MEDTECH INSIGHT
CITELINE COMMERCIAL

21 Feb 2024 | **Interviews**

Experts Press For New Artificial Intelligence Regulatory Approaches

AI-based innovations face substantial waiting times for approval in the EU and US

by Natasha Barrow

Rigid regulations are delaying patient access to life-saving technology and preventing AI innovation in the EU, researchers say. A new paper from the publishers of Nature gives concrete proposals for how to adapt EU regulatory approaches to support innovative health tech.

The ongoing shift towards more digitized health care is likely to exacerbate the trend of regulatory delay, researchers argued in a recent opinion piece published in *npj Precision Oncology*.

NPJ, or the Nature Partner Journals series, is a set of peer-reviewed open-access medical journals published by Nature Portfolio.

The paper suggests tangible solutions for addressing regulatory challenges to optimize safe approval pathways, including adaptations to the regulatory approval process for AI-enabled medical devices and improvements for post-market surveillance to allow for adaptive AI-enabled devices.

Increasingly, emerging health care solutions are not based on a single medicine or medical device but a system with interactions between technological, mechanical and chemical components, Stephen Gilbert, paper author and professor of medical device regulation at the Else Kröner Fresenius Center for Digital Health, told *Medtech Insight*.

Too often regulations treat medicines, medical devices, and AI separately, say the authors, who include professors at several German and French universities. However, there are emerging

innovations with interactions between patient data, AI and the prescriptions, design and dosing of medicines.

The legislative boundaries between medicines and medical devices do not reflect how these systems of medicinal products are being used in practice, Gilbert told *Medtech Insight*.

As an example, the paper cites the regulatory challenges posed by digital twins – real-time digital representations of a patient's physiological and clinical data that can be used to develop a more personalized treatment approach. However, the authors write, "comprehensive realization of the [digital twin] concept is precluded under current regulatory frameworks, as these require the pre-specification of device intended purpose."

Digital twins can only be marketed under a narrow-intended purpose. This system can, therefore, not adapt appropriately to patients when being used in clinic.

Furthermore, artificial legislative boundaries and rigid regulations are impacting the level of innovation seen in the EU, said Gilbert.

> *"Regulation dictates innovation" - Stephen Gilbert*

Fast-Track Programs For Novel Medical Devices

The authors argued that fast-track programs are needed for novel medicinal products.

Novel products often have traditional regulatory routes closed off to them and require specialist regulatory processes for approval. Innovators then face bottlenecks in market access because only a few regulatory approval bodies can review these novel products, the paper states.

The UK has introduced an innovator-friendly approach, said researchers, with the *airlock classification rule* that allows temporary early market release of medium-risk products. Once the product is released, it is subject to stringent post-market oversight akin to that of high-risk devices.

Independent Certification For Quality Management System

Expert review of medical device technical dossiers is extremely time-consuming and leads to regulatory bottlenecks. For low-risk AI-enabled medical devices, these detailed reviews do not necessarily deliver the same value as for high-risk devices, say researchers.

There is an alternative approach for quality management assessment in the EU. Under this approach, a sentinel device from an intermediate risk class is assessed in detail, and the quality management system is certified. Manufacturers can then use the certified quality management system to self-assess and release devices on the market.

However, this approach is not widely used for AI medical devices.

The paper also suggests independent laboratory testing of AI device performance as a way to speed up time to market.

Regulatory Process For On-Market Adaptive AI

Traditional regulatory approaches make it impossible to have adaptive continuous learning AI-enabled medical devices. This is because when changes are made to an AI-enabled medical device, the whole device has to go through reapproval. However, this approach neglects one of the primary benefits of AI: its ability to learn and adapt.

The EU AI Act proposes adaptive frameworks with careful oversight of real-world performance.

Under Article 66, an AI system is considered new and needs to undergo a new conformity assessment when a substantial modification occurs, such as change of intended purpose, operating system, or software architecture.

However, reassessment is not necessary for changes predetermined by the manufacturer, for AI systems that continue to learn after market placement.

The paper claims that this falls short of what is necessary because it does not allow AI systems to develop through real-time practical learning. Manufacturers are forecasting the changes before the device is placed on the market and do not have the opportunity to integrate real-time feedback.

It states that an ideal regulatory approach could be “bolder” to allow on-market adaptivity of AI devices by linking to transparent and well-designed real-world performance monitoring.

Overlapping AI Models To Account For Bias

Medical devices are typically approved for a narrow-intended purpose. This fixed model for generalist/broad-scope AI, such as large language models and generalist medical AI models, fails to exploit the generalist interpretation that it could provide.

Researchers suggest overlapping independent AI models should be used to moderate adaptive AI. These models are built on different AI approaches and trained on different data but come together to provide analysis of clinical data.

Health care providers can then triangulate their own views, with the views of the two independent AI systems to decide.