

Shortages of medicine Statement Discussion with the Group of Experts

Friday 4 June

12:30 - 13:30 CET

## Key stakeholders' position

FEAM
Federation of European
Academies of Medicine

- Medicines supply chain stakeholders, early 2017
- French Academy of Pharmaceutical Sciences, Report on "Unavailability of drug", 2018
- World Health Assembly, Call for addressing the global shortage of, and access to, medicines and vaccines in a coordinated manner at global level, Jan 2018
- European Association of Hospital Pharmacists (EAHP) together with 30
   national and European associations of patients, consumers, healthcare
   professionals and public health, request investigation starts on leading factors,
   May 2019
- Recurrent surveys from EAHP and the Pharmaceutical Group of the EU to document the issue

## Key EU documents and next steps



- EU Parliament Resolution, Shortage of medicines how to address an emerging problem, Sept. 2020
- EU Council Conclusion, Oct 2020
- EU Pharmaceutical Strategy; Nov 2020
- Proposal to extend the European Medicines Agency mandate, Nov 2020
- External study commissioned by the EU Commission to Technopolis;
   map root causes and assess the existing legislative framework
- EU Legislative proposal on Shortages of medicine planned for 2022

## Main points of FEAM draft statement

- Promote a pan-European approach to medicines shortages; Reliable information on shortages of European medicines is lacking.
- Install a consultation process to find common solutions to shortages of medicines by involving all stakeholders. A common European definition of shortages is needed to be able to assess the problem in a similar way across the 27 Member states and to collect data that are comparable and interoperable.
- FEAM encourages national agencies to increase their cooperation with the EMA and the European Directorate for the Quality of Medicines & HealthCare of the Council of Europe (European Pharmacopoeia) to make databases interoperable. A first pilot project could be developed and initiated by these agencies, financed at European level in order to be rapidly operational.
- Support the legislative proposal to reinforce EMA mandate
- Promote equal health access globally and avoid any unintended consequences of action taken at EU level on other actors in the world. While reducing occurrences of medicine shortages in Europe, this should not happen at the expense of other parts in the world and unintended consequences should be avoided.

## Discussion questions

- Do you have any national report, especially from your Academy on this topic that we could refer to?
- Have you been in contact with your national authorities about this topic?
- Have you been in contact with stakeholder on this issue at national level? (Associations, pharmaceutical industry, member of parliament...)
- Are you aware of national action plan on this subject?
- Do you have any particular view on the need for a common definition on shortages of medicines at European or global level?
- Do you have any particular view on what solutions could be found at European level to tackle shortages of medicine? If yes, what should be prioritized?