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Diagnostics Industry Helps MHRA Shape IVDs Roadmap As Part Of Future UK Regulation

UK regulatory update from industry and MHRA: February 2023

by Ashley Yeo

The MHRA will build its new UK system of medtech regulation on seven regulatory pillars, one of which is an IVD roadmap, says diagnostics industry association BIVDA. The trade body gave an update on the focus groups, UKAB numbers and timings for three awaited statutory instruments.

“We’re waiting for the first statutory instrument (SI),” said Ashleigh Batchen. “That’s a crucial next step as the UK continues to build its standalone medtech regulatory system, and would solidify that we have the [new] date of application,” BIVDA’s head of regulatory affairs told *Medtech Insight*.

The new date of application of the UK system will be 1 July 2024, a year later than initially planned by the Medicines and Healthcare products Regulatory Agency (MHRA). The deferral was suggested by the agency’s chief healthcare quality and access office Laura Squire in autumn 2022. (Also see "*MHRA Grants Extra Year For CE-Marked Devices To Access UK Market*" - Medtech Insight, 24 Oct, 2022.)

But as yet, nothing is official, meaning that companies and their legal departments cannot plan with certainty. Many in the industry feel that even an extra year, while being something of a relief, would still not bring medtech manufacturers into any sort of comfort zone.

This extra time for compliance would be implemented by the first of three SIs that will be the basis of the UK’s regulatory system. The second SI would be on post-market surveillance (PMS), and the third, and most important, would implement the bulk of the new regulatory system.

These steps were explained by the MHRA in a recent online seminar.

Batchen and BIVDA chief executive Doris-Ann Williams expect significant progress for the UK system in February. In January, the MHRA said it planned to focus on UK approved body capacity and mechanisms to advance innovation, and on gaining a better understanding of the scope available to admit selected medtech products approved in other jurisdictions onto the UK market

In Europe, the Swiss parliament has taken a lead in this area by approving the principle of allowing US Food and Drug Administration-approved onto the local market. Switzerland, like the UK, now finds itself a third country to the EU in terms of the medical device market and associated regulations.

SI Timetable

The first SI, formalizing the one year's deferral of entry in force of the main UK regulation, is expected in spring 2023, Batchen said. After its route through parliament it will be applicable immediately.

The proposed three- and five-year transition periods should also be clarified as to their start dates within the next month or so. The current assumption is that they will apply as of 1 July 2024 (and will last until mid-2027 and mid-2029, respectively.)

The SI for PMS should be issued in summer, but it will not be applicable until winter 2023, as, under World Trade Organization rules, it must be made available for review for 60 days.

The third SI, for the main regulation, is planned for winter 2023, and will be applicable in summer 2024.

Seven Pillars Of Regulation

The MHRA has established seven pillars of work with which to shape and deliver its future regulatory system. One is an "IVD Roadmap," on which the MHRA hosted a meeting on 10 February, supported by BIVDA and other IVD stakeholders.

Ahead of the meeting, BIVDA was anticipating fruitful discussions with industry experts, government representatives and other pivotal stakeholders on gaps to fill and where support is needed to ensure the health care system can access the full value of IVDs.

"This exercise should give industry a voice to feed into the thinking," said Williams, on elements like the accelerator pathway and future innovative devices access pathway (IDAP) mechanism. Batchen added: "It should clearly define the intentions of the MHRA on, say being aligned more closely with the EU and/or US FDA."

The MHRA has been rebuilding its IVD resources, which BIVDA is encouraged to see. The agency recently promoted Cristina Santirso-Margaretto to diagnostics lead, innovative devices. Since taking the role in January 2023, she has been open to hearing BIVDA's concerns on market access issues. Joseph Burt left the IVD industry to join the MHRA on 10 February as head of diagnostics.

BIVDA, too, plans to increase its regulatory capacity, and is currently recruiting for a junior executive to support Batchen.

The other MHRA pillars are: domestic assurance pathways; transitional arrangements and future regulation SIs; stakeholder engagement; software/artificial intelligence as a medical device; Northern Ireland; and compliance.

The diagnostics industry is also represented in the ongoing "pro-innovation regulation" work program by government chief scientific adviser and national technology adviser officer Patrick Vallance.

This program has a remit to focus on accelerating the development, testing, routes to market and uptake of new and *emerging technologies*. This is seen as key to encouraging R&D projects and investment into the UK.

Focus Groups Update

The remit and workload of the focus groups, intended initially by the MHRA to start in March 2022 on shaping the regulatory structure and fleshing out the content of the autumn 2021 UKCA marking consultation, have changed over time. They groups have also yet to start their work.

The MHRA altered the plan in autumn 2022, to have the focus groups write the guidance for the regulation. That was changed again when the MHRA announced that it would simply task the focus groups with testing the efficiency and readability of guidance written by the agency.

There will now be 17 focus groups, including one for IVDs (the full is list below). Trade associations, like BIVDA, will have an active role in several but not all 17 focus groups, although BIVDA feels 10 are relevant to its membership of 240, mainly SME, IVD companies.

The focus groups have been drawn from the consultation's chapter headings. Each one will have 10-15 participants from trade bodies, approved bodies, the devolved administrations and the MHRA. A separate group will be set up representing "patient engagement."

The 17 focus groups are: classification of general medical devices; IVDs including classifications; health institution exemptions; borderline products; software; medical device registration; implantable medical devices; conformity assessment; clinical investigations and performance studies; post-market surveillance (PMS) and vigilance; scope of medical device regulations;

economic operator requirements; remanufacturing of SUDs; UDI; custom-made products; environment and sustainability; and equality and diversity assessments.

The first piece of guidance to emerge will be for PMS, and will be laid "later in 2023," according the MHRA online seminar. Each focus group is expected to run for six to eight months.

Approved Bodies

Three UK approved bodies (UKABs) now have scope to oversee IVDs. UL International's scope was recently broadened significantly. BSI and SGS already had full scopes to manage UK IVD product files. The MHRA notes that three more approved bodies are "in process" and several more are in pre-application communication with the regulator.

"Taking an ambitious view, we're looking at five to ten additional UKABs in the lifetime of the immediate regulatory processes," Batchen said, hopeful that this number can be augmented further over time. The EU still has just eight notified bodies designated under the IVDR, she observed.

Just how many more businesses will actually apply to become a UKAB is uncertain. The MHRA's sharp increase in fees for medical device and diagnostic registration and oversight services could prove to be a hurdle, given the relatively small size of the UK market. (Also see "*UK MHRA's New And Increased Medtech Fees In Force in April*" - Medtech Insight, 1 Feb, 2023.)

However, were the SI to be substantially aligned with EU IVD and Medical Device Regulations, there would potentially be scope for abridged UK assessments for companies targeting both the EU and UK markets. "This could result in a smoother process for manufacturers – for both markets—subject to any accompanying regulatory requirements," Batchen suggested.