PGEU GPUE

Pharmaceutical Group of European Union
Groupement Pharmaceutique de l'Union Européenne

PGEU feedback on the European Commission Proposal for an EU Regulation on Artificial Intelligence

The Pharmaceutical Group of the European Union (PGEU), the organisation representing community pharmacists in 32 European countries, welcomes the European Commission's Proposal for an EU Regulation on Artificial Intelligence (AI) to establish a legal framework on AI Systems (''The Proposal'' hereafter).

We support the European Commission's general objective to ensure that the development and uptake of AI across the Single Market is conducted in a trustworthy way. As it develops fast, that AI will have a major impact on society and on a wide array of sectors of the economy is no longer a question.

In the healthcare sector, PGEU acknowledges the value of innovative technologies such as Big Data and AI and considers them a useful tool to support health professionals and EU health systems[1] [2]. In routine pharmacy practice at national level, we recommend that these tools shall always be accompanied by the supervision of pharmacists' expert and professional advice, to use them to improve workflow efficiency, while promoting patient safety, therapy effectiveness and offering the highest standard of pharmacy services and pharmaceutical care to patients. We consider that the integration of AI tools in routine practice should be complementary to the physical consultation with the pharmacist, to capture the full potential of the trustful relationship between the patient and the pharmacists. AI-driven tools should support community pharmacists interventions, enabling an informed decision by the patient based on the advice of the pharmacist. In this way , AI tools can make pharmacy operations more efficient and foster personalized care, improving safety and quality of services. Adequate regulatory frameworks are essential to ensure their trustworthy use, as well as to lay down the limits of AI applications in healthcare.

While we see great value in using AI in healthcare for enabling meaningful innovation, supporting health professionals and enhancing patient care, we are aware that it may also entail significant risks, for example in relation to the use of health and patient data.

Therefore we support the Proposal put forward by the European Commission as it provides a good basis to address use of AI systems which may affect health and safety of users and consumers as well as their fundamental rights. In particular, we appreciate that the Proposal focuses on high-risk systems, whose scope includes those AI applications being a safety component of a product, or is itself a product covered by EU harmonised legislation.

It will be key to ensure enhanced compliance standards on AI high-risk systems as set out in the Proposal, for example in relation to conformity assessment, human oversight, and the provision of information to users, such that high-risk AI systems are designed and developed to ensure adequate transparency and to enable users to interpret the outputs and use them appropriately. For that purpose, the AI systems falling into this category of risk should be accompanied by satisfactory and comprehensible instructions to the users of the system.

[1] PGEU Position Paper on Big Data & Artificial Intelligence in Healthcare
[2] PGEU Position Paper on Digital Health

In practice, these requirements shall be complemented by the provision of adequate training on AI techniques and approaches to the users of AI systems. Training on AI techniques and approaches (e.g. machine learning) should be provided to healthcare professionals, initiating at undergraduate level, and this must be supported by appropriate structures in the practicing environment. The workforce needs to be appropriately trained and financially supported during the introduction and application of AI systems in healthcare settings.[3] In healthcare, PGEU therefore supports EU coordinated strategies that aim to enhance the development of digital skills needed to successfully deploy new digital technologies, such as artificial intelligence, that aim to improve the quality of care and increase efficiency in Member States' health systems.[4]

In this respect, pharmacists are already increasingly integrating automated technologies within their practice, which generate significant benefits in terms of safe dispensing and saved working time on dispensing which pharmacists can spend on providing patients with professional advice and services. Examples include pharmacy dispensing software, automated pack dispensing robots, central filling systems and automated daily dosing systems.

In order to increase acceptance of AI in strategic sectors of public interest such as healthcare, PGEU believes that specific regulation of AI in healthcare – as envisaged by the European Commission in the context of the European Health Data Space - is needed to develop clear standards and legally binding assessment criteria to ensure transparency of AI systems. Transparent, clinically validated AI and systematic quality checks could foster the acceptance and trust among the users of AI systems in healthcare.

To fully harness the benefits of AI in healthcare, a key requirement is to develop trust by all stakeholders involved through guaranteeing a high level of data protection. Patient data must be processed under a high level of data protection standards within trustworthy infrastructures that enable the access to secure data services. It also has to be ensured that data access and analysis are amenable to European rules for privacy and data protection.

Community pharmacists remain a trusted source of reliable and independent health information for patients in the era of digitalization and of multiplication of information sources, by making the innovative digital and AI solutions integral to community pharmacy practice.

Therefore, PGEU strongly believes that communication and collaboration between patients, healthcare professionals and ICT developers is crucial to obtain the full potential of AI technologies and health data sharing as well as to build confidence and trust. In view of the next steps in the development of the Proposal, and with respect to specific impact of AI in healthcare, we would like to call upon European policy makers to meaningfully involve community pharmacists, as experienced users of digital health tools, in the formulation of such policies.

[3] CED-CPME-EFN-EPF-PGEU Consensus Framework on digital transformation in healthcare
[4] PGEU Position Paper on Pact for Skills