MASON HAYES & CURRAN

Digital Health Annual Review 2024

Introduction

The EU digital health landscape has continued to evolve throughout 2024 as stakeholders seek to implement sophisticated regulations aimed at protecting consumers, while safeguarding innovation and growth in the region. This has proven demanding for businesses trying to navigate everchanging market conditions while also staying abreast of their regulatory obligations. In this edition of our annual Digital Health Review, we highlight some of the key developments in 2024 and offer a look ahead to some developments to come in 2025:

- The General Product Safety Regulation came into effect in December, with an expanded scope extending beyond physical products to now capture software, mobile apps and AI systems. We address these changes and the challenges faced by consumers and digital health businesses alike in this new legislative era
- The EU Batteries Regulation came into operation earlier in 2024 placing more stringent obligations on producers in terms of sustainability, performance, and safety. We provide a detailed overview of the challenges faced by medical device and consumer wearable stakeholders seeking to comply with these new requirements
- The EU Digital Governance Act aims to increase and ease the sharing of data for the benefit of businesses and citizens. We provide insight into the re-use of data, the role of data intermediaries and the subject of data altruism as well as the role of European Data Innovation Board (EDIB) in this area
- The Court of Justice of the European Union considered the interplay of prescription medications and the GDPR in October. In particular, the CJEU offered determinations in relation to what constitutes 'health data' under the GDPR and the question of whether commercial competitors are permitted to bring legal proceedings for GDPR infringements

We hope you enjoy this latest edition of our Annual Digital Health Review.

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Michaela is Head of the Products practice. She advises clients in the pharmaceutical, healthcare, medical device, digital health, cosmetic, video game, software and general consumer product 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.

Jamie is a Partner in the Products practice. 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.

Brian is Head of our 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.

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Navigating the new compliance landscape

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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 Internet of Things (IoT) -connected products.

In recent years, the product safety legislative framework has undergone a significant reform at a European Union level. This reform includes an expansion of the meaning of the term 'product' and the introduction of new rules and regulations to ensure the safety of consumers. This is reflected by the implementation of the EU's General Product Safety Regulation, or 'GPSR'[1], which came into effect in December 2024. At the same time, the EU has proposed the reform of its product liability regime to address liability issues arising from digital technologies and artificial intelligence, circular economy business models and global value chains. In that regard, it proposed the revision of the EU Product Liability Directive (Revised PLD)[2].

As part of our in-depth analysis, we provide an overview of the upcoming changes in this space in the EU and how these proposed reforms will impact businesses and consumers alike. We also set out an overview of the interplay between the Revised PLD and the EU's proposed Artificial Intelligence Liability Directive, or 'AILD'.

Product Liability Directive

The Product Liability Directive (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 by having regard to what the public at large is generally entitled to expect, and by 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 Courts 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.[3]

The burden of proof is on a 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. If successfully invoked, a defendant

[1] EU/2023/988

[2] 85/374/EEC

[3] Case C-127/04 Declan O'Byrne v Sanofi Pasteur MSD Ltd and Sanofi Pasteur SA.

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, is arguably the most invoked. This applies where a defendant can show 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 claims under the PLD. This is subject to a long stop 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.

Why is a Revised PLD necessary?

The PLD was adopted almost 40 years ago in 1985. In that time, we have seen a dramatic change in the types of products on the market through developments in technologies like AI and machine learning.

As a result, the European Commission reviewed the PLD and proposed the reform of the existing product liability rules to meet the challenges presented by these technological advances as well as by:

- Products imported directly from outside the EU
- The emergence of new actors in the supply chain such as online marketplaces
- An increased awareness around environmental sustainability and the circular economy where products can be repaired, reused and refurbished

Incoming changes and features of the Revised PLD

The Revised PLD was adopted by the European Parliament in March 2024. It was then subsequently formally adopted by the European Council in October 2024.

The Revised PLD entered into force on 8 December 2024 and will apply to products placed on the market 24 months after this date.

There will be a protracted transitional period where product liability cases may be brought under the PLD or the Revised PLD depending on which regime is applicable.

There are several noteworthy reforms under the Revised PLD:

- **Product:** The Revised PLD expands the definition of a 'product' to expressly include software, including standalone software and AI systems.
- **Defectiveness:** New factors have been added into the Revised PLD for determining whether a product is defective, including a product's interconnectedness, self-learning functionality, and cybersecurity vulnerabilities.
- **Defendants:** The Revised PLD expands the pool of defendants that can potentially be held liable for damage caused by a defective product ensuring, amongst other things, that there is always an EU-based liable person for products bought from manufacturers who are based outside the EU.
- **Circular economy:** Where a product is upgraded or repaired outside the manufacturer's control, the company or person who modified the product should be held liable.
- **Damage:** The definition of 'damage' has been extended under the Revised PLD. It now brings in scope medically recognised damage including psychological health and damage from the destruction or corruption of data not used for professional purposes.

- **Scope of liability**: One of the previous statutory defences 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.
- **Products bought from non-EU manufacturers:** To ensure that consumers are compensated for damages caused by products manufactured outside of the EU, the importer or the EU-based representative of the foreign manufacturer can be held liable for damages.
- **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 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.
- **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[4] (CRD).

Scope of the Revised PLD

The Revised PLD explicitly applies to software, including standalone software, AI systems, digital manufacturing files, and related services. It also covers cases where an integrated digital service is necessary for a product to function, such as a car GPS system. 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.

The Revised PLD also broadens the pool of economic operators that may be potentially liable for a defective product.

In addition to manufacturers, importers and, in some cases, distributors of a product or component of a product, the Revised PLD also includes:

- The providers of related services
- 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.

[4] 2020/1828

EU Artificial Intelligence Act

The EU Artificial Intelligence Act 2024 (AI Act) is the world's first comprehensive piece of AI law.

The AI Act prioritises trustworthy AI by ensuring compliance with regulatory requirements and managing the relationship between providers and regulators. In contrast, the Revised PLD and the Artificial Intelligence Liability Directive (AILD) focus on addressing harm caused. The AI Act entered into force on 1 August 2024 with staggered implementation and is fully applicable 36 months after 2 August 2024.

High-risk AI software systems must be compliant by 2 August 2026, subject to a legacy provision. Other products, such as AI-enabled medical devices, lifts, and toys, will have additional time to meet their regulatory requirements. The applicable obligations will not take effect until 36 months after the Act enters into force, on 2 August 2027.

Core concepts of the AI Act and applicability

The AI Act adopts a risk-based approach to the regulation of AI systems. It seeks to regulate them by imposing a range of obligations on providers and deployers of those AI systems depending on the risk categorisation of the AI system. These obligations include requirements related to transparency, control and risk management, training and support and recordkeeping. The aim of the AI Act is to foster trustworthy AI in Europe and beyond, by ensuring that risks of powerful and impactful AI systems are addressed.

The AI Act has broad territorial application and is applicable to:

- Providers and manufacturers of AI systems
- Deployers, or users, of AI systems
- Importers, distributors, affected persons, and authorised representatives of AI systems

The AI Act imposes a far greater regulatory burden on AI developers rather than on users. The AI Act lays down an enforcement framework that is designed to regulate AI systems on a sliding scale of risk. The compliance obligations will be dictated by the risk category into which the AI system falls. There are four risk categories, including:

1. Unacceptable risk
2. High risk
3. Limited risk
4. Minimal or no risk.

Unacceptable risk AI systems

AI systems which are considered a clear threat to the safety, livelihoods and rights of people are banned. This includes systems such as social scoring by governments and toys using voice assistance that encourages dangerous behaviour. These will be banned from the EU market from 2 February 2025.

High-risk AI systems

High-risk AI covers a broad range of applications. These include AI used in medical devices, as a safety component in toys, and for managing critical infrastructure such as electricity supply. It can also include employment recruitment tools, credit scoring applications, and grade prediction technology in education. High-risk AI will be broadly divided into two categories:

1. AI systems that are used as a safety component in products or are themselves products falling under certain specified EU harmonisation legislation e.g. toys, medical devices etc. These are known as Annex I high-risk AI systems.
2. AI systems in certain areas will require registration in an EU database. These include educational and vocational training, law enforcement, and the management and operation of critical infrastructure, among others. These are referred to as Annex III high-risk AI systems.

Before these categories of high-risk AI systems can be put on the EU market, they will be subject to a stringent 'conformity assessment' process. This conformity assessment determines whether

the system meets all requirements in the Act. Providers dealing with Annex I high-risk AI systems will enhance their existing third-party conformity assessment procedure with their existing notified body. In contrast, providers of Annex III high-risk AI systems will conduct self-assessments in order to meet the same requirements.

Limited risk AI systems

Limited risk AI systems have a low risk of harm that can be remedied by making them more transparent. It is important that AI systems which interact directly with people are developed to ensure that the person is aware they are interacting with AI. These systems include chatbots, and generative AI.

Minimal risk AI systems

Minimal risk AI systems pose a minimal risk to the safety and rights of citizens. These are not subject to the obligations or restrictions under the AI Act. However, companies can choose to voluntarily adopt additional codes of conduct.

The AILD

The AILD is designed to revise and harmonise Member State's non-contractual, fault-based rules concerning claims for injuries arising from AI systems. In Ireland, this will impact claims in negligence under tort law.

The product liability regime under the PLD provides for a harmonised application of its strict liability rules across the EU. The more 'traditional' fault-based rules, however, tend to vary more from Member State to Member State. The worry is that Member States will, and to some extent already are, applying their fault-based national rules to cases about AI systems and models in differing ways. This is unfortunately creating a fragmented set of new legal tests and case law that lacks consistency, making it a very challenging environment to do business.

The AILD is designed to harmonise these fault-based rules across the EU. It does this through a range of mechanisms including, for example, using the same terms and definitions as those used in the AI Act. The AILD also provides for the introduction of disclosure requirements and rebuttable presumptions into national fault-based rules in alignment with similar proposed reforms under the Revised PLD.

The EU Parliament's Research Service published a Complementary Impact Assessment in September 2024. The assessment evaluated the AILD's relevance and effectiveness in the current legislative landscape, particularly considering the Revised PLD. The Complementary Impact Assessment has made several key recommendations, one of which is to transform the AILD into a Regulation. This would ensure it has direct application in each Member State, eliminating the need for transposing national legislation. The Complementary Impact Assessment is being considered by the European Parliament's Legal Affairs Committee and we await its decision as to whether it will accept its recommendations or not.

Features of the AILD

There are three key features worth highlighting in the proposed AILD in its current form:

1. **Scope:** The AILD would ensure that the scope of national fault-based liability regimes is broad. For example, you can have claims against any person, not just the manufacturer, for faults that influenced the AI system which caused the damage. The AILD also applies to any type of damage covered under national law, including damage resulting from discrimination or breach of fundamental rights like privacy, which could in some cases be broader than the Revised PLD's concept of 'damage.' Claims under the AILD can also be made by any natural or legal person. This contrasts with the PLD whereby it is just natural persons who can make a claim.

2. **Disclosure of evidence:** Similar to the new rules under the Revised PLD, national courts would have the authority, at the request of a potential claimant, to order providers of high-risk AI systems - as well as those subject to the provider's obligations and users of those systems - to disclose or preserve relevant evidence related to a specific high-risk AI system suspected of causing damage.
3. **Rebuttable presumptions:** For a fault-based claim to be successful, the defendant's negligent act or omission must be shown to have caused the damage in question. According to the EC, proving this causal link could be difficult for a claimant in a fault-based claim involving an AI system. This is because they may have to explain the inner functioning of the AI system and what a defendant did or failed to do to make the AI system behave in a way that it wasn't perhaps supposed to. This is understandably a high evidential bar that would be difficult for most claimants. It could also arguably result in an unfair barrier to claimants' access to justice. In those circumstances and, similarly, to the provisions introduced under the Revised PLD, the AILD would provide for a presumption of the causal link where certain conditions are met.

Collective redress

The CRD allows certain public representative bodies such as regulatory agencies and NGOs to bring claims on behalf of groups of consumers. Claims are brought under a very long and evolving list of EU product safety and consumer protection legislation.

'Qualified entities' representing groups of consumers can seek various forms of redress. Redress options can include repair, refunds and compensation, price reduction, contract termination as well as various types of injunctive relief, such as court orders compelling traders to stop the practice which has caused the infringement.

While the AI Act is not included, a range of consumer protection and product safety legislation, including the PLD, is on that list. As a result, it means that there is a possibility for qualified entities to bring claims against manufacturers under the PLD. It remains to be seen if that will happen and what it might look like. However, there is now a legislative basis for this happening in various Member States, including Ireland.

The CRD was adopted back in December 2020 and had to be implemented by Member States by June 2023. In Ireland, we now have the Representative Actions Act 2023 and the Irish Council for Civil Liberties was the first designated qualified entity under the Act. The CRD provides for various safeguards to avoid the opening of any sort of 'floodgate' of claims:

- **Dismissal of manifestly unfounded cases:** Courts are empowered to dismiss manifestly unfounded cases at the earliest possible stage of the proceedings.
- **Settlement:** There is the possibility that a claim can be settled subject to court approval.
- **Funding transparency:** A qualified entity will be required to publicly disclose information about its sources of funding. Under Irish law, third-party litigation funding is prohibited for parties with no interest in the dispute, making it challenging for qualified entities in the not-for-profit sector to fund large, sometimes cross-border, representative actions. This prohibition remains unchanged by the enactment of the 2023 Act, which allows third-party funding for representative actions "insofar as permitted in accordance with law."
- **Multiple claims by individual consumers:** Consumers are prevented from being involved in a collective action where they have previously received compensation from the same trader for the same cause of action.

The CRD forms part of the new EU product liability landscape and is worth bearing in mind alongside the Revised PLD and the AI Act. Although the EU's collective redress model is designed to be different from the US class-action system and contains

multiple measures to prevent opportunistic litigation, it will undoubtedly result in increased litigation risk for consumer-facing businesses. This is because consumers will be empowered to participate in a collective action whereas individually, they may not have had the means or appetite to do so. Consequently, Ireland could become an attractive forum for joint representative actions centred on EU-wide product liability claims. This is because it is the only remaining English-speaking common law country in the EU with a largely pro-plaintiff judiciary and extensive US-style discovery model. All these factors will likely lead to more product liability litigation. This could have secondary effects, such as a greater focus by businesses on achieving regulatory compliance. Businesses will aim to limit their risk of litigation exposure. Additionally, a more stringent regulatory culture may emerge.

Conclusion

The extended scope of the Revised PLD reflects the evolution of product liability to include not only physical products but also software applications and AI systems. These are now explicitly recognised as products under the Directive. The new rules intend to enhance consumer protection for damage suffered by defective products.

Even though the AILD has not been adopted, it is the subject of ongoing discussion at an EU level. Therefore, organisations and businesses must start preparing for how it may potentially impact them. Developers of AI systems should consider the legislative changes which may affect their product and ensure their compliance with the upcoming frameworks.

The trio of new legislation consisting of the AI Act, the Revised PLD and the proposed AILD will overlap. This is likely to result in the harmonisation of how AI systems are treated under EU product safety and product liability law. This will apply to both fault-based and strict liability claims. Producers will need to be aware of these legislative reforms in the context of the development of their products and the potential liability issues which could arise.

We recommend stakeholders monitor this evolving liability landscape as well as the potential for regulatory divergence outside of the EU. The EU is fast becoming an innovative frontier in this highly complex and exciting area of law.

Potential Liability for Chatbot Hallucinations?

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Chatbots are often the first point of contact with a company that a customer has on a website when they have a query. While the recent adoption of the EU's AI Act has attracted most attention for the regulation of chatbots, a notable small claims tribunal decision from Canada is a cautionary reminder that other areas of law will also apply to a chatbot.

Background

The case saw a chatbot give inaccurate information to a consumer who raised a query about an airline's bereavement fare policy. This was despite the relevant webpage of the website correctly stating the airline's bereavement fare policy. Relying on the chatbot's "hallucination", the consumer bought two full-price fares to attend their grandmother's funeral. When the consumer submitted an application for a partial refund, the airline was directed by the tribunal to comply and provide the partial refund.

The tribunal decision found that the airline had made a negligent misrepresentation as it had not taken reasonable care to ensure its chatbot was accurate. As a result, the airline was forced to honour the partial refund. While the airline argued that it was not responsible for information provided by its agents, servants or representatives, including a chatbot, the tribunal decided that this argument did not apply in this situation. This was due to the fact that the chatbot was not a separate legal entity and was instead deemed to be a source of information on the airline's website.

The airline also argued that its terms and conditions excluded its liability for the chatbot but did not provide a copy of the relevant terms and conditions in the response. Therefore, the tribunal did not substantively consider the argument. In addition, while the chatbot's response had included a link to the relevant webpage, the tribunal found that the consumer was entitled to rely on the information provided by the chatbot without double checking it against the information at the webpage.

Application in Irish law

Under Irish law, it is possible that a court would reach a similar conclusion, particularly in a consumer dispute. First, it is unlikely that a court would find that a chatbot was a separate entity from the chatbot's operator. Therefore, it would find that the chatbot constituted information on the company's website.

Irish law also prohibits misleading commercial practices. This includes the provision of false or misleading information that would cause an average consumer to make a transactional decision that they would not otherwise make. The provision of false information by a chatbot which results in a consumer making a purchase on the trader's website could therefore be deemed a misleading commercial practice in an Irish court.

While the point was not fully considered in the Canadian decision, a contractual clause which excludes the liability of a company for hallucinations by its chatbot in similar circumstances may not be enforceable in Ireland. Under Irish law, contract terms which are unfair are not enforceable against a

consumer. While terms which exclude a company's liability for chatbots are not uncommon, the fairness of a term such as this, particularly where the consumer has made a purchase from the company relying on the information provided by the chatbot, would be questionable.

Key takeaways

While chatbots are a useful tool for companies to interact with their customers, companies should be aware of the legal risks which arise through their use. While it is unlikely that this single tribunal decision from Canada will make companies liable for all chatbot hallucinations, it is a reminder that their use can lead to unexpected liability for the company operating the chatbot. The risk is more stark in a B2C setting as EU consumer law will generally not allow organisations to make consumers responsible for risks associated with poor product performance.

Companies will also have to consider their potential liability for chatbot hallucinations under the revised Product Liability Directive. The revised Directive entered into force in 2024 and the new rules will need to be implemented by Member States 24 months after its entry into force. The revised Directive will significantly modernise the EU's product liability regime, including by expanding the definition of a 'product' to include software, including standalone software, and digital manufacturing files. Under the new rules, software will be a product for the purposes of applying no-fault liability, 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. The revised Directive also seeks to expand the scope of liability beyond when a product was put into circulation to possibly include the time after circulation, including once the product has been placed on the market, if a manufacturer retains control of the product, for example through software updates and upgrades. Manufacturers may also be held liable for software updates and upgrades supplied by a third party, where the manufacturer authorises or consents to their supply, eg where a manufacturer consents to the provision by a third party of software updates or where it presents a related service (an integrated or inter-connected digital service) or component as part of its software even though it is supplied by a third party.

Organisations should also be mindful of the EU's proposed Artificial Intelligence Liability Directive, which is closely linked to and complimented by the revised Product Liability Directive. The proposed AI Liability Directive seeks to harmonise certain aspects of national fault-based civil liability rules for damage caused by AI systems, including high-risk AI systems, as defined under the AI Act. The draft text is currently making its way through the EU's legislative process. Once adopted, member states will have 2 years from its entry into force to transpose the legislation into their national law.

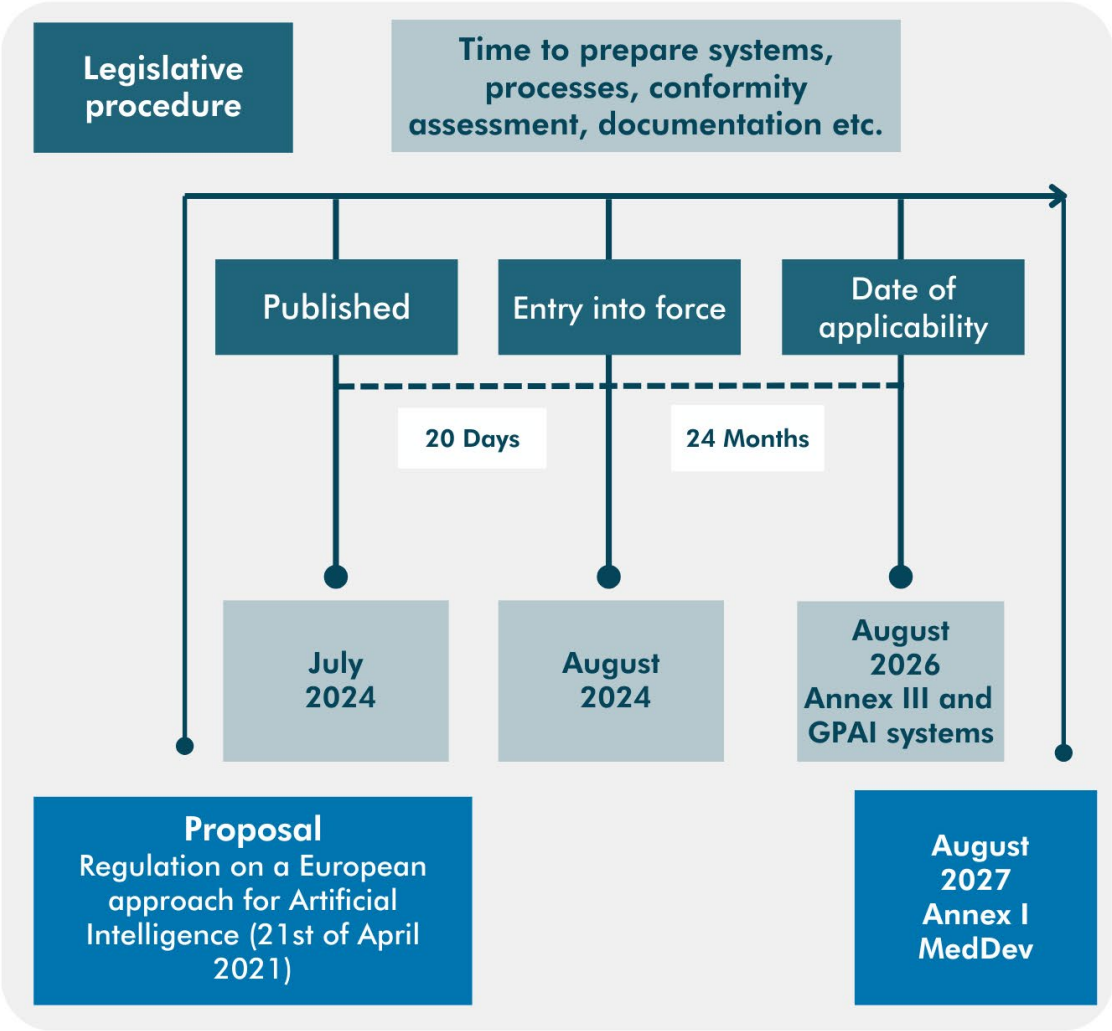
To reduce potential liability from chatbots, companies should regularly review the performance of their chatbots. In particular, the following could form part of the regular review:

1. Reviewing the output of chatbots to ensure that the information they provide aligns with the company's advertising and sales practices
2. Promptly investigating any customer-reported issues associated with their chatbots

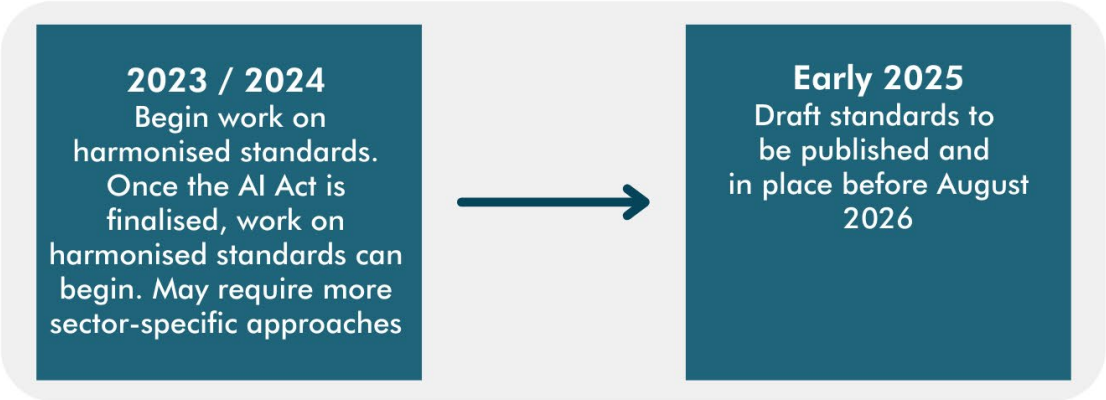
When the chatbot has been provided by a third party, ideally organisations should ensure that the contract with the third party affords it sufficient protection. Acceptable protection would include clearly outlining which party bears the liability for misleading/false information, and having appropriate obligations in place for the third party to make corrections to the chatbot in a timely manner. However, chatbot providers will resist very strongly any risk sharing which means organisations need to be vigilant about managing this risk in a practical manner, including by ensuring that related services are covered under their product liability insurance. So, when deploying chatbots with consumers, even for basic apparently benign use cases, thoroughly examine the risks associated with hallucinations and incorrect responses. If those responses cannot be fixed, consider another option or put in place a robust remedy process for your customers.

Timeline for Compliance with AI Act for Medical Devices

AI Act



Standards



Batteries Regulation in MedTech

Navigating the new compliance landscape

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Batteries are the beating heart of medical technology, and the new EU Batteries Regulation introduces stringent compliance requirements. Our Planning & Environment team examines which batteries are affected, outlines key sustainability and safety obligations, and highlights crucial steps for manufacturers, importers, and distributors. Discover how these rules impact your business and the importance of early compliance planning.

The importance of batteries to medical technology cannot be overstated. Implantable medical devices are powered by batteries. Substantial volumes of other medical equipment also rely on batteries either as their main or back-up power source.

The EU Batteries Regulation aims to ensure that batteries on the EU market are sourced and manufactured in a sustainable manner. The Regulation sets out, amongst other things, rules on the sustainability, performance, safety, collection, recycling and second life of batteries.

It is important that manufacturers, importers, distributors, or any person placing batteries on the EU market or putting them into service are aware of their obligations under the Regulation. While the Regulation applies to all battery categories, this article focuses on its implications for producers of "portable batteries," which are most commonly used in medical devices.

In-scope batteries

Broadly speaking, a battery includes non-rechargeable or rechargeable battery cells or packs of them, as well as batteries that have been re-used, repurposed or remanufactured. Portable batteries must be sealed, weigh 5kg or less, and not be a different category of battery covered by a separate provision of the Regulation.

The Regulation also applies to certain types of 'battery management systems', which control certain functions within a battery.

Producers

The Regulation uses the term 'producers' to describe persons who have obligations under the regime. The term 'producer' includes:

- Manufacturers
- Importers
- Resellers, and
- Distance sellers

Many of the obligations become applicable at the point the batteries are first placed or put into service on the EU market. This extends to producers of medical devices that incorporate batteries. However, if a producer places battery-operated medical devices on the market without the batteries being incorporated into the device at the time it is placed on the market, they may not have obligations under the Regulation. Instead, the obligations would apply to the battery producer that separately places the required battery on the market. If, on the other hand, a producer of a medical device incorporates a third-party's battery into the device, the producer of the medical device may have obligations under the Regulation.

Obligations on producers

The primary obligation under the Regulation is that batteries placed on the market or put into service shall not present a risk to:

- Human health
- Safety of persons
- Property, or
- The environment

However, the Regulation provides more specific obligations regarding 'sustainability and safety requirements' and 'labelling and information requirements'. We summarise some of these requirements for portable batteries that may be of interest to producers of medical technology.

1. Restrictions on substances

The use of certain substances in the production of batteries is restricted. The Regulation provides that batteries shall not contain more than 0.0005% mercury, 0.002% cadmium, and 0.01% lead, measured by weight. Further restricted substances are set out in Annex XVII of Regulation 1907/2006 and in Article 4(2)(a) of Directive 2000/53/EC. This restriction is in effect.

2. Performance and durability requirements

Portable batteries for general use, excluding button cells, must meet minimum values for the electrochemical performance and durability. These parameters are set out in Annex III of the Regulation. The minimum values will be set out in a delegated act to be adopted by the Commission by no later than 18 August 2027.

The parameters to which the minimum values will apply include things such as rated capacity, resistance to unplanned escape of material, and the capacity a battery can deliver under specific conditions.

This obligation will apply from 18 August 2028. However, this date could potentially be pushed by the Commission in a delegating act.

3. Removability and replaceability of portable batteries

Portable batteries incorporated into products must be readily removable and replaceable by the end-user at any time during the lifetime of the product. This only applies to entire batteries and not to individual cells or other parts included in portable batteries.

A portable battery is considered "readily removable by the end-user" if it can be removed from a product using commercially available tools. Specialised tools are not required, unless they are provided free of charge with the product. However, there is an exemption for appliances including *"professional medical imaging and radiotherapy devices" and "in vitro diagnostic medical devices"*.

Although this requirement is in effect, the Commission will ultimately publish guidelines so that there is a harmonised approach on its application throughout all Member States.

4. Labelling and marking of batteries

Batteries must bear a label containing the general information set out in Part A of Annex VI. This information includes things such as details on the manufacturer, date of production, and battery information. This obligation will apply from 18 August 2026. However, this date could potentially be pushed out by the Commission in a delegating act.

In addition, all batteries must bear the "crossed-out wheelie bin" symbol from 18 August 2025. This indicates that batteries are to be disposed of in a separate waste stream to regular waste.

5. CE marking

The Regulation establishes a framework for conformity assessment procedures for batteries. Battery manufacturers are required to prepare a declaration of conformity in electronic format since 18 August 2024. This document must be provided in the language(s) specified by each Member State where the batteries are being marketed.

By drawing up the declaration of conformity, the manufacturer assumes responsibility for the compliance of the battery with the requirements laid down in the Regulation. It is not sufficient to simply add the Regulation to an existing declaration of conformity.

Conforming batteries must be visibly, legibly, and indelibly marked with the CE marking before the battery is placed on the market. If it is not practically possible for the marking to be on the battery, then the marking must be on any packaging and documents accompanying the battery. The general rules on how to affix the CE marking to a product, including portable batteries, are available in the Commission's Blue Guide on the implementation of EU Product Rules 2022.

6. Management of waste and producer responsibility

Producers of portable batteries must ensure that all waste portable batteries are collected separately from other waste. This requires producers to:

- Establish a waste portable battery take-back and collection system
- Collect, free of charge, the waste portable batteries collected at collection points, and
- Ensure that the waste portable batteries collected are subject to treatment in a permitted facility by a waste management operator

Producers of portable batteries must attain, and maintain on an ongoing basis, at least the following collection targets for waste portable batteries:

- 45% by 31 December 2023
- 63% by 31 December 2027, and
- 73% by 31 December 2030

7. Due diligence and risk management

Producers having a net annual turnover of €40 million or more have additional obligations under the Regulation. These producers are referred to as "economic operators". Economic operators must implement battery due diligence policies from 18 August 2025. These policies must be third-party verified. The Commission is to publish guidelines on the requirements of due diligence policies by 18 February 2025.

Comment

In addition to the provisions already in force, the many other provisions of the Regulation will come into force on a gradual, phased basis over the next 12 years or so. The European Commission and Member States will implement secondary legislation to give full effect to the Regulation.

Specific obligations for manufacturers, importers and distributors of batteries are set out in Articles 38, 41, and 42 of the Regulation. Broadly speaking, they are required to ensure compliance with the other provisions of the Regulation.

Challenging Regulatory Decisions in the Life Sciences Sector

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Judicial review is the legal procedure by which the decisions, including acts and omissions, of bodies exercising public functions can be challenged and reviewed before the courts. In the Life Sciences sector, this could involve decisions made by regulatory authorities, such as the Health Products Regulatory Authority (HPRA). As a statutory body established to regulate medicines and devices, decisions of the HPRA are subject to judicial review, and several judicial review challenges have been taken against it previously.

Judicial review is generally not concerned with the merits of the decision, ie whether the decision was right or wrong. Rather, the courts will consider whether the decision-making process was lawful or unlawful. In this article, we outline some key considerations in relation to judicial review challenges.

Grounds for judicial review

If a person believes that a decision of a public body, like the HPRA, has strayed outside of the law or has been made without lawful authority, then that person can seek a review by the courts. An application for judicial review can be made on the following grounds:

- The decision is outside of the legal powers of the public body. This is often referred to as being "*ultra vires*". Either the public body did not have the legal power to act at all, or it exercised the power in a manner that amounts to an abuse, or mis-use, of the power.
- The public body has not adhered to fair procedures, or has not followed prescribed procedures, in reaching its decision. Often the argument is that the public body (1) was biased, prejudiced, or had prejudged matters; or (2) did not afford notice and/or a fair opportunity to be heard.
- The decision is irrational, unreasonable, or disproportionate. The court will examine if the decision and conclusion of the public body was so unreasonable or irrational that no reasonable body could have come to it.

Application requirements

Two key requirements to bring a judicial review challenge relate to the timeline and the two-step application process to the High Court.

Timelines

In judicial review, it is important for the person or group bringing the challenge (the applicant) to act without delay. An application for judicial review must be made, at the latest, within three months of the date on which grounds for judicial review first arose. Generally, the date on which grounds arise for judicial review is the date the relevant decision is made. In *Arthropharm (Europe) Ltd v HPRA*,[1] the date on which the decision of the HPRA to grant a marketing authorisation for a veterinary product was made

1. [2020] IEHC 16; [2022] IECA 109

was determined to be the date the decision was published on the regulator's website. This was so despite the fact that the applicant did not become aware of the decision until a later date.

While there is generally a three-month time limit for judicial review applications, specific statutes can impose shorter time limits or introduce other modifications and restrictions. For example, planning and procurement legislation set specific time limits for certain judicial review challenges. Applicants can also apply for an extension of time, in limited circumstances, and only with good and sufficient reason.

Process

An application for judicial review involves a two-step process:

1. Leave application

   First, an applicant must bring an application seeking "leave" or permission to bring the judicial review proceedings.

   The application for leave is usually made *ex parte*, ie without notifying the other party and without that party being present in court to oppose the application.

   The threshold to obtain leave is relatively low. The applicant must establish that:

   - They have 'standing', which means that they have a sufficient interest in the matter at issue
   - The decision is amenable to judicial review, ie it is a decision on a matter of public law, and
   - They have an arguable or stateable case

If the Court decides to grant leave to bring the proceedings, it also has discretion to order a stay on the decision of the public body. A stay may prevent the decision from coming into effect pending the hearing and determination of the proceedings.

2. The substantive hearing

   Once leave is granted, the proceedings must be served on the respondent public body and any other persons affected. The case then moves forward with the exchange of evidence and legal submissions. This process culminates in the substantive hearing of the case. Evidence is generally given on affidavit, rather than by way of oral evidence.

Limitations

The court can make a range of orders. These include, in particular, an order to set aside or quash the impugned decision of the relevant public body, such as the HPRA.

However, it is important to note that judicial review is not an appeal. The court will not substitute its own decision for that of the public body. Often, the court will remit (ie send the matter back) to the public body to reconsider its decision in accordance with law, as determined by the court.

In addition, judicial review remedies are discretionary in nature. This means that, even if a court finds in favour of an applicant, it may decide not to grant certain reliefs, based on the circumstances at issue in the case.

Also, while judicial review is a generally available remedy, it will usually not be available if there are adequate alternative remedies available to the applicant. Alternative remedies can include an entitlement to a statutory appeal, for example, which should be exhausted in the first instance.

Comments

The timelines and procedural requirements for bringing judicial review proceedings are stringent and the proceedings themselves, especially in specialised regulatory sectors like Life Sciences, can be complex. Our Public, Regulatory & Investigations team can provide expert guidance and advice to those considering or involved in judicial review proceedings.

Required Reading
Key Digital Health Documents

1. IMDRF Guidance: Good Machine Learning Practice for Medical Device Development: Guiding Principles
2. EU Commission Publication: Cyber Security in the Health Medicine Sector: A Study on Available Evidence of Patient Health Consequences Resulting from Cyber Incidents in Healthcare Settings
3. EMA Publication: Reflection Paper on the Use of Artificial Intelligence in the Medicinal Product Lifecycle (September 2024)
4. FDA Publication: Total Product Lifecycle Considerations for Generative AI-enabled Devices (November 2024)
5. EU Publication: Gradual Roll-out of EUDAMED (November 2024)
6. Team NB Questionnaire: Artificial Intelligence in Medical Devices (November 2024)
7. FDA Publication: Marketing Submission Recommendation for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions
8. WHO Publication: Benefits and Risks of Using AI for Pharmaceutical Development and Delivery
9. UK Guidance: Software and Artificial Intelligence as a Medical Device
10. MHRA Roadmap Towards the Future Regulatory Framework for Medical Devices

UPC Court of Appeal Rules Ireland Outside its Jurisdiction

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The Unified Patent Court (UPC) Court of Appeal, overturning the first instance ruling of the UPC Local Division in The Hague, has suspended a preliminary injunction (PI) that was granted in favour of Abbott. The injunction had prevented SiBio from distributing its continuous glucose-monitoring (CGM) device in Contracting Members States and the suspension applies specifically to Ireland.

The presiding judges reasoned that although Ireland is a signatory to the Agreement on a Unified Patent Court (UPCA), the fact that Ireland has not ratified the UPCA means it cannot be considered a Contracting Member State, placing it outside the jurisdiction of the Court.

The decision offers clarity on the extent of Ireland's involvement in the UPC and its jurisdiction until such time that the anticipated referendum is held to ratify the UPCA.

Background

Abbott filed a request for a PI on 20 March 2024 seeking to enforce its rights under its own CGM patent. The injunction was issued against SiBio in the Contracting Member States of Germany, France, The Netherlands and also Ireland. It was granted on 19 June 2024 for all the Contracting Member States named despite the fact that Ireland had not yet fully ratified the UPCA. The Court of First Instance acknowledged this fact stating that:

"...Abbott apparently wishes the order to also cover Ireland, which is a signatory state to the UPCA, and therefore a Contracting Member State, even though Ireland has not yet ratified the Agreement."

Seemingly, the fact that the UK had withdrawn its own ratification of the UPC meant that the application was not considered for this territory.

Although SiBio did not initially challenge the jurisdiction of the Court of First Instance regarding its decision on Ireland, it later appealed the PI specifically concerning its applicability to Ireland. SiBio argued that extending the scope of the order to include Ireland was "manifestly erroneous". The deciding judges of the Court of Appeal agreed:

"Only countries that have not only signed but also ratified the UPCA are Contracting Member States".

The appeal decision therefore effectively suspended the PI insofar as it extends to Ireland, offering greater clarity on the jurisdictional limits of UPC rulings.

Ratification plans

Ireland was due to hold a referendum on its ratification of the UPCA on 7 June 2024. However, the referendum was postponed to a later date and this date has yet to be determined. Since ratification would effectively transfer the jurisdiction of patent litigation from Irish courts to an international court, a referendum is necessary to amend the Irish constitution to allow for this change. If the first instance decision had stood unopposed, it may well have created political turmoil for being unconstitutional.

Reception in Ireland and further afield

The ruling will therefore be welcomed in Ireland as well as other countries in a similar position, such as Greece and Hungary, who have also signed but not yet ratified the UPCA. It will provide clarity for businesses with protection in these countries that any decision of the UPC will not extend to these territories and other means of enforcement will need to be considered.

Comment

The Court of Appeal has avoided a potential political slip-up by overturning the first instance decision and ruling that signatories to the UPCA who have yet to ratify the Agreement are not to be considered Contracting Member States. Until such time as these countries ratify the UPCA, any decision of the UPC will not apply to them. For Ireland, this means that it can rearrange its date for a referendum on ratification of the UPCA without fear that UPC decisions will overstep and seemingly ignore this fact, seeking to enforce remedies without jurisdictional authority.

The European Commission's Guidelines on the Data Governance Act

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The Data Governance Act, or DGA, aims to increase voluntary data sharing for the benefit of businesses and citizens by making it easier to share data in a trusted and secure manner.

So far, only 11 organisations have registered as data intermediaries and one organisation has registered as a data altruism organisation.

Ireland has been slow to implement the DGA. The Central Statistics Office has been designated as the competent body responsible for supporting public sector bodies in facilitating the re-use of public data. However, Ireland has yet to designate a competent authority, to which notifications can be made, to work with data intermediaries and data altruism organisations. The Irish Competition and Consumer Protection Commission is intended to be designated as the competent authority.

Highlights for data intermediaries and data altruism organisations

Re-use of data needs a legal basis

The DGA does not establish a right to re-use personal data or create a new legal basis for its re-use under GDPR. Instead, where the local EU law or Member State law permits the re-use of public data, the DGA facilitates this re-use and any sharing must be done in accordance with the DGA.

Data intermediaries

Data intermediation services are services that facilitate the sharing, exchange, or re-use of data between different parties, such as businesses, public sector bodies, or individuals, while ensuring privacy, security, and transparency. Data intermediation service providers act as neutral intermediaries, enabling organisations to share data in a way that complies with legal and ethical standards, including data protection laws like GDPR.

The DGA sets rules for providers of data intermediation services that connect the supply and demand of data. Certain service providers cannot be considered data intermediaries. These include internet of things platforms and services that focus on the intermediation of copyright-protected content. Data intermediation services may be possible on a B2C basis between individuals that seek to make their personal or non-personal data available, and potential data users.

Data intermediaries must notify the competent authority of their intention to provide their services under Article 11 of the DGA. At a data intermediary's request, the competent authority is required to confirm whether the intermediary complies with the notification requirements and the conditions for providing intermediation services under the DGA.

Data intermediaries must maintain strict neutrality, using acquired data solely to improve their services and must only share it with user-approved parties. To ensure this neutrality and avoid conflicts of interest, entities offering data intermediation services must

legally separate this function from any other services they provide. The pricing and terms of data intermediation services must be independent of whether clients use the intermediary's other services.

Data altruism

Data altruism refers to the voluntary sharing of personal or non-personal data by individuals or organisations for the public good, without expecting any direct compensation in return. Under the DGA, data altruism is encouraged to support research, innovation, and public interest projects, such as improving healthcare, environmental protection, and scientific advancements. This concept promotes the use of data for societal benefit while ensuring privacy and transparency.

In order for an entity to qualify as a data altruism organisation, it must:

- Operate on a not-for-profit basis and be legally independent from any entity that operates on a for-profit basis
- The data must be used for an objective of general interest
- Register with the competent authority
- Adhere to transparency requirements laid out in Article 20
- Protect the rights of data subjects and data holders laid out in Article 21
- Comply with the Rulebook, once it has been adopted. The Rulebook is currently being developed and will set security requirements as well as communication roadmaps and interoperability standards

International data transfers

While the GDPR has laid out protections in Chapter V for international data transfers, Article 31 of the DGA provides for similar requests where governmental authorities or courts in a third country request non-personal data. These protections cover all the scenarios in the DGA, such as public sector data, intermediation services, and data altruism organisations.

Article 31 requires that parties implement contractual, organisational, and technical measures to ensure governments' access in third countries is prevented where that would be in conflict with EU or national law.

There are two exceptions to this rule:

- If a third-country decision is based on a mutual legal assistance treaty with the EU or an EU Member State
- If the third-country decision meets specific legal criteria, including proportionality, judicial review, and consideration of EU legal interests

Before complying with a request, the entity granted the right to re-use the data, the data intermediation service, or the data altruism service must notify the data subject—unless doing so would compromise law enforcement purposes.

European Data Innovation Board (EDIB)

The European Commission established the EDIB to promote the sharing of best practices, particularly regarding data intermediation, data altruism, and the use of publicly held data that cannot be shared as open data. It also focuses on prioritizing cross-sectoral interoperability standards. For example, the EDIB has the power to propose guidelines for Common European Data Spaces on the adequate protection for data transfers outside of the Union. Thus far, they have not published any guidelines.

Comment

So far, not many organisations have registered to be data intermediaries or data altruism organisations. However, that may change as further certainty is brought by the European Commission and the EDIB through the guidelines on the DGA that they publish. Organisations should keep up to date on what data is made available by data altruism organisations and data intermediaries so that they can explore using this previously inaccessible data.

Prescription Medicines and the GDPR

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Background

A pharmacy (Lindenapotheke) had been marketing products on Amazon. These products could only be sold by pharmacies, but did not require a prescription.

Lindenapotheke's competitor, DR, sought an injunction prohibiting this practice on the basis it was an unfair commercial practice. DR argued that Lindenapotheke had infringed the GDPR by processing customers' health data without their consent.

Two questions were ultimately referred to the Court of Justice of the European Union (CJEU)[1]:

1. Do orders for non-prescription medicines amount to 'health data' under Article 9 GDPR, and
2. Can competitors bring legal proceedings for GDPR infringements?

Question 1 – what constitutes 'health data'?

The CJEU confirmed that where the data on purchases of medicinal products allow conclusions to be drawn as to the health status of an identified or identifiable person, it must be regarded as data concerning health. The CJEU referred to previous judgments, including *Lindqvist [2], OT [3] and Bundeskartellamt [4]*. It confirmed that the concept of 'data concerning health' must be interpreted broadly.

This approach aligns with the GDPR's objective to ensure a high level of protection for individuals. On this basis, the CJEU said there was no basis to distinguish between prescription and non-prescription medicinal products.

The CJEU found that data entered on online platforms when ordering pharmacy-only medicinal products is health data where "a link" can be established between:

- The product
- Its therapeutic indications or use, and
- A natural identified or identifiable person

The CJEU made clear that absolute certainty was not required. Article 9(1) would apply where there was a certain degree of probability that the medicinal products are intended for those customers. The CJEU also reiterated that Article 9 is triggered *irrespective* of whether the information is accurate or falls within the controller's stated aims.

The CJEU confirmed that a link could also arise even where the products are intended for someone other than the customer. This applies if it is possible to identify the individual and draw conclusions as to the state of their health. An example given is where the customer refers in the order to a family member.

1. *Case C-21/23 Lindenapotheke, (4 October 2024) please see here.*
2. *Case C-101/01, Lindqvist, (6 November 2003) please see here.*
3. *Case C-184/20, OT, (1 August 2022), please see here.*
4. *Case C-252/21, Bundeskartellamt (4 July 2023), please see here.*

On this basis, the CJEU concluded that customer information processed when ordering medicinal products online "*such as their name, the delivery address and the details required for individualising the medicinal products, constitutes data concerning health, within the meaning of those provisions, even where the sale of those medicinal products does not require a prescription" [5]*.

Question 2 – can competitors bring legal proceedings for GDPR infringements?

The CJEU stated that the GDPR does not prevent national laws from allowing this to occur. The CJEU noted that these types of actions are particularly effective in protecting data subjects. This is because they can help prevent a large number of infringements.

Conclusion

This case is another important ruling on Article 9 GDPR. It underlines the broad interpretation that will be applied to health data, and other special categories of data. The CJEU has reiterated that the controller's stated purpose and the accuracy of information are not relevant as to whether Article 9 applies. The key issue is whether there is a link of sufficient certainty between the information and an individual. This link must allow conclusions to be drawn about the person's health.

The case is also noteworthy as it clarifies that competitors are not prevented from bringing legal proceedings for unfair commercial practices based on GDPR infringements. This could present a significant avenue to challenge the actions of those engaging in unfair practices which infringe the GDPR.

5. Para, 94.

Recent MHC Events, Articles & Publications

Events & Webinars

- Mastering Product Claims in the EU
- NIS2 is Here - What You Need to Know
- Liability for AI and Products - A Whole New World
- Life Sciences - Legal & Tax Considerations for Ireland
- What the AI Act Means for Medical Devices
- Managing Technology Risk
- Data Privacy and Emerging Technology Regulation Masterclass
- Technology and Digital Disruption
- Artificial Intelligence - When Law and Business Collide
- Future Health Summit 2024

Publications

- 2024 in Review: Key Legal Developments in AI
- Wearables and the Evolving Regulatory Landscape - In-Depth Analysis
- Key Takeaways from Our 'Mastering Product Claims in the EU' Webinar
- Life Sciences Sector Update - In Brief (Summer 2024)
- Regulating Medical Devices in the EU and UK
- New EU Rules for Connected Products and Cloud Services

About us

Mason Hayes & Curran is a business law firm with 120 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.

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Chambers & Partners, 2024

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Legal 500, 2024

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