



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update of the HMA/EMA Task Force on availability of authorised medicines for human and veterinary use (TF AAM)

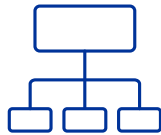
PCWP/HCPWP meeting - 15 November 2022

Monica Dias, EMA co-chair
Hugues Malonne, HMA co-chair

An agency of the European Union



Agenda



New structure and
composition



Work programme
to 2025



Updated terms of
reference



Extension of the
mandate for 3 years

Background on the TF AAM



- **Activities on hold** due to COVID-19 business continuity plan
- **Changes in the co-chairs:**
 - Noël Wathion's retirement
 - Kristin Raudsepp's departure from the Estonian Agency



- **New co-chairs appointed:**
 - Monica Dias (EMA co-chair)
 - Hugues Malonne (HMA co-chair)
- **Activities resumed** on 15 December 2021

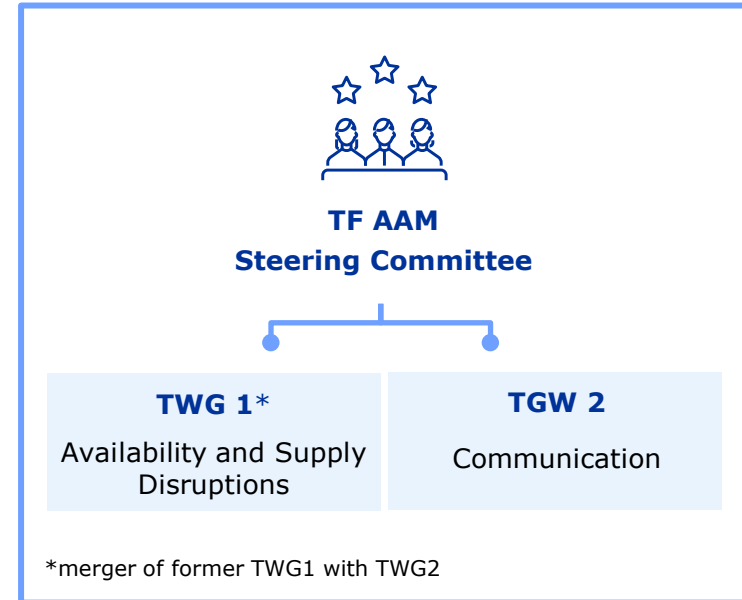
New structure of the TF AAM

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**



New composition of the TF AAM

STEERING COMMITTEE

New composition of the Steering Committee

New members appointed:

- Lead of theme 1 of the European medicines agencies network strategy
- Lead of Joint action on shortages
- Chairs of the CMDx
- New members appointed from SI, DE-PEI

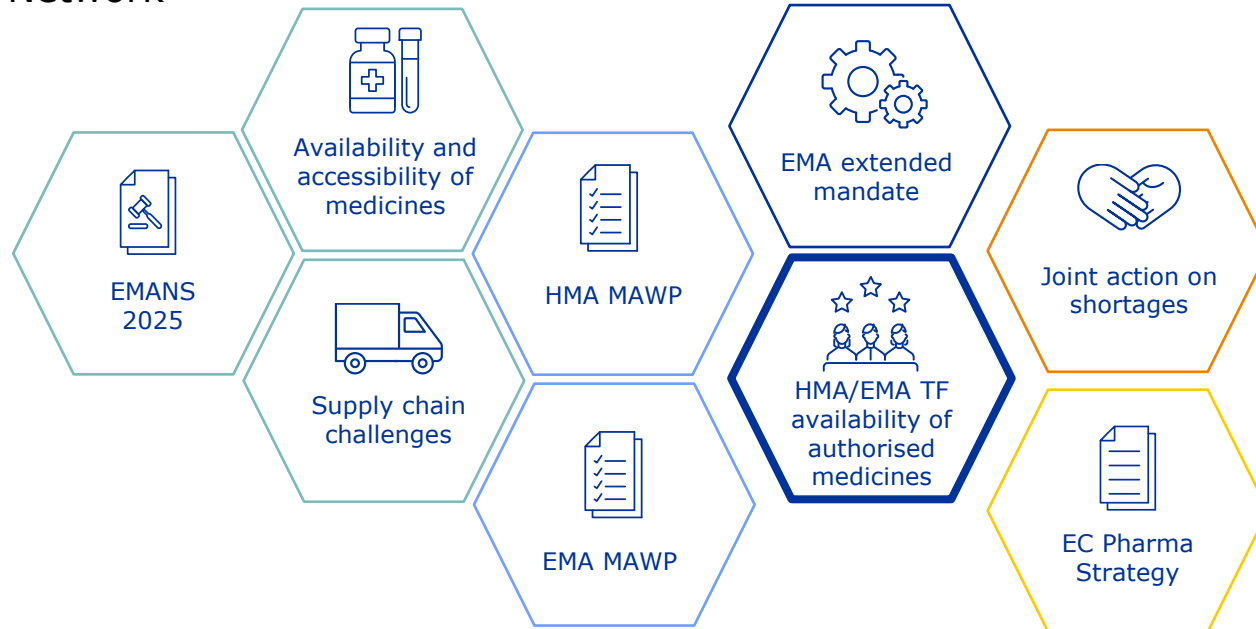


Steering Committee Members

- Hugues Malonne, HMA co-chair
- Monica Dias, EMA co-chair
- Maria Lamas, ES
- Rui Ivo Santos, PT (EMANS lead theme 5: supply chain challenges)
- Lorraine Nolan, IE (EMANS lead theme 1: availability and accessibility)
- Sylvain Giraud, EC
- Momir Radulović, SI
- Maximilian Ehrhardt, DE-PEI
- Domenico Di Giorgio, IT (lead joint action on shortages)
- Consuelo Rubio, ES
- Constance McDaniel, DE-BVL
- Kora Doorduyn, chair of the CMDh
- Laetitia Leletty, chair of the CMDv
- Brendan Cuddy, EMA
- Ivo Classen, EMA
- Darren Scully, IE & Maria Alcaraz, EMA (Co-chairs TWG1)
- Yngvil Knudsen, NO & Juan García, EMA (Co-chairs TWG2)

Supply and availability landscape and HMA/EMA TF AAM

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



Work programme to 2025

Work programme adopted

by the Steering Committee, and subsequently by HMA and the EMA Management Board

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)

Update of the terms of reference

- Terms of reference of the TF AAM initially drafted in 2016
- Current mandate of the TF AAM ending in December 2022
- Revision necessary in view of the new developments in the area of availability and shortages, the new structure of the TF AAM and the need to extend the mandate for a further 3 years
- Revised terms of reference adopted by the Steering Committee on 29 April 2022 and adopted by HMA via written procedure on 26 May 2022 and by the EMA Management Board on 16 June



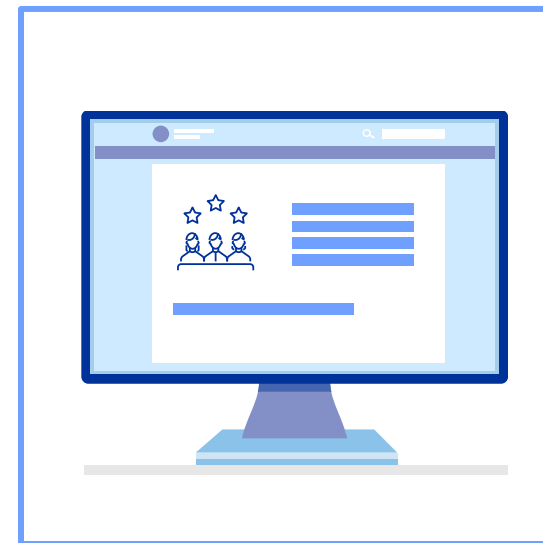
Terms of Reference

- I. Background
- II. Scope
- III. Composition/Membership and Secretariat
- IV. Working approach
- V. Mandate
- VI. Revision of the mandate

TF AAM: Activities to 2025



- TF AAM with mandate extended to 2025
- Two working groups of task force:
 - TWG1- Availability and Supply Disruptions
 - TWG2 – Communication
- Dedicated activities reflected in work programme
- Adopted:
 - Steering Committee on 28 January 2022
 - HMA on 6 May 2022
 - EMA-MB on 16 June 2022
- Published on [EMA/HMA](#) website



THEMATIC WORKING GROUP 1 (TWG1)

Availability and supply disruptions: Main activities (I)

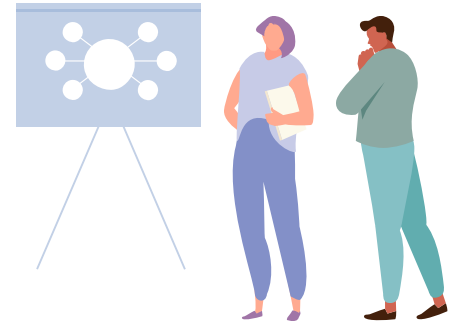


Proposals to change the legislation to improve prevention and management of shortages

- Pharma Strategy
- Draft by TWG1 → adopted by the Steering Committee → HMA consultation
- Proposals sent to the EC on 31st March according to the deadline

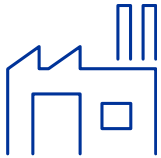
TWG1

Availability and supply disruptions



THEMATIC WORKING GROUP 1 (TWG1)

Main activities (II)

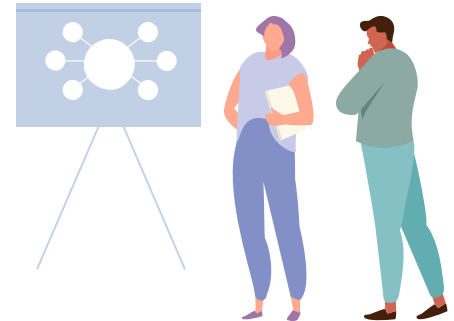


Good practice for industry on prevention of shortages of medicinal products for human use

- Initial discussion with industry associations on 12 September
- Ongoing written consultation

TWG1

Availability and supply disruptions



THEMATIC WORKING GROUP 1 (TWG1)

Main activities (III)

**Pilot project on implementing the guidance on detection and notification of shortages of medicinal products for MAHs**

- [Guidance on detection and notification of shortages of medicinal products for MAHs adopted by stakeholders](#), consultation with stakeholders and published on 1 July 2019
- Agreement to launch a pilot for the implementation of the guidance
- COVID-19 / activities of the TF AAM on hold
- Survey about availability of shortage reporting template at national level through the Medicines Shortages SPOC Working Party
- Continue the discussion/engagement under the pharma strategy

TWG1
Availability and
supply disruptions



THEMATIC WORKING GROUP 1 (TWG1)

Main activities (IV)



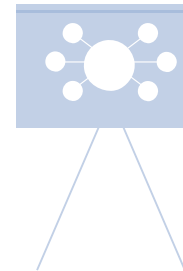
Activities in the field of the **veterinary** sector



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

TWG1

Availability and supply
disruptions



THEMATIC WORKING GROUP 2 (TWG2)

Main activities (I)



Commitment to transparency

- Publish work plan and composition of taskforce
- Regular updates and publications of outcome
- Review practices to enhance communication on supply problems to EU citizens, their representatives and healthcare professionals

TWG2 Communication



THEMATIC WORKING GROUP 2 (TWG2)

Main activities (II)

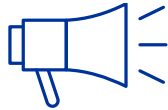
**Good Practice Guidance for patient and healthcare professional organisations on the prevention of shortages**

- [Good Practice Guidance](#) stakeholders (patients and healthcare professionals) consultation → adopted by the Steering Committee in May 2022 → published in July 2022
- In collaboration with stakeholders define metrics and monitor implementation of guidance and review practices
- Explore guidance for veterinary sector

TWG2
Communication

THEMATIC WORKING GROUP 2 (TWG2)

Main activities (III)



Communication to the public on medicines' availability issues

- [Good Practice Guidance for communication to the public on medicines availability issues](#) published in July 2019
- Monitor and analyse implementation of guidance and update as necessary

TWG2 Communication



THEMATIC WORKING GROUP 2 (TWG2)

Main activities (IV)



Multi-Stakeholder Workshop

March 2023

TWG2
Communication



Task force tracking progress of activities

- Implementation of [**ePI project**](#)
- Electronic formats of veterinary medicinal product information
- 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 packaging**
- Publication of information on **marketing status** 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



NEW COMPOSITION OF THE TF AAM

Thematic Working Groups



Thematic Working Group 1

- Darren Scully, HMA co-chair
- Maria Alcaraz, EMA co-chair
- Martina Unteregger, AT
- Jakub Velík, CZ
- Gabriele Eibenstein, DE-BFARM
- Inke Reimer, DE-BVL
- Juhl Jones Rie Devantier & Lene Margrethe Jacobsen, DK
- Maria Esplugues & Maria Criado, ES
- Ramiro Casimiro, ES-V
- Johanna Linnolahti & Julia Lehtinen, FI
- Carla Maione & Oscar Cruciani, IT
- Kristīne Edolfa-Kalniņa, LV
- Flore Demay, FR-ANSES
- Priscilla Schoondermark, NL
- Andreas Sundgren, NO
- Johan Andersson, SE
- Barbara Razingier, SI
- Janos Kovacs, EMA-V



Thematic Working Group 2

- Yngvil Knudsen, HMA-co-chair
- Juan García, EMA co-chair
- Klára Brunclíková, CZ
- Alina Hoskins, DE-BVL
- Juhl Jones Rie Devantier, DK
- Lene Margrethe Jacobsen, DK
- Diego Pernas, ES
- Katja Lindgren-Äimänen, FI
- Kim Notenboom, NL