Communication of the President of the Office of 19 May 2023 on the publication of the EMA on good practice recommendations for industry to ensure continuity of supply of human medicines, prevent shortages and reduce their impact.

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EMA has published recommendations for industry on PDF icon good practices to ensure continuity in the supply of human medicines, prevent shortages and reduce their impact.

Medicine shortages are a global health problem and are increasingly affecting European countries. Shortages can lead to medicine rationing and delay in critical treatments, with a significant impact on patient care. In addition, patients may need to use less effective alternatives and face an increased risk of medication errors. Ensuring the availability of authorised medicines in the European Union (EU) is a key priority for EMA and the European medicines regulatory network.

The guidance describes the various stakeholders involved in the medicine supply chain and their responsibilities and role in the prevention and management of medicine shortages. It provides ten recommendations for marketing authorisation holders, wholesalers, distributors and manufacturers to minimise the occurrence of medicine shortages and their impact. The recommendations include:

- informing national competent authorities of potential or actual shortages as early as possible and providing detailed information to better predict the possible impact and implement preventive measures;
- establishing robust shortage prevention and shortage management plans;
- optimising pharmaceutical quality systems and increasing resilience of complex, multinational supply chains;
- timely communication between the various stakeholders in the medicine supply chain;
- general principles to promote fair and equitable distribution of medicines to meet the needs of patients.

The recommendations are based on the analysis of causes of shortages and regulators' first-hand experience in coordinating the management of shortages, and industry associations have been consulted.

The guidance has been developed by the HMA / EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use, a joint working group established by EMA and the Heads of Medicines Agencies (HMA) focusing on the availability of authorised medicines, and was presented at a multi-stakeholder workshop on shortages held on 1 and 2 March 2023.

It complements the guidance for patients' and healthcare professionals' organisations published last year to help prevent and manage shortages of human medicines.

More information available on the website: https://www.ema.europa.eu/en/news/guidance-industry-prevent-mitigate-medicine-shortages [1]

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Links
[1] https://www.ema.europa.eu/en/news/guidance-industry-prevent-mitigate-medicine-shortages