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Fit For The Future: Industry Gets Involved As UK Medtech And Digital Health Care Regulation Reaches Turning Point

Greater convergence with EU regulations more likely under current UK schedules

by Ashley Yeo

The MHRA is in listening mode as it gathers feedback to shape the UKCA marking for medical devices. That, and how the agency precisely will oversee UK device regulation in the future, are front of mind for industry.

Coping with the regulatory changes brought about by the UK's exit from the EU is all-consuming for UK medical device industry stakeholders.

More important still is the way the regulator, the Medicines and Healthcare products Regulatory Agency (MHRA), can "future proof" UK medical device regulatory processes, and make it a system ready to handle the new generations of digital, artificial intelligence, combination products, companion diagnostics and ATMPs now coming through R&D.

The early foundations of the future UK device regulatory system are in place. The recently passed Medicines and Medical Devices Act 2021 empowers the government to enact the necessary legislation; and the system of device regulation using the UKCA marking came into force on 1 January and has got off to a good start.

A standstill period until 30 June 2023 allows CE-marked products to continue to circulate on the UK market.

As of 1 July 2023, UKCA marking becomes mandatory in the UK, but what it looks like and what it should do will be focus of an MHRA consultation, lasting up to three months, which is now

PHIL BROWN: 'VOICE OF MEDTECH IN THE WORKINGS OF THE MHRA MUST BE RAISED'

expected to be issued in early July.

Association of British HealthTech Industries regulatory director Phil Brown suspects that the earlier than anticipated consultation might indicate the MHRA's greater, rather than lesser, readiness to rely on the texts of the EU Medical Device and IVD Regulations. The former comes into force in the EU27 this month, and the latter in May 2022, under the current schedule.

The provisional schedule for developing the UK's statutory instrument appears to provide for a comment period around October, allowing a second draft to be developed at the end of December.

"That would leave only 14 months for industry to prepare for CA marking in the UK, and for more conformity assessment bodies to be accredited in the UK," Brown observed. The tight timing raises the prospect of the need to rethink the standstill deadline, or for creative solutions, perhaps including greater reliance on and recognition of conformity assessment certificates issue elsewhere, he said.

The MHRA has been in listening mode, soliciting ideas and views from trade bodies. As part of that process, the ABHI has canvassed its members and crystalized their key concerns, hopes and expectations for the new UK regulatory system.

Given the immense regulatory changes for the MHRA resulting from Brexit, and the challenges presented by COVID, industry is mindful that the regulator itself might undergo some form of change in how it oversees the medtech part of its portfolio.

Brown said, "Innovative regulation may well mean that the MHRA has to adapt. Having said this, we would not want to see the devices part of MHRA, and that expertise, lose its voice. The voice of medtech in the workings of the MHRA must be raised to ensure that expertise is recognized," he insisted, "and all the more so now that the agency's remit will include combination products, digital and other new product categories to regulate."

He proffered the notion that the agency's role in devices regulation might also extend, whereby it becomes more involved in device post-market surveillance (PMS) processes as well as vigilance, or it somehow links devices to the vigilance activities already undertaken within the pharma groups.

"It will be a tough ask within the MHRA for devices, and we must give the devices part the best support we can," said Brown.

Six Recommendations For UK Device Regulation Post-Brexit

In reviewing what the medtech industry needs from the new UK system, the ABHI focused on the themes of: market access/making products available on market; clinical evidence; PMS; conformity assessment; and cooperation and transitional arrangements, such as those relating to the MDR/IVDR, unique device identification (UDI) and rules surrounding certificates of free sale.

The six recommendations emerging from that work are summed up by Brown below:

- The UK system must capitalize on the MHRA's global reach. The agency should ensure it interacts with the International Medical Device Regulators Forum (IMDRF) and works more with other jurisdictions on best practice on innovation, digital regulation and other themes, be it with the US Food and Drug Administration or regulators in Australia, New Zealand, Canada or Singapore, etc.

- The SME-oriented medtech industry, already struggling with EU MDR and IVDR compliance costs, must ideally be sheltered from additional financial burden. Solutions include using different methods of conformity assessment, such as the Medical Device Single Audit Program (MDSAP), instead of working with the EU's quality management system. The aim, again, is to align with global requirements and equivalence.

- The UKCA standstill deadline of 30 June 2023 must be reviewed, as it will leave little time for manufacturers to comply. It is thought that the short deadline will constrict IVD manufacturers and IVD availability, in particular. Solutions include: continuing to use EU-issued CE marking certificates in the UK; another transition period beyond July 2023; or ensuring the UK conformity assessment bodies have the right sort of competence.

- Real world evidence should be factored into PMS and vigilance more effectively. This is where registries could play a bigger role. The idea would be to ensure a streamlining effect for manufacturers and make the UK more attractive to the global industry.

- To enable MHRA regulations to be future-proofed to cope with new technologies arising, such as digital combinations, 3D products, drug and device combinations and companion diagnostics, guidelines should play a greater role to avoid regulations needing to be rewritten. The agency should be able to refer to IMDRF guidance or use common specifications or standards to develop a system that is predictable and easy to work with.

- On innovation uptake, the National Health Service must be able to adopt the products the MHRA has regulated, if the efforts to develop a future-proofed – and speedier – UK

regulatory system are not to be wasted. There is a vital job to do in terms of "joining the dots" between the MHRA, clinical investigations, NICE, and NHS uptake. (The ABHI will launch a healthtech manifesto for innovation and integrated care in the coming weeks.)

These recommendations can be grouped into three priority themes, Brown noted: global interaction for the UK; future proofing the system to provide efficient market access; and fostering an environment that is favorable to medtech research and business from outside the UK.

Convergence With EU Now More Likely

Greater convergence with EU regulations could be an astute move for the MHRA, Brown speculated. He expects around 70% or more of commonality between the UK and MDR/IVDR systems.

Data compatibility, the art of developing data to demonstrate compliance across multiple jurisdictions rather than generating regulatory information that is slightly different for each market, possibly offers a quicker, slicker route for manufacturers to introduce innovations, Brown suggested.

In his view, this could even help create a future mutual recognition agreement with EU, including use of UK conformity assessment bodies (CABs) to assess products against the CE marking process.

> *"Stripping out the unnecessary from the MDR will be a key job for the MHRA to do." – Phil Brown.*

There is an opportunity for the UK as it develops the statutory instrument to assess which MDR requirements and processes can be removed, while keeping a focus on product safety.

The aim would also be to base UK regulation more on common specifications or standards, which are faster to develop and thus suited to fast-developing technologies. "Stripping out the unnecessary from the MDR will be a key job for the MHRA to do," said Brown.

The actions taken in response to COVID showed that the UK has processes that are able to provide safe regulatory oversight combined with the early adoption of innovation, said Brown. One of the pandemic's learnings has been that the pooling of resources and device expertise – be

it from NICE, the MHRA, the CABs, patient associations and industry—can work to good effect for patient care.

The ABHI will feed its findings into the MHRA consultation process.

“We are still at the beginning of story. We’ve seen the new system, and we now need to know how to steer it,” said Brown.