



21 July 2023
EMA/291443/2023

Minutes - Executive Steering Group on Shortages of Medical Devices (MDSSG)

19 June 2023, from 15:30 to 16:30 (CEST), WebEx

Co-Chairs: Emer Cooke (EMA) and Karl Broich (HMA)

Item	Topics
1.	<p>Welcome, declaration of interest and adoption of the agenda</p> <p>Co-Chairs welcomed the participants to the 2nd meeting of the Executive Steering Group on Shortages of Medical Devices (MDSSG).</p> <p>The MDSSG secretariat reviewed members and experts declared interests in accordance with the Agency's policy on handling of declarations of interests (DoI) of Scientific Committees' members and experts, applicable to members and experts of the MDSSG, and when not available in accordance with the EMA Management Board's policy on the handling of competing interests. The MDSSG Secretariat announced that no competing relevant interest for the meeting was identified.</p>
2.	<p>Minutes of the meeting of the MDSSG held on 15 March 2023 adopted by written procedure on 21 April 2023</p> <p>BfArM Co-Chair informed the MDSSG that the draft minutes of the meeting of the MDSSG held on 15 March 2023 were adopted by written procedure on 21 April 2023 with no comments received.</p>
3.	<p>Responsibilities of the MDSSG and the Medical Device Shortages Single Points of Contact (SPOC) Working Party & coordinated and complementary activities to be performed by EMA and DG HERA within a public health emergency (PHE)</p> <p>EMA and DG HERA presented their respective tasks in relation to monitoring and mitigating shortages of critical medical devices in the context of a PHE, as required by the Regulations (EU) 2022/123 and (EU) 2022/2372, respectively. The interaction between EMA, DG HERA and National Competent Authorities (NCAs), and other stakeholders were described.</p>
4.	<p>Medical Device (MD) Shortages SPOC Working Party (WP)</p> <p>a) Feedback from the meeting of the MD SPOC WP held on 31 May 2023</p> <p>EMA provided feedback from the first meeting of the MD-SPOC WP.</p>



Item	Topics
	<p>b) Rules of Procedure (RoP) of the Medical Device Shortages SPOC Working Party</p> <p>The RoP were adopted without comment/amendments. The document will be published on the EMA corporate website.</p>
5.	<p>Methodology for the establishment of the “public health emergency critical medical devices list”</p> <p>EMA informed the MDSSG that the document had been adopted by the Medical Device Shortages SPOC WP via written procedure on 7 June 2023. The document describes the methodology for the establishment of the list of critical medical devices in the case of a public health emergency.</p> <p>The methodology for the establishment of the “public health emergency critical medical devices list” was adopted by the MDSSG with the implementation of two comments raised during the meeting and will be published on the EMA corporate website.</p>
6.	<p>Overview of the IT development to support the implementation of the Regulation</p> <p>EMA provided an update on the current status of the development of the Critical Medical Device Shortages (CMDS) system. EMA started the development of CMDS in November 2022 and will finalise the minimum viable product (MVP) by early July 2023. This IT tool is an additional measure to enable a strengthened framework at the Union level for monitoring and reporting on shortages of critical medical devices during a PHE.</p>
7.	<p>AOB</p> <p>No points were raised.</p>

Next meeting: TBD

Note on access to documents

Some documents mentioned in the minutes cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).