



## Mandate, membership and working methodology for the EU Executive Steering Group

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EU Executive Steering Group on shortages of medicines caused by major events  
Agenda item 2  
4 March 2020



## EU Executive Steering Group on shortages of medicines caused by major events (1/4)

- In 2019 the EU Regulatory Medicines Network agreed to establish a dedicated managerial structure in case of a no deal Brexit scenario - the EU Executive Brexit Steering Group on Availability of Medicines
- As a result of the current COVID-19 infection which can have consequences for the supply of medicines, there is a need to also address supply shortages in this and other emerging situations in the most efficient way through a coordinated approach across the Network
- A dedicated structure for crisis management of medicines shortages is established, based on the existing EU Executive Brexit Steering Group on Availability of Medicines, but with a widening of the current scope to address other shortages due to major events
- The Steering Group will be composed of EC, Member States and EMA representatives, representing both the human and veterinary medicines field



## EU Executive Steering Group on shortages of medicines caused by major events (2/4)

- The role of the EU Executive Steering Group is to provide a strategic direction for an urgent and coordinated action within the Network to manage the risk of supply shortages in case of a crisis situation caused by major events by:
  - Steering, in a coordinated way, the process in case of potential supply shortages for human and veterinary medicines irrespective of their licensing route caused by major events, such as Brexit related supply shortages in a no-deal scenario at the end of the transition period, supply shortages stemming from the COVID-19 infection, including crisis communication
  - Dealing with any emerging issues, as escalated by EMA/CMDh/CMDv, by agreeing on the remedial action(s) to be undertaken
  - Agreeing on the content, timing and targeted audiences of any crisis communication
  - Overseeing the implementation of its agreed actions to be implemented by EMA in collaboration with CHMP/CVMP (for CAPs), and by CMDh/CMDv (for NAPs)
- Steering Group will not deal with more “routine” supply shortages and reports to the Pharmaceutical Committee, EMA MB and HMA



## EU Executive Steering Group on shortages of medicines caused by major events (3/4)

- Membership of the Steering Group is as follows:
  - Chair: EC representative
  - EC membership: 3 EC representatives
  - Member States membership : 7 representatives, including 1 alternate, nominated by the HMA Management Group (MG)
  - EMA membership: 3 representatives
  - CMDh Chair
  - CMDv Chair
  - Specialists in (crisis) communication: 1 representative from respectively HMA, EMA and EC



## EU Executive Steering Group on shortages of medicines caused by major events (4/4)

- Working methodology (adapted to the current situation):
  - Virtual meetings held on a weekly basis
  - *Ad hoc* meetings if considered necessary, agreed at short notice
  - Items for discussion can be proposed by any member
  - Secretariat will be provided by EMA 5.1.2e
  - Action list will be circulated after each meeting by the Secretariat