Medicine shortages: EU network takes steps to improve reporting and communication

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The European Union task force set up to address problems with medicines supply has published two documents today:

* [guidance for marketing authorisation holders on reporting of shortages in the EU](https://www.ema.europa.eu/documents/regulatory-procedural-guideline/guidance-detection-notification-shortages-medicinal-products-marketing-authorisation-holders-mahs_en.pdf)
* [good practice guidance for communication to the public on medicines’ availability issues](https://www.ema.europa.eu/documents/regulatory-procedural-guideline/good-practice-guidance-communication-public-medicines-availability-issues_en.pdf)

The task force was established by EU regulators to better address potential problems with medicines’ supply and to develop and coordinate actions to facilitate the prevention, identification, management of and communication about shortages.

Both documents lay the foundations for an improved and harmonised EU approach in reporting of and communication on medicines’ shortages and availability issues, a key public health priority for the EU network.

The first document provides guidance to the pharmaceutical industry, a key player in addressing shortages, to facilitate the detection and early notification to competent authorities. The guidance is based on a common definition of the term ‘shortages’, which should enable a more harmonised and timely approach in the detection and management of issues with the supply of medicines. A proposed template for shortage notification by companies is included in the guidance. The guidance and template will be implemented in a pilot phase, which is currently planned to start in the last quarter of 2019. Further information will be provided nearer the time.

The second document, addressed to EU [national competent authorities](https://www.ema.europa.eu/en/glossary/national-competent-authority) and EMA, lays out principles and examples of good practices for communication on shortages to the public, including patients and healthcare professionals. These groups require timely, accurate and up-to-date information on availability issues to ensure continuity of care. The guidance is based on a survey carried out by the task force in all EU Member States to collect information on how issues related to shortages and availability of medicines are measured and communicated to the public.

The documents are two key deliverables of the task force and they have undergone extensive consultation with stakeholder groups, including at a [multi-stakeholder workshop](https://www.ema.europa.eu/en/news/towards-improving-availability-medicines-eu) in November 2018. They are listed in the [work programme 2018-2020](https://www.ema.europa.eu/documents/work-programme/work-programme-hma/ema-task-force-availability-authorised-medicines-human-veterinary-use_en.pdf) , which has been recently updated.

The task force was set up by EMA and the [Heads of Medicines Agencies](https://www.ema.europa.eu/en/glossary/heads-medicines-agencies) (HMA), with representatives from the European Commission and [national competent authorities](https://www.ema.europa.eu/en/glossary/national-competent-authority), the chairs of the Co-ordination Group for [Mutual Recognition](https://www.ema.europa.eu/en/glossary/mutual-recognition) and [Decentralised Procedures](https://www.ema.europa.eu/en/glossary/decentralised-procedure" \t "_blank" \o "The procedure for authorising medicines in more than one European Union Member State in parallel. It can be used for medicines that do not need to be authorised via the centralised procedure and have not already been authorised in any Member State.   For more information, see the European Commission's Volume 2A -  Procedures for marketing authorisation -  Chapter 2 -  Mutual recognition.) – Human ([CMDh](https://www.ema.europa.eu/en/glossary/cmdh" \t "_blank" \o "Coordination Group for Mutual Recognition and Decentralised Procedures - Human -  the group responsible for the examination and coordination of questions relating to the marketing authorisation of human medicines in two or more Member States in accordance with the mutual recognition or decentralised procedure.   More information can be found under 'Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh)'.)) and Veterinary ([CMDv](https://www.ema.europa.eu/en/glossary/cmdv" \t "_blank" \o "Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary -  the group responsible for the examination and coordination of questions relating to the marketing authorisation of veterinary medicines in two or more Member States in accordance with the mutual recognition or decentralised procedure.   More information can be found under 'Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary (CMDv)'.)), the GMP/GDP Inspectors Working Group, the Working Group of Communication Professionals (WGCP) and the European Surveillance Strategy Working Group (ESS WG).

Shortages and availability problems are complex with no quick solutions. Medicine regulatory authorities are only one of the many actors involved in availability issues, however they play an important role in prevention and management. By bringing together experts from various EU member states, the work of the task force lays the foundations for an improved and harmonised EU approach in addressing the problems of medicines’ availability issues. Its mission is to develop and coordinate actions for better prevention, identification, management of and communication on issues that can affect the availability of medicines, in order to improve continuity of supply of human and veterinary medicines across Europe.