



New EU rules on medical devices to enhance patient safety and modernise public health

Brussels, 5 April 2017

The Commission welcomes the adoption of its proposal for two Regulations on medical devices which establish a modernised and more robust EU legislative framework to ensure better protection of public health and patient safety.

The new Regulations on medical and in-vitro diagnostic medical devices proposed by the Commission in 2012 will help to ensure that all medical devices - from heart valves to sticking plasters to artificial hips - are safe and perform well. To address this, the new rules will improve market surveillance and traceability as well as make sure that all medical and in vitro diagnostic devices are designed to reflect the latest scientific and technological state-of-the art. The rules will also provide more transparency and legal certainty for producers, manufacturers and importers and help to strengthen international competitiveness and innovation in this strategic sector.

Elżbieta **Bieńkowska**, Commissioner for Internal Market, Industry, Entrepreneurship and SMEs, said: *"I'm extremely happy that our push for stricter controls of medical devices on the EU market will now become a reality. Whether for medical devices, cars or other products, we must ensure stronger supervision in the interest of our citizens. We should not wait for another scandal instead we should start a discussion how to strengthen European oversight over Member States' market surveillance activities."*

The two new Regulations bring a number of improvements for medical and in-vitro devices:

Improve the quality, safety and reliability of medical devices: The new rules will impose tighter controls on high-risk devices such as implants, requiring a pool of experts at the EU level to be consulted before placing the device on the market. Controls will also be tightened on clinical trials as well as on the bodies that can approve the marketing of medical devices. The new rules will also cover certain, previously unregulated aesthetic products (e.g. coloured contact lenses that do not correct vision). In addition, a new system for risk classification in line with international guidelines will apply to *in vitro* diagnostic medical devices.

Strengthen transparency of information for consumers: The new regulations will make sure that vital information is easy to find. For instance, patients will receive an implant card with all the essential information, and a unique device identifier will be mandatory for every product so that it can be found in the new European database of medical devices (EUDAMED).

Enhance vigilance and market surveillance: Once devices are available for use on the market, manufacturers will be obliged to collect data about their performance and EU countries will coordinate more closely in the field of market surveillance.

Background

There are over 500,000 types of medical devices and *in-vitro* diagnostic medical devices on the EU market. Examples of medical devices are contact lenses, x-ray machines, pacemakers, breast implants and hip replacements and sticking plasters. *In vitro* diagnostic medical devices, which are used to perform tests on samples, include HIV blood tests, pregnancy tests and blood sugar monitoring systems for diabetics.

The [existing regulatory framework](#) dates back to the 1990s and consists of three Directives. However, problems with divergences in the interpretation and application of the rules, technological progress as well as incidents involving malfunctions of medical devices—i.e. the PIP breast implant scandal—highlighted the need for [revision](#) of current legislation. The Commission is also currently working on more structural and horizontal solutions for better market surveillance within the broader frame of a goods package reform.

To address this, the European Commission presented two legislative proposals on medical and in-vitro diagnostic [on 26 September 2012](#). This was followed by extensive expert consultations that resulted in an agreement on the general approach to the medical devices package among Member States' health ministers on 5 October 2015. The adoption of the package by Parliament, following today's vote in plenary, fully reflects the position of the Council reached in its first reading and in turn the agreement

of the co-legislators from June 2016, therefore allowing to conclude the legislative process.

To allow manufacturers and authorities to adapt, the new rules will only apply after a transitional period, namely 3 years after publication for the Regulation on medical devices and 5 years after publication for in the Regulation on vitro diagnostic medical devices.

More information

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Attachments

[Medical Devices factsheet.pdf](#)