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‘Move fast and break things’ must not endanger patient safety: Medical devices must remain under safeguards of the AI Act

The General Assembly of the Standing Committee of European Doctors (CPME) has adopted proposed amendments to the [Digital Omnibus on AI](#) and the proposal for a targeted revision of EU rules on [medical devices and *in vitro* diagnostics](#). European doctors reaffirm that the EU co-legislators must maintain medical devices and *in vitro* medical devices within the scope of the AI Act, and apply the requirements for high-risk AI systems set out in Chapter III, Section 2 of the AI Act.

CPME President Dr Ole Johan Bakke said “European doctors emphasise that the technology sector’s philosophy to ‘move fast and break things’ cannot be applied to medical innovation. We acknowledge the imperative to enhance European competitiveness, however if patients’ lives and public trust are damaged in the process, then this will ultimately inhibit the uptake of AI in healthcare.

“We must be clear: the accelerated process of the Digital Omnibus goes beyond simplification and threatens to become reckless and undemocratic deregulation without proper scrutiny from stakeholders, such as ethicists and healthcare professionals. European doctors cannot accept that high-risk AI innovation in medical devices will take place without the proper safeguards in place.”

Prof. Dr Christian Lovis, CPME rapporteur on AI, said “Different AI systems realities come into play. For example, deep learning algorithms for image recognition are distinct from generative AI systems such as medical scribe applications. The use of generative AI is adaptive and the same prompt may not deliver the same result twice. This requires appropriate safeguards and tailored rules such as human oversight.”

CPME Vice President Dr Péter Álmos added “European doctors are against the dilution of clinical evidence requirements for high-risk devices, we stress that direct clinical evidence from the manufacturer is essential to ensure patient safety and maintain public trust.”

The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.