Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2012/0267(COD)
Procedure completed	

In vitro diagnostic medical devices

Repealing Directive 98/79/EC 1995/0013(COD)
See also 2012/0266(COD)
Amended by 2021/0323(COD)
Amended by 2023/0005(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		24/10/2012
	PPE LIESE Peter	
	Shadow rapporteur	
	S&D ROTH-BEHRENDT Dagmar	
	ALDE TAYLOR Rebecca	
	Verts/ALE AUKEN Margrete	
	ECR CABRNOCH Milan	
Former committee responsible		
ENVI Environment, Public Health and Food Safety		24/10/2012
	PPE LIESE Peter	
Former committee for opinion		
INTA International Trade	The committee decided not to give an opinion.	
EMPL Employment and Social Affairs		21/11/2012
	S&D ESTRELA Edite	
ITRE Industry, Research and Energy	The committee decided not to give an opinion.	
IMCO Internal Market and Consumer Protection		10/10/2012
	PPE BERRA Nora	

Council of the European Union

Council configuration	Meeting	Date
General Affairs	3525	07/03/2017

	General Affairs	3484	20/09/2016
	Employment, Social Policy, Health and Consumer Affairs	3475	16/06/2016
	Employment, Social Policy, Health and Consumer Affairs	3351	01/12/2014
	Employment, Social Policy, Health and Consumer Affairs	3323	19/06/2014
	Employment, Social Policy, Health and Consumer Affairs	3280	09/12/2013
	Employment, Social Policy, Health and Consumer Affairs	3206	06/12/2012
European Commission	Commission DG	Commissioner	
	Health and Food Safety	MIMICA Neven	
European Economic and Social Committee			
European Committee of the Regions			

Key events

26/09/2012	Legislative proposal published	COM(2012)0541	Summary
22/10/2012	Committee referral announced in Parliament, 1st reading		
06/12/2012	Debate in Council	3206	
25/09/2013	Vote in committee, 1st reading		
10/10/2013	Committee report tabled for plenary, 1st reading	A7-0327/2013	Summary
22/10/2013	Results of vote in Parliament		
22/10/2013	Debate in Parliament		
22/10/2013	Decision by Parliament, 1st reading	T7-0427/2013	Summary
09/12/2013	Debate in Council	3280	
02/04/2014	Decision by Parliament, 1st reading	T7-0267/2014	Summary
19/06/2014	Debate in Council	3323	Summary
05/11/2014	Committee decision to open interinstitutional negotiations after 1st reading in Parliament		
01/12/2014	Debate in Council	3351	Summary
16/06/2016	Debate in Council	3475	
20/09/2016	Debate in Council	3484	
08/03/2017	Council position published	10729/4/2016	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	A8-0069/2017	Summary
04/04/2017	Debate in Parliament		
05/04/2017	Decision by Parliament, 2nd reading	T8-0108/2017	Summary

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	2012/0267(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Repealing Directive 98/79/EC 1995/0013(COD) See also 2012/0266(COD) Amended by 2021/0323(COD) Amended by 2023/0005(COD)
Legal basis	Treaty on the Functioning of the EU TFEU 168-p4; Treaty on the Functioning of the EU TFEU 114-p1
Other legal basis	Rules of Procedure EP 159
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/8/06746

Documentation gateway

Document attached to the procedure		SWD(2012)0273	26/09/2012	EC	
Document attached to the procedure		SWD(2012)0274	26/09/2012	EC	
Legislative proposal		COM(2012)0541	26/09/2012	EC	Summary
Document attached to the procedure		COM(2012)0540	26/09/2012	EC	Summary
Committee draft report		PE506.196	03/04/2013	EP	
Amendments tabled in committee		PE510.740	14/05/2013	EP	
Amendments tabled in committee		PE510.755	14/05/2013	EP	
Committee opinion	IMCO	PE508.086	20/06/2013	EP	
Committee opinion	EMPL	PE506.246	02/07/2013	EP	
Committee report tabled for plenary, 1st reading/single reading		A7-0327/2013	10/10/2013	EP	Summary
Text adopted by Parliament, partial vote at 1st reading/single reading		T7-0427/2013	22/10/2013	EP	Summary
Text adopted by Parliament, 1st reading/single reading		T7-0267/2014	02/04/2014	EP	Summary
Commission response to text adopted in plenary		SP(2014)471	09/07/2014	EC	
Council statement on its position		06593/1/2017	06/03/2017	CSL	

Council position		10729/4/2016	08/03/2017	CSL	Summary
Commission communication on Council's position		COM(2017)0127	09/03/2017	EC	Summary
Committee draft report		PE601.101	15/03/2017	EP	
Committee recommendation tabled for plenary, 2nd reading		A8-0069/2017	23/03/2017	EP	Summary
Text adopted by Parliament, 2nd reading		T8-0108/2017	05/04/2017	EP	Summary
Draft final act		00015/2017/LEX	05/04/2017	CSL	

Additional information

Research document	Briefing
National parliaments	IPEX
European Commission	EUR-Lex

Final act

Regulation 2017/746
OJ L 117 05.05.2017, p. 0176 Summary

Corrigendum to final act 32017R0746R(02)
OJ L 117 03.05.2019, p. 0011

Corrigendum to final act 32017R0746R(03)
OJ L 334 27.12.2019, p. 0167

Final legislative act with provisions for delegated acts

Delegated acts

2022/2985(DEA)	Examination of delegated act

In vitro diagnostic medical devices

PURPOSE: to propose a new legislative framework for in vitro diagnostic medical devices.

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

BACKGROUND: the current EU regulatory framework for in vitro diagnostic medical devices ('IVDs') consists of Directive 98/79/EC. It has demonstrated its merits but has also come under criticism in recent years. In an internal market with 32 participating countries and subject to constant scientific and technological progress, substantial divergences in the interpretation and application of the rules have emerged, thus undermining the main objectives of the Directive, i.e. the safety and performance of IVDs and their free movement.

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. It aims to put in place a robust, transparent and sustainable regulatory framework for in vitro diagnostic medical devices that is 'fit for purpose'. The framework is supportive of innovation and the competitiveness of the in vitro diagnostic medical device industry and should allow rapid and cost-efficient market access for innovative IVDs to the benefit of patients and healthcare professionals.

It should be noted that this proposal is adopted alongside a proposal for a Regulation on medical devices that are currently covered by the AIMDD and the MDD. While the specific features of IVDs and of the IVD sector require the adoption of a specific legislation distinct from the legislation on other medical devices, the horizontal aspects common to both sectors have been aligned.

The main elements of the proposal are as follows:

Scope and definitions: to a large extent, the scope of the proposed Regulation matches the scope of Directive 98/79/EC, i.e. it covers in vitro diagnostic medical devices. The proposed changes clarify and extend the scope of the IVD Directive. They concern:

- high-risk devices manufactured and used within a single health institution, which are subject to most of the requirements set out in

the proposal;

- tests providing information about the predisposition to a medical condition or a disease (e.g. genetic tests) and tests providing information to predict treatment response or reactions (e.g. companion diagnostics), which are considered as in vitro diagnostic medical devices;
- medical software, which is explicitly mentioned in the definition of IVDs.

To support Member States and the Commission in determining the regulatory status of products, the Commission may set up, in accordance with its internal rules, a group of experts from various sectors (such as IVDs, medical devices, medicinal products, human tissues and cells, cosmetics and biocides).

Definitions: this section has been significantly extended, aligning the definitions in the field of in vitro diagnostic medical devices with well-established European and international practice.

Making available of devices, obligations of economic operators, CE marking, free movement: this chapter covers mainly horizontal issues similar for both medical devices and IVDs. It 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). It also provides clarification with regard to the adoption and the scope of common technical specifications (CTS) for in vitro diagnostic medical devices.

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 new in the field of IVDs:

- a requirement has been introduced that within the manufacturer's organisation a 'qualified person' should be responsible for regulatory compliance. Similar requirements exist in EU legislation on medicinal products and in the national laws transposing the Directive on medical devices in some Member States.
- since in the case of 'parallel trade' with in vitro diagnostic medical devices application of the principle of free movement of goods varies considerably from one Member State to another and, in many cases, de facto prohibits this practice, clear conditions are set for enterprises involved in relabelling and/or repackaging IVDs.

Identification and traceability of devices, registration of devices and of economic operators, summary of safety and 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 IVDs;
- 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 performance studies, 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 . Any new designation and, in regular intervals, the monitoring of notified bodies are made subject to 'joint assessments' with experts from other Member States and the Commission, thus ensuring an effective control at Union level.

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 introduces a new risk-rule based classification system, built on GHTF principles, which replaces the current list of IVD medical devices in Annex II to Directive 98/79/EC.

In the new classification system, IVDs will be divided into four classes of risk: A (lowest risk), B, C and D (highest risk). The conformity assessment procedures have been adapted to match each of these four device classes. The proposal tightens and streamlines the different conformity assessment procedures during which the notified body audits the manufacturer's quality management system, checks the technical documentation, examines the design dossier or approves the type of a device. These are laid down in Annexes VIII to X. One conformity assessment procedure provided for under the IVD Directive (EC verification) has been deleted and the concept of batch testing has been clarified.

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 evidence: the proposal spells out the requirements for clinical evidence for in vitro diagnostic medical devices that are proportionate to the risk class. The key obligations are set out in Chapter VI while more detailed provisions are laid down in Annex XII. While most clinical performance studies follow an observational design and therefore the results obtained are not used for patient management and do not impact

treatment decisions, specific requirements have been introduced in Annex XIII for the conduct of interventional clinical performance studies and other clinical performance studies where the conduct of the study, including specimen collection, involves invasive procedures or other risks for the subjects of the studies.

The concept of 'sponsor' is introduced. The scope of the proposal remains restricted to clinical performance studies carried out for regulatory purposes, i.e. for obtaining or confirming regulatory approval for market access. Non-commercial clinical performance studies that do not pursue a regulatory purpose are not covered by this Regulation. Every interventional clinical performance study and other clinical performance study involving risks for the subjects of the study shall 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) made up of members appointed by the Member States due to their role and experience in the fields of medical devices and in vitro diagnostic medical devices and set up by Regulation on medical devices. The proposal mandates the Commission to provide technical, scientific and logistic support to the MDCG.

It empowers the Commission to adopt, where appropriate, either implementing acts to ensure uniform application of this Regulation, or delegated acts to complement the regulatory framework for in vitro diagnostic medical devices over time.

The future Regulation will replace and repeal Directive 98/79/EC.

BUDGETARY IMPLICATIONS: this proposal does not have any direct financial implications given that the cost-relevant arrangements are already covered in the proposal for a Regulation on medical devices.

To recap, 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).

In vitro diagnostic medical devices

The Committee on the Environment, Public Health and Food Safety adopted the report by Peter LIESE (EPP, DE) the proposal for a regulation of the European Parliament and of the Council on in vitro diagnostic medical devices.

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

Relationship to the proposal on a regulation for medical devices: a large part of this proposal on IVD (such as provisions on diabetes, HIV and DNA) is the same as the Commission proposal for a regulation on medical devices. These parts have been assessed together in the two reports. The amendments cover, for example, the role, the structure and the necessary improvement of the notified bodies, the surveillance system, the joint assessment, the scrutiny, identification and traceability and the role of the Medical Device Coordination Group (MDCG).

Members proposed, in particular, to improve the system of notified bodies. The personnel of the national authority responsible for auditing the work of personnel of notified bodies must have proven qualifications to do their work.

Notified bodies shall have permanent "in house" competent personnel and expertise.

The notified body shall publish a list of its staff responsible for the conformity assessment and certification of medical devices.

The transparency of fees charged by notified bodies for conformity assessment activities must be ensured.

The report also made improvements to the Commission proposal on the following point :

Ethics committee: the clinical performance study should be positively assessed by an independent ethics committee before it starts. The time limits are slightly extended to give the ethics committee and the authorities the time necessary to assess the proposal.

Genetic test: a device may only be used for the purpose of a genetic test after the person concerned has given free and informed consent to it. The person concerned must receive appropriate information on the nature, the significance and the implications of the genetic test before the device is used.

Genetic counselling: appropriate genetic counselling shall be mandatory before using a device for the purpose of predictive and prenatal testing and after a genetic condition has been diagnosed. Such counselling shall include medical, ethical, social, psychological and legal

aspects and shall be carried out by physicians qualified in genetic counselling.

Consent: a device may only be used for the purpose of a genetic test after the person concerned has given free and informed consent to it. The consent has to be given explicitly and in writing. It can be revoked at any time in writing or orally.

Testing of minors and incapacitated subjects: in the case of minors the informed consent of the parents or legal representative or minors themselves shall be obtained in accordance with national laws; consent shall represent the minors presumed will and may be revoked at any time, without detriment to the minor. In the case of incapacitated subjects who are unable to give informed legal consent, the informed consent of the legal representative shall be obtained.

Strict rules for persons unable to give informed consent such as children and incapacitated persons should be established at the same level as in Directive 2001/20/EC on clinical trials.

Non-discrimination: the text should reflect the UN Convention on non-discrimination on disabled people. Regarding definitions, for example, the term 'congenital abnormality' is viewed by persons with disabilities and their representatives as discrimination, and it is proposed to replace it.

Taking account of the needs of SMEs: in the area of in vitro diagnostic medical devices many companies offering these devices are SMEs, and amendments are proposed in the report to alleviate the burden. For example it must be possible to provide some information electronically and it is also specified that the information accompanied the product shall be provided in an official union language and not in any other language.

Scope: the amended text states that certain devices may only be supplied on a medical prescription, particularly Class D devices (high risk) and Class C devices in the following categories: (a) devices for genetic testing; (b) companion diagnostics.

Companion diagnostic means a device specifically intended for and essential to the selection of patients with a previously diagnosed condition or predisposition as suitable or unsuitable for a specific therapy with a medicinal product or a range of medicinal products.

Delegated acts: basic aspects elements of the Regulation such as general safety and performance requirements, elements to be addressed in technical documentation, the minimum content of the Union declaration of conformity, amending or supplementing the conformity assessment procedures, should only be amended through the ordinary legislative procedure.

Application of the Regulation: Members propose that the Regulation should be applicable three years after its entry into force, whereas the Commission had proposed five years.

In vitro diagnostic medical devices

The European Parliament adopted amendments to the proposal for a regulation of the European Parliament and of the Council on in vitro diagnostic medical devices.

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

The main amendments adopted in plenary were as follows:

Relationship to the proposal on a regulation for medical devices: a large part of this proposal on IVD (such as provisions on diabetes, HIV and DNA) is the same as the Commission proposal for a regulation on medical devices.

As for the abovementioned proposal, the amendments cover, for example, the role, the structure and the necessary improvement of the notified bodies, the surveillance system, the setting up of a Medical Device Advisory Committee, the obligation of manufacturers to take liability insurance with sufficient minimum coverage, the joint assessment, the scrutiny, identification and traceability, improved access to information for the general public and healthcare professionals and the role of the Medical Device Coordination Group (MDCG).

Members proposed, in particular, to improve the system of notified bodies. The personnel of the national authority responsible for auditing the work of personnel of notified bodies must have proven qualifications to do their work. Notified bodies shall have permanent "in house" competent personnel and expertise. The notified body shall publish a list of its staff responsible for the conformity assessment and certification of medical devices.

The transparency of fees charged by notified bodies for conformity assessment activities must be ensured.

Parliament also made improvements to the Commission proposal on the following points:

- Ethics committee: the clinical performance study should be positively assessed by an independent ethics committee before it starts. The time limits are slightly extended to give the ethics committee and the authorities the time necessary to assess the proposal.
- Genetic test: a device may only be used for the purpose of a genetic test after the person concerned has given free and informed consent to it. The person concerned must receive appropriate information on the nature, the significance and the implications of the genetic test before the device is used.
- Genetic counselling: appropriate genetic counselling shall be mandatory before using a device for the purpose of predictive and prenatal testing and after a genetic condition has been diagnosed. Such counselling shall include medical, ethical, social, psychological and legal aspects and shall be carried out by physicians qualified in genetic counselling.
- Consent: a device may only be used for the purpose of a genetic test after the person concerned has given free and informed consent to it. The consent has to be given explicitly and in writing. It can be revoked at any time in writing or orally.

Testing of minors and incapacitated subjects: in the case of minors the informed consent of the parents or legal representative or minors themselves shall be obtained in accordance with national laws; consent shall represent the minors presumed will and may be revoked at any time, without detriment to the minor. In the case of incapacitated subjects who are unable to give informed legal consent, the informed consent of the legal representative shall be obtained.

Strict rules for persons unable to give informed consent such as children and incapacitated persons should be established at the same level as in Directive 2001/20/EC on clinical trials.

No incentives or financial inducements are given except compensation for participation in the clinical performance study.

Non-discrimination: the text should reflect the UN Convention on non-discrimination on disabled people. Regarding definitions, for example, the term 'congenital abnormality' is viewed by persons with disabilities and their representatives as discrimination, and it is proposed to replace it.

Taking account of the needs of SMEs: in the area of in vitro diagnostic medical devices many companies offering these devices are SMEs, and amendments are proposed in the report to alleviate the burden. For example it must be possible to provide some information electronically and it is also specified that the information accompanied the product shall be provided in an official union language and not in any other language.

Advisory Committee: Parliament called for a multidisciplinary Medical Device Advisory Committee (MDAC) to be set up which should be composed of experts and representatives of the relevant stakeholders should be set up to provide scientific advice to the Commission, the Medical Device Coordination Group (MDCG) and Member States on issues of medical technology, regulatory status of devices and other aspects of implementation of this Regulation as necessary.

Scope: the amended text stated that certain devices may only be supplied on a medical prescription, particularly Class D devices (high risk) and Class C devices in the following categories: (a) devices for genetic testing; (b) companion diagnostics.

Direct to consumer advertising of devices classed as prescription only by this Regulation shall be illegal.

Delegated acts: basic aspects elements of the Regulation such as general safety and performance requirements, elements to be addressed in technical documentation, the minimum content of the Union declaration of conformity, amending or supplementing the conformity assessment procedures, should only be amended through the ordinary legislative procedure.

Application of the Regulation: Members proposed that the Regulation should be applicable three years after its entry into force, whereas the Commission had proposed five years.

In vitro diagnostic medical devices

The European Parliament adopted by 492 to 21, with 117 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council on in vitro diagnostic medical devices.

The report was sent back to the committee at the 22 October 2013 plenary sitting.

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

In vitro diagnostic medical devices

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.

In vitro diagnostic medical devices

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.

In vitro diagnostic medical devices

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 in-vitro diagnostic medical devices which replaces Council Directive 98/79/EC and Commission Decision 2010/227/EU.

The proposed Regulation aims to put in place a robust, transparent and sustainable regulatory framework for in vitro diagnostic medical devices for human use in the European Union (e.g. HIV blood tests, pregnancy tests, blood sugar monitoring systems for diabetics). It shall apply to performance studies concerning such in vitro diagnostic medical devices and accessories conducted in the Union.

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.

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 in vitro diagnostic medical devices before they can be placed on the market.

Availability of clinical data: the requirements on collection of data in clinical investigations on medical devices and performance studies on in vitro diagnostic medical devices have been considerably strengthened 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.

The Councils position sets out the verification by a designated reference laboratory of the performance claimed by manufacturers and a consultation with an expert panel as regards the evaluation for certain high-risk devices.

Information and counselling for genetic testing: Member States shall ensure that where a genetic test is used on individuals in the context of healthcare, the subject to the testing must be provided with relevant information on the nature, significance and implications of the test, as appropriate. In particular, there should be appropriate access to counselling where genetic testing provides information on diseases that are considered to be untreatable.

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 Councils 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.

Classification: the classification system for medical devices, and, even further, the classification system for in vitro diagnostic medical devices have been adapted to correspond to the rapid increase in scientific, medical and technical knowledge and to the resulting development of more and more advanced device.

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.

In vitro diagnostic medical devices

The Commission stated that the Councils 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 the in vitro diagnostic medical device (IVD) sector.

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:

- information and counselling for genetic testing in the context of healthcare: the Commission stated that: (i) it will report on the Member States' experience with the implementation of the obligations for information and counselling in the context of use of genetic tests; (ii) devices without any medical purpose, including those which are intended to directly or indirectly maintain or improve healthy behaviours, quality of life and wellbeing of individuals, are not covered under the definitions of the Regulation on in vitro diagnostic medical devices. Nonetheless, the Commission intends to monitor, on the basis of the market surveillance activities carried out by Member States, specific safety issues which might be linked to the use of these devices;
- 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 Councils position accepts the spirit of the European Parliaments 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;
- the identification and traceability related obligations and establishment of a Unique Device Identification (UDI) System: contrary to the Commissions 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 Councils 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 and provide for a longer transition period for the coordinated procedure for assessment of applications for clinical investigations in more than one Member State;
- specifying the obligations of manufacturers to follow-up on the real-life use of their devices after their placing on the market.

In vitro diagnostic medical devices

The Committee on the Environment, Public Health and Food Safety adopted the recommendation for second reading contained in the report by Peter LIESE (EPP, DE) 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 in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

The committee recommended the European Parliament to approve the Council position at first reading without amendments. It also took note of two Commission statements annexed to the draft legislative resolution.

The Commission:

- undertakes to present, no later than five years after the date of application of the Regulation, a report on Member States experience with the implementation of the obligations concerning the provision of information and counselling in the context of genetic testing;
- specifies that genetic testing intended for wellbeing or lifestyle purposes is not covered by the definitions in the Regulation. Nevertheless, the Commission will monitor specific safety issues which might be linked to the use of these devices.

Councils first reading position is in conformity with the agreement reached during the interinstitutional negotiations. The report is accompanied by a short justification which focuses on the following elements of the approved text:

- obligation for notified bodies to carry out unannounced inspections on the production site;
- strengthening of the 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 of notified bodies for them to successfully conduct their conformity assessment activities;
- obligation to submit extra conformity checks on class D devices from a European reference laboratory;
- obligation of the manufacturer to put in place measures to provide sufficient financial coverage in respect of their potential liability concerning defective devices;
- inclusion of clear provisions on informed consent, ethics committees, incapacitated subjects, minors, pregnant women, transparency as regards clinical trials of medical devices;

- individuals being tested with a genetic test should be provided with all relevant information on the nature, the significance and the implications of the genetic test, including appropriate access to counselling in the case where the test provides information on the genetic predisposition for medical conditions and/or diseases which are generally considered to be untreatable;
- strengthening the authorisation procedures and the overall system for traceability of devices, vigilance and post-market surveillance, to ensure constant monitoring and swift reaction should problems arise.

In vitro diagnostic medical devices

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 in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

A proposal to reject the Council proposal, submitted by the EFDD group, was rejected in plenary by 59 votes to 635, with 9 abstentions.

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

The proposed Regulation seeks to harmonise the rules for the placing on the market and putting into service of in vitro diagnostic medical devices (e.g. HIV blood tests, pregnancy tests, blood sugar monitoring systems for diabetics) and their accessories on the Union market which may then benefit from the principle of free movement of goods.

Parliament took note of two Commission statements annexed to the legislative resolution. With these statements, the Commission:

- will present, no later than five years after the date of application of the Regulation, a report on the Member States' experience with the implementation of the obligations for information and counselling in the context of use of genetic tests;
- stipulated that, with respect to genetic tests intended for wellbeing or lifestyle purposes, devices without any medical purpose, including those which are intended to directly or indirectly maintain or improve healthy behaviours, quality of life and wellbeing of individuals, are not covered by the definitions of the Regulation. Nonetheless, the Commission intends to monitor specific safety issues which might be linked to the use of these devices.

In vitro diagnostic medical devices

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

LEGISLATIVE ACT: Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

CONTENT: the Regulation lays down rules concerning the placing on the market of in vitro diagnostic medical devices for human use and accessories for such devices in the Union (e.g. HIV blood tests, pregnancy tests, blood sugar monitoring systems for diabetics.) It also applies to performance studies concerning such in vitro diagnostic medical devices and accessories conducted in the Union.

The purpose of the Regulation 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 classification system for medical devices, and, even further, the classification system for in vitro diagnostic medical devices have been adapted to correspond to the rapid increase in scientific, medical and technical knowledge and to the resulting development of more and more advanced device.

Devices manufactured and used in the same health institution are exempted from the Regulation, with the exception of the relevant general safety and performance requirements, if a number of conditions are fulfilled.

Notified bodies: the Regulation strengthens the provisions on the designation, organisation, monitoring and expertise of the notified bodies, which conduct the conformity assessment and certification for all in vitro 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 and performance studies on in vitro diagnostic medical devices have been considerably strengthened 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.

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 for each type of device.

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.

High-risk devices: the Regulation provides for the verification by a designated reference laboratory of the performance claimed by manufacturers of class D IVDs and a consultation with an expert panel applicable to Class D IVDs devices, in the case of their first certification and when common technical specifications are not available. While the notified body would not be bound by the opinion, it would have to provide a justification for not following it.

Genetic counselling: the Regulation provides that individuals being tested with a genetic test should be provided with all relevant information on the nature, the significance and the implications of the genetic test, including appropriate access to counselling in the case where the test provides information on the genetic predisposition for medical conditions and/or diseases which are generally considered to be untreatable.

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 and all higher levels of packaging, thanks to the establishment of a Unique Device Identification (UDI) System.

Manufacturers must have the UDI code assigned to their devices by the date of application and the UDI carrier must be placed on the device and all higher levels of packaging gradually depending on the risk class of the device.

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 26.5.2022.

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.