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Q&A: What's Next For UK Regs? ABHI's Phil Brown Discusses Post-Brexit Industry Strategizing

by Amanda Maxwell

How should the UK medtech regulatory landscape look once the country separates from the EU? Phil Brown of the Association of British Healthcare Industries is helping to spearhead the effort to shape industry's policy position on the matter. He spoke to *Medtech Insight* about options on the table and some potential implications.

Much uncertainty abounds about how the UK will regulate medical technology once it has left the EU. No one knows quite when that departure will happen following the public's Brexit vote in June, but the medtech industry is looking to get ahead of the debate by exploring the most likely regulatory alternatives.

The big question is, will the UK continue with plans to implement the EU's pending Medical Device and IVD Regulations, albeit with less influence over EU decision-making? Or will the country take a sharp turn and follow US FDA-style regulations?

These questions and other creative ways forward are the focus of the regulatory policy staff within the Association of British Healthcare Industries' Brexit Steering Committee, Phil Brown explained to *Medtech Insight*.

Brown was recently appointed to take over as director of technical and regulatory functions at the association. He is leading the ABHI regulatory policy work area with a mission to help create a unified industry position on how the UK regulatory future should look. His work is part of a broader Brexit initiative at ABHI: other experts are heading groups focused on wider medtech aspects impacted by Brexit, including: trade; manufacturing; R&D; people; and fiscal and IP.

Brown said in an interview that he believes, ideally, any future regulatory agreement would be

based on mutual recognition of the EU's *Medical Device Regulation*, or at the very least, the EU's "*New Legislative Framework*," to ensure continued access to the European Market.

But these are early days and nothing is cast in stone, he acknowledged. There are a series of complex, interrelated questions that need to be considered from the point of view of each possible outcome and its impact. *Medtech Insight*'s interview with Brown, captured below, shows just how wide-ranging and complex those considerations are.

Q **Medtech Insight: Could you imagine a future where the UK decides not to follow the Medical Device Regulations and whether it possible that the UK may go it alone and have its own medtech regulations?**

Brown takes on his new role at ABHI as Mike Kreuzer steps down as executive director of the organization. Kreuzer will stay on as ABHIs advisor to regulatory policy.

A Phil Brown: Speaking on a personal level as a regulatory professional of nearly 30 years, I cannot imagine a future where the UK is not aligned with the MDR. The global move toward regulatory convergence rather than divergence would suggest that globally regulation is aligning with an EU-style "New Legislative Framework" structure, anyway, rather than anything else.

However, the referendum result has allowed for a debate on the subject, and the consideration of several options does offer some interesting possibilities.

Q **What is your view in the short and the longer term about following the MDR?**

A The message we are giving members is that in the short term we should concentrate on the implementation of the MDR. After all, until such time that Article 50 is invoked triggering the start of the UK formally leaving the EU and even for two years post that, we will still be part of the EU and bound by the UK transpositions of

European law.

Longer term, the answer may be very different, but at present impossible to predict. It is always dangerous to make assumptions in such uncertain circumstances as you may end up making mistakes.

As an organization, however, ABHI has conducted a series of assessments which we will be sharing with our interested stakeholders in the coming weeks and months, on the understanding that these are indeed "living documents" and liable to change as a result of Government strategy.

Q To what extent will the chosen regulatory route satisfy critics out there of the EU medtech regulatory system as it currently operates, including those who say it is not strict enough?

A Without going into these assessments in any great detail – as they are complex – the general feeling is that the best option, offering the least risk for the industry, is the adoption of the MDR. With the significant raising of the bar with respect to safety and performance, particularly, we hope this will go a long way to answer the criticisms in certain areas of the media.

But the satisfaction of regulatory criticism lies not necessarily with the chosen regulatory pathways, per se, but more with the education efforts made by industry and organizations such as ABHI. It is only by appropriate explanation of how medical devices are controlled that criticism can be addressed.

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Q So what will be the first steps you will take in leading the regulatory policy

work area for the ABHI Brexit Steering Committee? How will you move forward in getting a position together in this area? Who will be involved? And how transparent will the process be?

A A subsection of ABHI's Technical Policy Group is obtaining data and intelligence on the Brexit impact. This information is then going to be married with the output of another sub-set, the "Implementation Working Group," focusing on the implementation of the Medical Devices Regulation. Both groups will work independently so that any impacts can be assessed objectively.

The Technical Policy Group [TPG] members are essentially the senior regulatory and technical personnel from the ABHI's membership. The TPG is one of the most widely and well attended policy groups within the ABHI, regularly attracting over 40 persons to the quarterly meetings.

The Implementation and Brexit Groups will be making recommendations to the TPG, which is where the collective positions will be generated. The whole process is as transparent as we can make it – although having said that, and as part of the process, the members will abide with requirements related to commercial sensitivity, *et cetera*.

Q **What are the main concerns of the UK medtech industry? What does it need to safeguard, in your view?**

A The main concern for the medtech industry at the moment is the uncertainty. Each of our members will have their own unique strategy for dealing with Brexit, as they range from SMEs to large medical device companies and from UK manufacturers to Authorized Representatives.

The true dilemma posed by Brexit, however, is whether opportunities are true opportunities or whether the "doom-and-gloom" predictions are more accurate – and then what to do as a result. At the moment, with the referendum still less than two months in the past, speculation and uncertainty are at the top of most people's agendas, making any form of regulatory strategic thinking almost impossible.

What needs to be safeguarded, though, is the British sense of pragmatism and realism. As things really do start to "come out in the wash," ABHI has to make sure that its members are fully informed and aware of all the potential outcomes so as to enable them to reach their most appropriate decision regarding strategy. In the short-term, however, questions are not wholly related to regulatory, as the fall in the value of the pound has meant many more business-related questions. ABHI is therefore busy on all fronts to make sure that business is informed, of which regulatory is just one part.

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Q **How does UK industry feel given its regulator may no longer be part of the formal process of law-making in the EU?**

A Over the years, the MHRA has become one of Europe's most influential competent authorities, and has often – in our eyes anyway – been a voice of reason in some tough negotiations – such as those for re-use of single use devices [SUDs], for example.

Although not set in stone, the possibility that the MHRA will be outside any formal EU regulatory process is not an eventuality we relish. Of course, this assumes that the UK will adopt the Medical Device Regulation in the future, which is not a foregone conclusion.

If the UK regulator is distanced from the formal law-making process, it will be important for the MHRA to engineer a role in which it can still be seen as an expert or as a resource for the EU. ABHI would certainly support this effort.

Having said this, and knowing that it may be premature to discount the possibility of a more indigenous regulatory platform in the future, a national regulatory system may allow UK manufacturers greater access and lobbying potential on regulation that affects the UK Industry. In such a case, it could be the rest of Europe that needs to then evaluate the pros and cons of the UK as an opportunity for investment and innovation.

Q **What, at the moment, do you think the options under discussion will be in terms of the future regulation of medical devices in a post-Brexit UK?**

A As part of our due-diligence, ABHI has already and principally considered two extreme situations and a number of secondary possibilities in between.

From an extreme viewpoint, we consider that the wholesale adoption of the Medical Device Regulation [MDR] as has been recently finalized would present the least confusion for industry and would maintain public confidence in the regulatory system. After all, the MDR has been largely welcomed by industry already and will represent a raising of the bar when it comes to safety and performance requirements.

On the flipside, a registration scheme based on the mutual recognition of regulatory structures in other territories, such as the EU or US FDA, may provide for the greatest flexibility and adaptability, and may actually encourage innovation and speed to market.

Each of these possibilities has drawbacks of course, none more so than in the case where the UK would adopt the MDR without being a member of the EU, as the UK would potentially have little influence over subsequent changes in the EU to regulation or publication of the *implementing and delegated acts* that have still to follow.

In the case of a registration-type scheme based on MRAs [mutual-recognition agreements], confidence in such a system – which involves mutually recognizing an existing approval by another government's body other than the UK MHRA – may be low when considering whether a registration scheme is appropriate for what is

regarded as a sophisticated medical device manufacturing nation.

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The learning curve imposed, the uneven playing field this would present to industry, as well as the difficulties with respect to European affiliates and notified bodies, would make this a greater challenge with little in the way of observed benefits.

ABHI is principally exploring four alternatives, according to Brown:

- Wholesale adoption of the EU MDR by the UK.
- A registration scheme based mutual-recognition agreements with other territories.
- An indigenous UK regulatory system based on the EU's New Legislative Framework.
- A UK regulatory system that is more aligned with US FDA.

Of course, there are a myriad of alternatives in between these two extremes. As an organization, we have considered just two of these alternatives – where an indigenous system based on the EU's New Legislative Framework would be comparable to the EU/global market, and perhaps a second possibility, where adoption of a system more aligned with the US FDA could flourish.

Assessments of these four potential systems have been made, determining their relative strengths, weaknesses, opportunities and threats. Again, as previously mentioned, each of these assessments have been determined after making huge assumptions as to outcomes and possible MHRA strategies. So our thinking is still arguably premature.

Q **Will the regulatory model depend on a broader, overall economic/trade agreement for medtech products?**

A Yes, without a doubt, as the regulatory system requirements are an adjunct of the overall business process.

The regulatory path is only one consideration when trying to determine what is best

for the UK medical device industry. Clearly, any future EU regulatory models will be influenced by the trade pathways taken.

Whatever trade path is taken, it will be important for the UK industry, competent authority and notified bodies to be part of the decision-making process.

Q **ABHI represents UK companies, but also subsidiaries of European companies and UK companies that have operations in other EU countries too. How do you think this will influence the position of ABHI?**

A The Technical Policy Group within the ABHI, which will be over-seeing any discussions on Brexit and/or implementation of the MDR, is made up of all members, including UK affiliates of EU companies and authorised representatives. This transparency will ensure that the outputs of ABHI are sympathetic to all needs and are therefore adequately addressed in any lobbying activities.

In some ways, of course – and completely tongue-in-cheek – the UK centricity of Brexit and the concerns of industry outside of the UK may be an opportunity for ABHI to initiate a recruitment drive.

Q **What is the likely future of notified bodies and authorized representatives in the post-Brexit era? And what news have you heard about how are they being affected now in terms of client numbers?**

A I'll answer the second question first. All notified bodies, whether in the UK or elsewhere, are *suffering from capacity issues*. The introduction of the MDR will only exacerbate this effect, as the role of the notified body is expected to significantly increase. ABHI, along with Eucomed and other medical device trade associations, are closely monitoring this situation – although affecting any remedial activity would be beyond our scope.

As for the first question related to client numbers, ABHI has no intelligence on the future fate of UK notified bodies, although it is genuinely hoped that they will be able to continue supporting UK industry in the New Legislative Framework context. Of

course, if government strategy dictates that the UK will follow alternative regulatory regimes, the outcomes for notified bodies are likely to be different.

The same can be said for authorized representatives – ABHI has no intelligence as to how they will be affected post-Brexit. It is a well-known fact, however, that the UK probably has more resident authorized representatives that any other EU member state, so, therefore, it is hoped that some agreement can be reached whereby their status is preserved.

Q What will be the overall financial impact of the various regulatory options post-Brexit on medtech companies and the medtech support industry?

A A financial impact of Brexit from a regulatory perspective has yet to be done. However, it was clear pre-referendum that the adoption of the MDR would certainly increase the financial burden of regulatory compliance – whether this was as a result of the increased clinical requirements, notified body audit requirements, classification changes, new labelling, or any number of other factors implicit in the regulation.

The financial aspects will only become apparent as the dust begins to settle and governmental policy evolves.

It should also be noted that ABHI understands that the plans for "fees" mooted by the MHRA are being re-modelled. The outcomes of these discussions will depend on what regulatory pathway is eventually chosen, but if this is not along the lines of the MDR adoption, then modification of previous discussions would clearly be in order.

As for support industries, the supply and demand principle and the required expertise can only mean one thing – an increase in workload. ABHI has been in communication with both lawyers and consultants as a result of the referendum to try and understand different scenarios and potential outcomes. Although it is impossible to say, and having once been a consultant myself, you could envisage that this is a good time to be in the support industries.

From the editors of Clinica