Evaluate Vantage

October 15, 2020

Post-Brexit device rules risk the UK falling behind

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The new regulatory scheme poses problems – but also opportunities, in the shape of possible alignment with the US.

The means by which the UK will regulate medical devices now it has left the EU is a pressing issue for medtech. At the start of September the UK government gave some indication of how this will work by announcing a new product stamp, the UK Conformity Assessed (UKCA) mark, to be mandated on all devices from mid-2023.

But there is a major complication: devices carrying the UKCA mark will automatically be ineligible for sale in Europe or Northern Ireland. This arguably ups the known risk that device makers could prioritise the EU market, relegating the much smaller UK – or more accurately, Britain – to the back of the queue.

“There is a risk for that, and that’s the game,” says Richard Devereaux Phillips, director of healthcare policy at the Association of British Healthcare Industries. “We’ve got to make sure that the UKCA marking process does not add any unnecessary cost burden and time, because that’ll see products fall off the UK market and that’s ultimately not in the interests of either industry or patients.”

Much is unknown at this stage, including whether companies will be able to submit the same safety and efficacy data to obtain UKCA marking as they will to get a CE mark. Of course, even if the data are the same, there will still be two submissions for each new device where previously there was one.

“Any time there is a separate regulatory pathway toward approval there is the potential for additional planning, resources and longer timelines,” Deanna Vella, vice-president at the UK diagnostics group DNAe with responsibility for regulatory affairs, tells *Evaluate Vantage*. And, should the UK and EU standards diverge over time, as Ms Vella believes is likely, the process will become still more onerous.

The largest device makers will be able to comply with these rules reasonably easily, but smaller medtechs will be faced with a choice: whether to prioritise access to the British market or that of the EU – easily 10 times bigger.

Looking west

There is one possibility that would certainly enhance the UK’s appeal: swapping regulatory alignment with the EU for alignment with the US.

“With Brexit the idea is to run their own show in the UK, with their own legislation,” says Marie Manley, head of the UK life sciences practice at the law firm Sidley Austin. “If the UK sees the US and other markets as the primary target, they may want to facilitate British industry being able to penetrate those markets.” Alignment with the US system is certainly on the radar, she adds.

Tom Oakley, CEO of the UK-based imaging group Feedback Medical, says that some form of harmonisation with the US regulatory system would be beneficial, and the closer the better. If some process by which a device with the UKCA mark could be fast-tracked through the FDA, for example, obtaining the British marking would become vastly more appealing, and devices would reach the UK faster.

It is far to early to say whether any such thing might be achievable. The political situation must be considered: if next month’s US election ends in a Donald Trump victory, any attempt to align with the US FDA could fall afoul of the administration’s inclination to favour US-based companies.

Joe Biden, meanwhile, has made it clear that should the UK violate the Good Friday Agreement – which does appear to be a possibility – there will be no trade deal with the US, leaving UK/US regulatory alignment off the table.

Ms Vella of DNAe is unconvinced of the benefits of UK/US harmonisation, partly because of the relative swiftness of the CE marking process compared with the FDA route. “Some companies still prefer to launch in the EU prior to launching in the US, and in those cases, it might be more advantageous to be more similar to the CE mark regulatory system.”

Challenges

It is easy to misjudge the difficulty of securing any form of regulatory alignment, Mr Devereaux Philips says. He points out that the EU has the only trade agreement in the world which includes that kind of harmonisation of technical regulation, where satisfying regulators in Italy allows a device on to the market in Germany or France.

“Because it’s all we’ve ever known I think we’ve probably underestimated how technically difficult and how rare it is,” he adds.

And, owing to complex treaties between Britain, Northern Ireland and the EU, the regulatory situation in Northern Ireland is particularly tricky. In this region, which is part of the UK but not of Britain, the CE mark will remain mandatory on medical devices. A separate conformity mark may also be used, the UK(NI) mark.

As with joint UKCA and CE marking, however, products carrying both the UK(NI) and CE marks will not be accepted in the EU market. And UKCA marked devices will not be accepted in Northern Ireland unless accompanied by the CE or CE and UK(NI) mark.

Summary of conformity marks' validity			
	Britain	**Northern Ireland**	**The EU**
CE mark alone	×	✓	✓
UKCA mark alone	✓*	×	×
UK(NI) mark alone	✓	×	×
UKCA + CE	✓	✓	×
UK(NI) + CE	✓	×	×
UKCA + UK(NI)	✓	×	×
UKCA + UK(NI) + CE	✓	×	×
**Devices that have been CE marked by Northern Ireland-based traders will be accepted in Britain beyond 30 June 2023. Source: UK government statements; EvaluateVantage interviews.*			

Despite the challenges, most specialists agree that the UK must hew closely to either the EU or the US. If the country creates rules that are markedly different from both these territories, many companies will make gaining UK approval a lower priority, and some might simply not bother at all. It is conceivable that for cheaper devices complying with such a regime would be so expensive that the market would not absorb the costs.

The MHRA has two and a half years to decide what demands to make of medtechs. The agency is seen as a world-leading regulator, Mr Devereaux Philips says, but it has never faced a task where the stakes are as high as they are now.