

UK's MHRA webinar on the new regulatory framework: 05 March 2024

Written by Robin Stephens, CEO

This morning (05 March 2024) the UK's Medicines and Healthcare products Regulatory Agency (MHRA) presented the first in a series of webinars that they are billing as "Med Tech Regulatory Reform: The first steps towards a new framework for medical devices in the UK".

This online session sought to provide insight into the scope of future new legislation in the UK, the proposed changes to the classification system, and the move from Essential Requirements to General Safety and Performance Requirements. If this is sounding anything like the EU MDR or EU IVDR then you have already got the main message from today's event: the UK will follow the EU regulations and IMDRF.

The webinar began with an overview of the current proposed legislative programme of the MHRA as shown in the roadmap published in January 2024. The three elements of the new regulations are:

1. Additional post-market surveillance requirements for the UK market (law to be passed later this year – dependent on the outcome of the general election);
2. An update to the main UK MDR 2002 legislation to bring forward "core" regulation that effectively is in line with the EU MDR – sometime this year or possibly early next;
3. A final piece of legislation to make any amendments necessary prior to full implementation in 2025.



From 2025 the current proposal is that the UK law – for UKCA Marking and only for England, Wales and Scotland – will effectively be the same as the EU MDR and IVDR with a few minor tweaks or guidance documents. This programme of mirroring the EU regulation is being termed as “greater alignment with international best practices”.

There will be one or two UK specific nuances, such as three additional categories of IVDs related technologies in particular and the “tailoring” of the EU GSPRs to the “domestic [GB] context”.

The three UK-specific additional IVD categories are:

- IVDs that monitor infectious load of life-threatening infectious diseases: Class D
- IVDs intended to screen, detect or diagnose neurodegenerative diseases: Class C
- IVDs intended to screen, detect or diagnose cardiovascular diseases: Class C

Beyond the proposed alignment of classification and GSPRs with the EU MDR / IVDR there was also a discussion about the foreseen enhanced and new requirements for product labelling, instructions for use (IFU), websites, etc. This included:

- The requirement to ensure that IFUs, etc. are also available on the manufacturer's or device specific website;
- Some environmental sustainability concessions (electronic IFU for *some* devices; potential to "agree with the user to provide a single copy IFU" instead of multiple ones if a number of the same devices are in use at the same location;
- All devices to carry a Unique Device Identifier (UDI);
- All devices to have details in their IFU or labels that facilitate the reporting of serious incidents to the manufacturer and the MHRA;
- Specific information for the end user with regard to clinical benefit associated with the device.

It is yet to be seen how these requirements will fit with the EU MDR / IVDR particularly with regard to use of EUDAMED (the EU members only database), the acceptance in the UK of CE Marked devices, and what need there would be for UKCA Marking, if any.

Of note, there was no mention at all of the philosophically different approach to medical device and IVD regulation by the FDA in the USA.

Are these proposals for "new" regulations in the UK truly new? In the author's personal view, no, as I would suggest these proposed new laws are designed to align with EU CE Marking requirements and effectively re-instate seamless movement of devices between the UK and EU. That may be desirable for large manufacturers who have a vested interest in having a harmonised European strategy but misses the opportunity to creatively look at true alternative approaches to regulation that actually address the needs of innovative technological advancements beyond merely the acceptance of PCCPs for AI.

Stay tuned for more news on this topic as it becomes available over the next months.