MEDTECH INSIGHT
CITELINE COMMERCIAL

22 Feb 2022 | **News**

UKCA Marking Debate Moves To Next Level: All Eyes On The MHRA

Industry is concerned about the UK regulator's ability to create the certainty needed for a successful medtech market

by Ashley Yeo

The MHRA is under pressure to deliver a new sovereign devices regulatory system in the tightest of timelines for the post-Brexit UK market. It has had no lack of support in this endeavor from system users, but industry is now keen to see the regulator deliver on its two-year plan issued in 2021, says the ABHI's Phil Brown, in this first part of a two-part industry view of future UK needs.

Patience and appreciation of the challenges that Brexit has set for the Medicines and Healthcare products Regulatory Agency (MHRA) have been hard wired into the UK devices industry. It too has been busy adjusting to the early stages of life outside the EU.

The task of building a new sovereign medtech regulatory system in less than two years, after three decades of largely successful participation in the EU system of conformity assessment and CE marking, is one few would have chosen. But an objective look at past records of achievement indicate that the UK regulator should be at least as capable as any global counterpart of succeeding in such an endeavor.

However, fulfilling the task with fewer resources while being asked to meet higher demands from patients and promising a fit-for-the-future system to regulate medtech and healthtech innovation makes for a challenge of huge proportions. Add the lingering complications posed by the COVID-19 pandemic and it's a full house of urgent issues for the MHRA to cope with.

So far, so hard. But the 10-week UK consultation on the UKCA marking and future regulatory mechanism to amend the 2002 UK Medical Device Regulation ended three months ago, and the

30 June 2023 standstill period deadline – until which time CE marked devices may remain in circulation in Great Britain – is now just a year and four months away.

With time slipping away, the traditionally supportive UK medtech industry is calling urgently for information about the shape of the future regulatory system. It keenly awaits the drafting of the new MHRA regulation this summer, as well as updates on other regulatory goals the MHRA set for itself in its 2021-23 delivery plan, issued in July 2021. (Also see "*UK MHRA Draws Up A Roadmap Of Patient Protection And Rapid Science Uptake*" - Medtech Insight, 5 Jul, 2021.)

Speaking to *Medtech Insight*, Phil Brown, director of regulation and compliance at the Association of British HealthTech Industries (ABHI), said the industry felt it needed more c*ertainty* about the ongoing work and progress at the MHRA.

The agency's workload has evidently been made tougher by significant losses in critical devices staff, with reports of a reduction of up to 25%. This translates into a significant loss of technical and regulatory expertise built up over many years.

Users of the system have expressed surprise. One long-standing IVD technical expert branded it as a "critically bad" series of developments for device regulation in the UK. The efforts required to bring in a whole new system – albeit a lean and mean one – should be supplemented, rather than sapped, said the source, who is based outside the UK.

Instead, there are staff cuts and a restructuring that is seeing the devices branch being swallowed into the agency's other structures, which would appear to be the opposite of good regulatory practice. The MHRA had "begun to shine," before Brexit, as a purveyor of global best practices. But given the direction it seems intent on taking, coupled with its loss of capacity, what can the agency do now to add value, the source wondered?

Industry Report To Inform Government On Proportionate Regulation

The ABHI is thinking along similar lines. In the wake of the consultation, which ended on 25 November, the association has been collating industry views on the future shape of the regulatory system. The exercise will result in a report that will inform the ongoing discussions led by the regulator and the government on the new UK regulatory instrument.

The views of every part of the UK devices industry – devices, diagnostics and digital, and large corporations and SMEs alike – were polled to give "as broad a picture we could get to make it representative of the membership," said Brown.

The report fills in the gaps in the MHRA consultation, he said. The final text will be useful as the basis for drafting unique position papers from the association on individual topics. Industry plans to provide input on the future secondary legislation that will be needed to flesh out the

primary Medicines and Medical Devices Act (MMDA) 2021.

Transition Timings Head List Of Major Concerns

The report focuses on key themes, chiefly the MHRA's aggressive timescale in putting together the regulation. The UK's regulatory transition from 30 June to 1 July 2023 must be carefully managed, Brown stressed. As it stands, all MHRA rules must be completed by autumn 2022 at the very latest, for manufacturers to be able to put UKCA markings on their products before the standstill deadline.

Complying with these requirements will be complicated for those UK manufacturers who need to transition to the EU Medical Device and IVD Regulations at the same time.

The timings on the availability of the UK guidances for industry on how to work with the regulation also remain for the time being a mystery. Clearly, guidances cannot be issued before the regulation is in place.

It all points to a difficult time for companies that wish to continue supplying the regulated UK devices market.

"There has to be a pragmatic discussion on dealing with the transition time through the 2023 implementation date," Brown insisted. Until mid-2023, the CE marking will continue to apply in Great Britain. But there could be cases where sponsors of products currently legally placed on the EU market cannot or will not update their expired EU certificates, which would affect UK product availability.

Other ABHI Report Hot Topics

Aside from the short transition time, the ABHI report has revealed the other hot topics for industry to be:

- UK labeling needs, including the possibility of using e-labeling in the UK;
- How the MHRA will regulate innovative digital products;
- How industry should factor in re-usability, maintenance, re-manufacturing and other sustainability credentials that the National Health Service is likely to demand for medtech products;
- The availability and development of innovation and research mechanisms, such the joint MHRA and NICE innovative device access pathway (IDAP) pilot project. Such innovation pathways must lead to quick adoption – and preferably quicker than happens under rapid access mechanisms in the EU;
- How to marry UKCA markings with NHS procurement;

- What the industry must do to factor in equality, diversity and inclusion (EDI); and
- Ensuring the MHRA can maintain a global role and the trust of fellow international regulators, at the same time as managing its input and expertise to guarantee it can fulfil domestic assurance needs.

EU Compatibility – The Starting Point Of The Consultation

Brown feels that industry's demands and the needs of the MHRA are "not a million miles away from each other." He also hopes the MHRA will use the learnings gained during the COVID experience.

Many of the views submitted for the ABHI's report reflect UK industry's preference for some level of EU regulatory alignment. Indeed, the MHRA's consultation was pitched in such a way as to ask why the UK *should not* maintain a system allied to the CE marking system.

Industry maintains that expecting manufacturers to duplicate regulatory efforts to meet EU and a different set of UK demands would likely see industry prioritize its registration efforts in the EU, where the returns are naturally bigger.

The lack of resources and regulatory understanding at SMEs must also not be ignored, Brown observed. In that context, the recent Innovate UK initiative on funding of early-stage SME regulatory expertise is a welcome move. (Also see "*£7M UK Fund To Help Medtech SMEs Through Regulatory Minefield*" - Medtech Insight, 14 Feb, 2022.)

The MMDA says UK regulation should be such that it promotes an attractive market for manufacturing and clinical trials locally. The system should not overburden "an already-overly burdened industry," Brown continued. The fear is that by raising hurdles too high, manufacturers might find it hard to justify launching in the UK market.

While the standstill guidance allows unilateral recognition of the CE marking in the UK, it is not mutual recognition. For the UK to have any chance of securing mutual recognition with the EU on medtech regulation, it must set up a system that the EU can recognize.

The MHRA chairman Stephen Lightfoot last year expressed a wish that UK regulation of health care products should be patient- and disease-led, rather than technology-led. Such an approach might make mutual recognition with Europe a lot more longer term, the ABHI director speculated. (Also see "*MHRA Chairman Lightfoot Ready To Lead Post-EU Agenda For UK Devices*" - Medtech Insight, 24 May, 2021.)

"The MHRA will always be a competent regulator," said Brown, but he also asked: "Does it have the capacity to be able to operate a system as broad and as complex as is demanded by CE

marking?" In addition, the UKCA marking timings are looking increasingly impractical, he said.

The second part of industry's views of future UK device regulatory needs will appear in a subsequent article in Medtech Insight.