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EU Horizontal legislation and its interaction with the IVDR

AUTHOR: DENISE MCDERMOTT, SGS BELGIUM

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Introduction

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices (IVDR) establishes the legal framework for placing in vitro diagnostic devices (IVDs) on the EU market. Manufacturers seeking a CE mark for an IVD must comply with the requirements of the IVDR and other EU legislation applicable to the device. Conformity with the applicable legislative requirements is formally declared in the EU Declaration of Conformity.

Horizontal legislation extends across various sectors and areas of policy, and there are several that impact IVDs specifically. This whitepaper provides an overview of selected horizontal legislation relevant to IVD manufacturers, highlighting its interplay with the IVDR and outlining key considerations for regulatory compliance.

List of Abbreviations

Abbreviation	Meaning
AIA	Artificial Intelligence Act
CE	Conformite Europeenne (European conformity marking)
EU	European Union
IVDs	In Vitro Diagnostic Medical Device
IVDR	Regulation (EU) 2017/746 on in vitro diagnostic medical devices
MDCG	Medical Device Coordination Group
MDR	Regulation (EU) 2017/745 on medical devices
NB	Notified body
EAIB	European Artificial Intelligence Board- AI Board

While the IVDR establishes the core regulatory requirements for IVDs, other horizontal regulations may also have implications for manufacturers and should be considered where applicable. This whitepaper examines several regulations of particular significance to IVD manufacturers, including Regulation (EU) 2024/1689 on Artificial Intelligence (AI Act), the European Health Data Space Regulation (EU) 2025/327, and the Packaging and Packaging Waste Regulation (EU) 2025/40. The regulations addressed in this whitepaper are illustrative rather than exhaustive. A number of other horizontal legislative measures, such as the Data Act (Regulation (EU) 2023/2854) and the Data Governance Act (Regulation (EU)

2022/868), may also have implications for IVD manufacturers depending on the nature of their products, services, and data-processing activities.

Regulation (EU) 2024/1689 on artificial intelligence (AI)

The EU has Published in July 2024, Regulation (EU) 2024/1689 (AI Act or AIA) is an important piece of legislation that lays down rules for artificial intelligence and may apply to manufacturers of IVDs incorporating AI systems, depending on the product and the manufacturer's role.
Under Article 3(1) of the AI Act, an AI system means;
"*a machine-based system that is designed to operate with* ***varying levels of autonomy*** *and that* ***may exhibit adaptiveness*** *after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments*."
The AIA places high-risk product requirements on manufacturers, deployers (e.g., hospitals, laboratories), importers, and distributors (Article 2).
According to the AIA, devices are classified as high-risk AI systems when they meet the following criteria: when the AI system is intended to be used **as a safety component of a product**, or the **AI system is itself a product**, covered by the Union harmonization legislation listed in Annex I of the AIA, and is required to undergo a **third-party conformity assessment**. In this context, the harmonization legislation listed in Annex I of the AIA includes Regulation (EU) 2017/745 MDR and Regulation (EU) 2017/746 IVDR. The safety component referred to here should fulfil a safety function for that product or AI system, and a defect in such a system would endanger the health and safety of individuals or property.

The key dates surrounding the AI Act include:
12 July 2024 – Published in the Official Journal of the European Union (OJEU)
1 August 2024 - Entered into force
2 February 2025 - Chapter I on general provisions and chapter II on prohibited AI practices shall apply
2 August 2025 – General purpose AI model rules apply, provisions on penalties apply

Regulation (EU) 2026/1744 of the European Parliament and of the Council of 8 July 2026 amending Regulations (EU) 2024/1689, (EU) 2018/1139 and (EU) 2023/1230 as regards the simplification of the implementation of harmonized rules on artificial intelligence (Digital Omnibus on AI), published 24 July 2026, did not create any new obligations but it did extend the application date of the high-risk requirements as follows;

Provision	Application date before Omnibus	Application date after Omnibus

High-risk requirements apply for Annex III Article 6(2)/Annex III high-risk systems: application of the relevant Chapter III provisions	2 August 2026	2 December 2027
Article 6(1)/Annex I Article 6 (high-risk systems) and the corresponding obligations in this Regulation shall apply – This deadline encompasses high risk IVDs	2 August 2027	2 August 2028

For IVDs that fall within the scope of the AIA, the conformity assessment procedure follows that of the IVDR, with classification and sampling rules determined by the IVDR. From 2 August 2028, high-risk AI systems that are safety components of, or are themselves, IVDR devices requiring notified body conformity assessment will become subject to the applicable AI Act requirements. Manufacturers will therefore need to demonstrate compliance with both the IVDR and the AI Act as part of the conformity assessment process.

Many aspects of the AI Act overlap with the IVDR, including conformity assessment, technical documentation, cybersecurity and risk management, and the 2026 AI Act omnibus amendments are intended to reduce duplication between the two. There is, however, increased focus within the AIA on data governance and transparency. The AIA also places an obligation on manufacturers to design AI systems with measures that enable effective human oversight, including the ability to disregard or override outputs and interrupt operations.

According to the AI Act, the notified body will examine the technical documentation and shall be granted access to the training, validation, and testing data sets used (Annex VII 4.3). When a notified body is evaluating the conformity of a high-risk AI system (Chapter III, Section 2), it shall be granted access to the training and trained models of the AI system (Annex VII Section 4.5). The AI Act states that such access shall be subject to existing Union law on the protection of intellectual property and trade secrets.

Much of the detailed implementation guidance for the AI Act remains under development, as are the harmonized technical standards needed for conformity assessments under Article 40. Consequently, notified body expectations for combined IVDR/AI Act assessments are still evolving. The European Artificial Intelligence Board was established in 2024 to provide guidance on AI matters including implementation of the AI Act. As the regulatory framework continues to evolve, further guidance on the application of the AI Act to medical devices and

IVDs is expected from the European Commission and the EAIB. Additional guidance may also be developed by sector-specific bodies such as the Medical Device Coordination Group (MDCG) and Team-NB.

European Health Data Space Regulation (EU) 2025/327

As healthcare becomes increasingly digital, the European Health Data Space (EHDS) Regulation (EU) 2025/327 establishes a framework intended to support the secure exchange, access, and use of electronic health data across the European Union. The EHDS regulation outlines suitable methods for the use of electronic health data and lays down rules for electronic health record systems ('EHR systems').

The definition of an EHR system according to the Regulation is;
"*any system whereby the software, or a combination of the hardware and the software of that system,* ***allows personal electronic health data*** *that belong to the* ***priority categories*** *of personal electronic health data established under this Regulation to be* ***stored, intermediated, exported, imported, converted, edited or viewed****, and intended by the manufacturer to be* ***used by healthcare providers when providing patient care*** *or by patients when accessing their electronic health data.*"

The priority categories are specified in Article 14(1) of the Regulation, and their main characteristics are described in Annex I. Manufacturers of IVDs intended to exchange electronic health data with EHR systems should assess the applicability of Regulation (EU) 2025/327, particularly the requirements set out in Article 27. Manufacturers of IVDs that work with the software components of EHR systems need to comply with the applicable interoperability and logging requirements (Annex II, Section 2). Manufacturers of EHR systems are subject to additional requirements, including the preparation of technical documentation, the drawing up of an EU declaration of conformity, and obligations relating to corrective actions. Furthermore, when interoperability is claimed, the provisions on common specifications for EHR systems should also apply. The EU Commission is required to adopt these common specifications by 26 March 2027.

The key dates surrounding the EHDS *include;*
26 March 2025 - Entered into force
26 March 2027 – Date of Implementation
26 March 2031 - EHDS requirements begin to apply to the priority electronic health data categories (per Article 14 these categories include medical imaging or medical examination data including laboratory and other diagnostic results and reports)

Where interoperability between an IVD or its software and an Electronic Health Record (EHR) system is claimed under Regulation (EU) 2025/327, manufacturers need to demonstrate compliance with the applicable requirements of both the IVDR and the EHDS. The CE marking of conformity under the EHDS is outlined in Article 41, and there are no notified bodies involved. The conformity assessment procedure under the IVDR remains unchanged.

Packaging/Packaging Waste Regulation EU 2025/40

In addition to product-specific regulatory requirements, IVD manufacturers may also need to consider legislation governing the environmental impact of packaging and packaging waste throughout the product lifecycle. Packaging/packaging waste regulation (EU) 2025/40 (PPWR) was published in the Official Journal on 22 January 2025 and lays down rules for extended producer responsibility. It promotes packaging waste prevention by means such as re-use and reduction of packaging and applies to all packaging and packaging waste (Article 2(1)). Certain PPWR requirements are reduced or modified for contact-sensitive IVD packaging; however, IVD packaging remains within the scope of the PPWR and manufacturers should assess compliance with all applicable provisions.

The key dates surrounding the PPWR include:
11 February 2025 – Entry into force
12 August 2026 – Date of Application

Regarding recyclable packaging, exemptions apply for immediate packaging in direct contact with medical devices or IVDs, and outer packaging where it is required to preserve product quality (Article 6 (11) (b) (c)). The PPWR refers to packaging that is intended to be used for products falling within the scope of the IVDR as 'contact-sensitive packaging'. Article 7 outlines the minimum recycled content for packaging; however, contact-sensitive plastic packaging for medical and in vitro diagnostic devices is exempt from this requirement (Article 7(4)). The scope of any exemptions may be reviewed in the future in accordance with the provisions of the PPWR (Article 7(11)). The IVDR contains the primary requirements for IVDs; however, IVD packaging should meet both IVDR and PPWR rules and manufacturers are expected to comply with all applicable EU legislation relevant to their products, including horizontal legislation such as the PPWR. Furthermore, any packaging changes made by a manufacturer should be fully evaluated to ensure continued compliance with both legislative frameworks. In June 2026, the European Commission published an official Guidance Document for Regulation (EU) 2025/40 and additional guidelines are expected over the coming years.

Conclusions

Horizontal legislation applies across multiple sectors, and many, some of which are outlined in this white paper, need to be considered by IVD manufacturers. In addition to meeting the requirements of the IVDR, manufacturers must remain aware of a broad range of EU legislation that may affect the design and development of their devices.

The regulatory landscape continues to evolve, with new requirements emerging through legislation such as the Artificial Intelligence Act (AIA), the European Health Data Space (EHDS) Regulation and the Packaging and Packaging Waste Regulation (PPWR). As requirements such as these develop, manufacturers should take a proactive approach and assess the potential impact of new obligations on their products and conformity assessment strategies.

Compliance with horizontal legislation should be viewed by manufacturers as part of a holistic regulatory framework that supports the safety and performance of IVDs throughout their lifecycle. Early identification and evaluation of applicable horizontal legislation can help minimize compliance risks and support continued conformity with applicable EU regulatory requirements.

The European Commission provides a range of resources, guidance documents and legislative updates that can assist manufacturers in monitoring and implementing relevant horizontal legislation. The following sources may be useful:

- Information on AI Act: AI Act | Shaping Europe's digital future
- Digital Omnibus on AI Regulation: Regulation (EU) 2026/1744 of the European Parliament and of the Council of 8 July 2026 amending Regulations (EU) 2024/1689, (EU) 2018/1139 and (EU) 2023/1230 as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI)
- AI Board: AI Board | Shaping Europe's digital future
- AI Act single information platform: AI Act Single Information Platform | AI Act Service Desk
- Questions and answers on the European Biotech Act; QANDA_25_3079_EN.pdf
- European Health Data Space Regulation (EU) 2025/327 Regulation - EU - 2025/327 - EN - EUR-Lex
- Packaging/packaging waste regulation EU 2025/40 Regulation - EU - 2025/40 - EN - PPWR - EUR-Lex
- Guidance Document for Regulation (EU) 2025/40 EUR-Lex - C(2026)3702 - EN - EUR-Lex

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