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# EU AI Act Legal Deep Dive Part 2: Balancing Medtech Innovation with Safety

by [Eliza Slawther](#)

The EU AI Act could introduce rigorous regulatory requirements for AI-based medical devices in addition to those contained in the MDR/IVDR. Lawyers from Cooley LLP tell *Medtech Insight* how changes to the commission's proposal could improve its impact on medtech while keeping patients safe.

Tomorrow (June 14), the European Commission's landmark AI Act proposal is scheduled to undergo a plenary vote by members of the European Parliament, which could see the draft text move into the final high-level negotiation phase, known as trilogue discussions.

In an article published last week, expert lawyers at Cooley explained what the AI Act means for medtech, why it remains uncertain, and when it might apply. (Also see "[EU AI Act Legal Deep-Dive Part 1: What Can Medtech Expect, And When?](#)" - Medtech Insight, June 7, 2023.)

In this second deep-dive legal analysis article, Cooley lawyers forecast the impact that the AI Act might have on:

- Conformity assessments;
- Patient access to innovative healthcare products;
- Areas for improvement in the draft text.

They also look at how the EU approach to

## Why Is the AI Act So Controversial?

As a horizontal regulation, the AI Act covers all sectors and uses of AI systems. In particular, EU political groups have been divided on issues such as the issue of using biometric identification such as facial recognition technology in public spaces.

Many of the AI Act's most contentious and

regulating AI differs from the UK framework.

## Are Dual Conformity Assessments Necessary?

The AI Act is, in its current form, likely to see those medical devices included in its scope required to demonstrate conformity with both MDR/IVDR rules and the AI Act, resulting in a dual conformity assessment process. Typically, in EU law, there is a clear delineation statement that enables sector-specific legislation to prevail above other applicable regulations.

According to Article 43(3) of the draft text, the responsibility for conducting AI Act conformity assessments will lie with the notified body that assesses a product for MDR/IVDR compliance. Many medtech industry stakeholders fear this will place additional burden on medtech notified bodies and manufacturers alike, at a time when many already face capacity challenges. (Also see "[Industry Calls For Single Conformity Assessments To Cover EU MDR, EHDS And AI Act](#)" - Medtech Insight, Feb. 24, 2023.).

Indeed, BSI Group announced in April that it has teamed up with Japan's Citadel AI to ensure it is sufficiently prepared to conduct conformity assessments for AI-based medical devices . (Also see "[Are Notified Bodies AI-Ready? BSI Teams Up With Expert Firm On Conformity Assessments](#)" - Medtech Insight, April 25, 2023.).

But is it really necessary for multiple conformity assessments to take place for products that are both medical devices and AI systems? Cooley lawyers Elizabeth Wright and Edward Turtle think not.

Wright and Turtle told *Medtech Insight* that it is "very common" for multiple legislations to apply to products without the need for multiple conformity assessments, particularly for general consumer goods such as electronics.

"The [electromagnetic compatibility legislation](#) that applies to certain types of medical devices is a case in point," the

hotly debated provisions do not directly apply to medical device manufacturers. However, the longer that EU policymakers and politicians fail to reach an agreement on the AI Act text, the further delayed its implementation is for the medtech sector.

## Key Takeaways

- Multiple conformity assessments for medical devices that fall within the AI Act and MDR/IVDR scopes may not be necessary.
- The AI Act text should be specific and streamlined to avoid adding unnecessary burdens on the medtech industry.
- The UK initially planned to take a non-

lawyers said. “Usually, the [MDR/IVDR] conformity assessment procedure addresses all requirements at once, removing the need for multiple assessments.”

This being said, Wright and Turtle note, conformity assessments for existing AI medical devices “may need to be redone”

to reflect the new requirements, even if the AI Act does not introduce the need for a separate conformity assessment for new products.

legislative approach to AI governance, but as the risks of this technology become more apparent, high-level politicians are beginning to push for regulatory intervention.

## Impact on Patients

In principle, Wright and Turtle said, the AI Act may enhance patient access to healthcare, and could “radically improve” the quality of this care - for instance by making diagnoses more accurate.

However, AI systems pose unique safety, security and clinical concerns that must be addressed. For instance, AI systems must be explainable and transparent, so that clinicians can interpret the outcomes of analysis made by these machines correctly. Bias is also a risk of AI that must be mitigated.

“The AI Act is designed to address these concerns to ensure that AI technologies are deployed appropriately in line with fundamental rights and values,” Wright and Turtle said. “On the other hand, there is always a risk in regulating AI, particularly in a manner that is very prescriptive, as the EU is proposing.”

This “prescriptive” regulatory approach risks negatively impacting innovation by limiting or delaying how quickly products are brought to market and therefore reach patients.

“It is important to strike a balance to retain an appropriate level of flexibility and scope for innovation by not creating too burdensome requirements, while at the same time protecting patients and other end users,” they added.

## What Changes Could Be Made?

The trilogue discussion stage, which will begin following a positive European Parliament plenary vote in favor of the current draft text, could create the opportunity for this balance to change. It is therefore “hard to gauge” at present whether the AI Act will cause disruption to health care services and innovations, or whether changes will need to be made to mitigate that risk, Wright and Turtle said.

The lawyers have identified two “key areas” of potential risk in the current draft text that may need to be managed: refining the definition of AI systems and avoiding regulatory duplication.

“The commission’s proposal took an extremely broad view of what should be considered as constituting an AI system, which would have brought a large number of software systems into its scope,” Wright and Turtle said, adding that this initial definition would include “far more” products than should be considered “true AI.”

The EU council and parliament have sought to narrow the definition, they note, which is important as “an overly-broad approach could be very burdensome” for software developers across the health and medtech industry.

The second point for improvement outlined by the lawyers relates to the interaction between the AI Act and other regulations, a theme explored in more depth in a previous Medtech Insight article which the same Cooley experts contributed to.

“There is a concern in the health care context, which is already highly regulated, that the AI Act could add another regulatory hurdle that imposes disproportionate burdens for providers of AI technologies,” Wright and Turtle said.

“It will be important to ensure that requirements in the final text are streamlined and avoid potentially duplicated or contradicting obligations to those imposed by other relevant legislation,” they added.

## **Could the UK Follow the EU?**

Ensuring that AI systems are safe and effective is a priority for policymakers across the globe, but the EU is one of the first to propose a dense, horizontal regulation on AI. Many critics of the AI Act warn that this will drive innovation out of the EU, into locations with more relaxed AI regulation, but as explained by Cooley lawyer Turtle, it is unlikely that the EU will see a mass exodus of AI-based medical devices.

The UK, which is now free post-Brexit to set its own laws around AI, had until last month opted for a ‘light-touch’ AI governance framework based on non-statutory guidance. (Also see "[What The UK’s “Non-Statutory” AI Regulatory Framework Means For Medtech](#)" - Medtech Insight, April 3, 2023.).

However, as noted by Turtle, the UK government’s position has shifted in recent weeks and although a formal proposal is yet to be revealed, there are calls among politicians for stricter rules on AI. On June 12, British prime minister Rishi Sunak said the UK should be the global home for AI regulation, suggesting the UK could reverse its original position that new legislation on AI is unnecessary.

“Regardless of the UK approach, it is unlikely that medtech companies will avoid the EU market entirely, even if the AI Act imposes significant regulatory burdens,” Turtle said.

“There are nearly half a billion EU consumers, which is a huge market to ignore,” he explained, adding that it has been proposed that the AI Act will apply “extra-territorially” to AI providers based anywhere in the world, so long as the system they manufacture affects EU users.

Establishing a company outside of the EU will therefore not enable them to avoid complying with the AI Act, Turtle said, assuming these companies wish to service the EU market.

“One trend we might see, however, is for medtech start-ups to look to launch outside the EU, to allow them to scale outside the restrictive environment of EU regulation, and then only come into the EU market at a more mature stage.”

Much of the discussion around AI regulation also assumes that industry opposes regulation of AI, but Turtle said this is not the case. “It should also not be overlooked that many AI providers are calling for more regulation,” he said, “because the lack of certainty in laws applying to these technologies can also have a detrimental effect on development.”