Briefing

EU Legislation in Progress

7 December 2015

European Parliament

Medical devices and *in vitro* diagnostic medical devices

SUMMARY

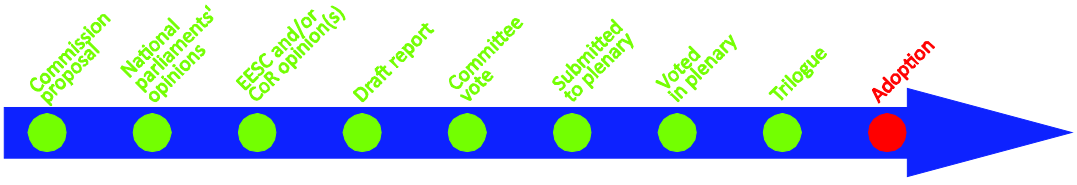
Medical devices and *in vitro* diagnostic medical devices cover a wide array of products, from sticking plasters, to heart valves, to state-of-the-art analytical laboratory equipment, with over 500 000 devices on the EU market.

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, to update the framework. Following Parliament's first reading in April 2014, the Council agreed its position in October 2015. Interinstitutional negotiations are under way, with trilogue meetings having taken place on 13 and 28 October, on 11 and 28 November, and on 3 December.

Stakeholders generally welcome the progress made, with industry asking for the elimination of burdensome requirements, and patient and consumer associations stressing the need for information.

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

Committee responsible:	Environment, Public Health and Food Safety (ENVI)	COM(2012) 542 and COM(2012) 541
Rapporteurs:	Glenis Willmott (S&D, UK) Peter Liese (EPP, Germany)	*of 26.09.2012* *procedure ref.*: 2012/0266(COD) 2012/0267(COD)
Next steps expected:	Further trilogue negotiations	Ordinary legislative procedure



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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 has so far been debated for over three 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, and interinstitutional trilogue negotiations between Council, Parliament and Commission started on 13 October 2015.

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 impact assessment identified systemic and specific issues. Systemic ones concerned: oversight of notified bodies; post-market safety; the regulatory status of products; transparency and traceability; access to (independent) external expertise; obligations and responsibilities on the part of economic operators; and the management of the regulatory system. Specific issues included: regulatory gaps or uncertainties with regard to certain aspects (for example, the reprocessing of single-use devices; genetic tests); the classification of IVDs; the need to adapt requirements to technological, scientific or regulatory developments; and the lack of provisions for a coordinated assessment of applications for those clinical investigations on medical devices that are to be conducted in several Member States.

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.

Parliament's starting position

On 14 June 2012, Parliament adopted a resolution on defective silicone gel breast implants made by French company PIP, in which it called on the Commission to develop an adequate legal framework to guarantee the safety of medical technology, recommending an urgent revision of the MD Directive.

Stakeholder views

AIM (Association Internationale de la Mutualité) calls for: a centralised procedure for high-risk medical devices instead of many different notified bodies; the obligation for manufacturers to have compulsory liability insurance to ensure adequate coverage for patients in case of harm; and the transfer of the burden of proof that a faulty device is the cause of harm from the patient to the manufacturer. Commenting on the first reading vote in the Parliament plenary, AIM observes that 'economic reasons were more important than the health and well-being of citizens'. Furthermore, AIM has reportedly said that the assessment of high-risk devices should not be the responsibility of notified bodies, but of the EU, and that the additional obligations with regard to notified bodies suggested by the Council do not adequately guarantee patient safety.

MedTech Europe, the alliance of Eucomed (representing the European medical devices industry) and EDMA (representing the *in vitro* diagnostic medical devices industry), generally welcomes the progress made, but points to some areas of concern ahead of the trilogue. Eucomed argues that the 'scrutiny mechanism' is redundant, but – if added – should be made workable and predictable, and that the case-by-case approach towards clinical evaluation should be maintained, with scientifically sound definitions for 'clinical data' and 'clinical equivalence'. For reuse of single-use devices, a single

harmonised high level of safety should be ensured, and hazardous substances used in a device should be controlled and labelled based on actual risk of exposure, and not only on hazard. In addition, unnecessary complexity and disproportionate measures should be eliminated. EDMA takes the view that the requirements concerning clinical evidence added by the Council should be adapted to the specific nature of IVDs so as not to create an unnecessary burden for companies, and that the conformity assessment should reflect the risk-based approach to avoid regulatory problems. It is of the opinion that the definition of 'companion diagnostic' should only include those IVDs that select patients for a specific therapy; that the new classification system should be applied consistently and adhere to international standards; and that labelling requirements should focus on information that is essential for the user.

The Association of Medical Devices Reprocessors (AMDR) applauds the Council's proposal, but disagrees with a number of 'disproportionately burdensome requirements'. In particular, it urges negotiators in the trilogue to: strike out Articles 15.0 and 15.6 to avoid an inequitable regulatory system for single-use reprocessors/remanufacturers; do away with the provision on the reprocessing of critical medical devices, as it creates an anticompetitive burden; and eliminate the requirement for a 'contractual' relationship between competing manufacturers, considering it 'impractical and unnecessary'.

The European Patients' Forum (EFP) asks for a number of areas to be addressed in the trilogue. With regard to patient safety, it believes that both the Council's and Parliament's approach (i.e. special notified bodies and an expert panel) is needed. Concerning post-marketing surveillance and vigilance, it agrees with Parliament's proposals that the measures should apply to all incidents, and that information should also be collected about users' errors. As for transparency, EFP appreciates that the Council has endorsed provisions on: the summary on safety and clinical performance for high-risk and implantable devices; the information to patients on implants; access to the Eudamed database; and on results of clinical investigations. However, EFP regrets that Member States did not commit themselves to progress on patients' involvement in governance, for instance in ethics committees.

The European Consumer Organisation (BEUC) considers that the new legislation, while bringing about improvements for consumers, still needs improving. It argues that clinical experts, rather than non-experts, should be in charge of checking the devices, and that manufacturer liability still needs to be strengthened. Moreover, BEUC thinks that there should be more and better information on medical devices for consumers, as well as, in case of problems, follow-up and compensation for the harm suffered.

Advisory committees

The Committee of the Regions (CoR) did not deliver an opinion, given the low impact of the proposed measures on local and regional authorities. The European Economic and Social Committee (EESC) issued its opinion on the two proposals on 14 February 2013. The EESC advocates a high-quality, EU-wide, uniform approval procedure prior to the placement on the market of high-risk MDs and IVDs; and considers fast access to the latest medical technologies an important benefit for patients. It expresses concerns that introducing a centralised pre-market authorisation system would cause further delays, applauds the introduction of a unique device identification (UDI) for each device, and would welcome a fully workable central registration tool (Eudamed). It supports strengthening of patients' position, proposes the establishment of an 'Advisory

Committee' made up of stakeholder representatives to remedy the 'weak involvement' of civil society, and considers it necessary to add provisions for better education and training of healthcare professionals. Commenting specifically on IVDs, the EESC recommends that the principle of assessing the risks and benefits of a device should apply to all products alike, including in-house tests. Moreover, it is concerned that the definition of 'companion diagnostic' proposed in the IVD regulation is too broad and could lead to legal uncertainty.

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. The main elements included: stricter rules for designating notified bodies and for monitoring their activities by national authorities; additional provisions on manufacturers' responsibilities for following up the quality, performance and safety of devices placed on the market; strengthened rules on clinical investigation so as to increase the availability of reliable clinical data on medical devices; the requirement for manufacturers and importers of devices to register themselves and their products in a central EU database; and setting up an EU portal for reporting serious incidents and corrective actions by manufacturers.

During the discussions, the need to find the right balance between more patient safety and faster access to innovative devices was stressed. According to Council sources, 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 that does not substantially deviate from the partial agreement, the main difference being that it completes it with the recitals.

National parliaments

A number of national parliaments examined the proposal, but none submitted a reasoned opinion.[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

The dossier was assigned to Parliament's Committee for the Environment, Public Health and Food Safety (ENVI). The Committee's reports were discussed in plenary in October 2013, with 343 amendments adopted on the MD proposal and 261 amendments adopted on the IVD proposal in plenary on 22 October. Although the reports were then referred back to the ENVI Committee, the outgoing Parliament completed its first reading on both on 2 April 2014.

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. Two further committees gave opinions: the Committee for Employment and Social Affairs (EMPL), rapporteur Edite Estrela, S&D, Portugal (on MDs and an IVDs), and the Committee for Internal Market and Consumer Protection (IMCO), rapporteur Nora Berra, PPE, France (on MDs and IVDs). The legislative resolutions on the MD and IVD proposals of 2 April 2014 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.
- **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).

References

Medical devices, European Parliament, Legislative Observatory (OEIL).

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

Endnotes

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

[2] See IPEX: the subsidiarity deadline for medical devices and *in vitro* diagnostic medical devices was 27 November 2012.

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