What happened with the HMA/EMA Task Force on availability of authorised medicines for human and veterinary use (TF AAM) since 2018

Session 1: Setting the scene

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HMA/EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use (TF AAM)

Background

- In December 2016, the TF-AAM was established to provide **strategic support** and advice to **tackle disruptions** in supply of human and veterinary medicines and **ensure** their **continued availability**.

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

Main Achievements

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

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

Guidance on detection and notification of shortages of medicinal products for MAHs
Definition of shortage and harmonised template for reporting shortages

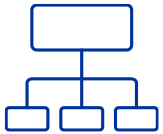
Improving information sharing within EU network – Single Point of Contact (SPOC)
Network for sharing of information among EU authorities

Good practice guidance for communication to the public on medicines' availability issues

Link between EMA shortage catalogue and national shortage registers on EMA and HMA websites

Main changes since November 2018

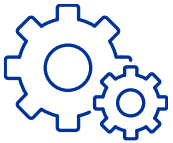
- **Activities on hold** due to COVID-19 business continuity plan
- **Activities resumed** on 15 December 2021



New structure and composition

Work programme to 2025

Updated terms of reference



Extension of the mandate for 3 years

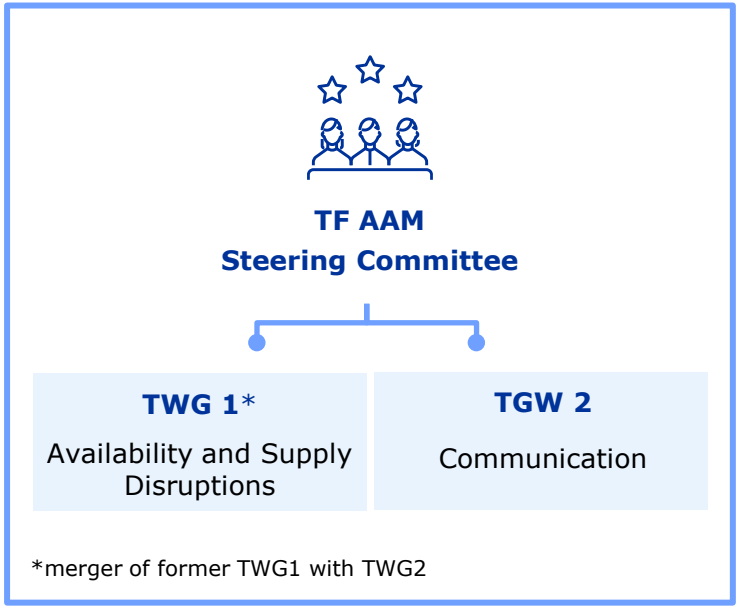
New structure of the TF AAM

New structure consisting of 2 thematic working groups (TWG)

Agreement to have a new structure and composition of the TF AAM to ensure alignment of the activities within the EU Regulatory Network:

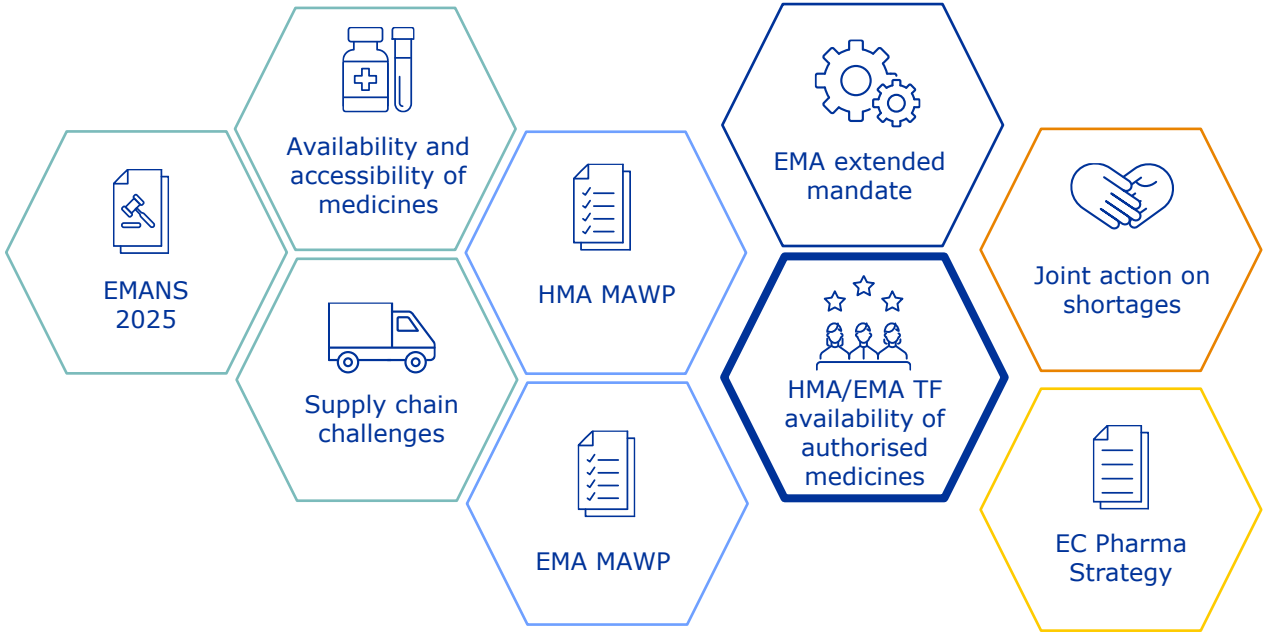
- European medicines agencies network strategy (EMANS) to 2025
- Joint action on shortages
- EMA extended mandate

The new structure and composition will **streamline processes, foster synergies and will avoid duplication of work within the network**



Supply and availability landscape and HMA/EMA TF AAM

Supply and availability **Hub** within the EU Regulatory Network



Work programme to 2025

Work programme **builds on the objectives** described in theme 1 of the European medicines agencies network strategy to 2025 and **includes actions** from:

- HMA multi annual work programme
- EMA Single programming document
- Ongoing actions from previous work programme
- Actions related to availability of medicines assigned to existing working groups within the European Medicines Regulatory Network (e.g. ePI, biosimilars)

Alignment with Joint Action on shortages and the EC Pharmaceutical Strategy ensures synergies and avoids duplication of work within the network

Work Programme

5 Objectives

12 Actions

25 Indicators (KPIs)

Availability and supply disruptions: Main activities

Proposals to change the legislation to improve prevention and management of shortages

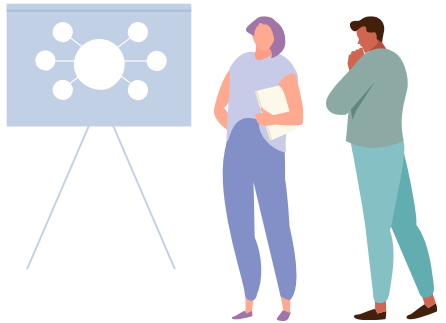
Good practice for industry on **prevention of shortages** of medicinal products for human use

Activities in the field of the **veterinary** sector

Activities to increase **harmonization** within the EEA and with **international** partners

TWG1

Availability and supply disruptions



Communication: Main activities

Commitment to **transparency**

Good Practice Guidance for **patient and healthcare professional organisations** on the **prevention of shortages**

Communication to the **public** on medicines' availability issues

Multi-Stakeholder Workshop

March 2023

TWG2
Communication

Task force tracking progress of activities

- Implementation of ePI project
- Fostering public awareness on approval standards, safety, effectiveness and immunogenicity of biosimilars. Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU
- Promotion on use of multi-lingual packs
- Publication of information on marketing status in the EU of centrally authorised medicines

Any questions?

See websites for contact details

Heads of Medicines Agencies www.hma.eu
European Medicines Agency www.ema.europa.eu

The European Medicines Agency is an agency of the European Union