

Concluding remarks and next steps

HMA/EMA workshop on availability of authorised medicines, 9 November 2018

Availability of medicines is a national, European and global matter

- **Significant impact on public health** and contributes to **health inequalities**
- Longstanding problem; there are **no quick solutions but firm steps are being taken**
- **Multi-factorial issue** that must be tackled in close collaboration with all stakeholders
- Need to **identify all the factors** to have a complete overall picture **and identify in which framework they have to be addressed and discussed**

Availability of medicines is a national, European and global matter

- Call for further **harmonisation, simplification of reporting and improved communication**
- Acknowledge the **important role of pharmaceutical industry** in the prevention and management of medicines availability issues
- Recognise there are specific aspects that will require national, European and global **action by regulators AND stakeholders**
- Stakeholder's perspectives on how to address availability issues have provided rich **input to be reflected into the deliverables of the Task Force**

Impact of Brexit on medicines availability

- Working on the **assumption that UK will become a third country** after 29 March 2019
- **Centrally authorised medicines (CAPs)**: fewer medicines affected but situation as regards possible alternatives can be more difficult to address; EMA is closely monitoring CAPs considered critical and evaluating potential mitigation measures to minimise any disruptions in supply
- **Nationally authorised medicines (NAPs)**: large volume of medicines affected; working on alternatives at national level
- **Veterinary medicines (VMPs)**: face similar issues as human use medicines
- **Pragmatism, preparedness and communication are key**

Addressing shortages caused by supply chain disruption

- Progress towards EU-wide shortage definition is needed to improve reporting and further develop metrics
- Important steps to improve reporting:
 - More information around available alternatives
 - Reporting system open to all supply chain actors
 - Further explore how to incorporate healthcare professionals and patients in the reporting process
 - Single portal for reporting
- Specific feedback from stakeholders to be provided

Communication – improving access to information on availability issues

- Most EU/EEA authorities already publish information on shortages however current public communication practices can benefit from:
 - More harmonisation
 - Better coordination across the network
 - Higher visibility and accessibility of the information by patients and healthcare professionals
 - A multidisciplinary approach within agencies and more interaction with target audiences

Communication – improving access to information on availability issues

- In addition,
 - information sharing within the EU network should be improved
 - access to guidance on reporting, management and communication of shortages to be facilitated through the EU Regulator's manual

Next steps

- Proposals have been presented
- Need to be discussed further by the TFAAM and all MSs
- Additional input from stakeholders will be sought after through targeted consultations
- Any comments on the workshop welcome to the secretariat
(AAMTFSecretariat@ema.europa.eu)
- A high-level meeting report will be published on the EMA and HMA websites
- EMA/HMA/EC will provide regular updates on the work of the TFAAM and will consult as needed