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Work programme 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[1] 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, resulting in 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 involving all stakeholders. An HMA-EMA task force has been set up to develop and coordinate actions that are necessary to facilitate a better prevention, identification, management and communication of shortages to ultimately ensure continuity of supply of human and veterinary medicines.

2. Scope

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

- when medicines are authorised but not marketed (or no longer marketed);
- when medicines authorised and marketed 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)[2] or quality defects.

3. Composition of the task force

The task force is a working group 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

[1] EU Medicines Agencies Network Strategy to 2020: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/12/WC500199060.pdf
[2] GMP, GCP and GDP are legal standards for ensuring that products are consistently tested, produced, controlled and distributed according to their quality specifications.

Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) and Veterinary (CMDv)). The task force establishes links with existing working groups and ensures that any activities related to availability issues in their field will be reflected in their respective work programmes. In the context of preparing for the UK's withdrawal from the EU, the task force will provide a platform to facilitate and coordinate actions between member states, EMA and the EC. The task force is composed of a steering committee that provides strategic oversight, as well as three working groups addressing availability issues from the three critical angles: marketing authorisation, supply disruption and communication.

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 - Marketing authorisations

This group looks at ways to minimise supply disruptions and avoid shortages by facilitating authorisation and marketing of medicines using the existing regulatory framework. Its actions were agreed in February 2017 and are as follows:

Thematic working group 1: marketing authorisations	
Agreed actions	**Status / timelines**
Improve information exchange on availability issues of paediatric formulations and provide best-practice guidance to member states by establishing a dedicated paediatric task force and regular interaction with EMA's Paediatric Committee.	Completed
Facilitating the approval of generics and biosimilars through joint evaluations (work sharing) and shortened timetables. This will facilitate the market entry for these medicines and help to increase users' access to medicines.	Completed
Support the European Observatory and facilitate the supply of medical radioisotopes by promoting work sharing and reduced timetables.	Q4 2019
Review existing procedure for withdrawals of medicines, to include need for a transition period to allow better planning for any disruptions.	Q4 2020
Facilitate and promote the use of multilingual packages to enable transfer of medicines with the appropriate translation of the package leaflet to other countries experiencing shortages, in particular in smaller markets.	Q4 2020
Encourage accelerated procedures by mutual recognition to extend marketing authorisations to countries where companies would not normally seek marketing authorisation.	Q4 2019
Identify potential supply issues for medicines due to UK's withdrawal from the EU and avoid shortages of authorised medicines as a result of UK's withdrawal from the EU by:	Q4 2019

Thematic working group 1: marketing authorisations	
• Providing practical guidance to implement regulatory changes required following Brexit (e.g. change of reference member states).	Completed
• Monitoring implementation of required regulatory changes.	Ongoing

3.1.2. Thematic working group 2 - Supply chain disruptions

This group focuses on strategies to improve prevention and management of shortages caused by disruptions in the supply chain. Its actions were agreed in February 2017 and are as follows:

Thematic working group 2: supply disruptions	
Agreed actions	**Status / timelines**
Develop concept of reportable shortages by agreeing an EU-wide definition of medicine shortage.	Completed
Develop guidance for companies on reporting of shortages.	Completed
Facilitate management and monitoring of shortages across the EU by developing metric to “measure” shortages.	Q4 2019
In collaboration with thematic working group 3 encourage best practices within stakeholders to prevent shortages.	Q4 2020
Review existing guidance documents for authorities regarding how to best manage and minimise the impact of shortages (including shortages that may arise as a result of UK withdrawal from EU).	Completed

3.1.3. Thematic working group 3 - 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 agreed in February 2017 and are as follows:

Thematic working group 3: communication	
Agreed actions	**Status / timelines**
Internal communication within the EU network	
Establish a process for internal cooperation and sharing of information within the EU network, by setting up single point of contacts in human and veterinary agencies in the EU.	Q2 2019
In collaboration with thematic working group 2, develop guidance for companies on reporting shortages to improve coordination within the network.	Completed

Thematic working group 3: communication	
Agreed actions	**Status / timelines**
External communication to the public and transparency	
Map and analyse current public communication practices by national competent authorities in EU member states and EMA on medicines availability and shortages, as well as existing resources across the EU.	Completed
Develop good practice guidance for communication to the public on medicines' availability issues advising EU authorities on the minimum set of information as well as criteria for public communication.	Completed
Give access to the public to clear and useful information on medicine availability problems and supply disruptions across the EU: • Provide a single point of reference for information on shortages and availability on EMA and HMA websites (by linking to relevant national webpages). • Develop a dedicated webpage on HMA and EMA websites with relevant information on the task force.	Completed Completed
Enhance interaction with stakeholders for better management and communication of supply problems	
Organise a multi-stakeholder workshop to gather stakeholders' perspectives on how to address availability issues and to allow their contribution to the deliverables of the task force (e.g. when to report shortages).	Completed
In collaboration with thematic working group 2 encourage best practices with stakeholders to prevent shortages.	Q4 2020

3.2. Cross working group actions

The following action is being carried out jointly by all working groups.

Cross working group action	Timeline
Develop operational guidance for the SPOC network on EU cooperation on medicines' availability issues.	Q4 2019

4. Governance

The steering committee oversees the work of the three 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 twice a year to the HMA and to EMA's management board.

This work plan will be updated as required taking into account any new developments and especially the Agency's business continuity plans in the context of UK's withdrawal from the EU.