Medical devices and *in vitro* diagnostic medical devices

The current EU approval system for medical devices (MDs) and *in vitro* diagnostic medical devices (IVDs) is based on conformity assessment by 'notified bodies'. A number of scandals stressed the need to tighten the regulatory framework for such devices. The European Commission's proposals for regulations on MDs and IVDs, being discussed in parallel, are extensive and will repeal all existing rules. Votes in Parliament at second reading are expected during the April I plenary.

Background

MDs and IVDs cover a wide array of products, from sticking plasters, to heart valves, to state-of-the-art analytical laboratory equipment, with over 500 000 devices on the EU market. The EU legal framework for such devices was harmonised in the 1990s. The European Commission presented a pair of proposals for regulations in September 2012. Both proposals have common horizontal aspects, but their specific features require separate legal acts. The legislation is complex, wide-ranging and highly technical.

European Commission proposals

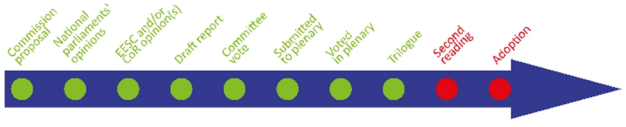
The proposals mainly focus on the scrutiny of devices before they are placed on the market, and their surveillance after becoming available, as well as on their traceability along the supply chain. Elements include, among other things, stricter criteria for designating and monitoring notified bodies, adaptation of the classification rules and streamlining of the different assessment procedures.

European Parliament position

Parliament adopted its first-reading position on 2 April 2014. The legislative resolutions on the MD and IVD proposals amended the Commission proposal heavily. The Council agreed its positions in October 2015. The subsequent interinstitutional negotiations concluded after eight months. The compromise mainly centred on stricter requirements for notified bodies, stronger pre-market scrutiny and post-market surveillance, including manufacturers' liability insurance; strengthened rules for high-risk devices and certain other categories of devices, including special requirements in the case of devices that contain substances having endocrine-disrupting properties or substances that are carcinogenic, mutagenic or toxic for reproduction; and increased transparency and traceability, including (for MDs) the provision of essential product information ('implant card') to patients, and (for IVDs) genetic counselling about the consequences of DNA tests.

The agreed texts were endorsed by the Council's Permanent Representatives Committee and by Parliament's Committee on the Environment, Public Health and Food Safety (ENVI) on 15 June 2016. After legal-linguistic revision, both draft texts were adopted by the Council at first reading on 7 March 2017. The Commission published its communications concerning the position of the Council on the adoption of the regulations on MDs and IVDs on 9 March. The ENVI Committee approved its recommendations for second reading on MDs and IVDs at its meeting of 21 March. Parliament's second-reading vote to formally endorse the position of the Council is due to take place during the April I plenary session. This would complete the adoption procedure, with the MD regulation becoming applicable three years after publication, and that on *in vitro* diagnostic medical devices five years after publication.

Second reading: 2012/0266(COD) (MDs) and 2012/0267(COD) (IVDs); Committee responsible: ENVI; Rapporteurs: Glenis Willmott (S&D, United Kingdom) and Peter Liese (EPP, Germany).



See the EPRS 'EU Legislation in Progress briefing', Medical devices and *in vitro* diagnostic medical devices

EPRS | European Parliamentary Research Service
Author: Nicole Scholz, **Members' Research Service**
PE 599.366