Brussels, 20 March 2025

EU rules on medical devices and in vitro diagnostics – targeted evaluation: EFPA Statement

Context

Founded in 1981, the European Federation of Psychologists' Associations (EFPA) is the European umbrella organisation for national psychologists' associations (1). EFPA develops psychology education, science, and professional practice, and contributes psychological theory and practice to quality of life including health and wellbeing of people living in Europe. EFPA brings together some 300,000 psychologists through its Full Members.

EFPA is an engaged stakeholder in current EU-level activities and discussions surrounding mental health and places particular importance on the societal impact of digitalisation—having previously issued a statement related to the topic of this evaluation (2).

We appreciate the work happening around regulating the use of digital technologies for healthcare—from health technology assessment to medical device regulation in the EU—as safe and effective solutions are of the upmost importance to further strengthen and innovate healthcare systems. As psychologists, we would like to emphasise the importance of considering the specifics of mental healthcare in this regard to ensure that the right level of regulation and types of assessment are introduced.

Level of regulation

The current regulation appears challenging for certain types of psychological interventions such as digital mental health apps. Such apps are often interventional in nature but, compared to other Class IIa medical devices, typically of comparatively lower risk.

This viewpoint has already been acknowledged outside of the EU, with the TGA in Australia, and MHRA and NICE in the United Kingdom considering dedicated regulation for digital mental health. In the EU context this would likely involve a combination of exempted classes of development as well as methods of assessment that are well matched for psychologically oriented tools for treatment, assessment and other forms of intervention.

Consideration should be given to the level of regulatory processes on the basis of risk posed in order to develop a ‘right touch’ approach that balances safety with the need to encourage agile and inclusive development. In practice this may look similar to the levels of risk outlined in the EU AI Act.

Type of assessment

Digital mental health solutions supplement or transform established practice in mental healthcare. The psychological dimensions of these solutions may warrant a more tailored rather than generic approach.

Where regulation is warranted in relation to digital mental health technologies, it is important that processes are in place that can appropriately assess this type of health technology based on relevant psychological criteria—relating to cognition, affect and behaviour—rather than through the lens of a traditionally physiological approach.

Conclusion

A realignment of risk for digital mental health may be needed to facilitate innovation and uptake of good (digital) practices.

Given the extent of this topic EFPA recommends further consultation with relevant stakeholders to develop a process of risk categorisation and methods of assessment suitable for digital mental health.

We remain committed to further input and collaboration on this topic.

References

1 – European Federation of Psychologists' Associations https://www.efpa.eu

2 – EFPA Statement on The Impact of the "Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices" on the Evaluation of Tests Based on Measurement Theory (January, 2023) https://www.efpa.eu/regulation-eu-2017745-medical-devices-efpa-response