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Digital Health

Mid-year Review 2025

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Welcome

Digital Health Mid-year Review 2025

The EU digital health regulatory landscape has continued to evolve throughout 2025 as stakeholders seek to implement sophisticated regulations aimed at protecting consumers, while safeguarding innovation and growth in the region.

This has proven to be demanding for businesses trying to navigate ever-changing market conditions while also staying abreast of their regulatory obligations.

In this edition of our Digital Health Review, we highlight some of the key developments so far in 2025, such as:

- New international principles for the safe development of AI medical devices
- Recent analyses of the scope of telemedicine services by the European Court of Justice
- New EU product liability rules covering digital health products, and
- The European Health Data Space and its impact for digital health stakeholders

Our Digital Health Review serves as a trusted resource for keeping up with the latest trends, regulatory updates, and emerging policies in EU digital health. Whether you are a healthcare professional, a technology developer, an investor, or a policymaker, we aim to provide you with the actionable insights to help you navigate regulatory challenges and seize the opportunities in this rapidly evolving sector. We hope you enjoy this edition of the Review.

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Michaela is Head of Life Sciences. She advises clients in the pharmaceutical, healthcare, medical device, digital health, cosmetic, video game, software and general consumer products sectors on various regulatory compliance matters. She has particular expertise in wearables and software medical devices. She frequently advises clients on the applicable regulatory framework, regulatory approval, labelling, packaging, traceability, safety and liability issues. Michaela also represents manufacturers in product liability claims and enforcement action by regulators.

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Jamie is a Partner in the Life Sciences team. He advises a variety of international clients in the life sciences, consumer products and technology sectors on the application of domestic and EU regulatory regimes throughout the life cycles of their products. He regularly advises clients on matters such as the applicability of regulatory frameworks, regulatory approval, labelling, packaging, traceability, recalls, safety and liability.

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Brian is Head of the Artificial Intelligence (AI) team. Brian re-joined us in January of 2023, having spent time in-house as Chief Intellectual Property counsel with an Irish AI fintech start-up. During that time, he gained significant experience in operationalising and commercialising AI platforms and solutions. He led AI invention harvesting and international patent and trademark portfolio filing projects. He was also part of a team that conceived and developed a bespoke inhouse software invention and R&D tagging tool that has applications in the trade secret space also.

Contents

Latest Digital Health Sector Insights from our Team

01

New IMDRF Guidance on AI Medical Device Development

Principles for safe AI devices

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The International Medical Device Regulators Forum (IMDRF) has recently published key concepts and principles for the development of high-quality medical devices which incorporate AI. The guidance further highlights the need for a robust framework that sets out the 10 guiding principles, which outline what should be included to support the responsible development of AI and machine learning-enabled medical devices. These guiding principles set out clearly how developers should begin to develop AI and machine-learning medical devices. They are a useful tool for developers to use as guidance to ensure devices which are being placed on the market are safe, effective and of high-quality.

The IMDRF has published guidance titled 'Good Machine Learning Practice for Medical Device Development: Guiding Principles'. The guidance reviews key concepts and principles for the promotion and development of safe, effective and high-quality medical devices that incorporate the use of AI. The IMDRF sets out 10 guiding principles for the responsible development of AI and machine learning (ML) enabled medical devices that highlight the need for a robust and well defined framework for the design, development, testing, deployment, and monitoring of medical devices powered by AI and ML. These are:

1. **Multi-Disciplinary Expertise:** Development teams must have a deep understanding of clinical workflows, patient risks, and the integration of the AI/ML device. This doesn't just include the technical aspects of the model, it also encompasses clinical relevance and usability.

2. **Good Software Engineering & Security:** Robust software engineering principles are foundational. This includes rigorous data quality assurance, strong data management, adequate cybersecurity measures and meticulous documentation of design and risk management decisions. The IMDRF highlights the need to '*ensure data authenticity and integrity*.'

3. **Representative Data:** Data used for training and testing must accurately reflect the intended patient population.

4. **Independent Training & Test Sets:** Training and test datasets must be strictly independent of each other to prevent overfitting, and to ensure realistic evaluation. All sources of dependence must be carefully considered and addressed.

5. **Best Available Reference Datasets:** The chosen reference data should be based on the best available methods to ensure the clinical relevance and well-characterisation of data collected. The limitations of the data must be understood.

6. **Tailored Model Design:** The model design should be appropriate for the available data and should address known risks such as overfitting or security concerns. The design must support mitigation of risks and allow for the safe and effective use of the device.

7. **Human-AI Team Performance:** For models with human interaction, the focus should be on the performance of the entire Human-AI team, not just the AI model in isolation. Human factors and model interpretability are key considerations.
8. **Clinically Relevant Testing:** Testing must simulate real-world clinical conditions with appropriately designed test plans independent of the training datasets. Factors such as the patient population, clinical environment, and interaction of the Human-AI team should be considered.
9. **Clear User Information:** Users must have ready access to clear information about the device, its performance characteristics, the limitations of the model, and how to raise concerns. This information must be appropriately tailored to different user groups like healthcare providers and patients.
10. **Ongoing Monitoring & Retraining:** Models need continuous monitoring in real-world use to ensure performance and safety. Where retraining is implemented, robust controls are needed to manage risks like overfitting, unintended bias, and performance degradation due to dataset drift.

Conclusion

In this guidance, the IMDRF has highlighted the need for a rigorous and iterative approach to software device development. This approach should encompass diverse expertise, strong software engineering practices, and careful attention to data quality, bias, and clinical relevance.

As a further development, the Medical Device Coordination Group has also now published guidance on the interplay between the Medical Devices Regulation, In Vitro Diagnostic Medical Devices Regulation and the EU AI Act.

Read the IMDRF guidance online.

As a further development, the Medical Device Coordination Group has also now published guidance on the interplay between the Medical Devices Regulation, In Vitro Diagnostic Medical Devices Regulation and the EU AI Act.

02

Defining Borders in Borderless Care

Telemedicine and the EU's free movement principles

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Telemedicine is redefining the delivery of healthcare by enabling remote consultations, treatment and patient monitoring.

As these services are still relatively new and undefined, guidance from the European Court of Justice (ECJ) on the scope of what constitutes 'telemedicine' under EU law is arguably overdue.

A recent Opinion of the Advocate General (AG), Athanasios Rantos, provides greater clarity on this issue.

Background

The AG Opinion in Case C-115/24 Österreichische Zahnärztekammer, delivered on 8 May 2025, originates from a request for a preliminary ruling from the Austrian Supreme Court. The request relates to a dispute between the Österreichische Zahnärztekammer (ÖZ), the Austrian Dental Chamber, and UJ, an Austrian dentist. UJ was contracted by Deutsche Zahnklinik GmbH (DZK), a German-based provider of remote aesthetic dental treatments, to perform dental examinations on its behalf in Austria.

The ÖZ applied for an interim injunction prohibiting UJ from carrying out dental activities in Austria on behalf of foreign companies that do not hold certain professional licences required under Austrian law.

The Opinion considers three central questions:

1. Is telemedicine limited solely to digital services, or can telemedicine include physical elements, for example exams and treatment?
2. Is a foreign provider of telemedicine services required to comply with the professional rules of the host State?
3. Are certain Austrian licensing requirements in dentistry consistent with the freedom to provide services under the Treaty of the Functioning of the European Union (TFEU)?

1. Telemedicine: digital or hybrid care?

To determine the scope of telemedicine services, the AG considered the application of Directive 2011/24, which sets out patients' rights in cross-border healthcare. As a telemedicine service is not defined within the Directive, the AG's interpretation of this concept was informed by a 2008 Commission Communication.

This Communication defines 'telemedicine' as:

'the remote provision of healthcare services by means of [ICT] in situations where the healthcare professional and the patient … are not physically located in the same place. It requires the secure transmission of medical data and information by text, sound, image or other means necessary for the prevention and diagnosis, treatment and follow-up of patients.'

On this basis, the AG was satisfied that only services that are entirely remote and ICT-based will fall within the scope of the meaning of the term 'telemedicine'. While the services provided by UJ could not therefore be classified as telemedicine, services provided by DZK may be considered telemedicine if they can be separated from the physical aspects of the treatment.

2. Do foreign providers of telemedicine services need to comply with host State rules?

The EU's legal framework on the recognition of professional qualifications, specifically Article 5(3) of Directive 2005/36, provides that a foreign service provider must follow local rules when moving to a host country. This prompted the question as to whether DZK could be considered to have 'moved' into Austria by providing telemedicine services through its contracted relationship with UJ. The AG emphasised that Article 5(3) is triggered only by physical movement into the host State. As DZK operated from Germany, the remote provision of its services should not therefore equate to movement into Austria, as required under the EU's framework.

The AG also considered whether telemedicine services fall within scope of the EU's E-Commerce Directive[1]. To do so, these services would have to qualify as information society services, which are regulated by the service provider's own Member State. In the Opinion, it was accepted that telemedicine services would meet this definition in instances where the services are provided for payment, and are performed remotely and electronically.

Applying this analysis would mean that a foreign provider of telemedicine services would not be obliged to comply with laws of a host State unless there is physical cross-border movement, or the services involve non-ICT aspects. In this case, DZK provided services that combined remote treatment planning carried out remotely in Germany with face-to-face dental care delivered in Austria. The remote elements of DZK's services would therefore fall within the scope of both Directive 2005/36 and the E-Commerce Directive, and as a result, would be regulated by German law alone. However, the activities of UJ could be regulated under Austrian Law, as these services are performed in-person in Austria, and cannot be considered an ISS.

3. Telemedicine and the freedom of establishment

In order to address the third question, and in line with the analysis of the first two questions, the AG reformulated this part of the preliminary reference to focus on compatibility with the principle of freedom of establishment provided for in Article 49 TFEU.

In the AG's view, the compatibility of Austrian Law with the principle of freedom of establishment in this case depends on whether DZK is considered to be established in Austria, or whether it merely provides cross-border services.

The Opinion discussed the implications of both as follows:

- If the national court finds that DZK is not established in Austria, and is instead considered a cross-border service provider, these services will fall within the scope of what can be considered as telemedicine services. In this case, Austrian law would not apply to these services, and no conflict arises with the EU's principles of free movement.
- However, if the national court finds that DZK is established in Austria through its contractual relationship with UJ, the effect of the national law must be analysed in light of freedom of establishment under Article 49 TFEU. Under this principle, any national measure which obstructs establishment could be treated as a restriction on establishment, even where this is non-discriminatory.

1. Directive 2000/31

A foreign provider of telemedicine services would not be obliged to comply with laws of a host State unless there is physical cross-border movement, or the services involve non-ICT aspects.

These restrictions may be justified in certain circumstances, where they can be justified as an appropriate and proportionate means of securing a competing public interest.

Judgment awaited

The judgment of the ECJ in this case is awaited. In the meantime, the AG's Opinion does set out one reasoned and logical interpretation of the applicable EU law that the Court may ultimately adopt, noting that AG Opinions, although non-binding, are viewed as influential in the Court's reasoning, and are often followed in sum or in part.

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03

Product Liability in Life Sciences

Key features of the revised PLD

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The EU's revised Product Liability Directive (Revised PLD) represents a significant shift in the EU's product liability landscape. With its expanded scope, modernised definitions, and evidential reforms, the Revised PLD is particularly relevant to the Life Sciences sector.

In this article, we explore the key features and implications for manufacturers, developers, and stakeholders in the sector.

The European Commission's reform agenda

Historically, the concepts of product safety and liability used to be confined to 'bricks and mortar' products. Now, the term 'products' encompasses much wider concepts, including:

- Software
- AI systems
- Mobile apps
- Hardware products with integrated software, and
- IoT-connected products

To address these developments, the various product safety and liability legislative frameworks have recently undergone significant reform at the European Union level.

As part of this reform, the EU has adopted a range of complementary product safety and liability measures designed to meet the challenges of the digital age and the deployment of artificial intelligence (AI).

A cornerstone of this package of measures is the EU's Artificial Intelligence Act 2024[1] (AI Act). It entered into force on 1 August 2024. The AI Act seeks to foster trustworthy AI through compliance with regulatory requirements and managing the relationship between providers and regulators. The Revised Product Liability Directive[2] is another central component of this reform agenda and works alongside the AI Act. It has adapted the strict liability regime applicable to producer liability for defective products[3]. The changes aim to address liability issues arising from digital technologies and AI, circular economy business models, and global value chains.

Originally intended to operate in tandem with the now-shelved proposal for an EU Artificial Intelligence Liability Directive (AILD), the Revised PLD now assumes a more prominent role. In addition to the AI Act and the Revised PLD, other complementary legislative measures include a revision of horizontal product safety rules (the General Product Safety Regulation[4] or GPSR) and sectoral product safety legislation.

1. Regulation (EU) 2024/1689
2. (EU) 2024/2853
3. Product Liability Directive 85/374/EEC
4. (EU) 2023/988

For the Life Sciences sector, there have also been significant recent sectoral product safety legislative reforms, including the EU Medical Device Regulation[5] (MDR) and the EU In Vitro Diagnostic Medical Devices Regulation[6] (IVDR). Similarly, expected reform is underway for medicines with the European Commission's proposal for a new Directive[7] and a new Regulation[8] to revise and replace the EU's current general pharmaceutical legislation (the EU Pharmaceutical Package).

These significant reforms underscore the EU's holistic approach to safety and liability, recognising that they are two sides of the same coin. While legislation like the AI Act and the GPSR aim to prevent harm through risk management and regulatory compliance, the Revised PLD ensures that where these measures fail, effective remedies and redress are available to consumers. In this way, the Revised PLD plays a critical role in reinforcing consumer trust and legal certainty in the use of digital technologies across the internal market.

One of the key functions of the Revised PLD is to close existing gaps in liability. It does this by extending strict liability to cover software and digital products. It also clarifies the definition of "defect" in the context of software and AI. In addition, it enhances access to evidence and eases the burden of proof for claimants in certain circumstances. These changes aim to ensure that injured parties can obtain redress in situations where software and AI systems cause harm, even where fault is difficult to establish.

For those operating in the Life Sciences sector, particularly manufacturers and providers of innovative technologies, this reform marks a critical shift. Given how this reform may significantly affect their liability exposure, manufacturers and developers in the Life Sciences sector should familiarise themselves with key features of the Revised PLD.

Product Liability Directive

The Product Liability Directive[9] (PLD) established an EU-wide system of strict liability for product liability claims. This means that there is no requirement for a claimant to prove that a defendant producer was negligent or at fault.

The PLD provides that a producer is liable for damage caused wholly or partly by a defect in their product. A product is considered 'defective' if it fails to provide the safety that a person is entitled to expect.

This assessment is an objective one. It is carried out with regard to what the public is generally entitled to expect, and with reference to a range of circumstances, including:

- The presentation of the product
- Its reasonably expected uses, and
- The time it was put into circulation

The concept of '*putting a product into circulation*' isn't explicitly defined in the PLD. However, case law from the Court of Justice of the EU (CJEU) clarifies that a product is put into circulation when the product leaves the production process and enters a marketing process in the form it is offered to consumers. This includes products like medical devices that are not explicitly placed '*on the market*' prior to their first use.

Under the PLD, the burden of proof is on the claimant to prove the damage, the defect, and the causal relationship between the two. In Ireland, claimants commonly bring a product liability claim in tandem with a claim in negligence and/or in contract.

Several statutory defences are available to producers under the PLD and, if successfully invoked, a defendant can avoid liability for a defective product. These defences include:

- That the defect did not exist at the time the product was put into circulation, or that the defect came into being afterwards
- The 'state of the art' defence – ie that the defect was not discoverable due to the state of scientific and technical knowledge at the time the product was put into circulation

It is also important to be aware that there is a limitation period of three years to bring a claim under the PLD. This is subject to a longstop provision where a claimant's right of action will be extinguished 10 years after the product's date of circulation, if they haven't brought a claim in that time.

5. Regulation (EU) 2017/745
6. Regulation (EU) 2017/746
7. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0192
8. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0193
9. 85/374/EEC

Revised Product Liability Directive

The PLD was adopted in 1985. In the 40 years since, we have seen a dramatic change in the types of Life Sciences products on the market due to developments in technologies like AI and machine learning. There has also been an increase in products imported directly from outside the EU, and the emergence of new actors in the supply chain, like online marketplaces. As a result, the European Commission proposed a reform of the PLD to address these challenges.

The Revised PLD was adopted by the European Parliament in March 2024. It was then formally adopted by the European Council in October 2024. The Revised PLD entered into force on 8 December 2024 and applies to products placed on the market 24 months after this date.

There will be a lengthy transitional period during which product liability claims may be brought under either the PLD or the Revised PLD, depending on which regime is applicable. Member States have until December 2026 to transpose the Revised PLD into their national legislation.

The Revised PLD is designed to ensure that the EU's strict product liability regime remains fit for purpose. This is particularly important in an era of increasingly complex and software-driven technologies, including AI systems.

The Life Sciences sector is particularly affected, as the use of AI and software in products like digital health tools and medical devices may now lead to greater liability risks for manufacturers and developers under the Revised PLD.

This liability exposure for harm caused by a defective product may continue to arise in the traditional sense, or where the defect stems from complex or autonomous behaviour of AI-driven systems. As a result, relevant stakeholders in the Life Sciences sector should familiarise themselves with the noteworthy reforms and features under the Revised PLD, including:

- **Product:** Under the PLD, the general consensus was that liability applied only to software embedded in tangible products, meaning standalone or digital-only software typically fell outside the scope of the regime.

  This uncertainty has been categorically addressed by the Revised PLD, which expands the definition of a 'product' to expressly include software. This revised definition includes both standalone software and digital manufacturing files. It makes clear that software is a product, irrespective of the mode of its supply or usage and whether it is stored on a device or accessed through a communication network, cloud technologies or supplied through a software-as-a-service model.

  While the term 'software' is not defined in the Revised PLD, the recitals make clear that it applies to software of all kinds, including operating systems, firmware, computer programmes, applications, and AI systems.

  The Revised PLD includes several limited exceptions. One exception concerns pure information, such as software source code. Another applies to free and open-source software that is not developed or used as part of a commercial activity.

  This wider definition of what is considered a 'product' will expand the scope of liability for software products beyond those incorporated into a tangible product, as required under the PLD. As a result, it will have far-reaching consequences for software developers in the Life Sciences industry. This means that medical apps, AI-based diagnostic tools, and software-dependent medical devices could all give rise to claims under the Revised PLD.

- **Defectiveness:** New factors have been added into the Revised PLD for determining whether a product is defective. These include a device's cybersecurity vulnerabilities, self-learning functionality, and interconnectedness. For example, this could apply to a smart insulin pump that communicates wirelessly with a continuous glucose monitor and a smartphone app.

- **Defendants:** The Revised PLD expands the pool of 'economic operators' that can be held liable for a defective product. In addition to manufacturers, importers, and in some cases, distributors of a product or a component of a product, the Revised PLD also includes:

  - The providers of related services[10]
  - Authorised representatives
  - Fulfilment service providers
  - Third parties making substantial modifications to products already placed on the market, and
  - Online platforms in certain circumstances. This occurs when they play more than a mere intermediary role in the sale of products between traders and consumers

  The Revised PLD's expanded definition of an 'economic operator' is designed to ensure that there is always an EU-based representative liable for damage caused by a defective product. This could be the designated authorised representative, importer, or fulfilment service provider.

10. A digital service that is integrated into or inter-connected with a product without which a product would be incapable of performing some or all of its functions.

The inclusion of related service providers is particularly relevant to the Life Sciences sector. This is because many medical devices now use and rely on cloud-based platforms, AI-driven analytics, and app integrations to deliver remote patient monitoring in real time. The Revised PLD includes as an example of a related service *'a health monitoring service that relies on a physical product's sensors to track the user's physical activity or health metrics'*. As a result, related service providers that may previously have considered themselves outside the scope of strict product liability laws now have a potential liability exposure if their service contributes to a product's defect and ultimately to any harm caused to consumers.

Damage: The definition of 'damage' has been extended under the Revised PLD. It now brings in scope medically recognised damage to psychological health and damage from the destruction or corruption of data not used for professional purposes. Now, a product may be considered defective even in the absence of a physical injury, for example where using a defective product causes the claimant severe stress or anxiety.

- **Scope of liability:** One of the statutory defences under the PLD allows the original manufacturer to avoid liability for defects that emerge after the product is put into circulation.

Under the Revised PLD, the scope of liability may be extended to the time after a product was put into circulation where it is still under the manufacturer's control. For example, where a product has been substantially modified through software updates.

This is particularly significant for connected devices, where the hardware manufacturer retains the ability to supply software updates or upgrades to the hardware by itself or via a third party. As a result of these new provisions, manufacturers of medical device products with digital elements may be liable for damage arising from changes to those digital elements that occur after the physical product is placed on the market.

- **Discovery:** The Revised PLD introduces a discovery model for statutory product liability claims. Under this model, a claimant who has presented facts and evidence sufficient to support a plausible claim can seek an order from a defendant to disclose relevant evidence at its disposal. While this is a significant development for civil law EU countries, it would have minimal effect in Ireland as we already have discovery in civil proceedings. In addition, the Revised PLD expressly acknowledges that it does not affect national rules on pre-trial disclosure of evidence.

The Revised PLD provides that where a defendant fails to disclose relevant evidence in response to a request, the product in question will be presumed to be defective.

- **Rebuttable presumptions:** The Revised PLD contains rebuttable presumptions on defectiveness and causation designed to ease the burden of proof for claimants. For example, in cases where a product is technically or scientifically complex, it may be excessively difficult for a claimant to prove the defect or the causal link between the damage and the defect. In these cases, a court may presume the defectiveness of the product or the causal link, if the claimant has met certain conditions.

The Recitals to the Revised PLD offer guidance on how national courts should assess technical or scientific complexity on a case-by-case basis, taking into account a range of factors. These include the complex nature of the product itself, with innovative medical devices expressly cited as an example of such a complex product.

Reference is also made to other factors including the complex nature of the underlying technology, such as machine learning, and the complex nature of the information and data to be analysed by the claimant.

The Recitals also highlight the potential complexity of establishing causation. For example, proving a link between a pharmaceutical or food product and the onset of a health condition or demonstrating a connection that requires an understanding of the inner workings of an AI system.

"The inclusion of related service providers is particularly relevant to the Life Sciences sector. This is because many medical devices now use and rely on cloud-based platforms, AI-driven analytics, and app integrations to deliver remote patient monitoring in real time.

The Recitals to the Revised PLD also offer guidance about how an assessment of excessive difficulties should be carried out by national courts on a case-by-case basis. While a claimant should provide arguments to demonstrate excessive difficulties, proof of these difficulties should not be required. The Recitals to the Revised PLD give an example of a claim concerning an AI system and note that a claimant should not be required to explain an AI system's specific characteristics or how those characteristics make it harder to establish a causal link.

- **Limitation provisions:** The Revised PLD contains two modifications to the pre-existing ten-year 'longstop provision' or 'expiry period'[11]:
  - First, an extension to 25 years in certain cases involving latent personal injuries, unless the injured person has, in the meantime, initiated proceedings against a potentially liable economic operator.
  - Second, where a product has been substantially modified, the calculation of time runs from the date that the substantially modified product has been placed on the market or put into service.
- **Collective redress:** Businesses may not only be liable for harm caused to individual consumers by defective products. They may also be subject to a collective redress action if a product defect impacts the collective interests of a group of consumers/litigants under the Collective Redress Directive[12](CRD).

Artificial Intelligence Liability Directive

As discussed, alongside the revisions to the PLD, the EU also proposed the Artificial Intelligence Liability Directive (AILD) to revise and harmonise Member States' non-contractual, fault-based rules concerning claims for injuries caused by AI systems. In Ireland, this would have impacted on claims in negligence under tort law.

While the Revised PLD provides for a harmonised application of strict liability rules across the EU, the more 'traditional' fault-based rules tend to vary widely across Member States. The AILD sought to address the concern that Member States would apply their national fault-based rules inconsistently to cases about AI systems and models.

The European Commission announced the withdrawal of the AILD from its 2025 Work Programme[13] on 11 February 2025. The reason provided for its withdrawal was that the Commission saw *'no foreseeable agreement'* on the proposal.

The Commission stated that it would assess whether another proposal should be tabled, or another type of approach should be chosen. This may provide an opportunity for stakeholders to express their opinions on what, if any, new proposal or approach should be adopted to specifically address damage caused by AI systems.

> *While a claimant should provide arguments to demonstrate excessive difficulties, proof of these difficulties should not be required.*

11. A claimant's right of action is extinguished upon the expiry of a specified time limit from the date the product was placed on the market or put into service, unless legal proceedings have been initiated against a potentially liable economic operator within that period.
12. 2020/1828
13. https://commission.europa.eu/publications/2025-commission-work-programme-and-annexes_en

Conclusion

The extended scope of the Revised PLD reflects the evolution of product liability within the EU and the realities of modern, technologically advanced products. In the absence of the AILD, the AI Act and the Revised PLD will act as a bilateral model for regulating safety and liability. This will lead to greater harmonisation in how AI systems are regulated under EU product safety and liability law.

For the Life Sciences sector, where AI is increasingly integrated into medical devices, diagnostics, and digital health tools, the expanded scope is particularly impactful.

The potential liability exposure of manufacturers and producers is increased by a range of notable features under the Revised PLD including:

- The inclusion of standalone software and AI systems within the definition of a product
- The broader range of economic operators who may be held liable for damage caused by a defective product, and
- The introduction of rebuttable presumptions of defectiveness and causation

As Member States move to transpose the Revised PLD into their national legislation by the December 2026 deadline, companies in the Life Sciences sector should assess these reforms. In addition, they should consider how these reforms may affect their product development, risk management, and litigation strategies moving forward.

For the Life Sciences sector, where AI is increasingly integrated into medical devices, diagnostics, and digital health tools, the expanded scope is particularly impactful.

04

A Major Step Forward in Digital Healthcare

New European Health Data Space Regulation adopted

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The EU Council has adopted the European Health Data Space Regulation, marking a major advance in digital healthcare. We examine how this framework, approved in January 2025, establishes new standards for accessing and sharing health data across the EU, benefiting patients, healthcare providers, researchers and industry.

The European Union has taken a significant step forward in digital healthcare with the adoption of the European Health Data Space Regulation (EHDS) on 21 January 2025. The EHDS is expected to come into force in March 2025 and will gradually roll out over the coming years. This landmark legislation aims to transform how health data is accessed, shared, and utilised across the EU. It promises benefits for patients, healthcare professionals, researchers, and industry stakeholders.

Patient rights and control

Under the EHDS, EU citizens gain unprecedented control over their health data. Patients will have immediate access to their electronic health records, free of charge. They will also be able to share this information with healthcare providers across national borders. The EHDS enables patients to add information to their records, correct errors, and maintain oversight of who accesses their health data, while ensuring their privacy through robust security measures.

For healthcare delivery, ie “primary use”, patients will be able to restrict access to use of their health data. Member States will also have the option to provide for a full opt-out, enabling people who do not want to take part in the exchanges under the EHDS to revert to the previous method of exchanging medical records.

Patients will also have a right to opt-out specifically from their health records being used for health research, policy-making and re-use, ie “secondary use”, in an easy and reversible way. However, for certain important public interests and under strict safeguards, including transparency requirements, the opt out will not apply.

Healthcare professional benefits

For healthcare professionals, the EHDS aims to streamline access to patient records across different systems and borders. This improved interoperability aims to enhance care quality by providing comprehensive patient histories and eliminating redundant tests and procedures. This aims to allow faster access to critical health information, particularly valuable in emergency situations or when treating patients from other EU Member States.

Secondary use framework

The EHDS creates a structured environment for health data research while maintaining strict privacy protections. Researchers, industry professionals and public institutions will be able to access larger pools of high-quality health data. Additionally, they will be able to know what data is available, where, and of what quality.

However, restrictions will apply to the use of this data:

- Data must be processed in secure environments
- Only anonymised or pseudonymised data can be accessed
- Use is restricted to specific purposes benefiting society
- Individual privacy protections remain paramount
- Technical requirements and data storage

The EHDS mandates specific requirements for electronic health record systems. Healthcare providers and manufacturers must implement harmonised software components for interoperability, logging and security. This requirement extends across the healthcare technology spectrum, from hospital record systems to imaging devices such as ultrasound and MRI scanners.

Implementation and governance

The EHDS is expected to come into force in March 2025 and will roll out in phases. Between 2025 and 2027, the focus will be on developing technical specifications through secondary legislation. From 2027 to 2029, Member States will establish data hubs and connect to EU-wide infrastructure. Full implementation is targeted for 2029, supported by joint pilot projects between the European Commission and Member States. Provisions relating to clinical trials and human genetic data are set to apply from 2031.

Oversight will be maintained through a new European Health Data Space Board, with digital health authorities in each Member State and dedicated bodies managing data access requests.

Conclusion

For the life sciences and healthcare industry, the EHDS presents both opportunities and obligations. The EHDS represents a fundamental shift in how health data is managed and utilised across the EU. Organisations will benefit from standardised access to health data for research and development purposes, while also facing new requirements for data sharing, interoperability and security. The EHDS is expected to foster innovation in medical devices, digital health applications, and pharmaceutical development.

While the implementation timeline extends several years into the future, organisations are advised to begin preparing to capitalise on the opportunities presented by EHDS now while also preparing for compliance with these new requirements well in advance of the applicable dates.

For the Life Sciences and healthcare industry, the EHDS presents both opportunities and obligations.

05

Regulation of Medical Devices in the EU and the UK

Recent updates

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The regulatory landscapes within the European Union and the United Kingdom have seen significant changes in the last year.

We provide an overview of the relevant changes introduced in both jurisdictions. We also highlight upcoming legislative developments and outline their potential impact on manufacturers of medical devices and other relevant stakeholders.

European Union's regulatory regime

The EU medical device framework has been subject to significant changes over the last few years. The MDR[1] and the IVDR[2] replaced the previous regulatory framework governing medical devices and in vitro diagnostic devices.

The MDR and the IVDR were implemented to ensure that only safe and effective devices are placed on the EU market, to protect patient safety and public health while at the same time supporting innovation.

Update on transitional provisions

Regulation (EU) 2024/1860 is an amending regulation which modifies the provisions of the MDR and the IVDR. It introduced transitional provisions for certain in vitro diagnostic devices to ensure patient safety and continued availability of devices was adhered to.

This regulation addressed the risk of a potential shortage of availability of in vitro diagnostic devices due to the slower transition from the previous In Vitro Diagnostic Directive[3] (IVDD) to the IVDR.

The amending regulation extends the IVDR transition timelines while also recognising previously issued IVDD certificates as valid during the longer transition timelines.

This approach permits manufacturers to continue placing devices on the market which are IVDD compliant, while transitioning their devices to the IVDR.

The regulation also added a new Article 10a which places additional obligations on manufacturers in instances where they anticipate an interruption or a discontinuation of supply of a device.

The MDR Current Transitional Provisions designate the following deadlines:

- 26 May 2026 for custom-made Class III implantable devices.
- 31 December 2027 for Class III and Class IIb implantable devices.
- 31 December 2028 for other Class IIb, Class IIa, Class I devices, i.e. sterile or with measuring function, and Class I devices, i.e. not sterile and without measuring function.
- Devices for which notified body involvement was not required under the Directives but is required under the MDR can be placed on the market until 31 December 2028. This deadline applies provided they continue to comply with the applicable Directives and there are no significant changes in design or intended purpose.

1. Regulation (EU) 2017/745
2. Regulation (EU) 2017/746
3. 98/79/EC

The IVDR Current Transitional Provisions outline the following key dates:

- The IVDR is applicable since 26 May 2022, however transitional periods were introduced to allow manufacturers time to adapt to the new requirements
- 31 December 2027 for Class D devices, i.e. highest-risk
- 31 December 2028 for Class C devices
- 31 December 2029 for Class B devices and Class A devices placed on the market in sterile condition

EUDAMED

The amending regulation further provides that the European medical devices database (EUDAMED) will be rolled out gradually. This gradual implementation of the database will be crucial for tracking and managing medical device information. The functionality of EUDAMED has not yet been fully verified.

The European Commission released a EUDAMED roadmap setting out the gradual roll out of the database. Each module on EUDAMED will undergo independent audits to determine whether it can be deemed functional. A notification will then be published if the module is functional and meets the relevant requirements.

The EUDAMED Modules and Status Roadmap outlines an indicative timeline, as follows:

- Actor Registration: available since December 2020
- UDI/Device Registration: available since October 2021
- Notified Bodies and Certificates: available since October 2021, however some functionalities remain under development
- Vigilance and Post-Market Surveillance: under development, expected to be completed and mandatory around mid-2025
- Market Surveillance: under development, expected to be completed and mandatory around mid-2025
- Clinical Investigations and Performance Studies: under development, not expected to be completed before Q3 2026

EC evaluation

The European Commission recently initiated a targeted evaluation regarding the provisions of the MDR and the IVDR. This evaluation was open for feedback until 21 March 2025.

The evaluation aimed to assess the performance of the medical device legislative framework.

Focus was placed on the impact of the legislation on the availability of devices in the EU. This included consideration of 'orphan devices' and devices for small populations, as well as the development of innovative technologies.

The evaluation aimed to help the Commission assess whether the current frameworks:

- Are effective, efficient, and proportionate
- Meet current and emerging needs
- Align with other actions, and
- Have added EU value

The Commission will evaluate the feedback received to identify relevant areas for improvement and alignment with other EU policies. The Commission is planning to adopt the findings of this consultation in Q4 2025. By then, it is aiming to identify any gaps which require strengthening and address issues identified during the transitional period of both Regulations.

Each module on EUDAMED will undergo independent audits to determine whether it can be deemed functional.

United Kingdom's regulatory regime

Following a public consultation on the future of the regulation of medical devices in the UK in June 2022, the Medicines and Healthcare Products Regulatory Agency (MHRA) published the UK government's response. The response outlined the intended regulatory reform and set out the relevant transitional arrangements for CE marked devices placed on the Great Britain market. These were later put in place in 2023.

The MHRA released a roadmap in January 2024 detailing the future regulatory framework for medical devices in the UK. The regulatory roadmap sets out:

- The relevant steps and timelines for implementing a new regulatory framework for medical devices in the UK
- A route to deliver enabling regulations via a series of statutory instruments, and
- A specific focus on new regulations for post-market surveillance (PMS), new regulations for pre-market requirements, policy development and software including artificial intelligence (AI) and digital mental health products

Core elements of the new framework are intended to be put in place this year.

The UK government also put in place legislation in December 2024, 'The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024'. This new legislation aimed to clarify and strengthen the post-market surveillance requirements for medical devices in use in Great Britain. These measures officially came into force on 16 June 2025. They amend the UK Medical Devices Regulations 2002 (UK MDR) by inserting a new Part 4A on post-market surveillance (PMS) requirements for medical devices.

These updated PMS requirements will include notification requirements for incidents, and stringent preventive and corrective actions which will need to be in place after the device is first approved for the market.

The amended regulations set out the below updated requirements:

- Manufacturers will be mandated to have robust PMS systems including periodic safety reports for medium and high-risk devices.
- Manufacturers must conduct reviews of PMS data to identify any safety trends. There will also be stricter requirements for reporting serious incidents and field safety notices.
- A legal requirement for unique device identifiers (UDIs) will be introduced, ensuring that effective recall and corrective actions can take place promptly and efficiently.
- Manufacturers will be required to have appropriate measures in place to mitigate risks and prevent further incidents. Appropriate field safety corrective actions must be implemented if required.

The MHRA has published a suite of guidance designed to assist medical device manufacturers in understanding and preparing for these new amended PMS requirements. The guidance includes detailed instructions for writing and issuing effective field safety notices.

Comment

The European Commission initiated the targeted evaluation of the MDR and the IVDR earlier than the legally required deadline due to challenges faced during the transitional period of the regulations. Due to these challenges, the transitional periods were extended. It remains to be seen whether the outcome and adoption of the feedback received during the evaluation can address these transitional issues and achieve the regulatory coherence which the regulations set out to accomplish.

The updated UK MDR marks a step forward in ensuring that medical devices used across the region are safe, effective and are continually monitored for any safety or performance issues. The impact of these heightened PMS requirements remains to be seen on medical device manufacturers and stakeholders involved in placing medical devices on the UK market.

It is evident that both jurisdictions are working towards recognising the importance of transparency and public safety. They are also focusing on effective recall mechanisms, enhanced market surveillance measures, and regulatory collaboration to help shape coherent medical device frameworks.

TOP 10

Digital Health recommended reading

01

Team NB: Position Paper on European Artificial Intelligence Regulation V2

02

MedTech Europe: Towards a Revised EU Regulatory Framework for Medical Devices

03

EU Commission: Frequently Asked Questions on the European Health Data Space

04

EMA/HMA: Workplan on 'Data and AI in medicines regulation to 2028'

05

IMDRF Guidance: Good Machine Learning Practice for Medical Device Development - Guiding Principles

06

MDCG 2025-4: Guidance on the safe making available of medical device software (MDSW) apps on online platforms (June 2025)

07

MDCG 2025–6: FAQ on Interplay between the Medical Devices Regulation (MDR) & In vitro Diagnostic Medical Devices Regulation (IVDR) and the Artificial Intelligence Act (AIA) (June 2025)

08

MDCG 2019-11 Rev. 1: Qualification and classification of software - Regulation (EU) 2017/745 and Regulation (EU) 2017/746 (June 2025)

09

MHRA Guidance: Digital Mental Health Technology - Regulation and evaluation for safe and effective products

10

MHRA Guidance (Collection): Medical devices: post-market surveillance

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Events & Webinars

- CPD on Demand: Product Liability in Life Sciences – Recent Reforms
- CPD on Demand: In-House Counsel Masterclass - Recent Developments in IP
- CPD on Demand: Staying Ahead of Cyber Threats for 2025
- CPD on Demand: Employment Law Top Tips - The Future of Work

Publications

- Digital Health Annual Review 2024
- A Major Step Forward in Digital Healthcare

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Mason Hayes & Curran is a business law firm with 124 partners and offices in Dublin, London, New York and San Francisco.

We have significant expertise in product, privacy and commercial law, which are sectors at the forefront of Digital Health law. We help our clients devise practical and commercially driven solutions for products regulated under complex and ever changing EU health and technology regulatory frameworks.

Our approach has been honed through years of experience advising a wide range of clients in diverse sectors.

We offer an in-depth understanding of the Digital Health regulatory landscape, with a strong industry focus. We ensure our clients receive clear explanations of complex issues, robustly defend their interests and devise practical value-adding solutions for them whenever possible.

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