EMA
EUROPEAN MEDICINES AGENCY

Transfer of Task Force on Availability of Authorised Medicines for Human and Veterinary Use activities and The Working Group of the MSSG on the Vulnerability Assessment Methodology

12th Industry Standing group (ISG) meeting

Presented by Vanessa Bennett on 26 February 2025

Supply and Availability of Medicines and Devices, Regulatory Science and Innovation Task Force (TRS-SAM)

A walk-through TF-AAM history

External events

2012

Quality defects leading to shortages of medicines

2019

Commissioner-Designate Hearing: Commissioner-Designate Kyriakides highlights TF-AAM's work on shortages

2020

COVID-19 pandemic

2022

EMA Extended Mandate (Reg 2022/123)

2023

EC Reform of the EU Pharmaceutical Legislation Proposal

EC Communication on Addressing medicine shortages in the EU

TF-AAM achievements

2016

Launch of HMA/EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use with its 3 thematic working groups (TWGs), publication of reflection paper

2017/2018

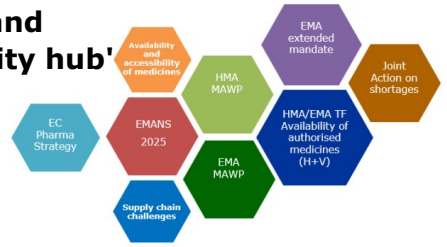
Brexit preparedness activities

2018

Multistakeholder workshop on availability

Dec 2021

Restart of TF-AAM activities* as **'supply and availability hub'**



2023

Ongoing: Work on Union list & Shortage Prevention and Mitigation Plans (SPMPs)

Multistakeholder workshop on shortages

2024

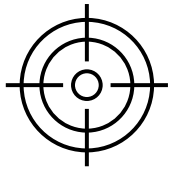
TF-AAM closure and transfer to new legal structures

Framed EMA mandate extension

Input to the EC to incorporate in the proposed pharmaceutical legislation to improve the prevention and coordinated management of shortages

**Merging of TWG 1 and 2, TWG 3 renamed as TWG2*

TF-AAM – beginnings and conclusions



Objectives

- ❑ Improve **sharing of information** and best practices among **EU regulatory authorities** for better cross-EU coordination.
- ❑ Develop strategies to improve **prevention** and **management** of **shortages** caused by disruptions in the supply chain.
- ❑ Encourage **best practices** to prevent shortages.
- ❑ Foster **collaborations** with **stakeholders** and enhancing communication of supply problems to EU citizens.
- ❑ **Track progress** on supply and availability activities ongoing under the **Joint Action on Shortages (CHESSMEN)**.

Achievements

- ✓ Spearheaded activities on supply and availability of medicines which are now enshrined in **EMA extended mandate (Regulation 2022/123)** and provided input for incorporation in EC Reform of the **EU Pharmaceutical Legislation Proposal**.
- ✓ Fostered EU-wide coordination, i.e. creation of **EU SPOC network**.
- ✓ Provided harmonised **reporting** and **guidance**: First EU-wide definition of shortage and guidance on communication to the public.
- ✓ Enabled **multistakeholder collaboration**:
  - ✓ Multi-stakeholder workshops on availability medicines (2018) and on shortages (2023).
  - ✓ Good practice guidance documents issued for patients, healthcare professionals and industry.

The closure of the TF-AAM

- Work of TF-AAM not only **spearheaded activities** in the area of shortages but also led to **formalisation of structures and activities** post COVID-19 (e.g. establishment of SPOC WP, MSSG).

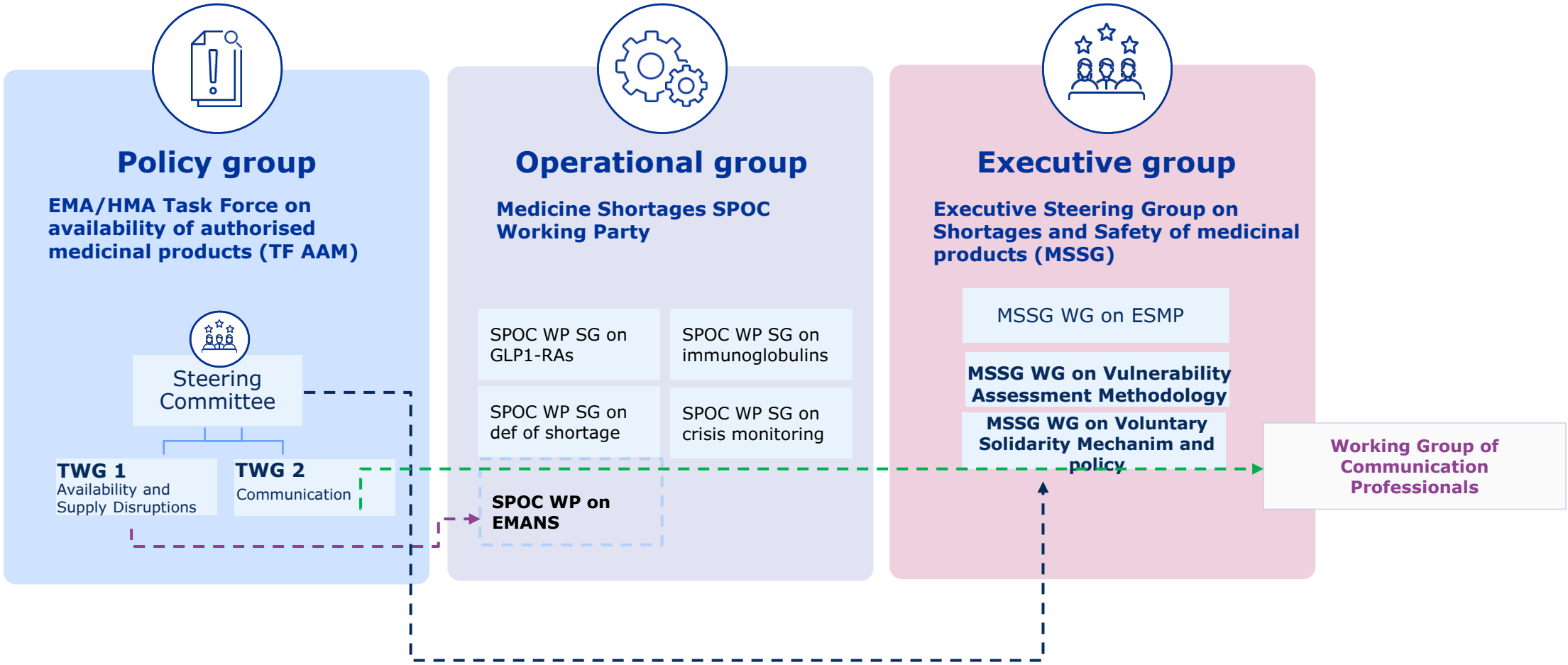
- The legal basis now enshrined via EMA's extended mandate (Regulation 2022/123) enables the MSSG and SPOC WP to **continue the important work of the temporary TF-AAM**.

- The **New EU pharmaceutical legislation** proposal currently under negotiation, together with the initiatives foreseen in the **European Commission communication on tackling medicine shortages in the EU** will further reinforce security of supply for critical medicines and prevention of shortages.

Appropriate time to transition important work of TF-AAM to new legal structures

- Agreement by HMA/EMA TF-AAM on 10 September 2024 and HMA on 5 December 2024 to discontinue HMA/EMA TF-AAM activities and for these to be transferred to the MSSG, SPOC WP and WG on Communication Professionals (WGCP)

Transition of TF-AAM Structures to SPOC WP and MSSG



Availability of medicines: EU level coordination

Operational group

Medicine Shortages SPOC Working Party

- Monitoring and mitigation at all times
- List of critical medicines during a PHE/ME
- Monitoring of demand and stock during a PHE/ME

Subgroups:

- SPOC WP SG on GLP1-RAs
- SPOC WP SG on immunoglobulins
- SPOC WP SG on def of shortage
- SPOC WP SG on crisis monitoring
- SPOC WP SG on EMANS 2028

SPOC WP Members

Technical support

Executive group

Executive Steering Group on Shortages and Safety of medicinal products (MSSG)

- Monitoring of events, including shortages
- Recommendations
- List of main therapeutic groups of medicines, List of critical medicines for PHE/ME
- Monitoring of shortages, supply, and demand during PHE/ME
- Recommendations and opinion on ME

Working Groups:

- MSSG WG on ESMP
- MSSG WG on Vulnerability Assessment Methodology
- MSSG WG on VSM and policy

MSSG Members/Experts

SPOC WP Members

European Commission

Link with WGCP & other groups as necessary

Normal Circumstances, preparedness and Crisis

MSSG Working Group on VSM and policy: Revised mandate and objectives

Mandate

The Working Group will work on MSSG activities related to the Voluntary Solidarity Mechanism and other policy activities related to the availability and supply of medicines, including the implementation of EMANS 2028 (theme 5 Goal 1 activities)

Objectives

Concretely, the Working group will be responsible for activities related to:

Shortages response and preparedness

Progress on ongoing activities around mitigation and prevention of shortages of human medicines (outstanding activities of the TFAAM and EMANS 2028).

Supply and Availability Hub

Track progress on ongoing and planned supply and availability activities, to streamline processes, ensure synergies and avoid duplication of work within the network (e.g., CHESSMEN, NPL, CMA).

Communication

In collaboration with Working Group of Communication Professionals (WGCP) enhance communication on supply problems and provide guidance and good practice documents.

Work of the MSSG Working Group on VSM and policy will be supported through the technical SPOC WP on EMANS 2028. Adoption of deliverables will be undertaken by the MSSG.

MSSG Working Group on Vulnerability Assessment Methodology: Mandate and objectives

Mandate

This new Working Group will be established to finalise a methodology to allow for the evaluation of vulnerabilities with respect to the supply chains of critical medicines as set out in Article 130(1) of the proposed pharmaceutical legislation. It will also consider associated provisions included in the Critical Medicines Act.

Objectives

To deliver a practical methodology by the agreed deadline without duplication of existing processes or excessive burden on actors involved.

Working arrangements

- This work will take the DG GROW/ HERA Technical Report and the work of the CM Alliance into consideration. It will prepare for implementation of provisions set out in the proposed pharmaceutical legislation and proposed Critical Medicines Act.
- The Working Group will stay in close contact with the new MSSG WG on the VSM and Policy to ensure alignment, in particular the SPP/ SMP pilot.

Adoption of deliverables will be undertaken by the MSSG.

Conclusions

- **Ten years ago**, the primary responsibility for managing medicine shortages laid with individual EU member states.
- Work of TF-AAM not only **spearheaded activities** in the area of shortages but also led to **formalisation of structures and activities** post COVID-19 (e.g. establishment of SPOC WP, MSSG) which are now enshrined in EMA's extended mandate (Regulation (EU) 2022/123).
- Work of the TF-AAM has now been **transitioned** to the MSSG and SPOC WP and **will continue** through these structures. Strong collaboration between the different MSSG Working Groups and SPOC WP Subgroups to ensure alignment and to avoid any potential overlap.
- **Close collaboration** with relevant stakeholders via diverse composition of Working Groups and Subgroups.
- The **proposed EU pharmaceutical legislation** currently under negotiation, together with the initiatives foreseen in the **European Commission communication on tackling medicine shortages in the EU** will further reinforce security of supply for critical medicines and prevention of shortages. This will be complemented by the proposed Critical Medicines Act.
- **Report** of TF-AAM activities of the last 8 years currently being drafted for scientific publication (Timeline Q2 2025)

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