EMA/724592/2022 Rev.2[1]

# Work programme until 2025 of the HMA/EMA task force on availability of authorised medicines for human and veterinary use

## 1. Background

Unavailability of medicines in the EU, either because medicines are not marketed or due to supply disruptions, has been recognised by HMA and EMA as an area of great concern[2] affecting all stakeholder groups. Indeed, problems with the availability of medicines have an impact not only on the supply chain but ultimately on healthcare systems, with a significant impact on end users. With respect to veterinary medicines, shortages may cause concern for animal health and welfare in cases where alternative medicines do not exist or are not marketed. As causes of unavailability are multifactorial, the solutions require actions at different levels and involve all stakeholders. An HMA-EMA task force was set up in 2016 to develop and coordinate actions that are necessary to facilitate prevention, identification, management and communication of shortages to ultimately ensure continuity in the supply of human and veterinary medicines. Its mandate has been renewed in December 2021 and will last until December 2025.

The Task Force will function as a "supply and availability hub" and will track progress of supply and availability activities that the European medicines regulatory network is undertaking under the following EU projects:

- the European Medicines Agency's network strategy to 2025
- the European Commission's Pharmaceutical Strategy for Europe
- the 'Joint Action on Shortages', a three-year plan, starting at the end of 2022, to enhance national systems in tackling medicines shortages in a harmonised way

## 2. Scope

The work programme covers centrally and nationally authorised products, both for human and veterinary medicines, in the following cases:

[1] This document was modified on 7 October 2022 to clarify the duration of the mandate.
This document was modified on 17 May 2023 to reflect the addition of a new task to set up the EU list of critical medicines and to update timelines of activities:
- Implementation of recommendations for EU/EEA regulators on collecting key information for shortage management
- Development of best practices on process in place to withdraw medicines permanently from the market
- For veterinary medicines, analysis of results of the EC study on shortages of human medicines

[2] EU Medicines Agencies Network Strategy to 2020:
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/12/WC500199060.pdf

- when medicines are authorised but not marketed (or no longer marketed)
- when authorised and marketed medicines are affected by supply-chain disruptions that directly affect their availability.
  Such disruptions may occur due to problems with good manufacturing practice (GMP), good clinical practice (GCP), good distribution practice (GDP)[3] or quality defects, or because of commercial interruptions or an increase in demand.

# 3. Composition of the task force

The task force is composed of representatives from the national competent authorities, EMA and the European Commission, as well as the Chairs of the medicines regulatory bodies representing the European Union (EU) Member States, Iceland, Liechtenstein and Norway (the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) and the Coordination group for mutual recognition and decentralised procedures for veterinary medicinal products (CMDv)). The task force has links with existing working groups and ensures that any activities related to availability issues in their field will be reflected in their respective work programs.

The task force is composed of a steering committee that provides strategic oversight, as well as two working groups addressing availability issues from the critical angles *Availability and Supply disruption* and C*ommunication*.

The groups meet mainly via teleconference and provide quarterly progress reports to the steering committee.

## *3.1. Details about groups and agreed actions*

### 3.1.1. Thematic working group 1 – Availability and Supply disruptions

This group focuses on strategies to improve prevention and management of shortages caused by disruptions in the supply chain. Its action plan was adopted by the steering committee on 28 January 2022 and subsequently by HMA and EMA-Management Board and are as follows:

| **Thematic working group 1 – Availability and Supply disruptions** | |
|---|---|
| **Actions** | **Timelines** |
| **Identify the specific root causes of shortages and develop strategies to improve prevention and management of shortages** | |
| Propose changes to legislation to the EC to improve prevention and management of shortages | Q1 2022 – Completed |
| Development of best practices on process in place to withdraw medicines permanently from the market | Q1 2023 |
| Analysis of recommendations listed in the EC report on the root causes of shortages of medicines (link) as well as in other sources, and decide on their implementation | Q2 2023 |
| Development of best practice guide for industry on prevention / management of shortages of medicinal products (pending link) | Q2 2023 – completed |

[3] GMP, GCP and GDP are legal standards for ensuring that products are consistently tested, produced, controlled and distributed according to their quality specifications.

| Thematic working group 1 – Availability and Supply disruptions | |
|---|---|
| For veterinary medicines, analysis of results of the EC study on shortages of human medicines (link) to explore if the root causes of shortages are similar for shortages of veterinary medicines, and if actions for human medicines could be adapted for veterinary medicines | Q1 2025 |
| **Actions** | **Timelines** |
| Implementation of agreed strategies to harmonize criteria to improve shortage management and prevention at national level | Q4 2025 |
| **Improve coordination of information and actions for EU regulatory authorities, stakeholders and international partners** | |
| Launch a pilot on implementing the "Guidance on detection and notification of shortages of medicinal products for MAH in the Union (EEA)" | This action has been cancelled – a survey found that the guidance is already implemented by most Member States |
| Implementation of recommendations for EU/EEA regulators on collecting key information for shortage management | Q4 2023 |
| **Improve coordination of information and actions for EU regulatory authorities, stakeholders and international partners** | |
| Improve cooperation on shortages and harmonization with international partners through implementation of guidance in the area of supply disruptions developed by ICMRA and the Global Regulators Working Group | Q4 2024 |
| In collaboration with thematic working group 2, explore good practice guide on prevention / management of shortages of medicinal products for veterinary use | Q4 2025 |
| **Improve capacity to monitor and coordinate medicines' availability and supply** | |
| Develop a common framework/methodology for forecasting demand data for medicines in the EU/EEA | Q1 2022- Completed Reflection paper is published |
| **Ensure the security of supply and the availability of critical medicines** | |
| Refine the methodology from the EC structured dialogue initiative on the Security of Supply of Medicines to create a EU list of critical medicines | Q2 2023 |
| Establish the EU List of critical medicines | From Q3 2023 |

### 3.1.2. Thematic working group 2 - Communication

This group focuses on improving timely access to up-to-date information on availability issues, for all actors within the network as well as users of medicines. The group looks at ways to enhance

interactions and communication with stakeholders as well as improving collection and sharing of information between regulatory authorities and pharmaceutical industry. The group's actions were adopted by the steering committee in on 28 January 2022 and subsequently by HMA and EMA-Management Board and are as follows:

| Thematic working group 2: Communication | |
|---|---|
| **Actions** | **Timelines** |
| **Improve coordination of information and actions for EU regulatory authorities, stakeholders and international partners** | |
| Finalise good practice guide for patient and healthcare professional organisations on the prevention of shortages | Q1 2022 – Completed and published |
| Provide analysis of communication practices by national competent authorities on shortages | Q1 2022 - Completed |
| Enhance communication of supply problems to EU citizens, their representatives and HCPs | Q4 2022 |
| Review of practices following publication of good practice guide | Q4 2024 |
| In collaboration with thematic working group 1, explore good practice guide on prevention / management of shortages of medicinal products for veterinary use | Q4 2025 |
| Monitor implementation of good practice guidance for communication to the public on medicines' availability issues to the public by surveying national competent authorities | Continuous |
| **Improve coordination of information and actions, including implementation of best practices, both for EU regulatory authorities, stakeholders and international partners** | |
| Organise a second multi-stakeholder workshop on stakeholders' perspectives and follow-up on the outcome of the first workshop | Q1 2023 |

### 3.1.3. Coordination of activities in the area of availability

HMA/EMA task force on availability of authorised medicines (TF AAM) also acts as a hub for tracking activities in the area of availability and shortages. These actions are as follows:

| Monitoring activities for taskforce | |
|---|---|
| **Actions** | **Timelines** |
| **Improve coordination of information and actions for EU regulatory authorities, stakeholders and international partners** | |
| Implementation of the ePI project as this is one of the recommendations highlighted in the EC shortages study | Q4 2022 |
| Review of ongoing pilot exercise and stakeholder feedback on promoting use of multi-lingual packs | Q4 2022 |
| Promotion of development of electronic formats for veterinary medicinal product information | Q1 2023 |

| Monitoring activities for taskforce | |
|---|---|
| Creation of European Shortages Monitoring Platform (ESMP) | Q1 2025 |
| Foster public awareness on approval standards, safety, effectiveness and immunogenicity of biosimilars | Q4 2025 |
| **Actions** | **Timelines** |
| **Increase transparency on availability to facilitate targeted regulatory actions and communication with patients, healthcare professionals and health technology assessment bodies** | |
| Assessment of feasibility to publish information on marketing status throughout the EU of centrally authorised medicines (as provided by marketing authorisation holders to EMA) | Q4 2023 |

# 4. Governance

The steering committee oversees the work of the two thematic working groups to ensure that their work objectives meet the overall objectives of the task force. It also monitors the groups' progress and ensures that the necessary resources are made available.

The task force meets by teleconference four times a year and reports quarterly to the HMA and to EMA's management board.

This work plan will be updated as required, taking into account any new developments.