



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HMA/EMA Task Force on Availability of Authorised Medicines – update on progress

PCWP/HCPWP meeting - 2nd June 2020



Joint EMA/HMA Task Force to address medicines' availability issues



Aims

- Assess reasons for non-marketing of authorised medicines
- Establish definitions and metrics to enhance shortage management
- Improve sharing of information among EU regulatory authorities
- Develop communication strategies within the Network and with other healthcare actors



Scope

- Medicines authorised but not marketed (or no longer marketed)
- Medicines affected by supply disruptions



Working groups

Thematic Working Group 1 - **Marketing of authorised medicinal products**

Thematic Working Group 2 - **Supply Chain Disruption**

Thematic Working Group 3 - **Communication**

Main Achievements



[Guidance](#) on detection and notification of shortages of medicinal products for MAHs



Key information for shortage management and monitoring by EU regulators (Metrics)



Good practice [guidance](#) for communication to the public on medicines' availability issues



Improving information sharing within EU network – Single Point of Contact (SPOC)
Set-up and pilot for sharing of information among EU authorities (April – August 2019)



HMA/EMA [workshop](#) (November 2018 multi-stakeholder meeting)

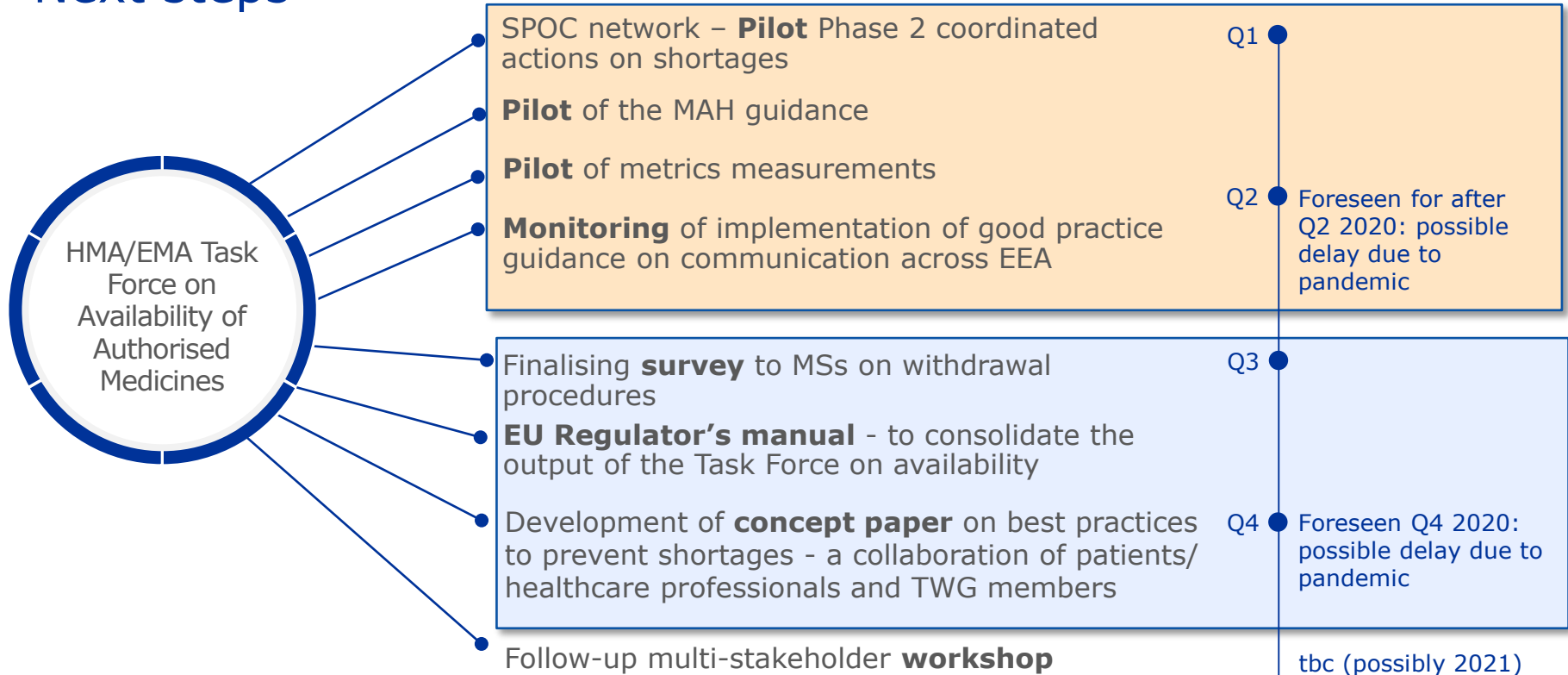


Link between EMA shortage catalogue and national [shortage registers](#) on EMA and HMA websites

The EU SPOC Network during COVID-19

- the SPOC system is a comprehensive and valuable platform to share information on medicines' availability issues for human and veterinary medicinal products. It has improved the collaboration amongst the NCAs in the management of shortages and availability issues in the EU (such platform did not exist before).
- Shared information, in **early February 2020**, on the potential **impact of the outbreak in China** on the availability of **critical medicines** in the EU market.
- Monitored the **impact of the Covid-19 pandemic on the supply of medicines** in the Member States, and collected regular updates on current shortages or anticipated shortages for medicines (e.g. medicines used in hospital ICUs). Feedback gathered is used to report to the EU Exe Steering Group on Shortages.
- Gathered **feedback from Member States** with regards to shortage notifications submitted by Industry through the i-SPOC system in the context of the Covid-19 pandemic.

Next steps



EMRN strategy to 2025

Strategic focus areas:

1. Availability and accessibility of medicines
2. Data analytics, digital tools and digital transformation
3. Innovation
4. Antimicrobial resistance
5. Supply chain challenges
6. Sustainability of the Network and operational excellence

EMRN strategy to 2025 - consultations

- During Stakeholder consultation - **Patients and Consumers Working Party (PCWP) and Healthcare Professionals Working Party (HCPWP)** 3 March 2020
- Collaborative work with EC on Pharma Strategy in May/June
 - A final draft will be ready by mid-June for endorsement by HMA and EMA Management Board.
 - Launch of 2 month public consultation from July with deadline in September 2020.
 - EMA/HMA virtual meeting - finalisation + adoption November 2020

Thank you

Thanks to TF AAM members, colleagues from HMA and EMA

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