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TURN AND FACE THE STRANGE CH-CH-CHANGES: THE NEW MEDICAL DEVICES REGULATIONS

The new EU Medical Device Regulation and the EU In vitro Diagnostics Regulation (together, the "**Regulations**") were adopted by the European Parliament in April 2017 and entered into force on 25 May 2017. They fundamentally change the way medical devices will be regulated going forward. So why and how are the Regulations changing and what do businesses need to consider?

Why are the Regulations changing?

In short the impetus for change is based on technological changes and recent scandals that have shown some of the shortcomings of current medical device regulation.

Widely publicised scandals in relation to 'PIP' breast implants and DePuy metal hip replacements, in the opinion of European Commission, highlighted "*the weaknesses of today's legislation*".

In any event the old legislation is from the 1990s and therefore was due some amendments. On this basis there are now two new regulations:

- Regulation (EU) 2017/745 on medical devices; and
- Regulation (EU) 2017/746 on in vitro diagnostic medical devices.

The Commission considers the Regulations will achieve the following:

- improve the quality, safety and reliability of medical devices;
- strengthen the transparency of information for consumers; and
- enhance vigilance and market surveillance.

How are the Regulations changing?

There are a lot of changes including:

- There is a broader definition of medical devices / in vitro diagnostic medical devices. For example software is expressly included as a "*medical device*" and the new definition includes not only traditional devices but also products previously considered accessories to those devices (e.g. cleaning and disinfecting products).
- The Regulations also extend to products without an intended medical purpose. Examples given of these include:
  - contact lenses and other products introduced in or onto the eye;
  - products introduced into the body via surgically invasive means in order to modify anatomy;
  - substances used for dermal or other fillers;
  - equipment for liposuction, lipolysis or lipoplasty;
  - lasers for skin treatments such as skin resurfacing, tattoos or hair removal; and
  - equipment for brain stimulation.
- There is a new Medical Device Coordination Group charged with introducing common specifications for medical devices.

- Certain devices will be upclassified as being considered more risky, and the risk classification for in-vitro medical devices will be changed bringing it more into line with the risk classification for medical devices.
- There are more stringent requirements for conformity assessment and CE marking, with many more products requiring review by approved reviewing authorities (called 'notified bodies').
- There are changes to traceability and transparency requirements. A revised European database for medical devices (**EUDAMED**) requires a unique device identifier (**UDI**) to allow medical devices to be traced.
- There is enhanced market and post-market surveillance, with increased rights of regulatory authorities to conduct audits.
- There are enhanced requirements on notified bodies with a redesignation process required and consistent reassessment of them.
- For the first time all the actors in the supply chain will have potential responsibility for defects in devices, and manufacturers outside the EU will need EU based authorised representatives.
- Manufacturers (or their authorised representatives) are required to have at least one person responsible for regulatory compliance.

What do businesses need to do and by when?

The good news, given the sheer scale of the changes required, is that there are lengthy transition periods. Businesses need to comply in full with the medical devices regulations by **26 May 2020** and by the in-vitro devices regulations by **26 May 2022**. The challenge is nonetheless considerable, and a number of stakeholders have complained that there is insufficient time for an orderly transition.

The impact of the Regulations depends on the role of the business. Issues which medical devices businesses need to consider include the following:

- A product portfolio assessment is likely to be required including pipeline products, for example to consider whether any products are caught by the broader definitions or have been upclassified?
- Consider changes to contracts in light of the new obligations and liabilities.
    - Secure budget for increased compliance costs, including bringing on board responsible persons.

The impact of Brexit could of course also be relevant to UK businesses active in this area - but it would be very unwise at this time to conclude that the Regulations will not apply in the UK and to use Brexit as a reason not to comply with the Regulation.

FIND OUT MORE

If you would like to discuss the Regulations and their implications for you and your business, please contact **Gustaf Duhs**

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