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MHRA Must Seize UK Digital And Diagnostics Opportunity: ABHI Perspectives On Enabling Regulation – Part 2

Consultation on UKCA marking expected in August

by Ashley Yeo

IVD and healthtech industry representatives give their views on how the future UK medtech system can be shaped to be agile and responsive to patients' needs, mindful that the regulator must deliver a standalone regulatory system and functional UKCA marking in less than two years.

The starting gun is yet to be fired for the UK Medicines and Healthcare products Regulatory Agency's (MHRA) consultation on the UKCA marking, which had initially been expected in early July. The UK devices and diagnostics industry is aware that the clock to the 30 June 2023 end-of-standstill period is already less than two years away. The 10-week (possibly longer) consultation is now likely to kick off in early August, after the UK parliamentary recess has started.

That is the expectation of Steve Lee, director of diagnostics regulation at the Association of British HealthTech Industries. Lee and the ABHI's digital lead Andrew Davies were speaking to *Medtech Insight* in the second of a two-part discussion on "Enabling Regulation," in which they set out the imperatives for a successful post-EU regulatory ecosystem for IVDs and digital health care products for the UK. Listen to the audio file from the 14 July discussion, attached below.

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Lee hopes the way the UK will regulate IVDs will borrow heavily from the EU IVD Regulation (2017/746)—but with the hindsight of the lessons learned since it was published four years

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ago. COVID-19 has also delivered lessons that could help shape future medtech regulatory practice. Lee pointed to the rapid MHRA actions, such as derogations and the Target Product Profiles (TPP) exercise, that were based on the MHRA's "pull" for necessary technologies—rather than the manufacturer's "push."

STEVE LEE, ABHI

As the consultation progresses, the ABHI hopes the criteria that emerge for the UKCA marking and UK medtech regulation generally will exceed those that it has recommended as minimum standards in its own Enabling Regulation initiative. It says the future UK system should: support the development of a globally competitive UK that uses best practice from international jurisdictions; seek to become a future-proofed system that can cope with advanced innovations in medtech, healthtech and combination products; and foster early patient access to safe technologies.

IVD Needs In The UK System

The industry also recommends that the MHRA should be able to "step up" to support orphan products in the UK, post-IVDR, should the need arise. The regulator could also act as an approved body itself, to speed matters, the ABHI suggested.

But a UKCA marking hard stop of 30 June 2023 will likely not provide enough time for IVD products to transition to the UKCA marking in the UK, Lee warned.

There are just three approved (notified) bodies for IVDs in the UK (BSI, SGS and UL). To address the potential capacity issue for approved bodies (devices and IVDs), Lee suggested some solutions, including: EU notified bodies applying to work in the UK market – possibly making it more efficient for manufacturers to secure certificates for both jurisdictions; and using highly-specialized approved bodies, for, say, digital or drug-device combination products.

EU IVDR Concerns For UK-Based Industry

The cliff edge for IVDs must be avoided, but in the EU, a similar scenario is playing out in its early stages ahead of the 26 May 2022 IVDR implementation date. The EU system to date has just five notified bodies at EU IVDR level (compared with 21 under the Medical Device Regulation). Most IVDs will need a notified body to comply with IVDR in the future. (Also see "*Another Italian Notified Body Is Designated Under The MDR*" - Medtech Insight, 14 Jul, 2021.)

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It is doubtful if an EU IVDR one-year deadline delay would be sufficient – even if the European Commission were to agree to it. But any extension still looks unlikely, and in any case, companies must not bank on a delay, said Lee.

A Separate Pathway For Digital Products?

While the UK industry and MHRA both eschew UK divergence from the EU IVDR and MDR for its own sake, the fast-emerging need for appropriate digital health care products regulation might be a case where UK divergence could be useful, said Davies. No single jurisdiction has a complete framework for digital. The challenge for the MHRA – and other regulators – is how to take a holistic approach to these technologies in all their different types.

The health technology assessment body for England and Wales, the National Institute for Care and Health Excellence (NICE), acknowledged recently that it needs to do more for digital health care products. Capacity at NICE is an issue, Davies acknowledges, and the ABHI will press for more healthtech products to go through NICE processes.

> *"We need a dialog with the public about how data can and should be shared in order to bring wider benefit." – Andrew Davies.*

But a NICE evaluation is not the only route for UK medtech and healthtech, he said, adding that the majority of traditional medtech products have not had NICE's involvement on their way to market. The aim should be to use the appropriate route for the risk level of the product in question, he stressed, and the NICE route is not appropriate for every medtech product. NICE is undergoing a five-year system-wide review, partly to ensure it is using the right methodologies.

COVID Spin-Offs For IVDs And Digital Devices

Lee and Davies agreed that there is still a long way to go yet in the COVID-19 journey. The UK should already be thinking about the legacy initiatives that can be used in the future, for instance the agility shown in the UK ventilator challenge, and the MHRA's ability to take pragmatic decisions quickly. The UK could use derogations and TPPs more, said Lee.

The sharing of data was a big legacy of COVID, said Davies. The public's and patient trust in the regulatory system is a key issue. On data collection, "We need a dialog with the public about how data can and should be shared in order to bring wider benefit," said Davies. That key consideration is developed in the UK's new Life Sciences Vision, released this month.

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Enabling Regulation Pt 1 – June 2021: What MHRA Chair Lightfoot Must Address For UK Devices

The first ABHI-*Medtech Insight* audio recording on Enabling Regulation was published on 17 June, where chairman Phil Kennedy and the association's director of regulatory and compliance Phil Brown emphasized the key medical device needs that MHRA chairman Stephen Lightfoot should address in constructing the UK's standalone regulatory system. (Also see "*UK ABHI Perspectives On Enabling Regulation – Part 1: Regulatory Certainty Vital For Medtechs*" - Medtech Insight, 17 Jun, 2021.)

ANDREW DAVIES, ABHI

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