UK Medical Device Regulatory changes – Economic Operators

The recently published ”Government response to consultation on the future regulation of medical devices in the United Kingdom” has given us some insight into the UK Government’s intentions for the new UK Regulatory Framework due to be released in 2023.

We continue our summary of sections from the UK Government’s response with a look at the impact on various Economic Operators: manufacturers, importers and distributors, UK responsible persons, and health institutions.

Manufacturers

Several new measures are proposed that have an impact on manufacturers of medical devices and IVDs, such as:

- An obligation to have in place measures to recompense those impacted by any adverse incidents with their products on the UK market.

- A requirement to operate an appropriate Quality Management System (QMS) for all classes of device including specific detailed QMS requirements for manufacture of Class I devices, custom-made devices, general *in vitro* diagnostic medical devices.

- Manufacturers must have within their organisation at least one Qualified Person or, for SMEs, to have a Qualified Person permanently and continuously at their disposal. A Qualified Person will be required to have qualifications or regulatory experience that exceeds minimum standards (which will be set out in the regulations).

Health Institutions

A Health Institution is defined as “an organisation, the primary purpose of which is the care or treatment of patients or the promotion of public health” (hospitals, clinics, laboratories, etc.). Such organisations under the proposals are:

- obliged to meet the relevant essential requirements for **‘**In house’ manufactured or modified devices, including operating within an appropriate QMS, having and retaining technical document, and ensuring that the provisions on adverse incident reporting are met.
- required to register *medical devices* that have been manufactured or modified ‘in house’.
- *required to register clinical investigations and performance studies* with the MHRA.

Exemptions will continue for Health institutions which provide routine or specialist diagnostic services to other Health Institutions where devices meet a patient group’s specific need that cannot be met (or cannot be met at the appropriate level of performance) by an alternative device on the market.

Other exemptions for in-house manufactured devices or IVDs (In-house exemptions) will apply. These exempt Health Institutions from UKCA Marking requirements, the involvement of an Approved Body, and the need to have a certified QMS, though an appropriate QMS will be required. NB: “In-house exemptions” will not apply to *medical devices manufactured on an ‘industrial scale’ (to be defined) or where services are provided for commercial or profitable purposes*.

In addition, the MHRA will be:
- empowered to request *further information* about the devices a Health Institution has manufactured or modified ‘in-house’, including details about the manufacturing processes.
- enabled *to restrict* the availability of devices manufactured or modified ‘in-house’ as part of activity inspections of Health Institutions.

Importers and Distributors

The proposed introduction of obligations on importers and distributors of medical devices and IVDs is to proceed. These obligations include:

- retention of documentation records (to be defined) for a specified time period
- to have in place measures for the safe storage and transportation of devices.
- to ensure appropriately labelling is applied and all devices have a UDI.
- to inform the MHRA, manufacturer, and UKRP (as applicable) of a medical device which does not meet the requirements of the UK medical devices regulations.
- to operate to an appropriate Quality Management System.
- to capture and report complaints and customer feedback to the manufacturer.
- to provide information about themselves to MHRA.
- to co-operate with MHRA during investigations.
- to inform MHRA if they are aware of any issues that will interrupt supply or cause a shortage of medical devices.
- to inform manufacturer or UKRP that they intend to import the device (importers only).
- to provide their details on medical device packaging or document accompanying the medical device (importers only).

Clear requirements with supplementary guidance documents are to be provided to clarify which devices are included in the requirements.

Conclusion:

The UK government has indicated that significant changes to the current UK MDR 2002 regulations will be introduced in 2023. Manufacturers wishing to place their devices on the UK market will have to comply with important new requirements. Health Institutions must adapt to considerable changes. Importers, Distributors and UK Responsible Persons are also impacted.

Economic Operators that place devices on the EU market will already be familiar with the direction of change from their application of the EU Medical Device Regulations (2017/745 and 2017/746).

An early Gap Analysis is a great way to establish what your organisation needs to do and make plans to maintain compliance. Please contact us for any further information.