ALISON NEWSTEAD, PARTNER,
SHOOK, HARDY & BACON INTERNATIONAL L.L.P.

THE EXPANDED SCOPE OF THE NEW MEDICAL DEVICE REGULATION (MDR) – ARE YOUR PRODUCTS NOW SUBJECT TO THE GREATER SCRUTINY OF THE REGULATORS?

Medical device manufacturers in the EU have been busy preparing for, and now implementing, the changes introduced by the new Medical Device Regulation (MDR) (Regulation (EU) 2017/745) which came into force in May 2021. While there has been significant focus on ensuring compliance with the MDR's new requirements, the introduction of the MDR may lead to an increase in recall activity and regulatory action as the regulations start bedding in and regulators start working with the new regime.

A key driver of a potential increase in recall activity is that the new MDR substantially expands the scope of products covered. A new, broader definition of medical devices will now also cover certain products that do not have a medical intended purpose, but may be similar to a medical device in terms of the way that they function or their risk profile. Of particular concern here, is a product's ability to cause infection or injury.

The inclusion of such products within the scope of the Regulation is in response to concerns about various aesthetic products which have seen an exponential growth in use, particularly by the younger consumer demographic. This category of devices covers products such as cosmetic coloured contact lenses and iris implants; cosmetic implantable devices, such as implantable horns, buttock implants and silicone breast implants; and products such as dermal fillers used to fill facial lines and to add fullness to the lips and cheeks. The Regulation also extends to equipment used for liposuction and high-intensity radiation equipment used for tattoo and hair removal.

Many of these aesthetic products are widely available online, which means the range of products available is vast. More worryingly for consumers, the quality and safety profile of those products is also highly variable. Not having to comply with the MDR until now has meant that these products could often be produced relatively cheaply, easily and without the high standards of safety and significant vigilance requirements that apply to medical devices.

With reports of injuries growing (including major disfigurement and life-changing injuries), it is of little surprise that the EU has responded proactively to calls for increased regulation to protect consumers. Some commentators have indicated that certain products in this category should be regulated even more closely under the regime covering medicines. It will therefore be interesting to see how manufacturers respond, and regulators are able to better manage, the risks posed by these types of products, and whether we see further shifting of regulatory surveillance in this area.

Also significant, is that the scope of the MDR now covers devices designed for the purpose of "prediction and prognosis" of a disease or other health condition, including diagnostic tests for health and well-being. Whilst there are clear categories of products that will fall within this definition, there may be questions about interpretation as to what products are covered by the Regulation. Regulatory action may ensue if there is a discrepancy between manufacturer and regulator as to the interpretation of the MDR.

Manufacturers of products which were previously unregulated or regulated under a different regulatory regime may now find themselves forced to comply with a much more complex and stringent set of requirements – particularly in the manufacturing and post-market surveillance stage. They will also find themselves under the scrutiny of national EU medical device regulators, who often operate differently than regulators who are entrusted with ensuring the safety of general consumer products. Manufacturers can expect significantly more interest in their activities and closer scrutiny of their products, their market surveillance activities, and any corrective action that they propose.

Whilst some manufacturers will rise to the challenge of ensuring compliance, other manufacturers – many of whom are located outside the EU – may not be aware of the recent regulatory changes, or fail to act on them. This could lead to increased regulatory action to ensure that non-compliant products are not on the EU market.

With increased regulatory action, manufacturers and those in the supply chain are also likely to witness an increase in civil claims. That said, a proactive approach, under a tighter regulatory regime and scrutiny by regulators is more preferable than consumers having to seek redress through the Courts for injuries sustained.

ALISON NEWSTEAD, PARTNER,
SHOOK, HARDY & BACON INTERNATIONAL L.L.P.
CONTINUED FROM PREVIOUS PAGE

What can we expect in the UK?

As a result of the timing of the Brexit departure, the new MDR is not applicable in Great Britain (England, Wales and Scotland). It will, however, apply to Northern Ireland.

Given that the MDR does not apply to Great Britain, the UK government is seizing the opportunity to carry out a consultation of existing medical devices legislation (implemented as the Medical Devices Regulations 2002), with the aim of having a new regulatory regime in place by 1 July 2023 (when the UK will stop accepting CE-marked products).

Whilst the consultation has a distinct focus on health technology and innovation, patient safety is at the core. Views are canvassed on a broad range of issues that were included in the new MDR in the EU, including scope, classification of products, economic operators, registration and Unique Device Identifiers (UDIs), conformity assessment, clinical investigations and performance studies, post-market surveillance and vigilance, in vitro diagnostic medical devices (IVDs), software and implantable devices.

The consultation states that ***"in many areas, gaining and maintaining competitiveness in a global market will be best supported by alignment with internationally recognised best practice and standards."*** Therefore, it will be interesting to see just how far any new regulations in Great Britain deviate from the changes in the EU.

It appears that the UK government is open to proposals for additional products to fall within a new regulatory regime in Great Britain beyond those covered by the new MDR at EU level. To this end, the position in Great Britain may be more stringent for certain products than is currently the case in the EU.

Will the new regime be more flexible than we have previously seen? Will this make the regulatory landscape more easily navigable for manufacturers? The UK regulator, the Medicines and Healthcare products Regulatory Agency (MHRA), has emphasized that in any future regime it intends to ***"use both regulations and guidance to establish a fluid and effective approach to the oversight of medical devices and technologies. In some cases, this is likely to involve greater use of guidance than under the existing regulatory framework to ensure that we can keep pace with dynamic innovation in medical technologies, whilst maintaining high standards of patient safety."*** To this end, there may be less grey regulatory areas in Great Britain than in the EU, meaning that there is less risk of regulatory action with respect of new, innovative products that do not fit neatly within legislative definitions.

Manufacturers supplying products in the EU and Great Britain will need to keep a close eye on the consultation and determine whether any deviations need to be acted upon. Regulatory approaches may differ for the same products and care will need to be taken to ensure that compliance is achieved.