

Medical devices and *in vitro* diagnostic medical devices

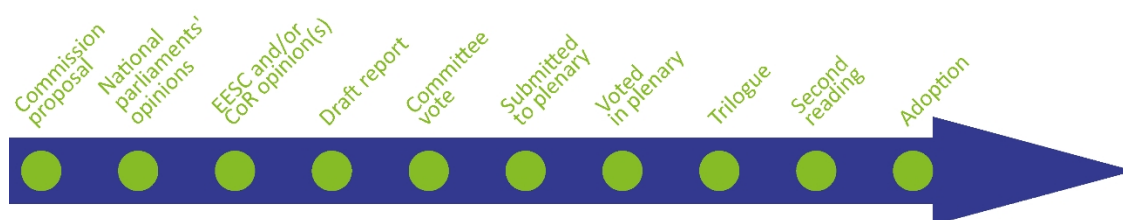
SUMMARY

Medical devices and *in vitro* diagnostic medical devices cover a wide array of products. 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.

Following Parliament's first readings in April 2014, the Council agreed its positions in October 2015. At the conclusion of the trilogues, agreement was reached on 25 May 2016. This was endorsed by the Council's Permanent Representatives Committee on 15 June and confirmed by Parliament's ENVI Committee on the same day. Both draft texts were adopted by the Council on 7 March 2017, and Parliament's second-reading vote on 5 April completed the adoption procedure. The regulation on medical devices will become fully applicable in May 2020, and that on *in vitro* diagnostic medical devices in May 2022.

Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, and Proposal for a Regulation of the European Parliament and of the Council on *in vitro* diagnostic medical devices

<i>Committee responsible:</i>	Environment, Public Health and Food Safety (ENVI)	COM(2012) 542 COM(2012) 541
<i>Rapporteurs:</i>	Glenis Willmott (S&D, UK) Peter Liese (EPP, Germany)	<i>of 26.9.2012</i> <i>procedure ref.:</i> 2012/0266(COD) 2012/0267(COD)
<i>Procedure completed:</i>	Regulation (EU) 2017/745 Regulation (EU) 2017/746 OJ L 117, 5.5.2017	Ordinary legislative procedure



This updates a previous edition, from January 2017: [PE 595.881](#).

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Introduction

Medical devices (MDs) cover a wide array of products, from sticking plasters, to dental filling material, to heart valves and X-ray machines. *In vitro* diagnostic medical devices (IVDs) range from pregnancy self-tests, to blood-glucose meters, to state-of-the-art analytical laboratory equipment. There are over 500 000 devices on the market in the EU. The industry employs [575 000](#) people in about 25 000 companies, of which 95% are small and medium-sized enterprises (SMEs).

The EU legal framework relating to MDs and IVDs was harmonised in the 1990s. Given the fact that these devices have become increasingly sophisticated and innovative, the European Commission has considered it necessary to adapt existing rules to technological and scientific progress, improve the safety and traceability of devices, and ensure greater transparency, including for patients/users and the general public. The need for a revision was further reinforced by the breast implants scandal of 2010, in which a French manufacturer (Poly Implant Prothèse, PIP) had apparently used industrial silicone for the manufacture of breast implants for a number of years, potentially harming thousands of women worldwide.

Against this background, the Commission decided to undertake a revision of the current legislative framework. On 26 September 2012, it presented a package consisting of two proposals for regulations: on [medical devices](#) ('MD proposal') and on [in vitro diagnostic medical devices](#) ('IVD proposal'), accompanied by a communication. Both proposals have common horizontal aspects, but their specific features require separate legal acts. The legislation is complex, wide-ranging and highly technical, and were debated for nearly four years. The European Parliament adopted its position in first reading on 2 April 2014, the Council agreed on its general approach on 5 October 2015. Interinstitutional trilogue negotiations between Council, Parliament and Commission started on 13 October 2015 and were concluded at the tenth meeting on 25 May 2016.

Existing situation

The current EU regulatory framework consists of three different pieces of legislation: for medical devices, it is [Council Directive 90/385/EEC](#) on active implantable medical devices ('AIMD Directive') and [Council Directive 93/42/EEC](#) on medical devices ('MD Directive'); for *in vitro* diagnostic medical devices, it is [Directive 98/79/EC](#) of the European Parliament and of the Council ('IVD Directive').

Unlike medicinal products, MDs and IVDs are not subject to a pre-market authorisation, but to a conformity assessment. Conformity is assessed by 'notified bodies' – public third-party organisations or private companies designated by the Member States. These bodies issue a certificate of conformity ('CE' mark) for all but low-risk devices,¹ the certification of which is handled by their manufacturers.

According to the Commission, the existing framework for regulating medical devices has proven its merits and is not fundamentally unsound. The revision aims to address a

number of weaknesses, such as differences in Member States' interpretation and application of rules, as well as regulatory flaws and gaps in regard to certain devices. This is to be pursued within the overall objective of guaranteeing a high level of protection of human health and safety, ensuring smooth functioning of the internal market, and providing a regulatory framework that supports innovation and the competitiveness of the European medical device industry.

The changes the proposals would bring

The main focus of the proposals is on the pre-market scrutiny and post-market surveillance of devices, and on their traceability along the supply chain. They relate to various aspects and include the following main [elements](#):

- extension and clarification of the scope, for instance as regards implants for aesthetic purposes (MD proposal) or high-risk devices manufactured within a single health institution (IVD proposal);
- provision of essential information to patients who are implanted with a device, including warnings or precautions to be taken (MD proposal);
- new provisions on the reprocessing of single-use devices, which is considered as manufacture of new devices and should, as a general rule, be prohibited (MD proposal);
- better traceability and transparency through: the requirement for manufacturers to fit their products with a unique device identification (UDI) system; the obligation for manufacturers of high-risk devices to make publicly available a summary of information regarding their safety and performance; and the further development of the centralised European database on medical devices (Eudamed), with publicly accessible information on devices, manufacturers and clinical investigations (MD proposal)/clinical performance studies (IVD proposal);
- stricter criteria for designating and monitoring notified bodies by national authorities, as well as strengthening the position of notified bodies vis à vis manufacturers, including unannounced factory inspections;
- adaptation of the classification rules and streamlining of the different assessment procedures, for instance by setting up a 'scrutiny mechanism', i.e. the obligation for notified bodies to notify an expert committee of new applications for high-risk devices, and (specifically for IVDs) by introducing a new risk-rule-based classification system with four risk classes – from A (low) to D (high);
- update of the rules on clinical evaluation and clinical investigation (MD proposal) and establishment of requirements for clinical evidence and clinical performance studies (IVD proposal), with the introduction of the concept of 'sponsor';
- strengthened vigilance and post-market surveillance, by establishing an EU portal where manufacturers must report serious incidents and corrective measures;
- creation of a Medical Device Coordination Group made up of members appointed by the Member States to achieve harmonised interpretation and practice across the EU;
- setting a transition period, with the new regulations becoming applicable three years (MD) and five years (IVD) respectively, after their entry into force.

Preparation of the proposal

In preparation for the [impact assessment](#) on the revision of the regulatory framework, the Commission held a public consultation in 2008, followed by another public consultation targeted at IVD-related aspects in 2010. The topics were also regularly

discussed at meetings of the Medical Devices Expert Group (MDEG), the Competent Authorities for Medical Devices (CAMD) network and other specific working groups.

The [opinion of the European Data Protection Supervisor](#) of 8 February 2013 on both proposals contained the following key recommendations: to add provisions on the processing and storage of data concerning the health of patients in the Eudamed database; to explicitly mention that periodic reports should only use anonymous data; to add that manufacturers need to obtain explicit consent from the data subject before any processing of patient health data takes place; and to determine a maximum retention period for personal data.

Stakeholder views

(Stakeholder positions expressed at different stages of the procedure, including during the trilogues, are presented in an [earlier edition](#) of this briefing.)

MedTech Europe, the alliance of Eucomed (representing the European medical devices industry) and EDMA (representing the *in vitro* diagnostic medical devices industry), [has welcomed](#) Parliament's final vote. MedTech Europe stresses the effort needed from all parties to implement the revised rules within the transition deadline, and points to the importance of early availability of notified bodies, among other things.

The European Consumer Organisation (BEUC) [has reportedly hailed](#) the adoption of the new rules, which would boost information to patients and strengthen the way devices are controlled. BEUC nevertheless considers that stronger safety standards could have been adopted, and regrets that patients will 'remain exposed to potentially harming devices for too long', given that the regulations enter into force in three and five years respectively.

Council

The Working Party on Pharmaceuticals and Medical devices started its examination of the MD and IVD framework in October 2012. It met for [50 days](#) in total under five consecutive presidencies. On 19 June 2015 (under the Latvian Presidency), the Employment, Social Policy, Health and Consumer Affairs (EPSCO) Council reached a partial general approach.

During the [discussions](#), the need to find the right balance between more patient safety and faster access to innovative devices was stressed. Most Member States were in favour of clarifying the procedures for designating notified bodies and ensuring that they meet similar standards throughout the EU, but without increasing the administrative burden unnecessarily. Many delegations reportedly expressed concerns about the reprocessing of MDs for single use. On 23 September 2015 (under the Luxembourg Presidency), the Committee of Permanent Representatives finalised the Council's position. On 5 October 2015, the Council agreed on a full general approach on [MDs](#) and [IVDs](#).²

Parliamentary analysis

The European Parliament Library briefing on [Safe and innovative medical devices](#) (October 2013) gives a short overview of the background, including stakeholder positions. The European Parliamentary Research Service (EPRS) [briefing](#) on IVDs (November 2014) elaborates on the then state of play of the IVD proposal. In its [Initial appraisal of the Commission's impact assessment](#) (January 2013), EPRS notes, among other things, that the social impacts considered could have covered aspects such as the safety and health of staff applying the devices, or employment in the medical devices sector, and that the impact assessment could have paid more attention to the expected impacts on SMEs. The

[document](#) prepared for the workshop on MDs and IVDs held by Parliament's Policy Department A (February 2013) outlines the specifics of the IVD proposal.

Legislative process

Parliament's proposed changes

The dossier was assigned to Parliament's Committee for the Environment, Public Health and Food Safety (ENVI). Two committees gave opinions: the Committee for Employment and Social Affairs (EMPL), rapporteur Edite Estrela, S&D, Portugal (on [MDs](#) and [IVDs](#)), and the Committee for Internal Market and Consumer Protection (IMCO), rapporteur Nora Berra, EPP, France (on [MDs](#) and [IVDs](#)). The reports were discussed in plenary in October 2013, with 343 [amendments](#) adopted on the MD proposal and 261 [amendments](#) adopted on the IVD proposal on 22 October. The proposals were then referred back to the ENVI Committee, and Parliament completed its first reading on both on 2 April 2014, prior to the conclusion of the last parliamentary term.

The legislative resolutions adopted on 2 April 2014 on the [MD](#) and [IVD](#) proposals amend the Commission proposal heavily and seek to introduce, among others, the following changes:

For the MD proposal

- **Scope:** implants for aesthetic purposes should fall within the scope of the regulation.
- **Assessment procedure:** an Assessment Committee for Medical Devices (ACMD) composed of specialists, patients' representatives and a European Medicines Agency (EMA) representative should be created, with the task of giving its opinion, on a case-by-case basis, for the assessment of certain high-risk medical devices.
- **Insurance:** manufacturers should be obliged to take out liability insurance to make sure that patients harmed are compensated for any damage.
- **Personnel and expertise:** it is proposed to strengthen provisions relating to the personnel in the notified bodies and within the national authorities responsible for the designation and monitoring of notified bodies, which should have permanent in-house competent personnel.
- **Special notified bodies:** for high-risk medical devices, the conformity assessment should be the responsibility of 'special notified bodies', to be designated by the EMA.
- **Coordination between Member States and the Medical Device Coordination Group (MDCG):** a multidisciplinary Medical Device Advisory Committee (MDAC) made up of experts and stakeholders should be set up, for providing scientific advice to the MDCG, the Commission and the Member States.
- **Labelling and disposal of single-use devices:** there should only be two types of labelling for devices – 'single-use' and 'reusable' – and only those labelled as reusable should be reprocessed. To ensure patient safety, the Commission should draw up a list of single-use devices unsuitable for reprocessing ('negative list').
- **Clinical investigations:** definitions on 'performance' and 'safety' (as provided in Parliament's amendments) should be introduced, and performance would encompass efficacy and patient benefit. For high-risk medical devices, manufacturers should draw up a report on their safety and performance aspects and on the outcome of their clinical evaluation. Authorisation for a clinical investigation should only be granted after approval by an independent ethics committee.
- **Information to patients and healthcare professionals:** manufacturers of an implantable device should provide the patient with an implant card and register the information contained therein in the patient's medical records.

- **Vigilance and market surveillance:** the reporting of incidents via the electronic system should include date and place of incidents, and where available, information on the patient/user or healthcare professional involved.

For the IVD proposal

- **In-house exemption:** in-house testing, i.e. tests performed within a single healthcare institution, are currently exempted from the requirements, with some specific provisions for class D devices. This should be adapted with regard to the needs of doctors and patients of such an institution.
- **Companion diagnostics:** it should be clarified that companion diagnostics are not subject to any in-house exemption.
- **Ethics committee:** the clinical performance study should be positively assessed by an independent ethics committee.
- **Genetic information, counselling and informed consent:** genetic counselling (which includes several aspects and is carried out by a qualified physician) should be mandatory before using a device for predictive and prenatal testing, and after a genetic condition has been diagnosed. A device may only be used for the purpose of a genetic test after the person concerned has given their free and informed consent.
- **Taking account of the needs of SMEs:** since many companies offering services in the area of IVDs are SMEs, their burden should be alleviated.
- **Medical prescription:** certain devices, particularly class D devices and class C devices in the genetic testing and companion diagnostics categories, should only be supplied on a medical prescription.
- **Application of the regulation:** it should become applicable three years after its entry into force instead of five, as proposed by the Commission (in line with the Commission proposal for MDs, which is also three years).

In September 2014, in the new legislative term, Glenis Willmott (S&D, UK) took over as MD rapporteur from Dagmar Roth-Behrendt (S&D, Germany), while IVD rapporteur Peter Liese (EPP, Germany) retained the dossier.

Trilogue

After eight months of interinstitutional negotiations, agreement was reached on the two proposals at the tenth trilogue meeting on 25 May 2016. The compromise on the proposed [MD](#) and [IVD](#) texts mainly centres on the following [points](#):

- **Stricter requirements for notified bodies, stronger pre-market scrutiny and post-marketing surveillance:** the surveillance of notified bodies by national authorities will be tightened. Notified bodies will have the right and obligation to carry out unannounced factory inspections, and they will have to employ medically skilled personnel. Provisions will be laid down on manufacturers' responsibilities for following up the quality, performance and safety of marketed devices, including responsibilities for liability in the event of damage caused by a defective device and on registering complaints. The availability of data will be strengthened, with manufacturers having to provide clinical evidence of the safety of their products, especially for those in higher risk classes, and patients participating in clinical investigation will be better protected in line with existing provisions under the Clinical Trials Regulation.
- **Strengthened rules for high-risk devices and certain other categories of devices:** before being placed on the market, high-risk class III implantable devices and class IIb active devices intended to administer and/or remove a medicinal product may undergo an additional assessment from expert panels, which will provide expertise

and guidance on clinical aspects to notified bodies, the MDCG and the Commission. The new MD provisions will also cover medical devices without an intended medical purpose, but with similar characteristics to medical devices (for example, fillers and coloured contact lenses for cosmetic purposes). Special requirements for manufacturers and notified bodies will apply in the case of devices that contain endocrine disruptors ([EDCs](#)) or carcinogenic, mutagenic, reprotoxic ([CMR](#)) substances.

- **Increased transparency and traceability:** a central database will be set up, which will cover economic operators, notified bodies, market surveillance, vigilance, clinical investigations and certificates. In addition, it will provide patients, healthcare professionals and the public with comprehensive information on products available in the EU. Devices will have unique identification to facilitate traceability throughout the supply chain up to the patient/user. Furthermore, patients implanted with a device will be provided with essential product information ('implant card'), including any necessary precautions. In the field of IVDs, patients will have to be informed about the consequences of DNA tests performed (genetic counselling).³

Subsequent steps in Council and Parliament

The Council's Permanent Representatives Committee endorsed the agreement on 15 June 2016, and it was confirmed by Parliament's ENVI Committee on the same day. The Commission stated that it too could support the agreement reached by the two co-legislators. The Council approved the agreement at ministers' level on 19 September ([political agreement](#)). After legal-linguistic revision, both draft texts were adopted by the Council at first reading on 7 March 2017. The Commission published 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 took place during the plenary session of 5 April. In line with the recommendations for second reading by its ENVI Committee, Parliament approved, without amendment, the Council positions at first reading. The adopted texts (on [MDs](#) and [IVDs](#)⁴) were published in the Official Journal on 5 May. The medical devices regulation will enter into force three years after publication, on 26 May 2020, and that on *in vitro* diagnostic medical devices five years after publication, on 26 May 2022.

References

Council, [Modernising EU rules for medical devices](#).

European Parliament, EPRS, [Medical devices and in vitro diagnostic medical devices](#), 'At a glance' note, January 2017.

European Parliament, Legislative Observatory (OEIL), [In vitro diagnostic medical devices](#).

European Parliament, Legislative Observatory (OEIL), [Medical devices](#).

European Parliament, [Medicines and Medical Devices](#), EU Fact Sheet, December 2016.

Endnotes

¹ The MD Directive divides devices into four risk classes – from I (low) to III (high).

² Including their respective annexes ([MDs](#) and [IVDs](#)).

³ The Commission will have to adopt implementing and delegating acts and produce guidelines for clarifying certain provisions. See also the recently published [new lists of references](#) of harmonised standards for medical devices.

⁴ Annexed to the legislative resolution on IVDs is a Commission statement regarding the provisions for information and counselling in the field of genetic testing and regarding genetic testing used for lifestyle and wellbeing purposes.

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