



Hospital pharmacists' first impressions on the revision of the General Pharmaceutical Legislation

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This week the European Commission finally released the long-awaited proposal for the revision of the General Pharmaceutical Legislation, comprised of a draft Regulation and a draft Directive to improve the delivery and availability of medicines for human use in the European Union (EU). The European Association of Hospital Pharmacists (EAHP) and its members welcome the publication that also marks the start of the negotiation process for this crucial piece of EU legislation. Despite the draft Regulation and the draft Directive being very

comprehensive, further amendments should be considered by the legislators, especially those

- Guaranteeing a very high level of patient safety across Europe
- Combatting antimicrobial resistance and fostering prudent use of antibiotics
- Ensuring accessibility and addressing the root causes of medicine shortages to adequately prevent and control them
- Upholding the high level of pharmacovigilance in Europe
- Enhancing the safety of the health workforce and the environment

Reflecting on the content of the proposal EAHP President András Süle stressed that "More ambitious measures are needed to enhance patients' access to high-quality and affordable medicinal products across the European Union. Unmet medical needs and access to medicines should be better addressed by utilising the unique compounding skills of hospital pharmacists and their expertise in pharmacology targeting the deconstruction and execution of therapies and in medicines procurement preserving the financial sustainability of healthcare systems. In addition to advancing innovation, patient safety should be put at the centre of the legislation. Seamless transitions between the interfaces of different health settings need to be considered during the implementation of the proposal to ensure that the patient care started in hospitals can be continued in the community."

Linked to the serious threat of antibiotic resistance that jeopardises the effectiveness of standard treatments EAHP Vice-President Darija Kuruc Poje highlighted that "Arrangements need to be made to ensure that essential antibiotics are maintained on the entire European market including an increase of European production sites to lower dependency on international markets. The subscription models proposed in the UK and Sweden are an interesting approach for guaranteeing availability. There are however some questions that remain. Due to national particularities, criteria for the establishment of the subscription model, which factor in national needs, must be defined. In the interest of patient care, also, reimbursement of treatment options outside the subscription model would need to be ensured. In addition, to safeguard the availability of antibiotics, also stewardship programmes need to be supported in order to encourage prudent use of them by healthcare professionals and patients."

EAHP has released an Opinion on the Revision of the General Pharmaceutical Legislation that outlines specific concerns and urges the legislators to ameliorate the proposal in the fields of patient safety, antimicrobial resistance, accessibility of medicines, including medicine shortages, pharmacovigilance and the environment.

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1. The European Association of Hospital Pharmacists (EAHP) is a not-for-profit organisation that defends the interests of more than 27.000 European hospital pharmacists from its 35 European member organisations. EAHP works to develop knowledge on hospital pharmacy to ease the improvement of care and outcomes for patients in the hospital setting. The

Association achieves this through science, practice, research, education, as well as sharing best-practice and responsibility with other healthcare professionals. More information about EAHP is available [HERE](#) [2].

2. Read EAHP's Opinion on the Revision of the General Pharmaceutical Legislation [HERE](#) [3]

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Links

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