

Medical devices: Council mandates presidency to start talks with EP

On 23 September 2015, the Permanent Representatives Committee finalised the Council's position on two draft regulations aimed at modernising EU rules on medical devices and in vitro diagnostic medical devices. This allows the Luxembourg presidency to start talks with the European Parliament with a view to reach an agreement as early as possible. The first trilogue-discussions are scheduled for 13 October 2015. The Council's position is expected to be endorsed by the EPSCO Council on 5 October.

Compared to 19 June 2015, when the substance of the Council's negotiating stance was agreed, outstanding technical work concerning mainly the preamble of the two draft regulations has been completed. The core elements of the Council's view remained, however, unchanged.

The Council and EP follow the same objective

"Previous contacts with the European Parliament have made it clear that the Council and Parliament pursue the same objectives: to work towards creating a solid legal framework which will allow patients to access safe and high quality medical devices while creating the necessary conditions for a competitive and innovative EU market", said Lydia Mutsch, minister for health of Luxembourg and President of the Council.

[Medical devices: Council getting ready for talks with EP](#)

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

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.

[Text setting out the Council's position on medical devices of 21 September 2015](#)

[Annex to the text laying out the Council's position on medical devices of 21 September 2015](#)

[Text setting out the Council's position on in-vitro medical devices of 21 September 2015](#)

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