Medical devices: Council getting ready for talks with EP

On 19 June 2015, the Council agreed the substance of its negotiating stance on two draft regulations aimed at modernising EU rules on medical devices and in vitro diagnostic medical devices. This is a step towards providing the presidency with a mandate to start talks with the European Parliament with a view to reach an agreement as early as possible.

The two draft regulations on medical devices cover a wide range of products, from sticking plasters to hip replacements, pacemakers and laboratory tests for assessment of medical interventions.

The main objective of the two draft regulations is to ensure that medical devices are safe. This would be achieved by strengthening the rules on placing devices on the market and tightening surveillance once they are available.

"We are pleased that under the Latvian presidency major progress could be achieved to strengthen the rules on medical devices. Today’s agreement is a decisive step forward to improve patient safety and strengthen European competitiveness. Further work both within the Council and between the Council and the European Parliament is, however, needed to ensure that the benefits of the new rules are put into practice", said Guntis Belēvičs, the Latvian minister for health and President of the Council.

Placing on the market

Unlike pharmaceuticals, medical devices and in vitro diagnostic medical devices are not subject to pre-market authorisation. Instead, they undergo a conformity assessment to establish whether they meet the applicable standards before they are placed on the market. Depending on the risk posed by a product, the assessment may involve a so-called notified body. This is an independent body with specific expertise for certain types of medical devices which assesses whether these medical devices meet the relevant standards.

The Council further tightened the rules for the designation of notified bodies, for the monitoring of their assessment activities by national competent authorities and for co-operation of those competent authorities. The new rules would also give notified bodies the right and duty to carry out unannounced factory inspections.

Post-market surveillance

The Council added explicit provisions on manufacturers’ responsibilities for the follow-up of the quality, performance and safety of devices placed on the market.

Clinical investigations

The draft regulations provide also for strengthened provisions on clinical investigation with a view to increase the availability of reliable clinical data on medical devices. The Council focused its efforts in particular on the protection of those undergoing clinical trials.

More transparency for patients

The draft regulations seek to provide patients more transparency on the available devices, and increase their traceability.

Patients who are implanted with a device would be given key information on the product, including any precautions which might need to be taken. Manufacturers of high-risk devices would have to make publicly available a summary of their safety and performance, with key elements of the clinical data.

Increased traceability

Manufacturers of medical devices would have to fit their products with a unique device identification to ensure traceability.
Manufacturers and importers of both categories of products would have to register themselves and the devices they place on the EU market in a central database. An EU portal would be set up where manufacturers would have to report serious incidents and corrective actions they have taken to reduce the risk of recurrence. The Council took particular care to ensure that the traceability and identification rules can be implemented in practice.

Next steps

The agreement on the substance of the Council’s negotiating stance will allow the next presidency to take contact with the European Parliament to prepare negotiations between the two institutions. Once the Council has finalised some outstanding technical work concerning the preamble of the two draft regulations, negotiations between the institutions will be able to start.

- Presidency proposal of 11 June 2015 for a regulation on medical devices
- Presidency proposal of 11 June 2015 for an annex to the regulation on medical devices
- Presidency proposal of 12 June 2015 for a regulation on in vitro diagnostic medical devices
- Presidency proposal of 12 June 2015 for an annex to the regulation on in vitro diagnostic medical devices
- Reform of the EU rules for medical and in vitro devices

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