Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2024/0021(COD)	Awaiting Council's 1st reading position
Gradual roll-out of Eudamed, information obligation in case of interruption of supply and transitional provisions for certain 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 ENVI Environment, Public Health and Food Safety	Rapporteur	Appointed
	Committee for opinion EMPL Employment and Social Affairs	Rapporteur for opinion The committee decided not to give an opinion.	Appointed
	IMCO Internal Market and Consumer Protection	The committee decided not to give an opinion.	
Council of the European Union			
European Commission	Commission DG Health and Food Safety	Commissioner KYRIAKIDES Stella	
European Economic and Social Committee			
European Committee of the Regions			

Key events

23/01/2024	Legislative proposal published	COM(2024)0043	Summary
26/02/2024	Committee referral announced in Parliament, 1st reading		
23/04/2024	Decision by committee, without report		
25/04/2024	Decision by Parliament, 1st reading	T9-0368/2024	

Technical information

Procedure reference	2024/0021(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; Rules of Procedure EP 163; Treaty on the Functioning of the EU TFEU 114
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Awaiting Council's 1st reading position
Committee dossier	ENVI/9/14040

Documentation gateway

Legislative proposal		COM(2024)0043	23/01/2024	EC	Summary
Economic and Social Committee: opinion, report		CES0746/2024	20/03/2024	ESC	
Text adopted by Parliament, 1st reading/single reading		T9-0368/2024	25/04/2024	EP	

Gradual roll-out of Eudamed, information obligation in case of interruption of supply and transitional provisions for certain in vitro diagnostic medical devices

PURPOSE: to address risks of shortages of in vitro diagnostic medical devices in the Union and ensure the timely roll-out of Eudamed.

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: Regulation (EU) 2017/745 (Medical Devices Regulation (MDR)) and Regulation (EU) 2017/746 (In Vitro Diagnostic Medical Devices Regulation (IVDR)) of the European Parliament and of the Council set a strengthened regulatory framework for medical devices and in vitro diagnostic medical devices (IVDs).

The MDR has been applied since 26 May 2021. A transitional period has been extended by Regulation (EU) 2023/607 and will end on either 31 December 2027 or 31 December 2028, depending on the devices risk class and subject to certain conditions.

The IVDR has applied since 26 May 2022. In January 2022, the European Parliament and the Council adopted a staggered extension of its transitional period, ranging from 26 May 2025 for high-risk IVDs to 26 May 2027 for lower-risk IVDs, and to 26 May 2028 for certain provisions concerning devices manufactured and used in health institutions.

CONTENT: this Commission proposal aims to ensure availability of safe devices, essential for healthcare systems, and protect patient care. The latest available data shows that a high number of IVDs currently on the market has not factored in the new rules (nor has been replaced by other devices), meaning that those devices would no longer be available. The number of devices which have not factored in the new rules and are not expected to transition in time is particularly high for high risk IVDs (class D). These include important tests detecting infections in the context of blood transfusions or organ donations.

Therefore, this proposal for targeted amendments addresses two urgent issues.

Ensuring the availability of in vitro diagnostics

The proposal aims to further extend the transitional periods to give manufacturers and notified bodies more time to complete the necessary conformity assessment procedures for certain IVDs to mitigate the risk of shortages of these products, especially of high-risk IVDs, which are used, for example, to test for infections in blood or organ donations or for blood grouping for transfusions. This extension will be subject to conditions and therefore safeguard the high level of requirements set out by the legislation and protect public health.

The changes extend the transitional periods that are applicable to legacy devices, i.e., those covered by a certificate or declaration of conformity. The additional time granted to companies depends on the type of device:

- high individual and public health risk devices such as HIV or hepatitis tests (class D) would have a transition period until December 2027;

- high individual and/or moderate public health risk devices such as cancer tests (class C), would have a transition period until December 2028;

- lower risk devices (class B such as pregnancy tests and class A sterile devices such as blood collection tubes), have a transition period until December 2029.

The proposal also introduces a requirement for manufacturers to give prior notice to authorities, as well as to distributors or health institutions, if they foresee the interruption of supply of IVDs or medical devices, which would pose risks to patient care. This measure would enable healthcare systems to have more time to take action to safeguard patient care.

More transparency on medical devices

The mandatory use of the European database on medical devices, Eudamed, is key for the effective and efficient implementation of the Medical Device and IVD Regulations. It will increase transparency in the EU, providing an overview of all medical devices available on the European market. The proposal to enable and accelerate a gradual roll-out of Eudamed and notably speed up the launch of the parts of Eudamed that are already finalised, so that it is mandatory earlier (as from late 2025).

Lastly, this draft Regulation is being adopted in view of the exceptional circumstances arising from an imminent risk of shortages of in vitro diagnostic medical devices and the associated risk of a public health crisis, as well as the significant delay in the development of the last electronic system of Eudamed. To attain the intended effect of amending Regulations (EU) 2017/745 and (EU) 2017/746 and to ensure availability of devices whose certificates have already expired or are due to expire before 26 May 2025, to provide legal certainty for economic operators and healthcare providers, and for reasons of consistency as regards the amendments to both Regulations, this Regulation should enter into force as a matter of urgency.

Transparency

WÖLKEN Tiemo	Shadow rapporteur	ENVI	22/02/2024	Medical Mountains
WÖLKEN Tiemo	Shadow rapporteur	ENVI	29/01/2024	MedTech Europe
LIESE Peter	Member	18/03/2024	Bundesverband Medizintechnologie	
LIESE Peter	Member	04/03/2024	Bundesverband Medizintechnologie	
NIEBLER Angelika	Member	22/02/2024	Deutsche Sozialversicherung Europavertretung	