



Importers, distributors and assemblers



Background to changes

The European Union started to regulate medical devices in the 1990s with three separate directives. None of these created any obligations for importers and distributors. The Commission's 'Blue Guide' on the implementation of EU product rules nevertheless indicates that importers and distributors have an important role to play within the framework of regulatory compliance. The new Regulations eliminate this omission and largely implement the recommendations of the Blue Guide.

The new regulations on medical devices and in vitro diagnostic devices were adopted on 5 April 2017. They will be applied respectively from 26 May 2020 and 26 May 2022, although many of the requirements will start to manifest themselves during these transitional periods.

A significant change introduced by the new Regulations is the new role given to importers and distributors within the framework of regulatory compliance in the post-marketing phase. The new regulatory responsibilities of these economic operators are likely to influence their relations with manufacturers, in particular because of their obligation to verify manufacturers' compliance. The Regulations have created a new paradigm of how compliance is verified and how post-market surveillance is carried out in the European Union. Because this paradigm is untested, the evolving practice over the next few years is likely to shape interactions between all economic operators in a way that is difficult to anticipate and which will result in many surprises.



Actions

Manufacturers will need to:

- ✓ understand the obligations of importers and distributors;
- ✓ assess the impact of these obligations on the management of post-market surveillance; and
- ✓ update their agreements with importers and distributors to address the new requirements, in particular the potential for unilateral corrective action by importers and distributors.

Our understanding of this new supply chain paradigm is likely to significantly evolve with experience resulting from the interplay of the different actors as they come to terms with the new paradigm. It is also possible that the regulatory requirements will evolve. It is important for manufacturers to monitor future developments in this area and remain flexible to be able to adapt to any changed situation.

Get in Touch

Smart Support is designed to outline the impact of the new regulatory changes, in order for your business to prepare to navigate the transition and implement the new requirements.

Each Smart Support topic is written by an industry expert and reviewed by a topic expert and advisory panel, providing you with:

- ✓ An executive summary suitable for senior management
- ✓ Detailed practical guidance on what has changed and what this means for your organization
- ✓ Actions to take now and a summary of what is still to change

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