Empowering people's Self-Care through Artificial Intelligence

AESGP reply to European Commission's proposal for a regulation
of the European Parliament and of the Council laying down harmonised rules
on Artificial Intelligence and amending certain union legislative acts.

AESGP welcomes the European Commission's effort to develop a European approach for artificial intelligence (AI) that promotes Europe's innovation capacity while ensuring the creation of an ethical and trustworthy AI. If properly addressed, AI could bring tremendous benefits to the healthcare sector as a whole and some of its potential applications are already described in numerous publications.

Particularly in the self-care sector, AESGP believes that AI can help fostering a personalised self-care approach and empowering people to better manage their health and well-being, especially regarding the prevention, early detection and treatment of potential health concerns. AI, by analysing data shared by consenting individuals, could support them in practicing correct self-diagnosis and responsible self-care.

AESGP welcomes the risk-based approach but calls for internationally aligned criteria

Supervision of AI should be indeed proportionate to the intended use and led by defined **risk categories** with **clear internationally defined criteria**.

Data governance is a cornerstone for AI policy development

Discretionary application of GDPR and market fragmentation are major issues that need to be properly addressed in the coming years, concomitantly to AI policy development.

Clearly defined accountabilities and liabilities that allow progress and utility of AI

The development and use of AI-powered tools is subject to different contributors. As the development of the various applications of AI is progressing, it is becoming absolutely necessary that accountabilities and liabilities are clearly defined, in respect of user safety, developers' guidance and business certainty.

A regulatory framework with flexible mechanisms for quick adaptation to technology evolution

As recognised in the regulation proposal, the current fast-paced development of new technologies requires a change in the way these new services/products are regulated.

Fair and horizontal regulation

In the healthcare sector, the pharmaceutical industry is used to working in a highly regulated environment. The various types of products must follow a strict procedure of safety testing and extensive evaluations of their benefits before any marketing authorisation is issued by the authorities. Industry actors such as digital developers may be new to this highly regulated environment of traditional healthcare. Without overly limiting access to innovative technologies, regulators must ensure a fair level

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playing field for all actors by drafting and enforcing horizontal regulations across sectors while taking into account the particularities of the healthcare sector, respecting the benefit/risk profiles of the products and the data privacy of the patients.

Empower people's health and digital literacies for better understanding and use of AI

As a general principle, AESGP believes that there is a tremendous opportunity for health data to be used for personalised care and to empower people to take an active role in the management of their own health.

If general population is more informed on the added value of healthcare data for individuals and society, it could be more prone to register and use data while, consequently, increasing data quantity and quality. Information on rights, duties and possibilities granted by the use of healthcare data will create more competent and confident citizens in dealing with digitalization. The prerequisites must, therefore, be met for individuals to be the responsible owners of their data and to enact this sovereignty.

The need to build digital workforce capacity is already well recognized[1]. AESGP would highlight the fact that there are important needs in the training of both healthcare and digital experts, so that the ability to work cross-functionally is enhanced. AESGP believes that it is important to train people specialized in the field of artificial intelligence or data science, as well as to give basic training to the general population. Available and easy to understand education tools will be required for universal trust and use of data. Having everyone digitally and data literate will not only ensure responsible and adequate use of the digital tools, but will build trust and confidence in the system as well.

Europe must ensure a fit for purpose regulatory framework so that people can safely enjoy the benefits brought by digital transformation and new technologies. AESGP believes that industry, regulators, legislators and society at large have to work together to accelerate the effort, if Europe is to become a leader in the digital health space.

Brussels, 06 August 2021

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[1] Building digital workforce capacity and skills for data-intensive science
Available at http://www.oecd.org/publications/building-digital-workforce-capacity-and-skills-for-data-intensive-science-e08aa3bb-en.htm