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UK ABHI Perspectives On Enabling Regulation – Part 1: Regulatory Certainty Vital For Medtechs

by Ashley Yeo

With the UK on the cusp of a public consultation on the UKCA marking, directors at the ABHI stress the vital need for the MHRA to review all options in setting the right medtech regulatory framework.

"A once-in-a-generation opportunity" was how Medicines and Healthcare products Regulatory Agency (MHRA) chairman Stephen Lightfoot framed the regulatory task ahead for stakeholders in the UK medtech industry.

Now outside the EU, the UK is free to set its own regulatory standards and manage its domestic activity, with a remit to promote innovation, leverage international best practice, listen more closely to the patient voice and raise safety standards.

That was the sense conveyed by Lightfoot as he spoke during the Association of British HealthTech Industries (ABHI) recent conference on Enabling Regulation. There, he laid out in realistic terms the options for UK medtech as the MHRA develops the national regulatory system and the UKCA marking. (Also see "*MHRA Chairman Lightfoot Ready To Lead Post-EU Agenda For UK Devices*" - Medtech Insight, 24 May, 2021.)

Those views were echoed and supplemented by ABHI chairman Phil Kennedy and the association's director of regulatory and compliance Phil Brown. Speaking to *Medtech Insight* on 16 June (full recording below), they emphasized key elements that Lightfoot and the MHRA must embrace in establishing a system that also serves to encourage inward investment.

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Kennedy said “enabling regulation” was among five industry challenges (along with SME growth, environmental sustainability, UK innovation and investment, and NHS collaboration) that ABHI’s board has set for the association.

The new UKCA marking will be the focus of an MHRA consultation, which is due to be launched in mid-July for a 10-week period, Brown noted. Under that schedule, the full text of the new UK statutory instrument would emerge only some 12-14 months before the end of the standstill period on 30 June 2023. Timings for this process will be critical, he said.

Industry’s key demand is that the UK regulatory reset process, including the remit of the UKCA marking and the future guidelines and secondary legislation that will follow on from the Medicines and Medical Devices Act, must provide legal certainty and predictability for medtechs entering the UK market.

These themes, as well as post-COVID device regulation, the MHRA’s deeper participation in the Medical Device Single Audit Program and the IMDRF, and its use of international best practice potentially mirroring initiatives such as the US Food and Drug Administration's breakthrough devices program and 21st Century Cures Act, are discussed by Kennedy and Brown in the audio interview.

Part Two In July

This is the first of two *Medtech Insight* sessions with the ABHI. The second, in early July, will discuss new technologies, digital health care, IVD regulations – in the UK and EU – and patient safety considerations, with ABHI director of diagnostics regulation, Steve Lee, and the association’s digital lead, Andrew Davies.