Medical Devices Regulatory Update

October 2022

Latest updates on medical device regulations

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What is a medical device?

On 22 September, our CEO—Melissa Siah—featured in the Medical Device Manufacturing Centre (MDMC) Webinar "What is a Medical Device?". The webinar was presented with Marc Desmulliez, Manager of the MDMC, and Elaine Gemmell, Head of Regulatory Affairs at InnoScot Health.

Marc outlined the fundamental concepts that make a product a medical device, e.g. its intended purpose. Elaine then discussed the nuances of the regulatory borderlines between medical devices and other product types (including medicines, cosmetics, food supplements, PPE, biocides, machinery, laboratory equipment and software).

It was also a chance to catch a sneak preview of our Regtik software in action, with Melissa demonstrating two different topical case studies, i.e. products which lie on the medical device-IVD borderline interface, and how to appropriately qualify and classify products that combine wearables, software and mobile apps.

Read more on our blog

EU Commission to extend product liability to MedTech products

At the end of September the European Commission adopted two related proposals on no-fault liability for defective products:

- The first proposal, a revision of the 'old' Product Liability Directive, brings the legislation into the digital age by extending user compensation eligibility to all products; including medical health apps, software, and artificial intelligence (AI) systems.
- The second proposal complements the Product Liability Directive by providing liability rules specifically for damage caused by AI.

The proposals will now proceed through the legislative process, where they may still be amended.

These changes will particularly impact manufacturers of medical devices that include AI components, as well as developers of digital health apps. The leading European trade association for medical technology—MedTech Europe—warns that the proposals risk 'needlessly disrupting incentives to innovation.'

The first proposal will make it easier for users of software-based medical products to make compensation claims against manufacturers. Not only does the proposal specifically include software in the definition of 'product', but it also will be much more claimant friendly.

The proposal contains new rules about the disclosure of product information when a claim is made. In addition, it will extend the scope of damages claimable in relation to data losses, and introduce liability for the failure to supply cybersecurity updates. These changes will come as a significant change for manufacturers of medical devices involving any software components.

While the updating of product liability for the digital realm is welcome, these proposals could introduce legal uncertainty due to misalignment with the EU regulations on privacy (GDPR) and the proposed AI-Act, as well as national legislation at Member State level on data protection. We will monitor developments and keep you updated.

Read the EC's press release on the proposals here

MDCG issues new manual on borderlines

In early September, the Medical Devices Coordination Group (MDCG)—a working group of the European Commission—issued a new manual on Borderline and Classification under the EU MDR and IVDR. The MDCG is responsible for providing guidance on key issues from the medical devices sector, including Notified Body oversight, standardisation, market surveillance, new technologies and borderline and classification decisions.

The new manual does not entirely replace the old manual, which was issued under Directive 93/42/EC on medical devices, Directive 90/385/EEC on active implantable devices, and Directive 98/79/EC on in vitro diagnostic devices. It ran to 91 pages and described the MDCG's views on the tricky, nuanced distinctions between medical devices and IVDs, AIMDs, medicinal products, biocides, cosmetics and classification decisions. Much of that guidance will still continue to be influential for the MDR.

However, the new manual will go further as it records the MDCG's consideration of each section of the MDR/IVDR. The manual is so far only partly-populated, as many sections have not been yet been considered by the MDCG since the MDR/IVDR came into force.

One interesting case concerns a smartphone application for STI prevention, which allows for the exchange of information between different sexual partners. On the basis that the app only facilitates the exchange of information between partners, and only evaluates the risk of infection through indirect criteria, the Group decided that it should not qualify as a medical device, using MDCG Guidance 2019-11 on the qualification of software as a medical device to form their decision.

The new manual will provide clearer, more authoritative guidance on borderline and classification issues under the MDR/IVDR. Due to the EU's history of leadership in medical device regulation, it also has the potential to be influential globally as part of the international trend towards harmonisation. For example, the Therapeutic Goods Administration (TGA) of Australia recently released its own draft guidance on the boundary between medicines, devices and biologicals. The TGA aligned its position in many cases with guidance issued by the MDCG at the EU level.

Find out more about TGA's draft guidance

Read more about borderlines between devices and medicines in the EU

MHRA to endorse MDSAP audits

The UK government, in its June response to the consultation on the future regulation of medical devices in the UK, noted its intention to proceed with the proposal to utilise certificates issued under the Medical Device Single Audit Program (MDSAP) program as part of UK conformity assessment. There was broad support for the proposal, which will provide an alternative route to market for manufacturers.

UK Approved Bodies will be required to accept MDSAP certificates during conformity assessment. Adoption will be optional for manufacturers, but the program is expected to be popular as it will avoid duplication of audit processes.

The program allows MDSAP recognised auditing organisations to conduct a combined regulatory audit, so that manufacturers can be audited once for compliance with quality management system requirements of up to five different markets. This will enhance the supply of medical devices in the UK, whilst simultaneously retaining appropriate levels of scrutiny to ensure patient safety.

Read more about the MDSAP program here

Unsure whether the MDR applies?

Find out how we can help

MHRA Consultation: Key Points

On 26 June 2022, the Medicines and Healthcare Products Regulatory Agency (MHRA) published its response to its consultation on the future regulation of medical devices in the United Kingdom, including plans to reform how medical devices are regulated following the UK's exit from the European Union.

In a plan that the MHRA hopes will make the UK a focus for innovation, the proposed reforms have the potential to have a tremendous impact on MedTech startups, SMEs, as well as distributors and importers of medical devices in the UK.

The key points to take away from the MHRA's response include:

- Plans to expand the scope of the UK Medical Devices Regulations to include products with cosmetic or aesthetic purposes.
- The explicit exclusion from the UK MDR of products which contain or consist of viable biological substances or products which are foods.
- Changes to the classification rules to up-classify certain medical devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART).
- Changes to the classification of in-vitro diagnostic medical devices.
- The introduction of alternative routes to market, including reliance on approvals from other international regulators, abridged assessments, and a new premarket approval route for innovative medical devices.

UK MDR scope to be expanded

The government's response indicates that the scope of UK MDR will be expanded to cover a number of products which have previously been unregulated or regulated under different legislation. This is because these products have a similar patient risk profile to medical devices despite only having an cosmemtic purpose, i.e. no medical purpose.

This change will closely align the UK MDR with Annex XVI of the EU MDR. The Commission has also recently proposed a draft implementing regulation which would up-classify some Annex XVI products.

Up-classification of IVF and ART

The government intends to proceed with certain classification changes outlined in the consultation in relation to medical devices for IVF and ART.

The up-classification to Class III will only apply to substance-based devices used in vitro in direct contact with human embryos before implantation or administration, not to every tool used in IVF/ART.

UK to go beyond EU on nanomaterials

Medical devices incorporating nanomaterial are to be classified between Class IIa and Class III, depending on potential internal exposure levels.

The introduction of this rule would align with EU MDR, where such devices are caught by Classification Rule 19. However, the UK MDR 2002 would differ slightly in covering not only those devices incorporating nanomaterials, but also those generating them. This broader approach is not covered by EU MDR Classification Rule 19.

IVD up-classification imminent

The proposal states that the classification system applying to IVDs will be changed to adopt a series of rules closely mirroring the structure used by the IMDRF, where IVDs are classified as Class A, B, C or D.

Current rules allow roughly 80% of IVDs to be placed on the market on the basis of self-declaration. This will change under the new classification rules, under which most IVDs are expected to undergo Approved Body conformity assessment. This is a game changing increase in the level of regulatory scrutiny that will be applied to IVDs.

Read our full story on the proposed IVD classification changes

Need help classifying your medical device?

Find out how we can help

New UK Approved Body

A fourth approved body—DEKRA Certification UK—has been accredited to audit medical device submissions against the UKCA mark. The organisation's status as an approved body was confirmed by the MHRA on 2 September 2022. DEKRA joins BSI Assurance UK, SGS UK, and UL International in having UK approved body status for medical devices.

The accreditation of DEKRA will offer some relief to manufacturers who have faced lengthy waits at the three other UK approved bodies, but concerns remain over the adequacy of overall auditing capacity, particularly as the post-Brexit transition periods for obtaining the UKCA mark come to an end.

Given that UK designations can take between 12–18 months, there are fears that there will simply not be enough conformity assessment bodies to push through all of the devices required to switch over to UKCA marking.

Read more about the DEKRA accreditation

New EU Notified Bodies but capacity concerns continue

In early October, new EU Notified Bodies were designated under the MDR. Italian certification body

Ente Certificazione Macchine (ECM) is the latest Notified Body to be designated under the EU MDR, successfully transitioning from their previous status as a Notified Body under the old EU MDD. This designation takes the total number of Notified Bodies to 34 across the EU in total, with nine in Italy.

ECM's designation mainly concerns active non-implantable devices, and non-active non-implantable devices. They are also competent to assess non-active implants for dental use.

The other designation was Polskie Centrum Baden I Certyfikacji, the second Notified Body in Poland under the MDR.

It is to be hoped that these designations and the MDCG's recent 19-point action plan addressing Notified Body capacity will ease some of the challenges in ensuring sufficient capacity of Notified Bodies to support the medical device industry.

About Syntacog

Syntacog has developed a simple, cost effective solution for SMEs and startups, providing an AI guide to the medical device regulations across the UK, EU, USA and Australia. Our easy-to-use platform lets SMEs and startups explore the regulatory landscape and plan for future regulations before they become a major challenge.

You can also stay up-to-date on current developments by following our blog. Our blog covers news on the regulation of medical devices, standards and challenges in the industry. **Visit blog**

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