MEDTECH INSIGHT
CITELINE COMMERCIAL

30 Jun 2023 | **News**

EU Regulatory Roundup, June 2023: Medtech Shifts Focus To AI, Data And Digital

by Eliza Slawther

The European Commission's proposed AI Act entered high-level negotiations this month, generating a renewed interest among medtech stakeholders in this upcoming legislation and its impact on the sector.

On 14 June, the European Parliament adopted a draft mandate on the proposed Artificial Intelligence (AI) Act that will form the basis of its negotiations with the European Council and European Commission, known as trilogue discussions. The end result of these negotiations, which could conclude by spring 2024, will be a finalized version of the much-debated cross-sectoral regulation.

This *news in itself* was one of the top 10 most read articles among *Medtech Insight* subscribers in June, and an additional two stories focused on the AI Act also proved popular.

Lawyers from Cooley LLP *offered their analysis and insights* around the AI Act, outlining which medical devices will likely fall within the scope of the new regulation, when it might apply and how notified bodies will be affected.

The same group of lawyers also, *in a second article*, discussed the potential benefits of the AI Act and how changes to the draft text might help to minimize any negative impact on innovation.

The overlap with other regulations was also discussed by these legal experts, and this is a subject that has repeatedly been raised as a challenge for medtech companies looking to bring new products to, or keep existing products within, the EU market.

June was a quieter month for sectoral regulatory updates, with the most-read article of the month focusing on a paucity of new updates from the commission. *This piece* analyzed the

uncharacteristic change in pace of MDR/IVDR updates from EU policymakers.

MedTech Forum 2023

Coverage from the MedTech Forum 2023, which took place from 30 May-1 June in Dublin, Ireland, also featured in the top 10 this month. In the *opening plenary speech*, MedTech Europe CEO Oliver Bisazza stressed the importance of simplifying the EU's regulatory maze so that innovation can thrive across member states.

Bisazza acknowledged that despite being a single market, rules for accessing the EU are not yet truly harmonized and coherent, referencing the increasing number of legislations being pumped out of the commission on topics like digital health.

Indeed, the European Health Data Space (EHDS) was mentioned during numerous sessions at the MedTech Forum. During *one panel discussion*, three experts from different corners of the healthcare sector agreed that the wide scope of this initiative may prove difficult for the EU to deliver on.

The AI Act itself was also subject of a MedTech Forum 2023 *panel discussion* moderated by *Medtech Insight* senior writer Eliza Slawther, in which four experts – representing the commission, patients, industry, and healthcare professionals respectively – discussed their views on the AI Act and, more broadly, on the future of AI in medtech and health care.

The EU Regulation on Health Technology Assessment was also high on the agenda *during the MedTech Forum event*, with the clinical compliance lead from well-known notified body BSI suggesting that the expertise of these organizations could be better utilized during joint scientific consultations, without breaching the no-consultation rules set out in the MDR/IVDR.

Germany Also Pushing For Data Reform

The German government had originally planned to wait for the EHDS to be implemented before putting out national legislation on patient data use and protection, but it has now decided to get ahead of the game.

German policymakers introduced a draft law on governance and access to patients' healthcare data known as *Gesundheitsdatennutzungsgesetz – GDNG in June,* and have expressed ambitions for this new law to be implemented in January 2024. This will see the country's national legislation introduced far ahead of the EHDS, which is expected to take several years to reach the implementation stage.

In the UK, arrangements for national medtech legislation post-Brexit remain at the fore, and in mid-June the UK government published amended legislation implementing the extension of the periods during which certain EU-approved devices can still be sold in Great Britain.

Meanwhile, the *Medical Devices (Amendment) (Great Britain) Regulations 2023 will apply from 30 June and 1 July 2023*. This new framework was accompanied by guidance from the UK's medtech regulator.

Top 10 Articles In June 2023

The following table lists the most popular European regulatory and policy articles among our subscribers in June 2023. They explore the themes mentioned above in significantly more detail.

To read the May 2023 regulatory round-up, see: *EU Regulatory Roundup, May 2023: MDR Extension Updates Resume*

Rank	Title
1	*Is The Implementation Of The EU Medtech Regulatory Structure Entering A New Phase*
2	*EU AI Act Legal Deep-Dive Part 1: What Can Medtech Expect, And When?*
3	*MedTech Forum 2023: Europe's Regulatory Maze Must Be Simplified, But How?*
4	*EU AI Act Proposal Adopted By Parliament In Landslide Plenary Vote*
5	*Germany Moves Ahead Of EU With National Patient Data Use Draft Law*
6	*UK Medtech's Gateway To Regulatory Opportunity Is Open – But For How Long?*
7	*EU AI Act Legal Deep-Dive Part 2: Balancing Medtech Innovation With Safety*
8	*COCIR Report Maps Digital Health Market Access Routes In 6 European Countries*
9	*Notified Bodies Must Be Involved In EU Joint HTA Discussions, Urges BSI Clinical Compliance Lead*
10	*MedTech Forum 2023: Why The Commission Must Not 'Shoot For The Moon' With EHDS Plans*