Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2023/0005(COD)	Procedure completed

Transitional provisions for certain medical devices and in vitro diagnostic medical devices

Amending Regulation 2017/745 2012/0266(COD)
Amending Regulation 2017/746 2012/0267(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		
	Committee for opinion	Rapporteur for opinion	Appointed
	IMCO Internal Market and Consumer Protection	The committee decided not to give an opinion.	
	EMPL Employment and Social Affairs	The committee decided not to give an opinion.	
Council of the European Union	Council configuration	Meeting	Date
	Education, Youth, Culture and Sport	6785	07/03/2023
European Economic and Social Committee			
European Committee of the Regions			

Key events

06/01/2023	Legislative proposal published	COM(2023)0010	Summary
26/01/2023	Committee referral announced in Parliament, 1st reading		
14/02/2023	Decision by committee, without report		
16/02/2023	Decision by Parliament, 1st reading	T9-0052/2023	Summary
07/03/2023	Act adopted by Council after Parliament's 1st reading		
15/03/2023	Final act signed		
20/03/2023	Final act published in Official Journal		

Technical information

Procedure reference	2023/0005(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)

Procedure subtype	Legislation
Legislative instrument	Regulation
	Amending Regulation 2017/745 2012/0266(COD) Amending Regulation 2017/746 2012/0267(COD)
Legal basis	Treaty on the Functioning of the EU TFEU 168-p4; Treaty on the Functioning of the EU TFEU 114; Rules of Procedure EP 163
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/9/11070

Documentation gateway

Legislative proposal		COM(2023)0010	06/01/2023	EC	Summary
Economic and Social Committee: opinion, report		CES0203/2023	24/01/2023	ESC	
Text adopted by Parliament, 1st reading/single reading		T9-0052/2023	16/02/2023	EP	Summary
Draft final act		00001/2023/LEX	15/03/2023	CSL	

Final act

Regulation 2023/607
OJ L 080 20.03.2023, p. 0024

Transitional provisions for certain medical devices and in vitro diagnostic medical devices

PURPOSE: to ensure that patients across Europe have access to safe medical devices.

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

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: Regulations (EU) 2017/745 (MDR) and (EU) 2017/746 (IVDR) of the European Parliament and of the Council establish a new regulatory framework to ensure the proper functioning of the internal market for medical devices and in vitro diagnostic medical devices, based on a high level of health protection for patients and users.

In addition, the two regulations :

- set high quality and safety standards for medical devices and in vitro diagnostic medical devices in order to address the common safety issues related to these devices

- significantly strengthen key aspects of the previous regulatory framework such as the supervision of notified bodies, conformity assessment procedures, clinical evidence requirements, vigilance and market surveillance, while introducing provisions to ensure transparency and traceability of medical devices and in vitro diagnostic medical devices.

BACKGROUND: Regulations (EU) 2017/745 and (EU) 2017/746 of the European Parliament and of the Council establish a new regulatory framework to ensure the smooth functioning of the internal market as regards medical devices and in vitro diagnostic medical devices, taking as a base a high level of protection of health for patients and users.

In addition, the two Regulations:

- set high standards of quality and safety for medical devices and in vitro diagnostic medical devices in order to meet common safety concerns as regards such devices;

- significantly reinforce key elements of the previous regulatory framework, such as the supervision of notified bodies, conformity assessment procedures, clinical evidence requirements, vigilance and market surveillance, whilst introducing provisions ensuring transparency and traceability regarding medical devices and in vitro diagnostic medical devices.

Due to the impact of the COVID-19 pandemic, the date of application of the MDR was postponed by one year to 26 May 2021 by Regulation (EU) 2020/561 of the European Parliament and of the Council, while the date of 26 May 2024 was maintained as end of the transition period by which certain devices that continue to comply with Directive 90/385/EEC or Directive 93/42/EEC may be placed on the market or put into

service.

Despite considerable progress over the past years, the overall capacity of conformity assessment (notified) bodies remains insufficient to carry out the tasks required of them. In addition, many manufacturers are not sufficiently prepared to meet the strengthened requirements of the MDR by the end of the transition period. This is threatening the availability of medical devices on the EU market.

The overall goal of the proposed amendments is to maintain patients access to a wide range of medical devices while ensuring the transition to the new framework.

CONTENT: this proposal does not alter the MDR or IVDR in substance, nor does it impose any new obligations on the parties concerned. The main purpose of this proposal is to amend the transitional provisions, allowing for an additional period of time to transition to the MDRs requirements to avoid shortages.

In concrete terms, the proposal therefore aims to:

- extend the current transition period in Article 120 of the MDR, subject to certain conditions, so that only those devices that are safe and for which manufacturers have already taken steps to transition to the MDR will benefit from the additional time. The transition period would be extended from 26 May 2024 to 31 December 2027 for higher risk devices and to 31 December 2028 for lower and medium risk devices;

- delete the sell off deadline in the relevant provisions of the MDR and IVDR, i.e. the date until which devices that are placed on the market before or during the transition period and are still in the supply chain when the extended transition period is over can be made available.

The extension of the transition period is complemented by an extension of the validity of certificates issued under the previous Council Directives 90/385/EEC and 93/42/EEC for the devices benefiting from the extended transition period. Also the validity of certificates that have already expired since 26 May 2021 would be extended, subject to certain conditions.

Transitional provisions for certain medical devices and in vitro diagnostic medical devices

The European Parliament adopted by 537 votes to 3, with 24 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

Parliament adopted its position at first reading under the ordinary legislative procedure by taking over the Commission proposal.

The aim of the regulation is to address the risks of shortages of medical devices and in vitro diagnostic medical devices and thus maintain patient access to a wide range of medical devices.

Regulations (EU) 2017/745 (MDR) and (EU) 2017/746 (IVDR) of the European Parliament and of the Council establish a new regulatory framework to ensure the proper functioning of the internal market for medical devices and in vitro diagnostic medical devices, based on a high level of health protection for patients and users.

The MDR is applicable from 26 May 2021. The transition period provided for in the Regulation will end on 26 May 2024.

The IVDR is applicable from 26 May 2022. A staggered extension of its transition period, from 26 May 2025 for high-risk in vitro diagnostics to 26 May 2027 for low-risk in vitro diagnostics and to 26 May 2028 for certain provisions concerning devices manufactured and used in health care facilities, has been adopted.

Despite the steady increase in the number of notified bodies designated in accordance with Regulation (EU) 2017/745, the overall capacity of notified bodies is still not sufficient to ensure the conformity assessment of the large number of devices covered by certificates issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC before 26 May 2024. A large number of manufacturers, especially small and medium-sized enterprises, are not sufficiently prepared to demonstrate compliance with the requirements of Regulation (EU) 2017/745.

The amending Regulation therefore:

- extends the current transition period in Article 120 of the MDR, subject to certain conditions, so that only those devices that are safe and for which manufacturers have already taken steps to transition to the MDR will benefit from the additional time. The transition period would be extended from 26 May 2024 to 31 December 2027 for higher risk devices and to 31 December 2028 for lower and medium risk devices;

- deletes the sell off deadline in the relevant provisions of the MDR and IVDR, i.e. the date until which devices that are placed on the market before or during the transition period and are still in the supply chain when the extended transition period is over can be made available.

- extends the validity of certificates issued under the previous Council Directives 90/385/EEC and 93/42/EEC for the devices benefiting from the extended transition period. Also, the validity of certificates that have already expired since 26 May 2021 would be extended, subject to certain conditions.

Transparency

LUENA César	Member	14/02/2023	Edwards Lifesciences