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# IVDR And Brexit Outlook For IVD Firms: EU Themes To The Fore At Asian Medtech Associations Reg Networking

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By Ashley Yeo

**THIS MONTH'S ASIAN MEDTECH ASSOCIATIONS REGULATORY Networking discussions is split into two parts, the first being a guest presentation on EU themes, specifically a UK Brexit outlook and an update on the progress of the EU IVDR, which comes into full effect on 26 May 2022. Both have potentially far-reaching effects for Asian and other global medtech markets. Part two will feature AHWP and Asean updates, as usual. This editorial feature is hosted by Medtech Insight, along with the Asia Regulatory and Quality Consultancy (ARQon) and the Asia Regulatory Professionals Association (ARPA).**

As far as EU medtech regulations are concerned, most of the talk and almost all of the fears surrounding the lack of readiness of both the new system and of its users are coming from medical devices stakeholders. On the surface, the IVD industry seems relatively unflustered; and some of the smaller IVD firms are not even aware of how they will be impacted by it.

The worry for people like Simon Richards, who is the former chair of the British In Vitro Diagnostics Association (BIVDA) and now sits on its board,is that IVDs will be sidelined and will not get the attention they need in the three years' transition time remaining. While there is no room for complacency, IVD firms might be feeling a false sense of security, given that the IVDR deadline is two years later than that for the MDR (26 May 2020).

Richards has a broad involvement in EU regulatory matters, and works on the standards committee and regulatory affairs group of MedTech Europe.

At the recent Asian Medtech Associations Regulatory Networking discussions, he gave an update on Brexit as it affects the IVDs industry, and the EU In Vitro Diagnostic Regulation (IVDR), and the serious way in which the latter will impact industry in the EU and beyond. The general view is that the IVDR (2017/746) will place additional (and costly) burdens on innovators, in terms of file maintenance and post-market surveillance, in particular. Small companies may well feel the pain disproportionately. *(Also see "Heading For Crisis: The Upturn In EU Medtech Regulatory Output Is 'Not Enough' – MedTech Europe " - Medtech Insight, 10 May, 2019.)*

## Brexit – Preparations Ongoing, With All Bases Still Needing To Be Covered

As to Brexit, which for a brief but welcome period, is *not* at the top of the political agenda in the UK, it is still a case of "maybe," and not unequivocally "when," amid another deadline delay. Indeed, the "when" has already slipped twice this year – from 29 March 2019 to 12 April, and now, possibly, to the end of October. "No one can be sure of where we are on that given the lack of political alignment around the approach to be taken on Brexit," said Richards. Companies had been preparing

to work to a UK exit transition period ending in December 2020, with UK notified bodies remaining in place for that period. But that certainty has been ripped away.

For its part, BIVDA has been advising IVD companies to prepare for either an organized transition or for a "hard Brexit," ie, with no UK-EU trade agreement as (or if) the UK leaves the union. For IVD and medtech companies in general, a no-deal Brexit has impacts in three areas:

- Stock management. Coming out of Europe with a hard Brexit would mean trade tariffs would start to kick in. In short, for the UK, the free movement goods into and out of Europe would end. Companies have been advised that they would need to have higher levels of product in stock and the ability to manage that stock.

- Regulatory. There are now four remaining notified bodies in the UK: BSI, LRQA, UL and SGS, and, should a no-deal Brexit happen, they would no longer be recognized as notified bodies within the EU. In future, companies based outside the EU would be required to have an authorized representative (AR) in the EU27 – and those with an AR in the UK would have a problem to resolve. ARs and NBs are typically shown on the labeling of products, too, so there would be a need for time-consuming labeling changes. This represent a major problem. As it stands, the work patterns and programs of the four UK NBs remains unchanged until the point at which the UK leaves the EU.

- Staff and staffing, which are big issues for IVD companies in the UK, as many companies employ non-UK/EU nationals. Government guidance on this issue has indicated that currently employed EU nationals would have leave to stay indefinitely. However, the UK registration process has proved to be a concern for these staff and a worry for their employers.

IVD companies wanting to continue to access the EU market would have to face changing their notified body if it was based in the UK. TÜV SÜD, for instance, has offered a fast-track process for applications. *(Also see "EU Officially Designates Second Notified Body Under The MDR: TÜV SÜD Enters Center Stage" - Medtech Insight, 22 May, 2019.)* One Italian NB has offered a similar service. The UK notified body, UL, has gone into partnership with PCBC in Poland, which will work alongside UL and take on its registration work until UL makes its proposed move to Dublin, Ireland.

BSI has set up an operation in the Netherlands. The other UK NBs are also setting up overseas offices at present. But only one NB (BSI) has transferred operations out of the UK so far. As stated, UK companies will have to appoint EU27-based ARs, and as of now, the target deadline for all work, including labeling changes, is 31 October – if an "orderly" transfer out of the EU is to take place for the UK.

In addition, UK companies ship a lot of third-party products into Europe. This is another area where companies must reach out to third-party suppliers to ascertain that they have gone through necessary stages and would be ready for Brexit.

## IVDR and Brexit Considerations

The UK Medicines and Healthcare products Regulatory Agency (MHRA) has stated that the IVDR will be transferred into UK law and will be brought into service in May 2022, as it will be around the entire EU. The only difference is that for the UK market, UK – not EU – bodies would have regulatory oversight, and the database used would be the MHRA-endorsed system rather than Eudamed. In terms of bringing products into the UK, conformity with the IVDD, and with the IVDR up ahead, companies would be required to register products in the UK database; their previous EU registrations would not be carried over. That process would have to be overseen by a UK-based AR.

The UK would likely use a new "UK CA (conformity assessed) mark," rather than an EU CE mark on products for use locally. However, there is no clear guidance as to when the CA mark will be required. But "one good thing is that, as things currently stand, companies won't need to place the UK AR's name and details on the label."

Another positive is that the UK authorities have issued a lot of information for system users. For instance, BEIS (the UK Department for. Business, Energy & Industrial Strategy) has published a life sciences sector primer for businesses, on "preparing for EU exit if the UK leaves the EU without a deal."

## IVDR Implementation

The IVDR will be implemented in full on 26 May 2022, and industry has many concerns about the regulation, principally about the capacity of the notified bodies.

This will be a particularly acute problem for IVD companies, for, whereas 10% of IVD files need the involvement of a notified body under the IVDD, under the IVDR, as many as 90% will need to engage a notified body. At present, there are 22 notified bodies for IVD companies, but only 11 applications have been made so far by NBs wishing to be designated under the IVDR; and none have been approved. *(Also see "QUOTED. 11 June 2019. Bassil Akra." - Medtech Insight, 11 Jun, 2019.)*

"The commission is working to a road map of activities taking us through to 2022, particularly the implementing acts to support the legislation on unique device identification (UDI), which is required under the IVD Regulation."

But none of the standards that were previously harmonized (ie, approved to support the implementation of the IVDD) will be harmonized for the IVDR. This will necessitate a lot of new work. The commission has issued a requirement for the harmonization of some of the standards, but it is "highly unlikely we will have all the standards we need to implement the IVDR by 2022." The commission is focusing on some horizontal standards, but even with these, there will be a significant shortfall in standards. How industry addresses that remains to be seen.

Other pieces of infrastructure are changing too, for instance a new nomenclature will be created – based on medical device classification codes (CMD) system championed by the Italian authorities. *(Also see "EU Favors Italian Medtech Nomenclature Over GMDN For Revamped Eudamed" - Medtech Insight, 26 Mar, 2019.)* "We believe it will be aligned to the GMDN (Global Medical Device Nomenclature), although we also believe that devices within EU will have a different coding system to that used by regulatory authorities around the world."

The Eudamed database – a crucial piece of the EU regulatory infrastructure – is slightly behind schedule. The concern is that delays there will cause problems, because this infrastructure is the "spine of the system," and will be key in interactions between notified bodies and regulatory authorities.

The EU UDI system continues to be developed: GS1, in particular, seems to be the common standard in the EU. The EU will also have basic UDI as well as UDI (basic UDI is higher – family-level UDI). Again, industry is not clear on how this will work. While UDI won't go on labeling, it will go on certificates. The overall theme of the UDI generally remains a concern for the entire industry.

Finally, the so-called MDCG (the Commission's Medical Device Coordination Group) is being set up to support the implementation of the Regulation (and the MDR, 2017/745) in Europe. It also has several working groups that comprise members of the EU competent authorities and observers. There are 11 WGs under the MDCG, and a 12th is on the way.

**"We will see a reduction generally across the industry in products that are supplied, going forward," Simon Richards.**

So IVD companies are currently assessing their products against the new regulation. Richards believes that a number of products being reviewed won't progress – typically due to the cost of transferring to the new regulation and the process simply not being worth it financially given sales levels of the devices in question. "We will see a reduction generally across the industry in products that are supplied, going forward," he said.

The IVDR represents significant change for the industry, but Richards feels that the industry will still move forward, especially in the case of the newer IVDs, where, he claims, "we are seeing a reasonably seamless transfer." The changes will likely affect the older products more, and some manufacturers might view the IVDR as a good opportunity to review their portfolio. But Richards also comments, "We are all starting to see the extra burden that the regulation will place on us in terms of file maintenance regulation."

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