

On May 25, 2016, the [European Union \(EU\)](#) agreed on the new rules that will govern the placing on the European market of medical devices and in vitro diagnostic medical devices. Medical devices and in vitro diagnostic medical devices cover a wide range of products, from adhesive bandages to hip replacements, and from pregnancy tests to HIV tests.

These provisions will go into the final version of the long-awaited EU medical device and *in vitro* diagnostic (IVD) regulations, paving a way for a final adoption by the end of 2016.

This is a significant milestone in a legislative dossier that started back in 2012, with the aim to fill the regulatory gaps uncovered as technology evolved faster than the current regulatory regime, which had not been updated since 2007.

Edith Schippers, Minister of Health of the Netherlands and President of the EU Council stated, "This agreement matters to all citizens: sooner or later all of us enter into contact with medical devices to diagnose, prevent, treat, or alleviate diseases. The deal reached will improve patients' health and it will help to enhance the quality of life of disabled persons. It will also ensure a level playing field for the 25,000 medical device manufacturers in the EU, many of which are [small and medium-sized enterprises] SMEs and which employ more than half a million persons."

## What Do the Regulations Mean in Practice?

The new regulations, which will enter into force 20 days after publication in the Official Journal, will strengthen the rules for placing medical devices on the market as well as tighten market surveillance and vigilance. Unlike directives, which currently make up the medical device regulatory scheme in the EU, a regulation is directly applicable in member states without the need for a member state to translate the legislation into its own statutes.

## Stronger Powers for Regulators

In the EU, a notified body conducts conformity assessments for most medical devices under the relevant EU Directives and before medical devices can be placed on the EU market. Under the proposed regulations, the rules governing notified bodies will be tightened to strengthen the surveillance of the national authorities over the notified bodies. These rules will also give the notified bodies the regulatory power and responsibility to carry out unannounced audits and on-site inspections to ensure that the rules are correctly implemented by economic operators (similar to the Dawn Raids regimes well-known in the EU competition scene).

Additionally, each member state's regulatory body that is charged with monitoring compliance will also have specific and tightened regulatory duties regarding market surveillance. In practice, this means that national authorities will be entitled to seize, destroy, or render inoperable any device they find to present an unacceptable risk to the public health. They will have to be able to coordinate their efforts with their European counterparts to carry out pan-European products recalls, withdrawal, or to limit the availability of a product on the market.

## Strengthened Duties of Economic Operators

Manufacturers will have strengthened responsibilities to follow-up on the quality, performance and safety of the medical devices that they place on the EU market. They are, *inter alia*, expected to be able to act swiftly when concerns arise regarding their medical devices. As a corollary, manufacturers will have to operate their system in order to continuously collect data and improve the devices. Recent versions of the regulations give notified bodies the power to remove or suspend certificates pending the manufacturer's corrective actions, and the Commission is to make this information publicly available, thereby creating significant legal and reputational risk for non-compliant operators.

## High Risk and Implantable Devices

One highly contested amendment from the EU Parliament and Council is the additional step for experts to review submissions for high-risk devices and implants. The regulations seem to take the step of establishing requirements for high-risk device expert and laboratory reviews before the devices are placed on the market. Manufacturers of implants that are currently class IIb and do not have a design dossier should assess the impact that the new regulations will have on their regulatory processes and determine how to implement the new requirements.

## Next Steps

The Council's Permanent Representative Committee endorsed the agreement June 2016, after which the EU Parliament's Committee on Environment, Public Health, and Food Safety (ENVI) also endorsed the agreement. Once the texts are fully revised and in their final form, the provisions will have to be translated into the 24 official languages of the EU before being finally published in the EU Official Journal.

Following the regulations' entry into force, on publication, medical device and IVD manufacturers will have three years (five years for IVDs) to comply with these changes.

Considering the significant amount of work needed, waiting is not the answer. Manufacturers should start to carefully assess the upcoming changes when they are published and adequately build a plan to comply with the new regulations.

If you have any question on EU medical devices regulations, please contact one of the lawyers listed in this alert.

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