

PGEU Response to the EC Roadmap on Artificial Intelligence (AI) - ethical and legal requirements

The Pharmaceutical Group of the European Union (PGEU), the organization representing community pharmacists in 32 European countries, welcomes the European Commission's Roadmap aimed at addressing a number of ethical and legal issues raised by Artificial Intelligence (AI).

We support the Commission's general objective to ensure the development and uptake of lawful and trustworthy AI across the Single Market through the creation of an ecosystem of trust. As AI applications develop 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 AI and Big Data analytics and considers these technologies to be a useful tool to support health professionals and EU health systems. 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.

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.

In order 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.

Therefore, we consider a EU legislative initiative on AI, as envisaged under most policy options proposed by the Commission in the Roadmap, to be an adequate way forward to address the risks linked to the development and use of certain AI applications.

We welcome in particular a EU legislative initiative following a risk-based approach as already defined in the White Paper on AI published in February 2020. Taking this into account, we support Commission's "Option 3" proposal in the Roadmap, with a preference for the second sub-option, recommending a EU legislative instrument which could be limited to "high-risk" AI applications¹, including those which are likely to be deployed in the healthcare sector. We would as well support the proposed "Option 4", which envisages to implement the sub-option above while taking into account the different level of risks that could be generated by a particular AI application.

In view of the next steps in addressing ethical and legal issues related to AI, we urge the European Commission to involve community pharmacists, as experienced users of digital health tools, in the formulation of such policies as well as in the development of guidelines and methods on the deployment of AI in healthcare. To provide a full overview of our position on AI, please find attached to this feedback the PGEU Position Paper on Big Data & AI in Healthcare.

¹ For further details on the definition of "high-risk", please see the [White Paper on AI](#), p. 17