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Medical devices: Council confirms deal with EP

On 15 June 2016, the Council's Permanent Representatives Committee endorsed the agreement reached with the European Parliament on 25 May on the new medical devices regulations. The Commission stated that it can also support the agreement reached between the two co-legislators.

If the agreement is confirmed by the Parliament's ENVI committee the Council will approve the agreement at ministers' level. This is planned for September, once the draft regulations have been translated into all official languages. Following their legal-linguistic review the two draft regulations will be adopted by the Council and the Parliament, probably at the end of the year. The new rules will apply three years after publication as regards medical devices and five years after publication as regards in vitro diagnostic medical devices.

"The new EU rules have a twofold aim: making sure that medical devices and in vitro diagnostic medical devices are safe, while allowing patients to benefit from innovative health care solutions in a timely manner. They also contribute to promote growth and create jobs in the EU by offering manufacturers the right legal framework to produce the devices that patients ask for", said Edith Schippers, Minister of Health of the Netherlands and President of the Council.

Medical devices and in vitro diagnostic medical devices cover a wide range of products, from sticking plasters to hip replacements, and from pregnancy tests to HIV tests.

The new EU regulations:

strengthen the rules on placing devices on the market and reinforce surveillance once they are available; this will help to**ensure that medical devices and in vitro diagnostic medical devices are safe**
establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market**;** this will **allow** manufacturers **to act swiftly when concerns arise and** help them to **improve** their **devices continuously** on the basis of actual data
improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number; t**his will allow fast and effective measures in case of safety problems**
set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; this will enable them to **make better informed decisions**

Medical devices: deal reached on new EU rules
Reform of the EU rules for medical and in vitro devices

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