

EAHP Opinion on the Revision of the General Pharmaceutical Legislation

For the European Association of Hospital Pharmacists (EAHP), the revision of the General Pharmaceutical Legislation needs to ensure that the regulatory framework for medicinal products is not only adapted to strengthen the current practice but also to foster innovation and secure patient access to be fully futureproofed and ready for the challenges ahead. To support this aim EAHP 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.

Guaranteeing a very high level of patient safety across Europe

Patient safety is a fundamental cornerstone in the delivery of essential health services. Practising it across all healthcare settings prevents and reduces risks and lowers errors and harm that occur to patients during the provision of healthcare. In the revision of the General Pharmaceutical Legislation, patient safety should play an integral role and consequently, EAHP recommends

- the application of aggregated barcodes on the primary packing to further reduce errors and adverse drug events at the patient level in hospitals,
- improved usage of real-world evidence and the continuous analysis of pharmacovigilance data, especially for therapies targeting rare diseases
- including occupational health aspects in the summary of product characteristics (SmPC), in particular for hazardous medicinal products, and
- educating the public, including healthcare professionals, on the safe disposal of expired and/or unused medicinal products and medical devices, such as inhalers, insulin syringes or patches, to reduce their impact on the environment.

Additionally, EAHP would like to emphasise that replacing the paper package leaflet with a fully electronic version might not work for the entire supply chain. It could be feasible for products that are only sold in hospitals, provided that infrastructure for accessing electronic product information (ePI) is set up in all hospitals. However, for products supplied to out-patients paper package leaflets are still paramount since not all patients have sufficient digital literacy to only use these leaflets electronically. The safeguard of guaranteeing free-of-charge access to a paper version of the package leaflet should not place an additional burden on the pharmacist.

Combatting antimicrobial resistance and fostering prudent use of antibiotics

The emergence of antibiotic resistance (AMR) is widely recognised as a major public health problem that seriously jeopardises the effectiveness of standard treatments, rendering some ineffective for their approved indications. A variety of measures focused on the development of new agents, safeguarding those already on the market and stimulating appropriate use are needed. EAHP advocates for

- the creation of specific incentives to promote the development of new classes of antimicrobials,
- the implementation of arrangements to maintain essential antibiotics on the market, e.g. through contingency stock and alternative production by hospital pharmacists enabled where necessary, and
- the recognition and enhancement of the role of clinical pharmacy activities in the fight against AMR across Europe.

Ensuring accessibility and addressing the root causes of medicine shortages to adequately prevent and control them

Problems caused by medicines shortages are serious, threaten patient care in hospitals and require urgent action. For hospital pharmacists, patients must receive the medication they need to improve their health and prevent and cure diseases. Thus, EAHP calls for

- requiring the creation and regular maintenance of safety plans and risk assessments for manufacturers,
- the establishment of multistakeholder task force teams to perform joint risk assessments,

- the provision of information in regularly updated shortage monitoring systems to healthcare professionals, in particular, hospital pharmacists,
- incentivising timely sharing of information by companies, e.g. through a reward system or a whitelist,
- the development of a list of essential medicines that can be adjusted by countries to serve their national needs,
- mandating Member States to set up national task force teams, comprised of national agencies, industry and frontline healthcare professionals like hospital pharmacists that discuss and adopt proactive measures for combatting shortages,
- exploring the feasibility of raw material production in Europe for certain products, especially when it comes to products with a high dependency on outside sources,
- anchoring the role of healthcare professionals, in particular hospital pharmacists, in the field of compounding, meaning that compounding possibilities to offer adequate patient care should be enhanced.

Upholding the high level of pharmacovigilance in Europe

Hospital pharmacists play a significant role in adverse drug reaction reporting (ADR) because the most serious adverse events occur in hospitals, and ADRs account for a substantial proportion of hospital admissions. For EAHP, raising awareness about the importance of reporting is paramount for improving the reporting practice of healthcare professionals and fostering methods that increase the notification rate, e.g. by encouraging reporting by citizens and patients towards healthcare professionals.

Enhancing the safety of the health workforce and the environment

Due to their nature pharmaceuticals can have negative effects on the environment, including agriculture, aquaculture, livestock and, ultimately, humans and patients, EAHP strongly encourages the inclusion of information in the package insert on toxicity (for both humans and the environment), the environmental risks that are present and details on how the drug should be destroyed and where.

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