Basic information

2012/0266(COD)

COD - Ordinary legislative procedure (ex-codecision procedure)
Regulation

Procedure completed

Medical devices

Amending Directive 2001/83/EC 1999/0134(COD)
Amending Regulation (EC) No 178/2002 2000/0286(COD)
Amending Regulation (EC) No 1223/2009 2008/0035(COD)
See also 2012/0267(COD)
Amended by 2020/0060(COD)
Amended by 2022/0417(COD)
Amended by 2023/0005(COD)
Amended by 2023/0455(COD)
Amended by 2024/0021(COD)

Subject

2.10.03 Standardisation, EC/EU standards and trade mark, certification, compliance
3.40.11 Precision engineering, optics, photography, medical
4.20.05 Health legislation and policy
4.60.08 Safety of products and services, product liability

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	WILLMOTT Dame Glenis (S&D)	16/10/2012
	Shadow rapporteur MCGUINNESS Mairead (PPE) KRAHMER Holger (ALDE) RIVASI Michèle (Verts/ALE) YANNAKOUDAKIS Marina (ECR) SOUSA Alda (GUE/NGL)	

Former committee responsible	Former rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	ROTH-BEHRENDT Dagmar (S&D)	16/10/2012

Former committee for opinion	Former rapporteur for opinion	Appointed

	INTA International Trade	The committee decided not to give an opinion.	
	EMPL Employment and Social Affairs	ESTRELA Edite (S&D)	21/11/2012
	ITRE Industry, Research and Energy	The committee decided not to give an opinion.	
	IMCO Internal Market and Consumer Protection	BERRA Nora (PPE)	10/10/2012

Council of the European Union

Council configuration	Meetings	Date
General Affairs	3526	2017-03-07
General Affairs	3484	2016-09-20
Employment, Social Policy, Health and Consumer Affairs	3323	2014-06-19
Employment, Social Policy, Health and Consumer Affairs	3475	2016-06-16
Employment, Social Policy, Health and Consumer Affairs	3280	2013-12-09
Employment, Social Policy, Health and Consumer Affairs	3206	2012-12-06
Employment, Social Policy, Health and Consumer Affairs	3351	2014-12-01

European Commission

Commission DG	Commissioner
Health and Food Safety	MIMICA Neven

European Economic and Social Committee

European Committee of the Regions

Key events

Date	Event	Reference	Summary
26/09/2012	Legislative proposal published	COM(2012)0542	Summary
22/10/2012	Committee referral announced in Parliament, 1st reading		
06/12/2012	Debate in Council		
25/09/2013	Vote in committee, 1st reading		
09/10/2013	Committee report tabled for plenary, 1st reading	A7-0324/2013	Summary
22/10/2013	Decision by Parliament, 1st reading	T7-0428/2013	Summary
22/10/2013	Results of vote in Parliament		
22/10/2013	Debate in Parliament		

09/12/2013	Debate in Council		
02/04/2014	Decision by Parliament, 1st reading	T7-0266/2014	Summary
02/04/2014	Results of vote in Parliament		
19/06/2014	Debate in Council		Summary
05/11/2014	Committee decision to open interinstitutional negotiations after 1st reading in Parliament		
01/12/2014	Debate in Council		Summary
16/06/2016	Debate in Council		
20/09/2016	Debate in Council		
08/03/2017	Council position published	10728/4/2016	Summary
16/03/2017	Committee referral announced in Parliament, 2nd reading		
21/03/2017	Vote in committee, 2nd reading		
23/03/2017	Committee recommendation tabled for plenary, 2nd reading	A8-0068/2017	Summary
04/04/2017	Debate in Parliament		
05/04/2017	Decision by Parliament, 2nd reading	T8-0107/2017	Summary
05/04/2017	Results of vote in Parliament		
05/04/2017	Final act signed		
05/04/2017	End of procedure in Parliament		
05/05/2017	Final act published in Official Journal		

Technical information

Procedure reference	2012/0266(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Amendments and repeals	Amending Directive 2001/83/EC 1999/0134(COD) Amending Regulation (EC) No 178/2002 2000/0286(COD) Amending Regulation (EC) No 1223/2009 2008/0035(COD) See also 2012/0267(COD) Amended by 2020/0060(COD) Amended by 2022/0417(COD) Amended by 2023/0005(COD) Amended by 2023/0455(COD) Amended by 2024/0021(COD)
Legal basis	Treaty on the Functioning of the European Union TFEU 168-p4 Treaty on the Functioning of the European Union TFEU 114-p1
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/8/06745

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE507.972	12/04/2013	
Amendments tabled in committee		PE510.741	14/05/2013	
Amendments tabled in committee		PE510.765	14/05/2013	
Amendments tabled in committee		PE510.766	14/05/2013	
Amendments tabled in committee		PE510.767	14/05/2013	
Committee opinion	EMPL	PE506.249	20/06/2013	
Committee opinion	IMCO	PE507.987	08/08/2013	
Committee report tabled for plenary, 1st reading/single reading		A7-0324/2013	09/10/2013	Summary
Text adopted by Parliament, partial vote at 1st reading /single reading		T7-0428/2013	22/10/2013	Summary
Text adopted by Parliament, 1st reading/single reading		T7-0266/2014	02/04/2014	Summary
Committee draft report		PE601.098	15/03/2017	
Committee recommendation tabled for plenary, 2nd reading		A8-0068/2017	23/03/2017	Summary
Text adopted by Parliament, 2nd reading		T8-0107/2017	05/04/2017	Summary

Council of the EU

Document type	Reference	Date	Summary
Council statement on its position	06592/1/2017	27/02/2017	
Council position	10728/4/2016	08/03/2017	Summary
Draft final act	00014/2017/LEX	05/04/2017	

European Commission

Document type	Reference	Date	Summary
Commission document (COM)	COM(2012)0540	26/09/2012	Summary
Legislative proposal	COM(2012)0542	26/09/2012	Summary
Document attached to the procedure	SWD(2012)0273	26/09/2012	
Document attached to the procedure	SWD(2012)0274	26/09/2012	
Commission response to text adopted in plenary	SP(2014)471	09/07/2014	
Commission communication on Council's position	COM(2017)0129	09/03/2017	Summary

Follow-up document	SWD(2024)0076	22/03/2024	
Follow-up document	COM(2024)0560	29/11/2024	

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	IT_SENATE	COM(2012)0542	25/10/2012	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EDPS	Document attached to the procedure	N7-0042/2014 OJ C 358 07.12.2013, p. 0010	08/02/2013	Summary
EESC	Economic and Social Committee: opinion, report	CES2185/2012	14/02/2013	

Additional information

Source	Document	Date
European Parliament	Briefing	
European Parliament	Briefing	
National parliaments	IPEX	
European Commission	EUR-Lex	

Final act

Corrigendum to final act 32017R0745R(02)
OJ L 334 27.12.2019, p. 0165

Corrigendum to final act 32017R0745R(01)
OJ L 117 03.05.2019, p. 0009

Regulation 2017/0745
OJ L 117 05.05.2017, p. 0001 Summary

Delegated acts

Reference	Subject
2025/2675(DEA)	Examen d'un acte délégué
2025/2763(DEA)	Examen d'un acte délégué
2023/2796(DEA)	Examen d'un acte délégué
2022/2986(DEA)	Examen d'un acte délégué

2026/2661(DEA)	Examen d'un acte délégué
2026/2660(DEA)	Examen d'un acte délégué

Medical devices

2012/0266(COD) - 09/03/2017 - Commission communication on Council's position

The Commission stated that the Council's position overall **endorsed the objectives pursued by the Commission proposal**, namely to ensure an increased level of patient safety and public health protection, facilitate the smooth functioning of the internal market and support innovation in this important sector covering more than 500 000 products.

The Commission supported the position adopted unanimously by the Council.

The Commission can accept the **amendments made by the Council** to its initial proposal as regards:

- **the inclusion of certain products without a medical purpose in the scope** of the medical devices Regulation, even though the inclusion of the listed groups of products in the scope of the medical devices legislation is not automatic, as the Commission proposed, but is dependent on the adoption of the common technical specifications;
- **the exemption of devices manufactured and used in the same health institution** from some requirements of the legislation, although this exemption is introduced for the first time for medical devices, the position of the Council can be supported as it offers acceptable guarantees for control of these "in-house" devices;
- **financial coverage by manufacturers** in case of damage caused by defective medical devices: the Council's position accepts the spirit of the European Parliament's 1st reading position introducing a compulsory liability insurance for manufacturers, but by obliging the manufacturers to have measures in place to provide sufficient financial coverage in respect of their potential liability:
- **reinforcing the role and responsibilities for authorised representatives** who would be jointly and severally liable with the importer and manufacturer in case of damages suffered due to defective devices;
- **reprocessing of single-use medical devices**: the approach taken by the Council differs from the Commission's which foresaw that all reprocessors would be considered as manufacturers and that single-use devices for critical use could not be reprocessed. Nevertheless, the Commission considered that the Council's position appears to be an acceptable way forward to establish EU-wide minimum rules applicable to the reprocessing of single-use medical devices and can therefore be supported;
- **the use of hazardous substances in invasive medical devices**: if the Council's position diverges from that of the Commission, it is nevertheless acceptable as regards the possibilities for identifying and tracking the devices which the new system will guarantee;
- **the identification and traceability related obligations and establishment of a Unique Device Identification (UDI) System**: contrary to the Commission's proposal which only sets out the legal basis and the main principles of the future UDI system, leaving the details to the implementation stage, the Council's position sets out detailed rules for the implementation of the UDI system.

The Commission is also in favour of the new provisions aimed at:

- improving transparency of the information contained in the European Medical Devices Database (EUDAMED);
- strengthening the requirements for the designation and oversight of notified bodies;
- providing for the consultation of an expert panel on certain high-risk devices;
- reinforced requirements for clinical investigations and clinical data;
- specifying the obligations of manufacturers to follow-up on the real-life use of their devices after their placing on the market.

Medical devices

2012/0266(COD) - 08/03/2017 - Council position

The Council adopted its position at first reading with a view to the adoption of a Regulation of the European Parliament and of the Council on medical devices.

The aim of the proposed Regulation is to lay down rules on the placing on the market, the putting into service of **medical devices for human use** and their accessories in the Union. It replaces Council Directives 90/385/EEC and 93/42/EC which are no longer adequate to regulate the sector.

Its objective is to **enhance patient safety** by: (i) introducing more stringent procedures for conformity assessment and for post-marketing surveillance, and (ii) requiring manufacturers to produce clinical safety data, performance and unknown side-effects.

The new rules must take into account the experience of metal-on-metal artificial hips and faulty silicone breast implants.

Scope: this Regulation shall also apply, as from the date of application of common specifications (CS), to the **groups of products without an intended medical purpose** such as contact lenses, equipment for liposuction, lipolysis or lipoplasty.

The CS would apply as of six months after their entry into force or date of application of the Regulation.

Notified bodies: the Council position strengthens the rules regarding notified bodies in order to ascertain that notified bodies are designated and operate under harmonised conditions throughout the Union. These rules provide a stronger mandate to independent notified bodies in their assessment of medical devices before they can be placed on the market.

Reinforced requirements for clinical investigations and clinical data: the procedures for authorisation of clinical investigations have been further aligned with the rules on clinical trials on medicinal products, particularly as regards provisions on informed consent and protection of vulnerable subjects.

The Council position foresees a consultation with an expert panel applicable to certain **high-risk devices**.

Liability: manufacturers' responsibilities are clearly set out for the follow-up of the **quality, performance and safety** of devices placed on the market. The Council requested that manufacturers should put in place measures to provide **sufficient financial coverage** in respect of their potential liability under Directive 85/374/EEC concerning liability for defective products.

The **authorised representative** would be jointly and severally liable with the importer and manufacturer in case of damages suffered due to defective devices.

Identification and traceability related obligations: the Council's position sets out detailed rules for the implementation of the Unique Device Identification (UDI) system. The main features of the position are the requirement for manufacturers to have the UDI code assigned to their devices by the date of application and the requirement for the UDI carrier to be placed on the device and all higher levels of packaging gradually depending on the risk class of the device.

Reprocessing of single-use medical devices: according to the Council's position, reprocessing of single-use medical devices may only take place **when authorised under national law and in accordance with the provisions of the medical devices Regulation**. When reprocessing is allowed, the reprocessor must assume the obligations of a manufacturer.

European Medical Devices Database (EUDAMED): the proposed Regulation ensures **greater transparency** of information on devices placed on the market by setting up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU.

Medical devices

2012/0266(COD) - 23/03/2017 - Committee recommendation tabled for plenary, 2nd reading

The Committee on the Environment, Public Health and Food Safety adopted the recommendation for second reading contained in the report by Glenis WILLMOTT (S&D, UK) on the Council position at first reading with a view to the adoption of a regulation of the European Parliament and of the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

The committee recommended the European Parliament to **approve, without amendment, the Council position at first reading**.

Council's first reading position is in **conformity with the agreement reached during the interinstitutional negotiations**. The report is accompanied by a short justification which highlights the following elements of the approved text:

- the introduction of a **special procedure** involving an independent assessment carried out by a special expert panel of the highest risk devices of class III implantable and class IIb active devices administering or removing a medicinal product;
- the obligation for the manufacturer to put in place measures to provide **sufficient financial coverage** in respect of their potential liability regarding defective devices;
- strengthening the initial proposal which encourages manufacturers to seek **substitution of substances** that are carcinogenic, mutagenic or toxic for reproduction and substances having endocrine disrupting properties;
- the introduction of detailed provisions on conducting **clinical investigations** for medical devices with clearly defined rules and obligations on manufacturers, sponsors, participating subjects and the relevant authorities on informed consent, ethics committees, incapacitated subjects, minors, pregnant women, transparency;
- the introduction of provisions for the **reprocessing of single use devices**: reprocessing may only take place if allowed under national law, however, Member States may go beyond these provisions in further restricting or prohibiting this practice on their territory;
- the strengthening of provisions on the designation, organisation, monitoring and expertise of the **notified bodies** conducting the conformity assessment and certification for all devices on the Union market. These bodies shall have permanent availability of sufficient administrative, technical and scientific personnel for them to successfully conduct their conformity assessment activities;
- the strengthening of the authorisation procedures and the **overall system for traceability** of devices through the obligation for manufacturers to apply a post-market surveillance system according to the risk class and the type of device.

Medical devices

2012/0266(COD) - 05/04/2017 - Text adopted by Parliament, 2nd reading

The European Parliament adopted a legislative resolution on the Council position at first reading with a view to the adoption of a regulation of the European Parliament and of the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

A proposal to reject the Council proposal, submitted by the EFDD and ENF groups, was rejected in plenary by 66 votes to 635, with 2 abstentions.

In line with its recommendation for second reading by the Committee on the Environment, Public Health and Food Safety, Parliament approved, without amendment, the Council position at first reading.

The proposed Regulation seeks to establish rules to be complied with by medical devices and accessories to medical devices that are placed on the market or put into service in the Union for human use.

It replaces Council Directives 90/385/EEC and 93/42/EC which are no longer sufficient in regulating the sector.

Its objective is to enhance patient safety by: (i) introducing more stringent procedures for conformity assessments and post-marketing surveillance; (ii) requiring manufacturers to produce clinical safety data, performance and undesirable side-effects.

Medical devices

2012/0266(COD) - 05/04/2017 - Final act

PURPOSE: to ensure the proper functioning of the internal market with regards to medical devices and to improve the safety of medical devices for the benefit of patients.

LEGISLATIVE ACT: Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

CONTENT: the Regulation establishes **rules concerning the placing on the market of medical devices for human use** and accessories for such devices in the Union. It also applies to **clinical investigations** concerning such medical devices and accessories conducted in the Union.

It replaces Council Directives 90/385/EEC and 93/42/EC which are no longer adequate to regulate the sector.

Its objective is to enhance patient safety by: (i) introducing more stringent procedures for conformity assessment and for post-marketing surveillance, and (ii) requiring manufacturers to produce clinical safety data, performance and unknown side-effects.

The Regulation will also apply as from the date of application of common specifications (CS), to the **groups of products without an intended medical purpose** such as contact lenses, equipment for liposuction, lipolysis or lipoplasty.

Notified bodies: the Regulation strengthens the provisions on the **designation, organisation, monitoring and expertise** of the independent notified bodies, which conduct the assessment for medical devices before they are placed on the market and it strengthens monitoring by national authorities of notified bodies. The new rules also ensure that notified bodies meet the **same high safety standards** throughout the EU. Notified bodies made have sufficient administrative, technical and scientific personnel for them to successfully conduct their conformity assessment activities. **On-site audits, including unannounced visits**, must be carried out.

Availability of clinical data: the requirements on collection of data in clinical investigations on medical devices have been specified and aligned to those applicable for clinical trials on medicinal products for human use, particularly as regards provisions on informed consent and protection of vulnerable subjects (e.g. incapacitated subjects, minors, pregnant women.)

There is a **special procedure** involving an independent assessment carried out by a special expert panel of the highest risk devices.

Obligations of manufacturers : the Regulation sets out the obligations of manufacturers regarding monitoring the quality, performance and safety of devices placed on the market.

Manufacturers should, in a manner that is proportionate to the risk class, type of device and the size of the enterprise, have measures in place to provide:

- sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC;
- a system regarding the monitoring of quality and a post-market surveillance system.

The **authorised representative** would be jointly and severally liable with the importer and manufacturer in case of damages suffered due to defective devices.

The Regulation also requires Member States to take the measures necessary to allow health professionals, users and patients to **report suspected serious incidents** at national level using harmonised formats.

Identification and traceability of devices: in order to ensure that measures may be taken quickly if problems arise, the Regulation contains provisions regarding the registration of devices and of economic operators as well as detailed rules to ensure the traceability of medical devices right through the supply chain upto the end user or patient, thanks to the establishment of a **Unique Device Identification (UDI) System.**

Storage of the UDI code by health institutions and economic operators is mandatory for class III implantable devices.

Use of hazardous substances in invasive medical devices: manufacturers must provide a justification to the notified body regarding the presence of substances that are **carcinogenic, mutagenic or toxic to reproduction and/ or endocrine** disruptors above a certain concentration in invasive medical devices and devices that transport and store medicinal products, or other substances to be (re) administered into or removed from the body.

Single use devices: the reprocessing of single use devices may only take place if allowed under national law, and in conformity with the provisions of the Regulation. The reprocessor of a single-use device should be considered to be the manufacturer of the reprocessed device and should assume the obligations incumbent on manufacturers. However, in certain circumstances, Member States may provide for derogations to the rules in the case of reprocessing of medical devices by health institutions.

European Databank on Medical Devices ('EUDAMED'): the Regulation establishes a central data bank aimed at providing patients, health professionals and the public with full information on the products available in the EU, which will enable them to take decisions more easily.

ENTRY INTO FORCE: 25.5.2017.

APPLICATION: from 26.5.2020.

DELEGATED ACTS: the Commission may adopt delegated acts to amend non-essential elements of the Regulation. The power to adopt such acts is conferred on the Commission for a period of five years (renewable) from 25 May 2017. The European Parliament or the Council have the right to object to a delegated act within three months (which may be extended by thee months) from the date of notification of the act.

Medical devices

2012/0266(COD) - 26/09/2012 - Legislative proposal

PURPOSE: to revise the existing regulatory framework on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009.

PROPOSED ACT: Regulation of the European Parliament and of the Council

BACKGROUND: the current EU regulatory framework for medical devices, other than in vitro diagnostic medical devices, consists of Council Directive 90/385/EEC on active implantable medical devices (AIMDD) and Council Directive 93/42/EEC on medical devices (MDD) which cover a huge spectrum of products.

The existing regulatory framework has demonstrated its merits but has also come under harsh criticism, in particular after the French health authorities found that a French manufacturer (Poly Implant Prothèse, PIP) had for several years apparently used industrial silicone instead of medical grade silicone for the manufacture of breast implants contrary to the approval issued by the notified body, causing harm to thousands of women around the world.

In an internal market with 32 participating countries and subject to constant technological and scientific progress, substantial divergences in the interpretation and application of the rules have emerged, thus undermining the main objectives of the Directives, i.e. the safety of medical devices and their free movement within the internal market. Moreover, regulatory gaps or uncertainties exist with regard to certain products e.g. products manufactured utilising non-viable human tissues or cells and implantable or other invasive products for cosmetic purposes.

Triggered by the PIP breast implants scandal, the European Parliament adopted on 14 June 2012 a Resolution on defective silicone gel breast implants made by the French company PIP and called for an adequate legal framework to guarantee the safety of medical technology.

IMPACT ASSESSMENT: a separate impact assessment has been carried out by the Commission.

LEGAL BASIS: Article 114 and Article 168(4)(c) of the Treaty on the Functioning of the European Union.

CONTENT: this revision of the current regulatory framework aims to overcome the flaws and gaps and to further strengthen patient safety. A robust, transparent and sustainable regulatory framework is to be put in place that is 'fit or purpose'. The proposed framework is supportive of innovation and the competitiveness of the medical device industry and should allow rapid and cost-efficient market access for innovative medical devices, to the benefit of patients and healthcare professionals.

It should be noted that this proposal is adopted alongside a proposal for a Regulation on in vitro diagnostic medical devices (IVDs), such as blood tests, which are covered by Directive 98/79/EC. The horizontal aspects that are common to both sectors are aligned whilst the specific features of each sector require separate legal acts.

The main elements of the proposal are as follows:

Scope: the scope of the proposed Regulation corresponds to a large extent to the combined scopes of Council Directives 90/385/EEC and 93/42/EEC, i.e. it covers all medical devices other than in vitro diagnostic medical devices. However:

- the scope is extended to some products currently not covered by the AIMDD/MDD;
- some products which, in some Member States, are placed on the market as medical devices are excluded from its scope.

The **extension of the scope** concerns:

- products manufactured utilising non-viable human tissues or cells, or their derivatives, that have undergone substantial manipulation (e.g. syringes prefilled with human collagen), unless they are covered by Regulation (EC) No 1394/2007 on advanced therapy medicinal products. Human tissues and cells, or products derived from human tissues or cells, that are not substantially manipulated and that are regulated by Directive 2004/23/EC are not covered by the proposal;

- certain implantable or other invasive products without a medical purpose that are similar to medical devices in terms of characteristics and risk profile (e.g. non-corrective contact lenses, implants for aesthetic purposes).

Additional provisions as regards products that are not covered by the Regulation have been included, and concern:

- products that contain or consist of viable biological substances (e.g. living microorganisms);
- food covered by Regulation (EC) No 178/2002. Medical devices are excluded from the scope of Regulation 178/2002 (diagnostic probes or cameras, even when introduced orally, are therefore clearly excluded from the food legislation).

As regards products composed of substances or combinations of substances that are intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body, those products which fall under the definition of a medical device are classified in the highest risk class and should comply with the relevant requirements of Annex I of Directive 2001/83/EC on the Community code relating to medicinal products for human use.

Definitions: this section has been significantly extended, aligning the definitions in the field of medical devices with well established European and international practice, such as the New

Legislative Framework for the Marketing of Products.

Making available of devices, obligations of economic operators, reprocessing, CE marking, free movement: this chapter contains provisions that are typical for product-related internal market legislation and sets out the obligations of the relevant economic operators (manufacturers, authorised representatives of non-EU manufacturers, importers and distributors). The regulatory instrument of 'common technical specification' (CTS), which has proven useful in the context of the IVDD, has been introduced in the broader field of medical devices to allow the Commission to further specify the general safety and performance requirements (laid down in Annex I) and the requirements on clinical evaluation and post-market clinical follow-up (laid down in Annex XIII). The legal obligations on manufacturers are proportionate to the risk class of the devices they produce.

Minimum contents of key documents for the manufacturer to demonstrate compliance with the legal requirements are laid down in Annexes II and III.

The following concepts are also new in the field of medical devices:

- a requirement has been introduced that within the manufacturer's organisation a 'qualified person' should be responsible for regulatory compliance;
- clear conditions are set for enterprises involved in relabelling and/or repackaging medical devices;
- patients who are implanted with a device should be given essential information allowing it to be identified and containing any necessary warnings or precautions to be taken;
- strict rules on the reprocessing of single-use devices.

Identification and traceability of devices, registration of devices and economic operators, summary of safety and clinical performance, Eudamed: this chapter addresses one of the main shortcomings of the current system: its lack of transparency. It consists of the following requirements:

- economic operators must be able to identify who supplied them and to whom they have supplied medical devices;
- manufacturers must fit their devices with a Unique Device Identification (UDI) which allows traceability;
- manufacturers/authorised representatives and importers must register themselves and the devices they place on the EU market in a central European database;
- manufacturers of high-risk devices must make publicly available a summary of safety and performance with key elements of the supporting clinical data;
- **further development of the European databank on medical devices (Eudamed),** set up by Commission Decision 2010/227/EU, which will contain integrated electronic systems on a European UDI, on registration of devices, relevant economic operators and certificates issued by notified bodies, on clinical investigations, on vigilance and on market surveillance. A large part of the information in Eudamed will become publicly available.

The establishment of a central registration database will also do away with diverging national registration requirements which have emerged over recent years and which have significantly increased compliance costs for economic operators.

Notified bodies: the proposal sets out requirements for national authorities responsible for notified bodies. It leaves the ultimate responsibility for designating and monitoring notified bodies, based on stricter and detailed criteria laid down in Annex VI, with the individual Member State. At the same time, the position of notified bodies vis-à-vis manufacturers will be significantly strengthened, including their right and duty to carry out unannounced factory inspections and to conduct physical or laboratory tests on devices. The proposal also requires rotation of the notified body's personnel involved in the assessment of medical devices at appropriate intervals.

Classification and conformity assessment: the proposal keeps to the well established approach of dividing medical devices into four classes. The classification rules (laid down in Annex VII) have been adapted to technical progress and experience gained from vigilance and market surveillance. The different conformity assessment procedures are laid down in Annexes VIII to X and have been tightened and streamlined. The proposal also:

- reinforces the powers and responsibilities of notified bodies;
- introduces the obligation for notified bodies to notify an expert committee of new applications for conformity assessment of high-risk devices.

Clinical evaluation and clinical investigations: this chapter lays down the key obligations of manufacturers as regards the performance of the clinical evaluation needed to demonstrate the safety and performance of their devices. More detailed requirements are set out in Annex XIII which addresses the pre-market clinical evaluation and post-market clinical follow-up that together constitute a continuous process during the life cycle of a medical device.

The process for conducting clinical investigations is further developed, particularly through the concept of 'sponsor'. Non-commercial clinical investigations that do not pursue a regulatory purpose are not covered by this Regulation. Every clinical investigation must be registered in a publicly accessible electronic system which the Commission will set up.

Vigilance and market surveillance: the proposal introduces an **EU portal** where manufacturers must report serious incidents and corrective actions they have taken to reduce the risk of recurrence. The information will be automatically forwarded to the national authorities concerned. Where the same or similar incidents have occurred, or where a corrective action has to be taken, in more than one Member State, a coordinating authority will take the direction in coordinating the analysis of the case.

As regards market surveillance, the main objectives of the proposal are to reinforce the rights and obligations of the national competent authorities, to ensure effective coordination of their market surveillance activities and to clarify the applicable procedures.

Governance: a central role in achieving harmonised interpretation and practice will be assigned to an expert committee (the Medical Device Coordination Group or MDCG).

The proposal mandates the Commission to provide technical, scientific and logistic support to the MDCG. It empowers the Commission to adopt either implementing acts to ensure uniform application of the Regulation or delegated acts to complement the regulatory framework for medical devices over time.

With this proposal, other Union legislation is amended where a link exists with medical devices, including Regulation (EC) No 1223/2009 on cosmetic products and the Food Regulation 178/2002.

The future Regulation replaces and repeals Council Directives 90/385/EEC and 93/42/EEC.

BUDGETARY IMPLICATIONS: the operational resources necessary for the implementation of the initiative are covered by the appropriations proposed in the context of the proposed Health for Growth programme 2014-2020.

Estimated impact on expenditure (operational credits): **EUR 48.376 million**, of which

- Specific objective 1: establishing mechanisms to ensure harmonised implementation of the rules by all Member States with credible management at EU level with access to expertise: total EUR 29.782 million;
- Specific objective 2: enhancing transparency regarding medical devices on the EU market, including their traceability (Eudamed): total EUR 18.594 million.

Impact on administrative expenditure: EUR **20.369 million**.

Total appropriations for the period are EUR 68.745 million.

DELEGATED ACTS: the proposal contains provisions empowering the Commission to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union (TFEU).

Medical devices

2012/0266(COD) - 26/09/2012 - Document attached to the procedure

This Communication, together with the proposal to revise the legislation on medical devices and the proposal on in vitro diagnostic medical devices, constitute a response to the Council Conclusions on innovation in the medical device sector adopted on 6 June 2011 and to the European Parliament Resolution on defective silicone breast implants adopted in June 2012 . Both the Council and the European Parliament have pointed to the necessity of adapting the medical device legislation with the aim to achieve a suitable, robust, transparent and sustainable regulatory framework. Such framework should be central to fostering the development of safe, effective and innovative medical devices and in vitro diagnostic medical devices, for the benefit of European patients, consumers and healthcare professionals.

It is estimated that, in 2060, there will be twice as many Europeans aged 65 or over (152.6 million in 2060 compared to 87.5 million in 2010). An ageing population and changes in lifestyle will lead to an important evolution in disease patterns, with an increasing prevalence of chronic, and often multiple, diseases, such as cancer, diabetes, heart diseases, respiratory conditions, stroke, dementia and depression. In 2010, over one-third of Europe's population was estimated to have developed at least one chronic disease.

In this evolving and challenging context, medical devices and in vitro diagnostic medical devices will be of increasing importance to public health and medical care.

The need for a safe, transparent and sustainable legislation: appropriate legislation is fundamental to ensuring health protection and effective innovation and will:

- give patients, consumers and healthcare professionals confidence in the devices they might use every day;
- allow industry to bring safe, effective and innovative products to market quickly and efficiently;
- increase the ability of innovative companies to attract investors, estimate costs and anticipate procedures.

The need to restore patients', consumers' and healthcare professionals' confidence: in an internal market of 32 participating countries, important differences in interpreting and applying the rules have emerged, thus undermining the legislation's main objectives — the safety of devices and their free circulation within the internal market. Moreover, there are regulatory gaps or uncertainties with regard to certain products. The regulatory system has also suffered from a **lack of transparency and shortcomings in its implementation**, in particular in the fields of market surveillance, vigilance and the functioning of notified bodies.

In addition, **recent serious incidents involving medical implants** (e.g. breast implants, metal-on-metal hip replacements) have put patient safety at risk and revealed further shortcomings of the current legislation, especially with regard to post-market controls.

The proposed Regulations will:

- amend and clarify the scope of the legislation, to take into account scientific and technological progress and respond to tomorrow's needs. It is extended to include, for example, implants for aesthetic purposes and clarified as regards genetic tests;
- strenghten the supervision of the notified bodies by the Member States, in order to ensure that all bodies have the necessary competence to carry out the pre-market assessment of devices;
- guarantee the independency and the quality of pre-market assessment of devices, by clarifying and enhancing the position and powers of notified bodies vis-à-vis the manufacturers (e.g. regular checks on manufacturers, including unannounced factory inspections) and by providing an appropriate level of intervention of public authorities;
- clarify the obligations and responsibilities of manufacturers, importers and distributors. This encompasses diagnostic services, internet sales and parallel trade;
- ensure transparency, in particular through an expanded European database on medical devices and in vitro diagnostic medical devices partially accessible to the public. It will provide patients, healthcare professionals and the public at large with comprehensive information on products available on the EU market, enabling them to make better informed decisions;
- increase devices traceability throughout the supply chain, by requiring that manufacturers, on a risk-based approach, fit their devices with a Unique Device Identifier (UDI). This will allow fast and effective measures in case of safety problems;
- reinforce the rules governing clinical evaluation throughout the life of medical devices and in vitro diagnostic medical devices, to ensure patient and consumer safety;
- strengthen the provisions governing market surveillance and vigilance, allowing better coordination between authorities to ensure rapid and consistent responses to safety issues;
- make the management of the system more robust through mechanisms of effective coordination between authorities, with scientific support by the Commission, in order to ensure a uniform and sustainable implementation of the future Regulations.

The medical device and the in vitro diagnostic medical devices sectors are estimated to comprise more than 500,000 products. They contribute substantially to the EU's balance of trade, employ more than 500,000 people in about 25,000 companies, 80 % of medical devices companies and 95% of in vitro diagnostic medical devices companies being small to medium-sized or micro enterprises. In 2009, they generated annual sales of around EUR 95 billion (EUR 85 billion for medical devices and EUR 10 billion for in vitro diagnostic medical devices) in the European (EU/EFTA) market. Last but not least, they are sectors that invest heavily in research and development, as about 6-8 % of medical devices annual sales and 10% of in vitro diagnostic medical devices annual sales are ploughed back into research each year, equivalent respectively to some EUR 6.5 billion and some EUR 1 billion, usually through collaboration with healthcare professionals and academia.

It is estimated that the **establishment of a central registration tool** would help reducing the administrative costs by up to EUR 157million. Also an **EU vigilance portal** with central reporting of serious incidents instead of multiple reporting is expected to bring about non negligible reductions in administrative costs.

Health is a clear determinant of economic growth. In this context, innovation in the medical device and in vitro diagnostic medical device areas occupies a central place in initiatives falling in the framework of the Europe 2020 Strategy, in particular under the Innovation Union **and the** Digital Agenda for Europe **flagship initiatives.**

The proposed Regulations have the objective of bringing these two aspects together and are an essential 'push' factor for fostering an EU of active and healthy citizens.

Medical devices

2012/0266(COD) - 09/10/2013 - Committee report tabled for plenary, 1st reading/single reading

The Committee on the Environment, Public Health and Food Safety adopted the report by Dagmar ROTH-BEHRENDT (S&D, DE) on the 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.

The committee recommends that the position of Parliament adopted in first reading following the ordinary legislative procedure should amend the Commission proposal as follows:

Scope: devices for **aesthetic purposes** should also fall within the scope of the regulation. Furthermore, the Regulation shall not impede the continued application of measures within Directive 2002/98/EC and its five Daughter Directives setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components.

The risk of the use of nanomaterials shall be taken into account in the risk assessment process.

Assessment procedure for medical devices: for high risk medical devices, such as devices in class III, implantable devices and devices incorporating medicinal products, the report proposes to introduce the **possibility of providing an opinion on a case-by-case basis**, based on the **robustness of the clinical data** and the evidence that the device can be safely placed on the EU market.

To this end, Members proposed the **creation of an Assessment Committee for Medical Devices (ACMD)** in order to provide the case-by-case assessment where its members deemed it necessary to ask for the review of the clinical data.

The ACMD, placed under the aegis of the Commission, should be composed of the best specialists in various medical fields, as listed in categories or subgroups, which can be subject of modifications, notably in light of technical progress. Patients' representatives and a representative from the European Medicines Agency should also take part in the ACMD and contribute to the case-by-case assessments.

On the basis of this assessment of the clinical data, the Commission will adopt an opinion, which will be binding upon the Special notified body.

Notified bodies: Members proposed to strengthen provisions relating to the personnel in the national authorities responsible for the designation and monitoring of notified bodies. Personnel must have sufficient qualifications to audit the notified bodies for which they are responsible. Moreover, it should be ensured that notified bodies have permanent "in house" competent personnel.

Subcontracting must be the exception. Where subcontracting takes place, notified bodies should make publicly available the names of subcontractors and the precise tasks for which they have been awarded a contract. Once a year, notified bodies should be required to send documents to the relevant national authority to enable the verification of the subcontractors' qualifications.

Fees: Members welcomed the Commission's introduction of fees charged by national authorities for their activities related to the designation and monitoring of notified bodies. However, they added that those fees should be made public and comparable across Member States.

Special notified bodies: for high risk medical devices, such as devices in class III, implantable devices and devices incorporating medicinal products, the conformity assessment should be the responsibility of special notified bodies.

Those bodies should be designated by the European Medicines Agency (EMA) on the basis of the reinforced requirements on staff qualification and training.

The EMA shall establish, host, coordinate and manage the network of special notified bodies. The network shall contribute to the pooling of knowledge regarding medical devices.

Labelling and disposal of single use devices: Members considered that devices labelled as single-use should be really single-use and that **there should be only two options: single-use and reusable.** Furthermore, activities encompassed in the reprocessing of devices should be subject to stricter and more transparent standards.

As a result, only devices labelled as reusable should be reprocessed. To ensure the highest patient safety in the EU, **a list of single-use devices unsuitable for reprocessing** should be set up by the Commission after consultation of the Medical Device Advisory Committee.

Clinical investigations: since manufacturers must collate data to prove that their devices meet performance and safety requirements, Members have introduced definitions on "performance" or "safety".

Performance should notably be understood broadly so as to encompass efficacy and benefit to the patient, which must be checked in cases where clinical investigations apply.

Where clinical investigations are obligatory by virtue of the regulation, they must include **randomised clinical investigations** in the appropriate target population and well-controlled investigations.

Authorisation for conducting a clinical investigation shall be granted only after examination and approval by an **independent ethics committee**.

European databank on medical devices (EUDAMED): in order to strengthen the transparency of information, Members propose to ensure adequate levels of access for the public and healthcare professionals to those parts of Eudamed's electronic systems which provide key information on medical devices that may pose a risk to public health and safety.

Vigilance and market surveillance: Members wanted to ensure that the **reporting of incidents** and corrective measures through the electronic system includes date and place of incidents, and where available, information on the patient or user and healthcare professional, in full respect of privacy.

Coordination between Member States and Medical Device Advisory Committee (the MDCG): Members propose to set up a multidisciplinary advisory committee of experts and representatives of stakeholders and civil society organisations in order to provide scientific advice to the MDCG, and also to the Commission, and the Member States.

Penalties: Member States are invited to set and enforce serious penalties for manufacturers that commit fraud and cheat with regard to medical devices. Those penalties should be at least as large as the revenue gains from fraud or cheating. Penalties may include imprisonment.

Medical devices

2012/0266(COD) - 22/10/2013 - Text adopted by Parliament, partial vote at 1st reading/single reading

The European Parliament adopted **amendments** to the 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.

The issue has been **referred back to the committee responsible**. The vote has been postponed.

The main amendments adopted in plenary were as follows:

Scope: Parliament called for devices for **aesthetic purposes** to fall within the scope of the regulation.

Furthermore, the Regulation should not impede the continued application of measures within Directive 2002/98/EC and its five Daughter Directives setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components.

Assessment procedure for medical devices: for high risk medical devices, such as devices in class III, implantable devices and devices incorporating medicinal products, Parliament proposes to introduce the **possibility of providing an opinion on a case-by-case basis**, based on the **robustness of the clinical data** and the evidence that the device can be safely placed on the EU market.

To this end, Members proposed the **creation of an Assessment Committee for Medical Devices (ACMD)** in order to provide the case-by-case assessment where its members deemed it necessary to ask for the review of the clinical data.

The ACMD, placed under the aegis of the Commission, should be composed of the best specialists in various medical fields, as listed in categories or subgroups, which can be subject of modifications, notably in light of technical progress. Patients' representatives and a representative from the European Medicines Agency should also take part in the ACMD and contribute to the case-by-case assessments.

On the basis of this assessment of the clinical data, the Commission will adopt an opinion, which will be binding upon the Special notified body.

Insurance: to ensure that patients harmed are compensated for any damage and associated treatment as a result of a faulty medical device, that the risk of damage as well as the risk of the manufacturer's insolvency are not shifted to patients harmed by a faulty medical device, manufacturers should be obliged to take **liability insurance with sufficient minimum coverage**.

Notified bodies: Members proposed to strengthen provisions relating to the personnel in the national authorities responsible for the designation and monitoring of notified bodies. Personnel must have sufficient qualifications to audit the notified bodies for which they are responsible. Moreover, it should be ensured that notified bodies have permanent **"in house" competent personnel**.

Subcontracting must be the exception. Where subcontracting takes place, notified bodies should make publicly available the names of subcontractors and the precise tasks for which they have been awarded a contract. Once a year, notified bodies should be required to send documents to the relevant national authority to enable the verification of the subcontractors' qualifications.

Fees: Members welcomed the Commission's introduction of fees charged by national authorities for their activities related to the designation and monitoring of notified bodies. However, they added that those fees should be made public and comparable across Member States.

Special notified bodies: for high risk medical devices, such as devices in class III, implantable devices and devices incorporating medicinal products, the conformity assessment should be the responsibility of special notified bodies.

Those bodies should be designated by the European Medicines Agency (EMA) on the basis of the reinforced requirements on staff qualification and training.

The EMA shall establish, host, coordinate and manage the network of special notified bodies. The network shall contribute to the pooling of knowledge regarding medical devices.

Labelling and disposal of single use devices: Members considered that devices labelled as single-use should be really single-use and that **there should be only two options: single-use and reusable.** Furthermore, activities encompassed in the reprocessing of devices should be subject to stricter and more transparent standards.

As a result, only devices labelled as reusable should be reprocessed. To ensure the highest patient safety in the EU, **a list of single-use devices unsuitable for reprocessing** should be set up by the Commission after consultation of the Medical Device Advisory Committee.

The **reprocessing of devices** encompasses various activities to ensure that a medical device can be safely reused, ranging from decontamination, sterilisation, cleaning, disassembly, repair, component replacement and packaging. These activities should be subject to comparable and transparent standards.

Clinical investigations: since manufacturers must collate data to prove that their devices meet performance and safety requirements, Members have introduced definitions on "performance" or "safety".

Performance should notably be understood broadly so as to encompass efficacy and benefit to the patient, which must be checked in cases where clinical investigations apply.

For high-risk medical devices, in the interests of increased transparency, manufacturers should draw up a **report of the safety and performance aspects** of the device and the outcome of the clinical evaluation.

Where clinical investigations are obligatory by virtue of the regulation, they must include **randomised clinical investigations** in the appropriate target population and well-controlled investigations.

Authorisation for conducting a clinical investigation shall be granted only after examination and approval by an **independent ethics committee**.

Information to patients and healthcare professionals: Parliament called on the manufacturers of an implantable device to provide together with the device an **implant card** to the patient, and to record all the information contained on the implant card in the patient's medical records. The implant card shall also be made available by the manufacturer in an electronic format and Member States shall ensure that hospitals and clinics keep an electronic version on record.

In order to strengthen the transparency of information, Members proposed to ensure adequate levels of access for the public and healthcare professionals to those parts of Eudamed's electronic systems which provide key information on medical devices that may pose a risk to public health and safety.

Vigilance and market surveillance: Parliament wanted to ensure that the **reporting of incidents** and corrective measures through the electronic system includes date and place of incidents, and where available, information on the patient or user and healthcare professional, in full respect of privacy.

Coordination between Member States and Medical Device Advisory Committee (the MDCG): the resolution proposed to set up a multidisciplinary advisory committee of experts and representatives of stakeholders and civil society organisations in order to provide scientific advice to the MDCG, and also to the Commission, and the Member States.

Penalties: Member States are invited to set and enforce serious penalties for manufacturers that commit fraud and cheat with regard to medical devices. Those penalties should be at least as large as the revenue gains from fraud or cheating. Penalties may include imprisonment.

Delegated acts: basic aspects of this Regulation such as general safety and performance requirements, stipulations on technical documentation and the requirements for CE marking certification, as well as any amendments or additions to it, should be provided for only **through the ordinary legislative procedure**.

Medical devices

2012/0266(COD) - 08/02/2013 - Document attached to the procedure

Opinion of the European Data Protection Supervisor on the Commission proposals for a regulation on medical devices (MD) and amending Directive 2001/83/EC, Regulation (EC)

No 178/2002 and regulation (EC) No 1223/2009 and a regulation on in vitro diagnostic medical devices (IVD).

The proposed regulations will affect the rights of individuals in relation to the processing of their personal data. Amongst other issues, they deal with the processing of sensitive data (health data), a central EU-level database which includes personal data, market surveillance and record keeping.

The EDPS sees a need for **some clarifications with particular regard to sensitive data**, especially in relation to processing and storage in the database.

The EDPS recommends:

- that the draft MD Regulation and IVD Regulation specify that the provisions will apply in accordance with the national rules which implement **Directive 95/46/EC;**
- inserting in the IVD regulation, paragraphs regarding purposes for data processing, data subject rights and data retention periods similar to the MD regulation;
- inserting a definition of the term ‘subject’ in the proposed regulations;
- unambiguously prohibiting the inclusion of all patients' health data in the **clinical investigations module** of the Eudamed database;
- inserting provisions in the proposed MD regulation and the proposed IVD regulation that clearly define the situations and safeguards under which information containing patient health data will be processed and stored in the **Eudamed database concerning vigilance and post-market surveillance.** In particular, the proposed regulation should require that a risk assessment be carried out by the Commission before the processing and storage of any patient health data in the Eudamed database;
- explicitly mentioning that periodic reports should only be using **anonymous data**;

- adding in both proposed regulations that before any processing of data concerning health of patients takes place, manufacturers shall obtain **explicit consent from the data subject**;
- inserting provisions regulating how personal data should be managed as regards **surveillance by competent authorities** in the proposed regulations;
- inserting a **maximum retention period** for personal data under the proposed regulations.

Lastly, the **EDPS should be consulted** in relation to any delegated or implementing act adopted pursuant to the proposed regulations which might have an impact on the processing of personal data.

Medical devices

2012/0266(COD) - 02/04/2014 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 547 votes to 19, with 63 abstentions, a legislative resolution on the 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.

The report was referred back to the committee at the 22 October 2013 plenary session.

Parliament adopted as its position at first reading the text adopted on 22 October 2013 (*please refer to the summary of that date*).

Medical devices

2012/0266(COD) - 19/06/2014

The Council took note of a presidency progress report on two draft regulations on medical devices and on in vitro diagnostic medical devices.

Ministers provided **guidance for future work** on these files as regards the three following elements:

(1) The designation of conformity assessment bodies as notified bodies and the monitoring of these bodies: most Member States supported the idea of further clarifying the procedures for designating notified bodies and strengthening cooperation between Member States to ensure that notified bodies meet similar standards throughout the EU. But they also warned against increasing the administrative burden unnecessarily.

(2) The reporting of incidents, market surveillance and corrective measures: all Member States supported strengthened requirements on post-market surveillance and responsibility for follow-up by manufacturers, e.g. by collecting and analysing data on the performance of medical devices, in particular on adverse reactions in which they are involved.

However, as regards the balance between controls before and after placing devices on the market there were diverging views.

(3) The role and tasks of the medical device coordination group (MDCG): all delegations support the establishment of the MDCG. Most delegations support the idea to unify co-operation between Member States regarding medical devices and in vitro diagnostic medical devices by appointing one representative per Member State in the Medical Device Coordination Group (MDCG) rather than separate representatives for medical devices and in vitro diagnostic medical devices. There is broad agreement that the establishment of a network of reference laboratories is important for the proper evaluation of in vitro diagnostic medical devices.

As regards the evaluation of medical devices, however, many delegations have expressed an interest in either complementing the reference laboratories with device panels or replacing them entirely with device panels in order to provide relevant expertise input for regulatory measures.

Overall, many Member States stressed the need to develop a **consistent legislative package** that guarantees patient safety and facilitates innovation in order to improve treatments, decrease costs for patients and taxpayers, and preserve the competitiveness of the EU industry.

The Council instructed its preparatory bodies to continue examining the two files with a view to **agreeing a Council position in the autumn**.

Medical devices

2012/0266(COD) - 01/12/2014

The Council took note of a **presidency progress report** on two draft regulations on **medical devices** and in vitro diagnostic medical devices.

The report noted that considerable progress has been achieved on these files under the Italian presidency. However, further discussions are needed for the Council to agree its position.

Outstanding issues include:

- **aesthetics devices**: the report noted that 15 delegations favoured inclusion of aesthetic devices under the scope of the Medical device Regulation. Five delegations opposed this, mainly on the grounds that this would increased the financial and administrative burden on competent authorities;
- **ingested products**: the proposal on medical devices provides for inclusion of certain substances or combinations of substances intended to be ingested, inhaled or administered rectally or vaginally ("Ingested products") into the scope of the Regulation. It further provides that all these devices be classified as high risk devices ("Class III"). A compromise has been made in this area given that several delegations expressed concerns on the suitability of the proposal, especially in relation to the delimitation between medical devices and medicinal products. It was however generally recognised that such products could not fall outside the scope of both medicinal products and medical device legislation;
- **reprocessing of single-use devices**: the Commission proposal provides rules for reprocessing of single-use devices to make them suitable for further use within the Union. The Presidency believes that a compromise proposal that allows Member States to prohibit re-processing under national law but provides that if not prohibited re-processing should follow minimum harmonised rules could find support from a broad majority;
- **the unique device identification system**: the Commission proposal contains a requirement that manufacturers fit their devices with a Unique Device Identification (UDI) which allows for traceability. Important issues include the functionality of the system, and the nature and scope of requirements;
- **mechanisms for surveillance and appointment of the Notified Bodies responsible for conformity assessment of medical devices and In vitro diagnostic medical devices**: the main subject of controversy is the level of detail laid down in the legislative provisions and, consequently, what had better be left for guidelines;
- **scrutiny mechanism for certain high-risk devices**: almost all delegations state that the scrutiny procedure as proposed by the Commission is not possible to apply. Many delegations argue that a scrutiny mechanism before devices are placed on the market is not necessary. On the other hand, some delegations would wish to include a "pre-market scrutiny mechanism" for implantable devices in the highest risk class "Class III devices". There is scope for a possible compromise on this issue;
- **clinical investigation**: the discussion of the Working Party is currently going in the direction of further aligning the provisions on ethical and methodological principles to those for clinical trials of medicinal products;
- **tasks of the proposed medical device coordination group (MDCG)**: the progress report noted the discussions of the tasks of the MDCG is closely related to many of the other issues still subject to discussion. A central question is the legal status of the opinions from MDCG, where most delegations hold that this cannot be of a binding nature, as this would make it a decision-making body;
- **role of expert panels and reference laboratories**: while most delegations agree that there is a need for such laboratories for in vitro diagnostic medical devices in order to compare predicting powers of tests, few delegations see the same need as regards other medical devices. Instead, they favour the establishment of expert panels with competence for certain groups of devices.

The Presidency is satisfied to have contributed to the progress of the work and intends to **compile complete texts for both proposals** by the end of its tenancy.