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EU IVDR Timelines/ Transition Changes: What is due when

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In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR) of the European Parliament and of the Council have established a new regulatory framework to ensure the smooth functioning of the internal market as regards in vitro diagnostic medical devices covered by that Regulation, taking as a base a high level of protection of health for patients and users, and taking into account the small- and medium-sized enterprises that are active in this sector.

The European Commission issued a proposal on October 14, 2021, to amend the transitional implementation periods under EU IVDR. This proposal aims to prevent supply disruption of these essential healthcare products as the COVID-19 pandemic continues to play out.

Aims to extend the existing transitional period for:

- Devices covered by a certificate issued under Directive 98/79/EC and
- To introduce tailored transitional periods for devices that have to undergo conformity assessment involving notified bodies for the first time under Regulation (EU) 2017/746.

Necessity for new transitional provisions:

- The pandemic causing delays in conformity assessments by notified bodies;
- Under the IVDR, around 80% of IVD devices will require the control of notified bodies
- Time to complete the conformity assessment procedure (1 year plus 6 months for the manufacturer prior to the market release)
- Lack of notified bodies; making it impossible for manufacturers to conduct the legally required conformity assessment procedures in time

Devices that need to be compliant with IVD regulation by May 26th 2022

The IVDR date of application (DoA) has not been changed, remains May 26, 2022. Therefore, IVDR vigilance and PMS requirements apply from May 26, 2022. There are also some conditions for the transition extension.

- Class A IVD devices (for example, buffers, washing solutions, products for general lab use, instruments used for IVD procedures, and specimen receptacles) which are self-certified and do not require a notified body intervention under EU IVDR
- Brand-new in vitro diagnostic medical devices and products that have undergone a significant change in the design or its intended purpose will be subject to the new requirements

Manufacturers will have to prepare for the certification procedures under the IVD Regulation as soon as possible. That means that they will have to adapt their quality management system, their products and their technical documentation, and apply to a notified body well before the end of the transition periods.

New transitional periods for IVD devices

According to the class risk, several deadlines have been proposed for the other devices, to give Manufacturers the time to comply with IVDR requirements.

Notified body certification requirements for IVD devices		Transition Periods	
		End date for IVDD certificates /Last date for placing on the market	Last date for making available on the market*
With an IVDD certificate, requiring IVDR certificate		26 May 2025	26 May 2025
With no IVDD certificate (needing an IVDR certificate) and with a declaration of conformity dating before 26 May 2022	Class D	26 May 2025	26 May 2026
	Class C	26 May 2026	26 May 2027
	Class B	26 May 2027	26 May 2028
	Class A (Sterile)	26 May 2027	26 May 2028
No IVDD certificate and no IVDR certificate (Class A, non-sterile)		26 May 2022	26 May 2025

*Continued sale of devices lawfully placed on the market prior to 26 May 2022 will only be possible until 26 May 2025.

Requirements to be met for IVD devices to continue under IVDD after the DoA of IVDR

The devices for which did not required NB involvement under IVDD Directive, a declaration of conformity (DoC) can be drawn in accordance with the IVDD Directive and for which the conformity assessment procedure pursuant to this IVDR Regulation requires the involvement of a notified body, can be placed on the market or put into service until the transition periods; these devices will have until these dates to undergo a conformity assessment for the first time by Notified Body. However, the prerequisites shall apply:

- A DoC shall be issued under IVDD prior to May 26th, 2022 and continue to comply with Directive 98/79/EC
- Should not undergo any significant changes to the design, manufacture, or intended purpose.
- Need to implement a Post-Market Surveillance Plan in accordance with Annex III
- Develop a PMS Report or a Periodic Safety Update Report (PSUR) (Articles 78-81)
- Updating existing procedures on vigilance to meet the requirements according to IVDR requirements (Articles 82-87)
- Note is that 'other' adverse events shall be reported within 15 days rather than the 30 days under the previous Directives.
- The devices and economic operators shall be registered in the electronic system (EUDAMED) in accordance with the IVDR.

Health Institution(in-house devices) Exemption

In Article 113(3), the following points (i) and (j) are added:
Shall apply from 26 May 2024 ((i) Article 5(5), points (b), (c) and (e) to (i)):
Implementation of below requirements (devices are not transferred to another legal entity) is proposed to be postponed to 26 May 2024. The postponed requirements on health institutions relying on the exemption include:

- Having an appropriate quality management system;
- Compliance with either EN ISO 15189 or applicable national provisions, including accreditation;
- The ability to provide the competent authority with justification of their manufacturing, modification and use of these less regulated devices;

- The declaration of meeting the General Safety and Performance Requirements (GSPRs) under Annex I, IVDR;
- For class D devices, drawing up detailed documentation about the manufacture, design and performance data, to allow the competent authority to ascertain compliance with GSPRs and taking measures to ensure IVDs are manufactured accordingly;
- Review of experience and taking corrective action as a result.

Shall apply from 26 May 2028 ((j) Article 5(5), point (d)):

Health institutions will not be required to justify the use of these exempted IVDs for the target patient group's specific needs on the basis that patient needs cannot be met or met at the appropriate level of performance by an equivalent device until 26 May 2028.

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