B. Ollivere
Editor-in-Chief
editor360@boneandjoint.org.uk

The European Union Medical Device Regulations: lost in the wash?

With all the European discussions surrounding healthcare provision centring on Brexit and specifically the way the United Kingdom will trade, import, and export after leaving the European Union (EU), there has been – quite rightly – a certain amount of concern about the potential for disruption. The United Kingdom is a major pharmaceuticals exporter, providing drugs to mainland Europe and North America in vast quantities and in turn reciprocally importing medicines. There are supply chain concerns and cost implications, and the National Health Service (NHS) has started to stockpile medicines, fearing backlog at the ports and ballooning prices. This will, to a certain extent, offset some of the cost and logistical issues, although realistically only for a few weeks.

Attention has been paid to the issues surrounding radio-isotopes, many of which have a short half-life. These isotopes have a fascinating (and perhaps previously lesser-known) story behind them. Utilized for all sorts of things from bone scanning to cancer detection, radio-unstable isotopes are used for the majority of patients requiring any form of nuclear medicine imaging. While some are made in the United Kingdom, such as those used in positron emission tomography (PET) scanning, others are not. For those arriving from abroad, there are very careful transfer arrangements in place, landing at nonpassenger airports for direct transfer into unmarked vehicles, which keeps the transit times low and ensures that the isotopes are suitable for medical use. There is real concern and much planning is being undertaken to minimize these risks. This will, outside of orthopaedics, of course also affect some form of adjuvant cancer therapies.

Simultaneously, the EU has been edging in newer and stronger regulation for medical devices, which includes the implants we use. Announced on 5 May 2017, these EU Medical Device Regulations (MDR) are to be implemented fully by 25 May 2020, so we are starting to reach crunch point for their implementation.

Prior to the MDR, surgical implants that were not drugs or combination devices faced surprisingly little regulation. Up until this point, a device could earn a CE mark provided it was manufactured to the appropriate standard for medical implantation and received certification within one of the EU countries. A device could then be put forwards for approval by an agency such as the Medicines and Healthcare Products Regulatory Agency (MHRA), which monitors for problems and regulates claims and indications, but does not take a view on evidence of clinical efficacy per se.

The changes accompanying the EU MDR are dramatic, and it is not clear what will happen to the United Kingdom. We are leaving the EU halfway through a process. The onus will be on companies to provide data on effectiveness much more clearly and promptly. New conditions will need to be addressed for most legacy devices (i.e. those with a CE mark under the previous regulations). Any existing products must be recertified to abide by the new regulations. The vast majority of companies and implants will require updated clinical data, renewal of technical documentation, and improved labelling and packaging in order to sell even legacy implants with decades of use (such as the angle blade plate) in Europe. In addition, the implementation of the Unique Device Identification (UDI) system will be enforced to improve traceability. The idea is to use the UDI to help track devices throughout the supply chain, and this UDI will be added to all labels.

This is a huge amount of work and will undoubtedly utilize significant corporate resources for fear of losing the ability to sell to the world's largest devices market. If the United Kingdom chooses not to mirror EU arrangements, then we will be asking companies to put in similar work while continuing sales to a much smaller market.

However, the problems do not end there: the MDR includes much broader definitions of what is a medical device and what is not. This has led to device companies undertaking significant portfolio rationalization and removal of much in the way of medical devices. The major change, from the perspective of clinicians and device manufacturers, is that manufacturers will need to provide more in-depth clinical data that proves safety and performance claims and have tighter equivalency standards. This will be coupled with robust incident reporting that requires the expedient reporting of all incidents, injuries, and deaths directly to an EU portal, which will contain relevant data, so patients will have access to safety-related information. The deadline for reporting incidents that did not result in death or serious deterioration in health has been changed from 30 days to 15 days.

The best-case scenario in the United Kingdom is that we will see a reduction in the legacy devices that are available; for example, some manufacturers have ceased to produce self-tapping and standard screws. The worst-case scenario, of course, is that we end up with few legacy implants available. As we are a small market, it may take many years for newer developments to be introduced.

There are some positive steps one can take, though. If you are regularly using implants without published clinical series, then simply writing them up and publishing the data – without recourse to the implant companies – is likely to improve the chances of that implant being MDR-compliant. What we don't know yet is if that will make any difference in the United Kingdom or not. As they say, we will need to watch this space.