

Medical devices briefing: Medical Devices Regulation and contingency plans for a no-deal Brexit

Overview

Regulation of medical devices in the UK falls to the Medical and Healthcare Products Regulatory Authority (MHRA).

How medical devices are regulated will change over the next 18 months because of:

- The ongoing introduction and implementation of the new EU Medical Devices Regulation ((EU)2017/745)
- The UK leaving the EU on 29 March 2019, particularly in the event of there being no deal by that date.

This briefing:

- summarises the current regulatory framework for medical devices in the UK
- outlines the steps the UK Government is taking to ensure medical devices can continue to be properly regulated, in the interests of public safety and business efficiency, in the event of a no-deal Brexit
- summarises what these changes are likely to mean in practice for the manufacturers of medical devices.

Medical Devices – the current regulatory framework

The EU Medical Devices Regulation (MDR) entered into force on 25 May 2017. During its implementation period it will gradually replace the existing Medical Devices Directive and will apply in full from May 2020.

The MDR includes improvements to the current system, including:

- reinforcement of the criteria for designation and oversight of Notified Bodies
- changes in the classification of certain devices
- stricter control of high risk devices through a new pre-market scrutiny mechanism at EU level
- improved transparency through the establishment of a comprehensive EU database on medical devices and the establishment of Unique Device Identification (UDI)
- improved vigilance and market surveillance.

The UK is currently a member of the European devices regulatory framework, which includes work in preparation for full implementation of the MDR. This means:

- being a member of the Medical Devices Coordination Group (MDCG) and its committees
- being a member of the Competent Authorities Medical Devices (CAMD) network (former chair and current member of the elected Executive Group) and its sub-committees

- recognising the CE mark and having Notified Bodies (NBs) based in the UK which are able to certify the CE mark on medical devices.
- participating (currently leading) in Joint Actions with other member states designed to improve coordination and collaboration across the network in relation to the performance of market surveillance responsibilities.
- access to databases (e.g. EUDAMED) providing information on products on the market and pooling information about performance and safety.

Preparations for Brexit

The EU (Withdrawal) Act will bring EU law into UK law, this will be the case whether or not there is a deal.

In relation to the MDR, the Government has made clear that although the implementation period for the MDR crosses the Brexit date (29 March 2019), it will comply, and align UK law, with all key elements of the Medical Devices Regulation (MDR), subject to the usual parliamentary approvals.

Ideally any Brexit agreement would enable the MHRA to continue as part of the EU/EAA regulatory framework for medicines and medical devices. However, in the event of no deal being agreed, in order to maintain a high level of public health protection by the MHRA, the Government is putting in place contingency plans. These include enabling the MHRA to be able to take any decisions and carry out functions that are currently taken or carried out at EU level.

- The Department of Health and Social Care (DHSC) published a number of technical notices on 23 August 2018, including one on how medical devices would be regulated.
- During October the MHRA ran a consultation on proposals for how legislation and regulatory processes for medicines and medical devices would have to be modified in the event of the UK not securing a deal with the EU after the UK's exit. Many of the changes are of a technical nature, to remove relevant references to the EU, insert references to the UK and other similar changes. However, there will need to be some more substantial changes, outlined below.
- On 23 October the Secretary of State for Health and Social Care wrote to the suppliers of medical devices about the need for contingency planning to ensure that medical devices would continue to be available.

What will happen post Brexit?

Until the terms of any Brexit deal are known, it is only possible to comment on what might happen should there be no deal that allows the UK to remain as part of the EU devices regulatory framework.

Role and responsibilities of the MHRA Without a deal, the MHRA would no longer be part of the European devices regulatory network and would no longer be able to perform a variety of the roles it currently undertakes in Europe. For example:

- the MHRA would be unable to designate UK conformity assessment bodies (e.g. BSI) as EU Notified Bodies. The functions carried out by existing UK Notified Bodies for medical devices would need to transfer to Notified Bodies in the remaining EU27.
- the MHRA would no longer be a member of the Medical Devices Coordination Group or the Competent Authorities Medical Devices network. This would mean that the UK would be bound by the MDR but would not be able to influence ongoing discussions about its

interpretation and implementation, for example on the classification of medical devices (such as fluorescein), or the operation of the Unique Device Identifier (see below for more detail).

The MHRA would therefore need to take an expanded role in registration, assessment, and post-market surveillance of medical devices in the UK – this is described in greater detail below.

CE marking The UK is currently part of the European CE-marking system for medical devices. In the event of no deal, the Government has said it would unilaterally recognise the CE-mark for medical devices for a time limited period. This would ensure the continued supply of medical devices in the UK by allowing devices which are permitted in the EU/EEA to be marketed in the UK as at present.

However without an agreement there would no longer be Notified Bodies in the UK able to issue CE markings for medical devices. This would mean that UK manufacturers of medical devices would need to obtain a CE mark from a Notified Body in an EU member state, as well as an authorisation from the MHRA, if they wish to place the product on the market elsewhere in Europe and not just in the UK.

A new UK mark The Government has said that a new 'UK mark' to replace or run alongside the CE mark could be developed in future, but not for Exit day. A new 'UK mark' and/or other agreed international 'marks' could replace or supplement CE marks as an indication of conformity with UK requirements. However whether that UK mark would be recognised in Europe, or anywhere else except the UK, would need to be negotiated.

Placing devices on the UK market: Devices can now be legally placed on the UK market if they are in conformity with the MDR. In the event of no deal, from 29 March 2019 the UK will retain the current dual regulatory framework in which medical devices could be placed on the UK market (and put into service) either in conformity with the current requirements (based on EU Directives) or in conformity with the new EU MDR Regulations.

Registration of medical devices In the event of no deal it is proposed that registration requirements would be expanded to cover all medical devices and in-vitro diagnostics (IVDs) that are placed on the UK market. The responsibility for registering the medical device would fall to the economic operator (e.g. an importer, distributor or manufacturer) that first 'places the device' on the UK market. This economic operator (or UK 'sponsor') would need to be established in the UK and provide a registered address. There would be a grace period to allow time for compliance, which would – at least initially – require a small administrative fee broadly in line with the current registration charge for class I devices (£100).

Market Surveillance Currently, the UK relies on being part of the European devices regulatory network (EU, EEA, Turkey and Switzerland) to access relevant information on devices to support market surveillance work. The UK also relies on other Member States to take regulatory action in relation to manufacturers and/or authorised representatives based in their country.

In a no-deal scenario, the MHRA would continue to perform market surveillance of medical devices on the UK market. However, the MHRA would need to strengthen its market surveillance and assurance role to offset the benefits lost from being part of the EU devices regulatory network and to ensure the UK has sufficient ability to protect patient safety. The MHRA would retain the right to take enforcement action in respect of devices on the UK market, but only for justified safety grounds or non-compliance, as at present.

Unique Device Identifier The MDR will require all medical devices to be issued with a Unique Device Identifier (UDI), which will be recorded on the EUDAMED database. This requirement is expected to take effect in 2020. It is not clear whether the UK would continue to be part of this requirement should there be no deal, since the UK would not have access to the EUDAMED database. Were this to be the case it seems likely that the UK would need to develop an alternative mechanism of managing UDIs for medical devices, since the scheme applies world wide.

Discussions are currently ongoing to settle the details of how the UDI process would work in practice. This is a particularly significant issue for optical manufacturers and businesses, where problems have been identified in relation to spectacle frames, spectacle lenses and contact lenses. A sub-group of the Medical Devices Coordination Group (MDCG) is being set up, made up of Member States' competent authorities, along with observers from relevant stakeholder associations (including industry and healthcare professionals). However without a deal, neither the MHRA nor UK stakeholder bodies will be able to participate in this sub-group after 29 March 2019.

Borderline and classification A sub-group of the MDCG is also being set up to consider the classification of borderline products. This is key for the optical sector because it will include diagnostic staining agents (such as fluorescein). There will be a review of the MEDDEV document by June 2019, alongside which several key definitions are being considered by the European Medicines Agency (pharmacological, immunological, metabolic and diagnosis). Again, without a deal, neither the MHRA nor UK stakeholders will be able to participate in this important sub-group after 29 March 2019.

Supply chain contingency planning The DHSC is undertaking an analysis of supply chains for medical devices, identifying those products routinely imported into the UK from countries in the EU. In parallel the DHSC has suggested that all suppliers that source products from other EU countries should review their supply chains and determine what measures they need to take so that they can continue to source and supply products in the event of a no deal exit. Where companies have already put contingency plans in place, they have been asked to share details of their arrangements at mdcccontingencyplanning@dh.gsi.gov.uk.

This contingency planning is to ensure that the NHS has uninterrupted access to the full range of products that it relies on for delivering safe and effective patient care. It is not clear at this stage that optical devices (spectacles and contact lenses) are included within this contingency planning. While these products are provided privately to patients, the provision of eye care is an important part of the NHS.

The DHSC is also starting to consider whether UK manufacturers of medical devices will encounter difficulties in their own supply chains for materials.

Costs to UK businesses The Government has stated that its objective, post Brexit, is to minimise the risk to businesses and provide regulatory continuity. However, it has acknowledged that there would be ongoing costs for businesses. While Government has provided no estimates of potential costs for businesses, they have identified the following:

- Changes to the registration process would impose a direct cost on industry – those costs would depend on the scope and scale of the registration process.
- There would be costs associated with non-UK medical devices manufacturers having to nominate a UK 'sponsor' to place their products on the UK market. The Government has assumed that acting as a 'sponsor' for an overseas devices manufacturer would be cost neutral to the sponsor, on the basis that any regulatory costs incurred by the UK 'sponsor'

would be passed on to the overseas manufacturer through any commercial agreement between the two parties.

- Businesses currently operating in the UK which currently sell in the EU/EEA would need to adhere to additional UK only regulatory requirements, such as additional fees, legal and administration costs, in addition to the EU requirements they already comply with.
- There would also be familiarisation and set up costs as businesses transition into dealing with both systems. Added to which there would be costs to the MHRA of establishing and sustaining new regulatory capabilities; these will be largely recouped through fees.

Next steps

FODO will continue to work with officials at MHRA and Department of Health and Social Care to ensure that Government takes account of the concerns and needs of optical manufacturers and the wider optical sector as they prepare for both the implementation of the MDR and new arrangements post Brexit.

FODO will also continue to work with colleagues in Europe on the implementation of the MDR – in particular on seeking a solution to the use of the UDI and on the classification of borderline products such as fluorescein strips.

We will provide further briefings and updates over the coming months.

For further information contact info@fodo.com

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November 2018