EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HE the Ambassador
Permanent Representation of Estonia
Rue Guimard 11–13
B-1040 Bruxelles
BELGIUM

8 December 2025
EMA/382319/2025
Executive Director

Your Excellency,

Subject: Nomination of a representative in the Executive Steering Group on Shortages of Medical Devices (MDSSG) of the European Medicines Agency (EMA)

In accordance with Regulation (EU) 2022/123, the European Medicines Agency's **Executive Steering Group on Shortages of Medical Devices**, the so-called 'Medical Device Shortages Steering Group (MDSSG)' was set up on 15 March 2023 within the Agency. According to the MDSSG Rules of Procedure, members and observers are appointed for a three-year mandate by EU member states and EEA-EFTA countries.

Currently there is no member nominated for Estonia and I invite you to nominate a representative from your country as a member for a three-year mandate.

In making the nominations, I would like to draw your attention to the need for the MDSSG members to be able to make decisions on behalf of their Member State in an urgent manner, even during meetings, to allow for timely and coordinated actions in the EU. For the rules of procedure of the MDSSG please refer to Annex I.

In addition, I would like to highlight to you that Article 31 of Regulation (EU) No 2022/123 requires the Agency to ensure that the Executive Steering Group on Shortages and Safety of Medicinal products (MSSG) and the MDSSG cooperate in relation to measures to address public health emergencies. Therefore, for Members States where the national competent authority is responsible for both medicines and medical devices, having the same nomination for the MDSSG as that of the MSSG will facilitate this cooperation.

I would also like to remind you of the policy in place at the Agency regarding the handling of competing interests of scientific committees' members and experts, which will also be applied to members of the MDSSG. For further details please use the following link (EMA Policy 0044 - Handling of competing interests). In making the nomination for your Member State, please ensure that the nominee is or will be included in the Agency's European experts list with a declaration of interests (DoI) and CV as this is a requirement before a member can be involved in the activities of the

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Executive Steering Group. The contact point for the Agency's Experts database in your Member State can be of assistance for this inclusion in the European experts list.

A copy of this letter will be shared with the head of the relevant competent authorities in your country.

Yours faithfully,

Emer Cooke

Digitally signed by Emer Cooke
Date: 2025.12.08 14:46:00
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Emer Cooke
Executive Director

Enc.:
Annex I
Rules of Procedure of the MDSSG

ANNEX I

06 April 2023
EMA/903042/2022

Executive Steering Group on Shortages of Medical Devices

Rules of Procedure

1. General Considerations

Regulation (EU) 2022/123[1] (hereinafter 'the Regulation') 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.

One of the objectives of the Regulation is to monitor and mitigate potential and actual shortages of medical devices considered critical in order to address a given public health emergency. For this purpose, the Executive Steering Group on Shortages of Medical Devices (MDSSG) is established within the Agency to ensure a robust response to public health emergencies and to coordinate urgent actions within the Union in relation to the supply of critical medical devices.

The operational phase of the work of the MDSSG provided for in the Regulation will be triggered by the recognition of a public health emergency.

Article 2(a) of the Regulation defines a "public health emergency" as a public health emergency recognised by the European Commission in accordance with Decision No 1082/2013/EU[3,4]

2. Roles and responsibilities

The role of the MDSSG is to ensure a robust response to public health emergencies and to coordinate urgent actions within the Union in relation to the management of issues relating to the supply of medical devices.

The mandate of the MDSSG is to fulfil the tasks referred to in Article 21 to 24 of the Regulation.

[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
[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
[4] Article 2(a) references to Article 12(1) of Decision No 1082/2013/EU, which has been replaced by Articles 23(1), (3) and (4) of the Regulation (EU) 2022/2371 on cross-border health threats (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)

For public health emergencies the MDSSG may consult the EMA scientific Committees, their working parties, the Emergency Task Force (ETF), expert groups and/or the CMDh, MDCG, ECDC, HSC and any other relevant advisory committee on public health emergencies established pursuant to Union law.
The Executive Steering Group on Shortages of Medical Devices

Having regard to Article 21(1) of Regulation (EU) 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 21(4) of Regulation (EU) No 2022/123;

Adopts the following rules of procedure:

COMPOSITION

Article 1 - Members

1. The MDSSG is composed of a representative of the Agency, a representative of the Commission and one representative per Member State.
2. The representatives appointed by Member States shall have expertise in the field of medical devices, as relevant.
3. The representatives 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.
4. The MDSSG includes one observer of each EEA-EFTA state.
5. 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 MDSSG as observers.
6. Members and observers shall be appointed for a term of 3 years, which may be renewed.

Article 2 – (Co)-Chairs

1. The MDSSG shall be co-chaired by the representative of the Agency and by a representative of a Member State elected by and amongst the representatives of the Member States for a period of three years, renewable once.
2. The Co-Chairs are responsible for:
    - the efficient conduct of the business of the MDSSG;
    - 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 MDSSG;
    - 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 MDSSG 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 MDSSG 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 MDSSG 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 MDSSG 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 MDSSG may invite experts from the European expert list in specific scientific or technical fields, as appropriate.
3. The chairperson and vice-Chair of the Medical Device Shortages SPOC Working Party will be invited to attend the plenary meetings of the MDSSG to report on its activities.
4. The co-chairs may, on their own initiative, or following a request from one or more members, invite as observers and to provide expert advice:
    - representatives of medical device interest groups, such as representatives of manufacturers and notified bodies;
    - representatives of any other relevant actor in the supply chain for medical devices;
    - representatives of healthcare professionals' associations and patients and consumers organisations.
5. Representatives from EMA scientific Committees, their working parties, the ETF, expert groups, CMDh, MDCG, ECDC, the HSC and any other relevant advisory committee on public health emergencies established pursuant to Union law, 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 MDSSG shall be reached when an absolute majority of the members of the MDSSG 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 MDSSG, 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 MDSSG Secretariat in advance.
3. Whenever possible, recommendations of the MDSSG 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 MDSSG (i.e. favourable votes by more than half of the total number of MDSSG 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 MDSSG's opinion is deemed to be negative.

Article 5 – Organisation of meetings and reporting arrangements

1. The MDSSG shall meet regularly and in addition, whenever the situation requires, either in person or remotely, during a public health emergency or following a request for assistance referred to in Article 21(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 MDSSG via written procedure. In these cases, the opinion shall be submitted by the EMA Secretariat to the MDSSG 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 previous meeting 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 MDSSG Secretariat will circulate relevant 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 MDSSG 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 MDSSG, oral presentations by medical device 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 MDSSG 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 MDSSG.

Article 6 – Working parties

1. Where the public health emergency may lead to shortages of medical devices in more than one Member State, the MDSSG shall be supported in its work by a working party comprised of single points of contact related to shortages from national competent authorities for medical devices, the so-called Medical Device Shortages SPOC Working Party.
2. The Rules of Procedure of the Medical Device Shortages SPOC Working Party shall be agreed by the MDSSG, it shall be reviewed where and when needed. The MDSSG will also endorse the annual work plan of the Medicine Shortages SPOC working party.
3. The MDSSG may set up Ad-hoc Drafting Groups composed of multidisciplinary experts according to the tasks assigned to support the work of the MDSSG.
4. Whenever considered appropriate the MDSSG 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, the CMDh, MDCG, ECDC, the HSC and any other relevant advisory committee on public health emergencies established pursuant to Union law and any other union agency.

Article 7 – Guarantees of independence

1. Members of the MDSSG, experts and observers shall not have any direct interests in the medical devices 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 MDSSG shall be made available on the EMA's website.
2. Members of the MDSSG, 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/136875/2022)[5] are applicable to members of the MDSSG and experts involved in their activities.

[5] Policy/0044 - European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts (europa.eu) (EMA/136875/2022)

Article 8 – Code of conduct

1. Members of the MDSSG and experts shall abide by the principles set out in the EMA Code of Conduct (EMA/385894/2012) [6].

Article 9 – Transparency

1. Proceedings undertaken by the MDSSG 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 MDSSG.
3. The following information will be made publicly available on the dedicated space on the Agency webpage:
    - The list of members of the MDSSG, summaries of the agenda and the minutes of the MDSSG, 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 medical devices, their updates and the set of information required to monitor the supply of and demand for medical devices.
4. The MDSSG 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 MDSSG and its working party. This includes the following, among others:
    - Provide technical, scientific, regulatory and legal support to the MDSSG;
    - Prepare and co-ordinate the work of the MDSSG and its Working Parties in consultation with the Co-Chairs;
    - Organise meetings of the MDSSG ensuring timely circulation of meeting documents;
    - Liaise with the Scientific Committees of the EMA, their working parties, expert groups, the CMDh, MDCG, ECDC, the HSC and any other relevant advisory committee on public health emergencies established pursuant to Union law and any other union agency;
    - Ensure cooperation with the ECDC and other Union bodies, where relevant;
    - Ensure adequate coordination with the Scientific Committees of the EMA, their working parties, expert groups, the CMDh, MDCG, ECDC, the HSC and any other relevant advisory committee on public health emergencies established pursuant to Union law;
    - Inform the Medical Device Shortages SPOC Working Party about the set of information agreed by the MDSSG that is necessary to monitor the supply of and demand for medical devices included on the lists of critical devices;
    - Ensure adequate coordination with the Medicine Shortages Steering Group;

[6] The European Medicines Agency Code of Conduct

- Facilitate appropriate communication with manufacturers of medical devices, or their authorised representatives, as applicable, and, if appropriate, importers, distributors, relevant notified bodies, and other relevant actors of the medical device 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 MDSSG in cooperation with the Co-Chairs, as appropriate;
- Prepare the agenda and minutes of the MDSSG meetings in consultation with the Co-Chairs;
- Prepare and communicate relevant public information related to the activities of the MDSSG and to publish on the Agency webpage the list of members of the MDSSG, 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 MDSSG 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 MDSSG, which, by its nature, must be covered by professional secrecy.
2. When participating in international or other fora on behalf of the MDSSG, members shall ensure that the views expressed are those of the MDSSG.
3. When participating in international or other fora not specifically on behalf of the MDSSG, members shall make clear that the views expressed are their own views and not those of the MDSSG.
4. The decision to adopt or to amend these rules of procedure shall be taken by an absolute majority of the Members of the MDSSG (i.e. favourable votes by more than half of the total number of MDSSG 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 of Medical Devices: 15 March 2023

Favourable Opinion of the European Commission: 03 April 2023

Favourable Opinion of the EMA Management Board: 06 April 2023