16 June 2022
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HMA/EMA Task Force on Availability of authorised medicines for human and veterinary use (TFAAM)

Terms of Reference

I. Background

The lack of availability of authorised medicinal products that may never reach the market or that may become temporarily or permanently unavailable has been recognised as a significant issue. Therefore, improving the availability of medicines authorised in the European Union (EU) is a key priority for the European medicines regulatory network.

Unavailability of medicines may arise due to three main reasons:

1. Medicinal products are not authorised.
2. Medicinal products are authorised but are not marketed or no longer marketed.
3. Supply chain disruptions directly prevent the availability of authorised and marketed products.

The root causes for these reasons are diverse and multi-dimensional in scope and the Network has undertaken a number of initiatives in recent years to address the problems within its scope of responsibility and has been integrated in the different EU Medicine Agencies Network Strategies for the last few years.

The European medicines agencies network strategy (EMANS) to 2025[2] has been jointly developed by the Heads of Medicines Agencies (HMA hereinafter) and the European Medicines Agency (EMA hereinafter). This strategy builds on previous multiannual work plans of both the HMA and EMA.

The availability of medicines has been on the political agenda for many years, e.g. the Council conclusions on 'Strengthening the balance in the pharmaceutical systems in the EU and the Member States', during the meeting of the Working Party on Public Health at senior level on the basis of the Slovak Presidency on shortages or the European Parliament resolution of 17 September 2020 on the shortage of medicines – how to address an emerging problem[3]. The COVID-19 pandemic has moved this topic of concern to the highest level of the political agenda and has highlighted the need to ensure a coordinated approach for the benefit of the European population, e.g. the Council Conclusions on strengthening the European Health Union under the Slovenian Presidency[4] or the European

[1] This document was modified on 7 October 2022 to clarify the duration of the mandate.
[2] EMANs strategy to 2025
[3] European Parliament resolution on the shortage of medicines
[4] Council Conclusions on strengthening the European Health Union under the Slovenian Presidency

Commission Health legislative package, including Regulation (EU) 2022/123[5] on a reinforced role of the EMA in monitoring shortages during public health emergencies or major events. In the area of veterinary medicinal products, it is important to highlight that a new veterinary regulation[6] was published in 2019 and one of its main objectives is to increase the availability of veterinary medicines.

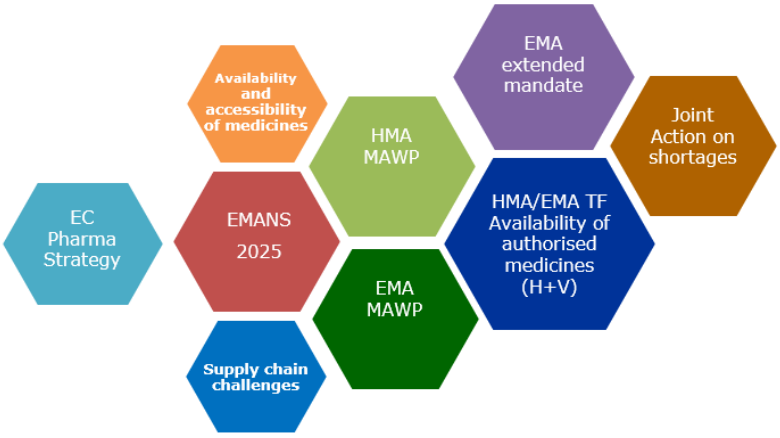
II. Scope

The scope of the HMA/EMA Task Force includes medicinal products for human and veterinary use, irrespective of the licensing route (centralised, national), and will focus on availability of authorised medicines, whereas non-authorised medicines will not be included in the scope of the HMA/EMA Task Force. A tailored approach will be required to take into account the specificities of human and veterinary medicinal products.

The HMA/EMA Task Force will provide strategic support, advice for coordination and concerted approach to the Network on the availability of the medicinal products authorised in the EU and deal directly with a number of actions proposed in the EMANS to 2025.

The HMA/EMA Task Force will function as an "supply and availability Hub" and will track progress on supply and availability activities ongoing under the Joint Action on Shortages and the European Commission Pharmaceutical Strategy for Europe[7], in order to streamline processes, ensure synergies and avoid duplication of work within the network (Figure 1).

Figure 1: Supply and availability landscape and HMA/EMA Task Force on availability as a supply and availability Hub



The HMA/EMA Task Force activities will focus primarily on structural and strategic solutions hence on "peace time" while the structures foreseen under Regulation (EU) 2022/123 such as the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) will focus on activities related to the preparedness for and during crisis situations. However, any lessons learnt from crisis situations and/or preparedness activities should be brought to the attention of the HMA/EMA Task Force so that consideration can be taken on the relevance for non-crisis situations. Similarly, the Task Force will engage with the relevant structures set up in the context of the extended mandate (e.g. MSSG or

[5] Regulation 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices
[6] Regulation (EU) 2019/6 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC
[7] https://ec.europa.eu/health/medicinal-products/pharmaceutical-strategy-europe_en

Medicine shortages Single Point of Contact (SPOC) Working Party) to ensure that any relevant guidance is taken into consideration for crisis situations.

The Task Force will take into account ongoing policy initiatives on this subject matter and will co-ordinate actions to ensure there is no duplication of effort or tasks.

III. Composition/Membership and Secretariat

The HMA/EMA Task Force is composed of representatives nominated by the interested National Competent Authorities (NCAs) as well as the Chairs of the CMDx, Medicine shortages SPOC Working Party, Good Manufacturing Practices and Good Distribution Practices Inspectors working group (GMDP IWG), Working Group of Communication Professionals (WGCP), European Surveillance Strategy Working Group (ESS WG) and Joint Action on Shortages, EMA and EC representatives.

The HMA and EMA have oversight of the Task Force. Members from participating NCAs will join on a voluntary basis. The Task Force is co-chaired by two co-chairs who are appointed for a term of three years, and consist of a senior NCA official nominated by the HMA and a senior EMA staff member. The Task Force is composed of a Steering Committee and two thematic working groups as follows:

Thematic Working Group 1 on availability and supply disruptions

Thematic Working Group 2 on communication

EMA provides administrative and scientific secretariat to the Task Force.

The participation of additional members of other HMA Task Forces/groups can be also considered by the Task Force.

IV. Working approach

Work will be conducted as far as possible by means of virtual meetings, teleconferences and e-mails. It is expected that the Task Force will convene monthly by teleconference.

Face to face meetings will, if possible, be held in the margins of Management Board and/or HMA meetings. Notably, the group will work in conjunction with the EU Presidency and will consult the European stakeholders as appropriate on specific aspects of the work.

The Task Force will approve the multiannual work plans of the thematic working groups that will set specific objectives and measures of success for each area.

The Task Force will report to both HMA and EMA Management Board. The Task Force Co-Chairs will report regularly to the EMA Management Board and at the HMA plenary session.

V. Mandate

The Task Force provides the strategic steer and management oversight to the overall availability related activities ensuring that thematic work plans are consistent with the overall Task Force work plan and strategic objectives for both human and veterinary medicines are in place. The Task Force will follow up other availability related activities not allocated to them to ensure consistency and avoid duplication of work. The Task Force is also in charge of ensuring that thematic working groups have specific objectives identified and progress measured while ensuring that resources are made available to support.

The Task Force will have at its core the following key areas taking into account the goals and timelines in the HMA and EMA multi-annual work plans and will monitor the progress of the initiatives and projects and advise the HMA and EMA within the scope of two main areas:

Medicinal products are authorised but are not marketed or no longer marketed.

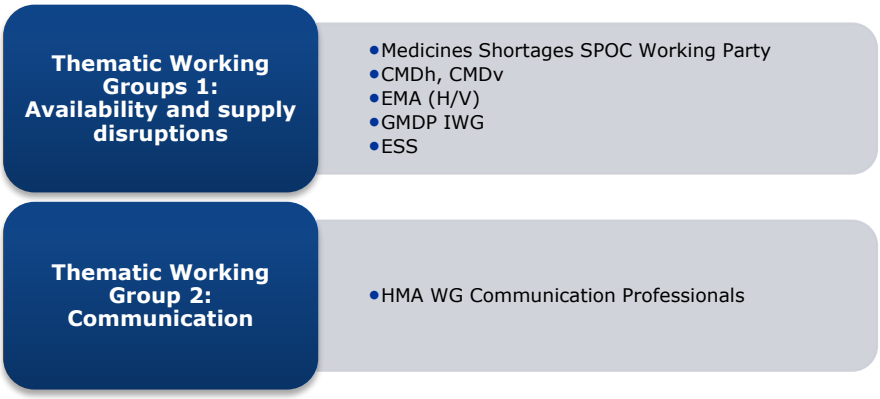
Supply chain disruptions directly prevent the availability of authorised and marketed products.

The Task Force establishes two thematic working groups to deal with topics and objectives involving availability and supply disruptions and communication (Figure 2).

Figure 2: Task Force on Availability of authorised medicines - organisation

The Task Force will make use of existing committees and working groups (Figure 3) as far as possible and will ensure that specific activities related to availability of authorised medicinal products are included in their work programmes. These groups will be asked to report back to the Task Force on progress.

Figure 3: Proposed Groups involved in each Thematic Working Groups



VI. Revision of the mandate

The mandate of the Task Force was reviewed in December 2021 and it was extended until December 2025. It will be subject to periodic review as may be required during that time, and subject to a full formal review by the HMA and the EMA at the end of the term.