national competent authorities for medicinal products, the so-called Medicine Shortages SPOC Working Party.
2. The Rules of Procedure of the Medicine Shortages SPOC Working Party shall be agreed by the MSSG, it shall be reviewed where and when needed. The MSSG will also endorse the annual work plan of the Medicine Shortages SPOC working party.
3. For major events related to the efficacy, safety or quality of medicinal products, the work of the MSSG will be supported by EMA scientific committees, their working parties, expert groups and/or CMDx.
4. The MSSG may set up Ad-hoc Drafting Groups composed of multidisciplinary experts according to the tasks assigned to support the work of the MSSG.
5. Whenever considered appropriate the MSSG shall consult its working parties on any scientific issue related to their specific fields of expertise or other Scientific Committees of the EMA, their working parties, expert groups and/or the CMDx.

Article 7 – Guarantees of independence

1. Members of the MSSG, experts and observers shall not have any direct interests in the pharmaceutical industry, which could affect their independence and impartiality. They shall act in the public interest and in an independent manner and shall make an annual declaration of interests or when a new interest arises. The Declarations of Interest of the members of the MSSG shall be made available on the EMA's website.
2. Members of the MSSG, experts and observers attending their 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 or impartiality with respect to the items on the agenda. These declarations shall be recorded in the minutes of the meeting.
3. 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)[4] are applicable to members of the MSSG and experts involved in their activities.

Article 8 – Code of conduct

1. Members of the MSSG and experts shall abide by the principles set out in the EMA Code of Conduct (EMA/385894/2012)[5].

[4] European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts (EMA/626261/2014)
[5] The European Medicines Agency Code of Conduct

Article 9 – Transparency

1. Proceedings undertaken by the MSSG shall be transparent.
2. 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 MSSG.
3. The following information will be made publicly available on the dedicated space on the Agency webpage:
    - The list of members of the MSSG, summaries of the agenda and the minutes of the MSSG, and their rules of procedure;
    - The recommendations, guidelines and measures taken at Union level and a summary report of the lessons learned;
    - The lists of critical medicinal products, their updates and the set of information required to monitor the supply of and demand for medicinal products.
4. The MSSG shall make any divergent opinions, and the grounds on which they are based, available to national competent authorities upon their request.

Article 10 –EMA Secretariat

1. Under the authority of the Executive Director, the EMA will provide technical, scientific and administrative support to the MSSG and its working party. This includes the following, among others:
    - Provide technical, scientific, regulatory and legal support to the MSSG;
    - Prepare and co-ordinate the work of the MSSG and its Working Parties in consultation with the Co-Chairs;
    - Organise meetings of the MSSG ensuring timely circulation of meeting documents;
    - Liaise with the Health Security Committee and any other relevant advisory committee on public health emergencies established pursuant to Union law;
    - Ensure cooperation with the ECDC and other Union bodies, where relevant;
    - Ensure adequate coordination with the EMA scientific committees, including the CVMP (where the public health emergency or major event related to zoonoses or diseases affecting only animals that have or may have a major impact on human health), their working parties, other expert groups including the ETF and/or the CMDx;
    - Inform the Medicine Shortages SPOC Working Party about the set of information agreed by the MSSG that is necessary to monitor the supply of and demand for medicinal products included on the lists of critical products.
    - Ensure adequate coordination with the secretariat of the IRN.
    - Ensure adequate coordination with the Medical Devices Shortages Steering Group;
    - Facilitate appropriate communication with marketing authorisation holders or their representatives, manufacturers, other relevant actors of the pharmaceutical supply chain, and representatives of healthcare professionals and patients and consumers.

- Contribute to the overall quality assurance and assurance of scientific and regulatory consistency of the documents/recommendations of the MSSG in cooperation with the Co-Chairs, as appropriate;
- Prepare the agenda, minutes of the MSSG meetings in consultation with the Co-Chairs.
- Inform the Commission and the Executive Director of the Agency, once it is considered that the major event has been sufficiently addressed. On the basis of that information or on its own initiative, the Commission or the Executive Director may confirm that the assistance of the MSSG is no longer needed.
- Prepare and communicate relevant public information related to the activities of the MSSG and to publish on the Agency webpage the list of members of the MSSG, the summaries of the agenda and minutes and the rules of procedure and recommendations, where appropriate.

Article 11 –General Provisions

1. The members of the MSSG as well as observers and all experts shall be bound, even after the cessation of their duties, not to disclose any information relating to the work of the MSSG, which, by its nature, must be covered by professional secrecy.
2. When participating in international or other fora on behalf of the MSSG, members shall ensure that the views expressed are those of the MSSG.
3. When participating in international or other fora not specifically on behalf of the MSSG, members shall make clear that the views expressed are their own views and not those of the MSSG.
4. The decision to adopt or to amend these rules of procedure shall be taken by an absolute majority of the Members of the MSSG (i.e. favourable votes by more than half of the total number of MSSG members eligible to vote).
5. The rules of procedure or any amendment to them shall enter into force after receiving a favourable opinion from the Commission and the EMA Management Board and will be made publicly available.

Adopted by the Executive Steering Group on Shortages and Safety of Medicinal Products: 24 March 2022

Favourable Opinion of the European Commission: 7 April 2022

Favourable Opinion of the Agency Management Board: 7 April 2022