A COVID free zone

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Editor

The temptation when I sat down to draft this editorial was to go with the obvious! Discuss the one topic that seems to dominate every news broadcast. What? No Brexit I hear you ask! We have a saying in the UK, "today's newspaper is tomorrow's fish and chip wrapper" and it's perfectly highlighted by the fact that having a Brexit story on the news would now be a welcome change. But very recently the implications of it became once again relevant to our specialist sector.

So, I mention Brexit (with a heavy heart and at great risk of having rotten fruit thrown at me) because this month the UK government announced its plans for medical device regulation in the UK post December 2020. For those looking for progress, well, take a deep breath. The document on regulating medical devices from the 1st of January 2021 states:

"The MDR and IVDR will fully apply in EU Member States from 26 May 2021 and 26 May 2022 respectively. As these regulations will not take effect until after the transition period with the EU has ended, they will not be EU law automatically retained by the EU Withdrawal Agreement Act and will therefore not automatically apply in Great Britain."

Currently, devices in the UK are regulated under:

- Directive 90/385/EEC on active implantable medical devices (EU AIMDD)
- Directive 93/42/EEC on medical devices (EU MDD)
- Directive 98/79/EC on in vitro diagnostic medical devices (EU IVDD)

These directives are given effect in UK law through the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002). These Regulations (in the form in which they exist on 1 January 2021) will continue to have effect in Great Britain after the transition period. I still suspect that there will be further changes after January 2021 as the UK government has also said that they are committed to improving the standards and scrutiny of medical devices that are used in the UK. It does seem strange though that many of the features of the new European medical device regulations are designed to do just that. We seem determined to do things differently.

And you would be forgiven for thinking this applied to the whole of the UK. But of course, that would be too easy. For those reading from outside of the UK and not familiar with the specifics of our name, I point out the deliberate references in the above underlined text to Great Britain as opposed to UK. So what about the parts of the UK that are not part of Great Britain? The government website goes on to say: "Under the terms of the Northern Ireland Protocol, from 1 January 2021, the rules for placing medical devices on the Northern Ireland market will differ from those applicable to Great Britain." "The Medical Device Regulations (2017/745) and the *in vitro* Diagnostic Medical Device Regulations (2017/746) will apply in Northern Ireland from 26 May 2021, and 26 May 2022 respectively, in line with the EU's implementation timeline".

I can hear medical device manufacturers from all over the world groaning! Of course they will have to get their head around having a separate legal framework for selling their devices in Great Britain but as this will likely be based upon their previous European legal framework (with no doubt a few subtle changes thrown in by the UK government between now and December), it shouldn't be too much bother. But to expect them to understand centuries of border history between the internal territories of the UK might be a step too far!

The document also discusses the concept of the new UKCA (UK Conformity Assessed) mark. The UKCA mark is a new UK product marking that will be used for a wide range of goods, including medical devices, being placed on the Great Britain market after the transition period. The government confirms that the UKCA mark will not be recognised in the EU, EEA or Northern Ireland markets, and products currently requiring a CE marking will still need a CE mark for sale in these markets.

The full details are available from the link at the bottom of the page and of course there are grace periods, implementation dates and exceptions.

But don't be too despondent dear reader. It's surprising how quickly we become used to doing things differently. Who would have thought 12 months ago that having a drink with a colleague would mean both of you sitting at a computer 50 miles apart and firing up Zoom or Teams! Stay Safe.

https://www.gov.uk/guidance/regulating-medical-devices-from-1-january-2021?utm_source=RESMaG&utm_campaign=6bdd004ac5-EMAIL_CAMPAIGN_2020_07_09_12_12_COPY_01&utm_medium=email&utm_term=0_9943df2982-6bdd004ac5-160393616