



Europe's medical AI reforms

Experts have criticised the EU's plans to revise medical data governance, following concerted pressure from US tech companies. Paul Webster reports.

European laws governing the use of European public health data for artificial intelligence (AI) development have long attracted wrath—and threats of economic retaliation—from US officials. But in November, 2025, when US Commerce Secretary Howard Lutnick tied US steel tariffs to a “recalibration” by the EU of the bloc’s digital regulations, the issue reached a crisis level. In response, according to observers in Brussels, intimidated European officials are now reforming regulations governing AI, health-care data, and medical devices.

Critics condemn these reforms as a surrender to economic blackmail that could jeopardise the responsible use of the many huge European health-care and medical databases that AI developers in the USA, as well as in Europe, hope to mine. However, they are welcomed by many leaders within Europe’s €170 billion medical devices sector, which employs over 900 000 people in more than 38 000 companies across the EU.

Speaking at a medical devices conference in Brussels on March 16, Olivér Várhelyi, who is the European Commissioner for Health and Animal Welfare, said proposed reforms to Europe’s Medical Device and In Vitro Diagnostic Regulations will soon “make it easier for companies to bring devices to the market” through “smarter regulation” of products, such as AI-driven diagnostic tools, that are “key to the future of healthcare”.

However, the reforms Várhelyi describes will fundamentally reshape how medical AI is governed in Europe and will weaken safeguards for medical AI, warns Hannah van Kolschooten, Researcher in Law, AI, and Health at the University of Basel, Basel, Switzerland. “If adopted, AI medical devices would remain labelled as ‘high-risk’, but would

no longer be subject to meaningful high-risk obligations”, she says. “In a domain where AI directly affects diagnosis, treatment, and patient health, this creates a serious regulatory gap with real risks for patients.”

Propelling these reforms, says van Kolschooten, is the fact that “the big American tech companies have moved into the European MedTech space”, and “Europeans are very afraid that they will ruin their economy by not agreeing with what the US is doing, by not listening to the US”.

The reforms to European medical AI governance described by Várhelyi and van Kolschooten are part of a broader push in Brussels to scale back data protection laws and rethink Europe’s AI Act, says Laura Lazaro Cabrera, Counsel and Director of the Equity and Data Programme at the Centre for Democracy & Technology Europe office, in Brussels, Belgium.

The primary targets of a lot of the EU’s rights-focused legislation are American companies increasingly involved in health care and medical enterprises in Europe, Lazaro Cabrera explains. “So, it would only be natural for the EU to enforce its rules against them, but it’s the first time where we see the US executive essentially intimidating the EU executive from fully implementing and enforcing these laws.”

In particular, Lazaro Cabrera points to Europe’s General Data Protection Regulation, which by default bans all processing of sensitive data, including health-care and medical data, that medical AI developers depend on, as well as Europe’s AI Act.

Hostility within the AI industry to European tech regulations is widespread, Lazaro Cabrera notes. A 2024 open letter from scores of European and US tech leaders, including Meta CEO Mark Zuckerberg,

warned European policy makers that “if companies and institutions are going to invest tens of billions of euros to build Generative AI for European citizens, they require clear rules, consistently applied, enabling the use of European data. But in recent times, regulatory decision making has become fragmented and unpredictable, while interventions by the European Data Protection Authorities have created huge uncertainty about what kinds of data can be used to train AI models.”

A spokesperson for the European Commission told *The Lancet*: “We have always been clear that the EU’s legislation is not up for negotiation. This remains absolutely unchanged. The EU has the sovereign right to regulate services operating in its market, irrespective of where those services originate from. Our digital legislation is protecting our values online in the EU.”

Emilia Javorsky, a researcher clinician with the California-based Future of Life Institute, warns that the American AI development model promoted by US officials and tech executives might not prove to be the wisest choice over the long term for medical AI development in Europe.

“In the United States”, she explains, “the prevailing ethos favors short-term wins, and extracting existing data over investing in the 21st century biology and health data commons needed to unlock AI’s potential in medicine.”

By contrast, Javorsky says, “the philosophical approach to health data in Europe, where it is treated as a public good requiring coordinated stewardship, is better suited to the structured, longitudinal, population-scale data collection that will be needed to make AI in medicine genuinely useful”.

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