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If You Build It, Will They Come? Vital That UK MHRA Creates Right Environment For Medtechs

Pragmatism urged as UK devices regulator decides how much or how little to regulate

by Ashley Yeo

The Medicines and Medical Devices Act presses the UK to regulate in such a way that makes the market attractive for industry and investment. Medtech manufacturers insist the MHRA must strike the right balance as it brings its 'plan for a new agency' to life, said the ABHI's Phil Brown, in the second of a two-part industry view of UK medtech's regulatory future.

In the post-Brexit discussions on the UK's future medical devices regulatory instrument, two opposing views have emerged. One is that, given its sophisticated health care system, the UK will need its own processes of regulatory approval, and enough qualified staff to take care of those needs.

The other suggests the regulator should pursue merely a registration scheme for medtech products that it recognizes from international markets, and admit them to the UK market after a process of domestic assurance.

The rationale for the latter approach is that products of a high standard will continue to reach UK patients, the technical work having already been done by sophisticated regulators elsewhere in the global industry.

This, they argue, would free up the MHRA to pursue projects on the regulation of cutting-edge innovation and digital technologies, using mechanisms like the innovative devices access pathway (IDAP). (Also see "*UKCA Marking Debate Moves To Next Level: All Eyes On The MHRA*" -

Medtech Insight, 22 Feb, 2022.)

In any event, the UK regulator should not involve itself in setting its own, new, technical requirements for registration. That is the view of the Association of British HealthTech Industries (ABHI).

"The UK's [technical requirements] should be at least the same as those of the EU, the US or other major world markets," said Phil Brown, the association's director of regulation and compliance. "There should be no place for a UK 'light touch' in this respect," he added. The regulator should avoid all risks of exposing patients to potentially harmful products.

He acknowledged that a consensus is emerging that the UK will opt for substantial MDR/IVDR alignment, ensuring its clinical data, technical files and biocompatibility needs are comparable to the EU's.

But if the MHRA were to limit itself to the ostensibly simple task of providing domestic assurance on a long-term basis, the question arises as to where the standalone UK can make a difference in medtech? How can that be reconciled with all the aims of the Medicines and Medical Devices Act (MMDA) 2021?

Brown believes that it could be in managing the process of how to conduct regulation. The UK system could be a simple one, consisting of registration of products, post-market surveillance and systems of registries. "That is where a UK national conformity assessment process could come into play," he said.

Trust could and should play a bigger role in the future, Brown added. "There should be an opportunity for the MHRA to trust industry to work to high standards and instal collaborative conformity assessment mechanisms, rather than employing punitive measures," he said.

In such a scenario, the regulator would have to work closely with conformity assessment bodies (approved bodies) and device manufacturers. This ethical business practice route has been proposed before by the ABHI as a pragmatic alternative for UK device regulation in the post-EU. (Also see "*A Global Approach To Medtech Regulation: The Post-EU Way Ahead For UK Industry?*" - Medtech Insight, 9 Mar, 2020.)

Domestic Assurance Route

But domestic assurance is not the straightforward exercise it might seem. Certainly, there are complications swirling around, Brown said.

The EU CE marking approval and US 510K clearance, for instance, involve quite different requirements to each other. A potentially unlevel playing field could arise, implying the need for

additional domestic assurance for certain products as part of the UK registration scheme.

Under this scenario, the MHRA would provide domestic assurance on the final 10% or so of a file, where the UKCA marking deviates from the MDR, in, for instance, areas like sustainability and regulation of software or artificial intelligence.

Importantly, the MHRA's device registration scheme should not extend to include a technical review process of CE marked products, particularly during the current "standstill period." Some products have already been affected in this way, Brown observed.

"Registration should be a straightforward process; it should not be used as a mechanism for conformity assessment or to challenge the way products have undergone the CE marking process," he asserted.

Keeping UK In Line With EU And Global Processes

Practices that result in putting the UK out of line with the EU, however well intended, must be considered thoroughly, Brown continued. The MHRA last year expressed a preference for an un-siloed approach to regulating health care technologies.

In its *Delivery Plan 2021-23*, the MHRA stated that the lifecycle of products will be at the core of its new structure. It promised to break down silos and to focus staff and expertise on where they can add most value.

But while this might allow for more streamlined regulatory processes in the UK, it will not fit with how other systems regulate, Brown argued.

Indeed, the MHRA's preferred pathway for devices is at odds with the views of experienced users of the UK system. A senior source operating in the global market took the view that the product lifecycle approach to regulation, i.e. assessing products by stage in the product lifecycle – pre-market, approval and safety – is a structure that does not work optimally for medical devices.

In contrast, the US Food and Drug Administration organizes its regulatory work by product category. Its staff look at the entire life cycle of a product, which is almost the opposite to what is proposed the MHRA plan. The FDA approach allows a complete overview of products by people who understand them.

It is also suggested the UK might secure a significant advantage by engaging with the proposed Medical Device Single Review Program (MDSRP), a companion to the Medical Device Single Audit Program (MDSAP). Signing up to the MDSRP, a tool being championed by US Center for Devices and Radiological Health director Jeff Shuren, would make the UK part of a global scheme and could be the driver for local market access and international alignment. (Also see "*Single*

Marketing Application Review For Multiple Jurisdictions On Horizon" - Medtech Insight, 6 Apr, 2017.)

In any event, the goal should be that companies coming to the UK avoid additional market entry burdens, Brown added. They should be able to supply the same regulatory documents that they have previously. In theory, the UKCA marking could make the UK attractive for industry by not forcing manufacturers to do much more to enter the UK than they currently do to enter other global markets.

But until the MHRA issues its draft regulation to replace the UK MDR 2002, the industry can only seek to favorably influence the regulator's thinking, notably, in the ABHI's case, by submitting the findings of its post-consultation report. Passage of the new regulation will enable the MHRA to embark on other important steps.

One of these is the promised fees consultation. But first, the regulator will have to know what services it is charging for, Brown observed. Industry does not yet know if it will be paying for technical file work, or whether the UK conformity assessment bodies will merely be dealing with the needs of the MDSAP, for instance.

The UK minister for Brexit opportunities Jacob Rees-Mogg this month indicated that it would become policy not to require firms entering the UK market to file duplicate safety tests for products that had been CE marked. Speaking to *The Times* on 19 February, the minister said making firms pay twice for the same test would be an unnecessary and costly burden.

MHRA's Timetable

Brown also wants industry kept up to date with the promises made by the MHRA in its Delivery Plan, which it describes as "a plan for a new agency."

In it, the agency promised to publish its consultation response with finalized policy positions by the end of March 2022, lay the statutory instrument by the end of March 2023, and issue key guidance documents by the end of December 2023.

The standstill period expires at the end of June 2023, after which the UKCA marking will be mandatory in Great Britain.

While the consultation was concluded on time in November 2021, Brown said there has been little evidence to show the MHRA has hit other milestones listed in 14 chapters of deliverables.

Factoring In Patient Safety In The Right Way

Chapter one of the MHRA plan was devoted to enhanced patient centricity; indeed, the patient safety thread runs throughout the plan. The 2020 Cumberlege review – the Independent

Medicines and Medical Devices Safety (IMDDS) review – stressed the importance of more engagement with patients. (Also see "*UK MHRA In The Spotlight As Cumberlege Review Puts Medtech Safety At The Top Of Health Agenda*" - Medtech Insight, 9 Jul, 2020.)

These needs should be balanced carefully, in Brown's view, and in such a way as to avoid adding layers of complexity that would hinder a product's route to the UK market. "Transparency is vital," he stressed, but care must be taken if more steps are to be added to the pathway to the UK market," he added.

Issues surrounding patient safety might be best addressed in codes of conduct, rather than via regulation *per se*, he felt. Information on commercial interactions should be collected and made open for scrutiny, he recommended.

Put simply, if an additional process adds to a company's regulatory burden, that company is likely to question the viability of the UK market.

Streamlining Processes, Cutting Staff

Making the UK devices market more attractive, as prescribed by the MMDA, would be helped by effective innovation fast-tracking mechanisms, like the IDAP process, which is seen as a streamlined way of getting products to patients. The IDAP is in pilot stage, but its scope is not clear and industry does not yet know what type of innovations would qualify for inclusion.

"We recognize that the MHRA and the whole system are under pressure, and we are really keen to assist the regulator and the CABs, where we can, to ensure we have streamlined processes," said Brown. The ABHI wants to ensure the agency retains its traditional levels of pragmatism. But it is deeply concerned that senior people are leaving the MHRA.

> *"It could not be more critical for the regulator to have people that understand devices regulations and the UK's interaction with Europe and internationally."*

Others despair at the "scandalous" situation unfolding, at "precisely the time when it could not be more critical for the UK regulator to have people that understand devices regulations, the history, the UK's interaction with Europe and internationally," the senior source said, commenting that having people walk out the door is "simply criminal."

Many believe the UK is still failing to get to grips with its chosen place in the world. Post-Brexit, the UK has a small medtech market in comparison with the EU's. UK decision makers are holding onto the notion that, in building a new, standalone UK regulatory system, that people will come. But that might not necessarily be the case for a smaller player in the world.

Observers suggest that the UK's USP should be seen not only from the regulatory perspective, but from a single market payer perspective, whereby the National Health Service is properly exploited to facilitate early use of products, by trained clinicians. The icing on the cake would be if the UK could succeed in aligning medtech regulation and reimbursement.

In spite of the uncertainties ahead, Brown seeks to be positive. "I'm sure the MHRA can maintain its success in the future, but it will need a lot of collaboration with relevant people to ensure that," he said. In any event, the MHRA must not shut industry out, Brown added. The agency need only look back a matter of months at the COVID experience to understand the value of a good working relationship with medical device manufacturers.

Part one of this two-part feature on medtech industry views of the future UKCA marking and UK regulatory system was published on 22 February.