

EAHP Position Paper on Shortages of Medicines and Medical Devices

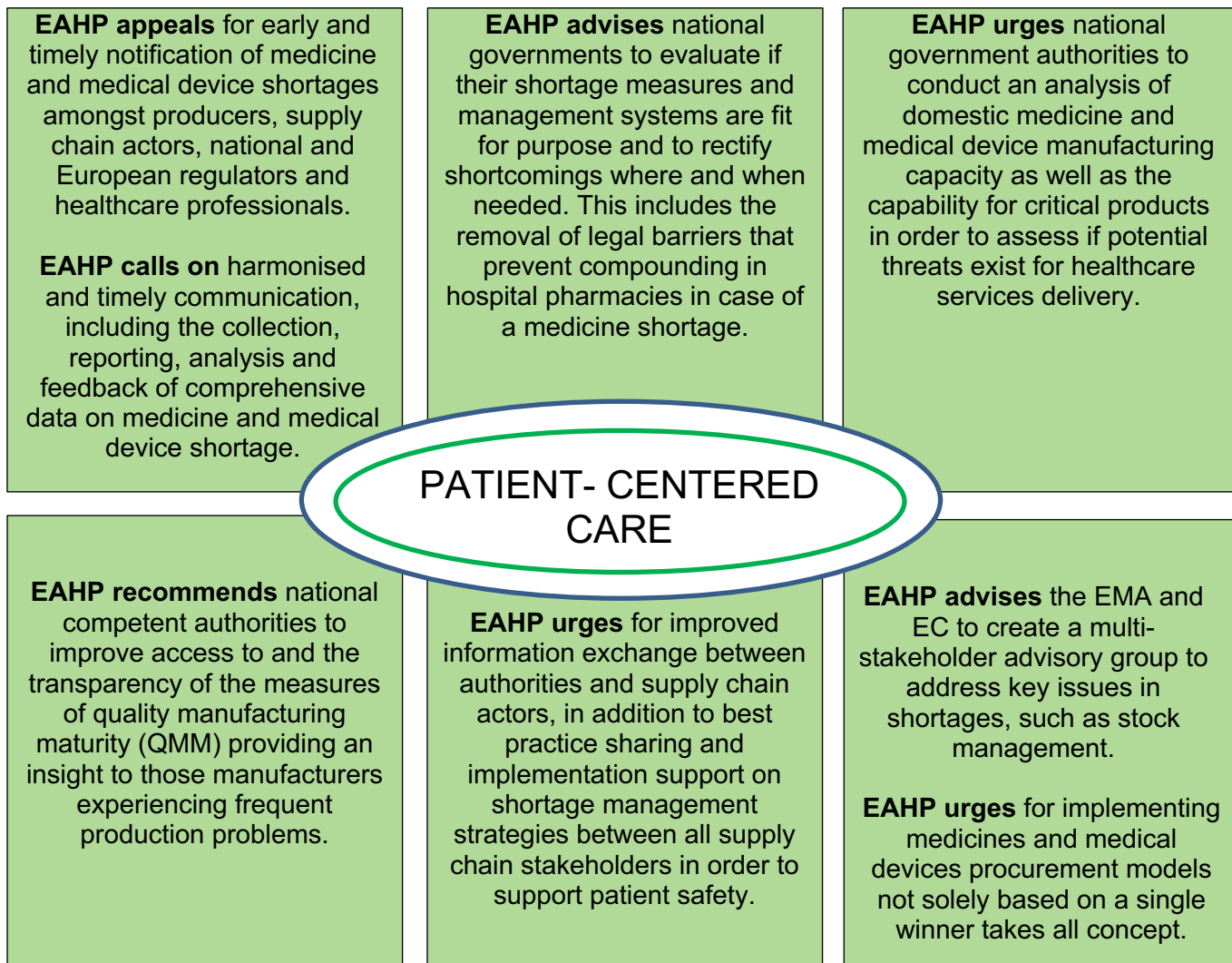
Medicine shortages is a growing global problem in health care that has been extensively reported and reviewed in scientific literatureⁱ ⁱⁱ. The European Association of Hospital Pharmacists (EAHP) was the first healthcare professional association in Europe to explore medicines shortages more than a decade ago. EAHP's reports and publications on shortages are amongst the most cited and referenced by many stakeholdersⁱⁱⁱ ^{iv}, international organisations^v, and European institutions^{vi}. Five pan-European surveys on medicines shortages in the hospital sector were conducted by the Association in 2013^{vii}, 2014^{viii} 2018^{ix}, 2019^x and 2023^{xi} to investigate the prevalence and nature of shortages and the resulting impact on patient care.



In the 2023 Shortage Survey^{xii}, for the first time, EAHP introduced questions regarding medical device shortages which affect patients across European hospitals. Shortages of medicines and medical devices can cause serious harm to patients and have far-reaching consequences for European health systems, especially when affecting patients with acute, life-threatening conditions or those living with cancer and other chronic illnesses.

The percentage of hospital pharmacists reporting medicine shortages to be an issue, especially in terms of delivering the best care to patients, has seen a significant increase in 2022 to 95% of respondents – compared to 86% in 2014, while more than 65% of them experienced medical device shortages^{xiii}. Such reports are alarming and demonstrate the urgent need to draft and implement a set of corrective regulatory and legislative patient-centred measures at the multi-stakeholder level across Europe.

EAHP advocates for a patient-centred holistic approach in mitigating shortages.



Multi-stakeholder collaboration and information exchange

To minimise impact on patients, all supply chain actors, including pharmacists and other healthcare professionals, wholesalers, manufacturers, and national/European competent authorities, have the obligation and responsibility to collaborate more closely to mitigate the shortages problem. Wholesalers and manufacturers must communicate more effectively to pharmacies and regulatory authorities about likely and current shortages. Such communication between supply chain actors should be facilitated by national/European competent authorities and carried out in a timely manner, containing information on how imminent the issue is and the expected duration of the shortage. Moreover, safety recommendations and available therapeutic/generic alternatives should follow in case of medicine shortages. Hospital pharmacists must provide information on stock levels of medicines and medical devices affected by a shortage, followed by guiding and facilitating the work of Drug and Therapeutic Committees in finding the most appropriate therapeutic substitutes.

EAHP appeals for early and timely notification of medicine and medical device shortages among manufacturers, supply chain actors, national and European regulators and healthcare professionals.

EAHP urges for improved information exchange between authorities and supply chain actors as well as best practice sharing and implementation support on shortage management strategies between all supply chain stakeholders to support patient safety.

Activities at European level

The problems created by medicines shortages have been widely reported by healthcare professionals^{xiv xv xvi xvii} as well as patients^{xviii} and acknowledged at the European level by the European Medicines Agency (EMA), the European Commission (EC) and the Heads of Medicines Agencies (HMA). This acknowledgement manifested itself on the one hand in the creation of the Executive Steering Group on Shortages of Medicines (MSSG)^{xix} and medical devices (MDSSG)^{xx} and on the other hand, through initiating the creation of the Union list of Critical Medicines often affected by shortages^{xxi}.

Further efforts should be invested in the development of a comprehensive communication strategy on shortages of medicines and accelerating the introduction of a European Shortages Monitoring Platform, expected to be operational in 2025. Only a comprehensive communication strategy on shortages across Europe will ensure that all supply chain actors, including hospital pharmacists, receive adequate information on all shortages in their countries. Consideration should also be given to putting in place more rigorous rules on issuing timely alerts about shortage problems. National early reporting systems that exist only for medicines in a few countries should be complemented by a European-wide database that lists reasons and estimated durations of shortages including medical devices. In addition, this system should include advice on alternatives which includes the expertise provided by hospital pharmacists.

Closer collaboration between European member states is crucial for the pan-European solution finding process as described in the MSSG Solidarity Mechanism, where a Member State may request assistance from the MSSG in obtaining stocks of a medicine during critical shortages^{xxii}. Furthermore, exchange of good practices amongst European countries is crucial as it provides insight and proactive mechanisms of possible solutions for shortages prevention and management plans as provided in the EMA's Good practice guidance for patient and healthcare professional organisations on the prevention of shortages of medicines for human use^{xxiii}.

The EMA and the EC are the most suitable actors to coordinate such action since they can build on their previous work, experience, expertise and involvement to date in this area. Further efforts should however be invested in ensuring that a minimum number of pharmaceutical manufacturers persists in the market and maintain active manufacturing capacity for critical medicinal products, which would assure that in case of supply disruption originating from a single manufacturer, another one could be able to respond and mitigate a shortage. Moreover, a requirement of six-month contingency stock should be ensured among manufacturers of critical medicines as defined by the European Commission^{xxiv}.

EAHP calls on harmonised communication, including collection, reporting, analysis and feedback of comprehensive data on medicine and medical device shortages.

EAHP advises the EMA and EC to create the multi-stakeholder advisory group to address key issues in shortages, such as creating contingency stocks of critical medicines and medical devices.

Activities at national level^{xxv}

The results of the 2023 EAHP Shortages Survey showed that only 51% of hospital pharmacists find national public shortages reporting systems to be fit for purpose^{xxvi}. Given this, efforts should be made to strengthen the robustness and functionality of these reporting systems.^{xxvii} Consequently, **EAHP calls on** harmonised communication, including collection, reporting, analysis and feedback of comprehensive data on medicine and medical device shortages. Furthermore, the 2023 EAHP Shortages Survey revealed the diverse procurement landscape that varies significantly across Europe, where 55% of hospital pharmacists stated that they

had experienced a shortage of a medicine in 2022, which was provided by a single manufacturer or wholesaler more than ten times. **EAHP urges** for the implementation of medicines and medical devices procurement models not solely based on a winner-takes-all concept^{xxviii xxix xxx}.



The French League Against Cancer, 2020. Medicine Shortages: a Lost Chance for All Patients- the Focus on Cancer.



45% of patients experiencing shortages in France are confronted with **change, delay or interruption of treatment** according to the French Patient Association, partner organisation of EAHP.^{xxxi}

Hospital pharmacists should remain vigilant and alert to the issue of medicine and medical device shortages as well as fully engage with prescribers and managers. To this end, they should raise awareness about the issue at local level and ensure the development and implementation of appropriate contingency plans for mitigating shortages, which are lacking as only 32% of hospital pharmacists report having them, according to the 2023 EAHP shortages survey^{xxxii}. To better address the impact caused by shortages on patients, hospital pharmacists should have sufficient information on manufacturers supply chain reliability. They should be able to mitigate shortages through small-scale production of a medicine, if feasible, without marketing authorisation.

EAHP advises national governments to evaluate if their shortages measures and management systems, including shortages reporting mechanisms are fit for purpose and to rectify shortcomings where and when needed. This includes the removal of legal barriers that prevent compounding in hospital pharmacies in case of a medicine shortage.

EAHP recommends national competent authorities to improve access to and transparency of the measures of quality manufacturing maturity (QMM) providing an insight to those manufacturers experiencing frequent production problems.

EAHP urges national government authorities to conduct an analysis of domestic medicine and medical device manufacturing capacities and capabilities for critical products to assess if potential threats exist for healthcare services delivery.

Hospital pharmacists expend significant time and energy finding alternatives and solutions to alleviate medicine and medical device shortages. Therefore, patients and healthcare professionals will always get support from hospital pharmacists in times of shortages. However, if we want to find the best solutions that provide the best health outcomes, we need to work together and be better prepared for future challenges.

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