6.1. Update on ongoing work on availability of authorised medicines

PCWP and HCPWP joint meeting
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EMA / HMA collaboration on shortages and availability of medicines – progress since April 2018 (1 / 2)

The **EMA-HMA Task Force on Availability of Authorised Medicines** and its **3 thematic working groups** (i.e. 1: Marketing of authorized medicinal products, 2: Supply Chain Disruption and 3: Communication) have met regularly, including face-to-face (June 2018) to agree on the first drafts of a number of deliverables.

Thematic Working Group 2 - Supply Chain Disruption has developed the following drafts:

- **Definition** of medicine shortage
- **Guidance** for Marketing Authorisation Holders on **reporting requirements**
- **Metrics** that could be used to measure shortages

EMA/HMA collaboration on shortages and availability of medicines – progress since April 2018 (2/2)

- In **August 2018**, the EMA-HMA Task Force published its work programme for the coming two years.
- A face-to-face **technical meeting** is scheduled for **8 November 2018** where industry stakeholders will be invited to join regulators (i.e. EMA, European Commission and EU competent authorities) with a view to gathering technical feedback on the deliverables of the Task Force.

A report from previous day will be provided

- The technical meeting will precede a **multi-stakeholder workshop** scheduled for **9 November 2018** where industry stakeholders, **healthcare professionals**, **patients/consumers** and academia/NGOs will be invited to join regulators with a view to gathering multi-stakeholders' perspectives on the work of the Task Force and discuss how these can contribute to its deliverables.

Scope of EMA / HMA technical meeting on 8 November 2018

The agenda is divided into **5 sessions**:

- Session 1: Availability of authorised medicines – current regulatory landscape
- Session 2: Implementing best practices already developed for shortage prevention
- Session 3: Impact of Brexit on medicines availability
- Session 4: Building on best practices and next steps
- Session 5: Conclusions

Draft shortage definition

A shortage of a medicinal product for human or veterinary use occurs when supply does not meet demand / need at a national level

Thank you for your attention

Further information

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