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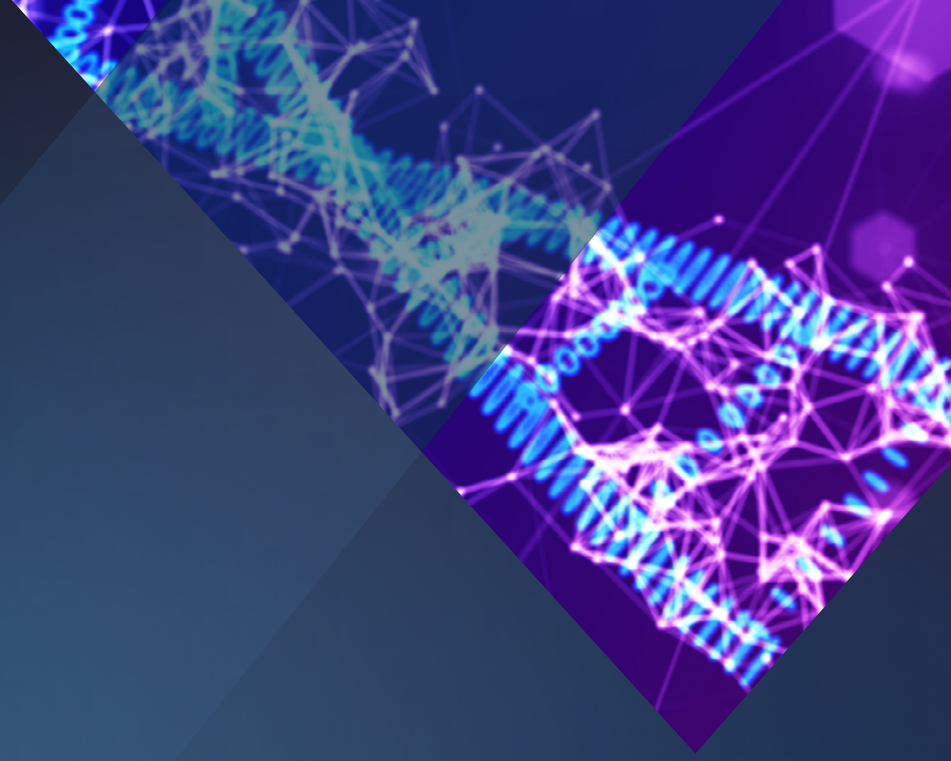

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Digital Health

Mid-year Review 2026

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Welcome

Digital Health Mid-year Review 2026

At the midpoint of 2026, the regulatory landscape for Digital Health and Life Sciences continues to evolve at a rapid pace, presenting both fresh compliance hurdles and strategic opportunities for stakeholders. Moving into the second half of the year, businesses must continue to adapt their systems and frameworks to ensure alignment with increasingly sophisticated EU and national requirements.

This Mid-year Review highlights the most significant legal and regulatory developments from the first six months of 2026, providing a critical pulse check for companies navigating these shifting tides:

- **High-risk AI Act classification metrics:** A review of the European Commission's landmark draft guidelines defining high-risk AI parameters, focusing on intended purpose exclusions, complex architectures and biometric data boundaries.
- **EDPB scientific research processing rules:** Key takeaways from newly adopted guidelines clarifying data subject consent mechanisms, storage limits for future projects and purpose compatibility under the GDPR.
- **Strict software update protections:** The impending arrival of stricter software update disclosures and anti-greenwashing measures coming into effect under the Empowering Consumers for the Green Transition Regulations.
- **Digital medicine promotion on social media:** New guidance from the Health Products Regulatory Authority (HPRA) targeting the active oversight and evolving boundaries of digital marketing and public-facing treatment promotion on social media platforms.
- **Uniform medtech assessment frameworks:** The European Commission's introduction of mandatory maximum assessment timelines and uniform pricing transparency rules for notified bodies under Implementing Regulation (EU) 2026/977.
- **Downstream supply chain diligence:** Vital clarification from the Court of Justice of the European Union (CJEU) in *Dürr Dental v Cattani* regarding the exact scope of a distributor's formal verification and "due care" obligations under the MDR.

We hope this Mid-year Review serves as a valuable resource to help your business maintain compliance and charter a clear strategic heading for the remainder of 2026 and beyond.

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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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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. In addition, he was also part of a team that conceived and developed a bespoke in-house software invention and R&D tagging tool that has applications in the trade. secret space also.

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Latest Digital Health insights from our Team

01

Draft Guidelines on high-risk AI classification

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The European Commission's draft Guidelines provide important practical direction on how high-risk AI systems should be classified under the AI Act. They offer guidance on intended purpose, Annex I and Annex III use cases, and the circumstances in which providers may seek to avoid high-risk classification.

Our Artificial Intelligence team explores how, despite the Guidelines being extensive and detailed, some key issues still require further clarification, including some Annex III categories, intended purpose, value chain responsibilities under Article 25 and the concept of substantial modification.

What you need to know

- The Guidelines give detailed guidance on how providers should assess whether an AI system is high-risk under the AI Act.
- Intended purpose is central. Providers seeking to avoid high-risk classification must understand this concept and how it is applied in the general-purpose AI space in particular.
- The Guidelines take a narrow approach to the Article 6(3) derogation, with providers expected to document their assessment carefully.
- Annex III use cases are dealt with in some detail, including biometrics, recruitment, workplace decisions, creditworthiness and election-related AI tools.
- Important areas remain unresolved, including intended purpose, Article 25 responsibilities across the AI value chain and the concept of substantial modification.

The European Commission published its highly anticipated and long-awaited draft guidelines on the classification of high-risk AI systems (Guidelines) on 19 May 2026. The Guidelines are comprehensive , running to some 164 pages in total. They are separated into three documents and cover:

1. General principles
2. Guidance on classifying Annex I high-risk AI systems, and
3. Guidance on classifying Annex III high-risk AI systems

We consider some notable takeaways from the Guidance including observations on some key Annex III high-risk use cases together with other topics like intended use.

Key takeaways

Determining high-risk classification

The Guidelines provide guidance on key concepts related to determining high-risk classification:

- **Intended purpose and avoiding high-risk classification:** The Guidelines highlight the importance of intended purpose for high-risk classification. In order to avoid high-risk classification, providers, in particular providers of general-purpose AI systems, will need to ensure that high-risk uses are explicitly and unequivocally excluded across all materials. They will also need to ensure that the product is not positioned as an AI system to be used for any high-risk uses. If these conditions are not fulfilled and high-risk uses are not explicitly excluded, particularly for AI systems that have broad application or are capable of these uses, then the AI system will be presumed to be intended to be used for those high-risk uses and classified as high-risk. Notably, the Guidelines do not mention any requirement to implement technical safeguards to avoid classification. This approach appears to set a lower standard than what is required to avoid classification for general-purpose AI systems under the Prohibited AI Guidelines.
- **Complex systems:** The Guidelines introduce the concept of "complex systems" such as several AI systems / architectures which form part of a more complex AI system. Notably, this covers AI agents also. It refers to the applicability of concepts such as intended purpose and the application of the derogations to these complex systems.
- **Reliance on Article 6(3) derogation:** The Guidelines note that the conditions are to be interpreted narrowly and provide detailed guidance on each condition. The Guidelines also provide further detail on what the documented assessment for relying on the derogation should contain. In addition, they note that providers can be subject to penalties where they improperly relied on the Article 6(3) derogation. Interestingly, it suggests that deployers should confirm that the derogation is relied on by checking the EU database as part of due diligence processes.

High-risk classifications under Annex III

The Guidelines also provide detailed guidance on the conditions and various elements of the high-risk classifications under Annex III, along with helpful practical in and out of scope examples. We consider the headline points arising from this part of the guidance:

- **Biometrics (Annex III, point 1(a), (b), and (c)):** The Guidelines state that the definition of biometric data under the AI Act is intended to be broader than under the GDPR. In addition, it is worth noting that while it does provide some context and examples, it does not definitively clarify the line between high-risk and prohibited biometric categorisation.
- **Recruitment (Annex III point 4(a)):** The Guidelines describe a test for a borderline AI system that may be useful for providers to leverage. The test involves assessing the AI system's potential impact on candidates' employment and career opportunities, or the risk of discrimination. It also provides detailed guidance on when targeted ads might be in and out of scope.
- **Decisions affecting work-related relationships (Annex III point 4(b)):** The Guidelines highlight that the decision does not have to be automated by the AI system necessarily to fall in scope, but rather if the human managing the system relies heavily on the output or the decision is "AI driven", it is enough to bring an AI system into scope.
- **Essential Services - Creditworthiness (Annex III, point (5(b)):** The Guidelines indicate that AI systems used for creditworthiness evaluations or credit scoring for access to *"non-essential private services"* will be out of scope and provide further detail on this concept.
- **Administration of justice and democratic processes - influencing the outcome of elections (Annex III, Point 8(b)):** Notably the Guidelines indicate that, in certain cases, AI-enabled targeting of political ads and chatbots intended to promote support for candidates or policies may be in scope. For chatbots, the Guidelines are clear that certain safeguards must be implemented to fall out of scope. These include replying to a user that it cannot give any voting advice when asked, or providing only neutral, factual, and informational content about elections.

Notably there are certain high-risk AI related topics that the Guidelines do not address. Unfortunately, despite the length and detail of the Guidelines, the following areas still require guidance and clarification:

- **Article 25(1):** While the Commission mentions Article 25(1), it does not provide any meaningful guidance on this provision which will have a major impact on both providers and deployers alike. However, the Commission notes in footnote 7 that separate guidelines will be issued on *"the practical application of rules for responsibilities along the AI value chain under Article 25 of the AI Act which will include more detailed explanations about the use cases where the three circumstances under Article 25(1) may apply"*.
- **Substantial modification:** The Guidelines do not address the concept of substantial modification in any detail. However, we note that the Commission has previously indicated as part of the Omnibus that separate guidelines on the practical application of the provisions related to substantial modification will be published. We suspect it may be addressed in the Article 25 guidance.

Where to next?

This note is just a high-level summary of some aspects of the Guidelines and focuses on the topics most frequently seen by us in practice. It is not intended to be a comprehensive summary of all the relevant recommendations made in the Guidelines. Our view is that organisations need to take the time now to review the Guidelines and to consider whether any further review of your AI systems is warranted.

"In order to avoid high-risk classification, providers, in particular providers of general-purpose AI systems, will need to ensure that high-risk uses are explicitly and unequivocally excluded across all materials.

02

New EDPB guidelines on scientific research processing

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The European Data Protection Board has issued new guidelines about data processing in scientific research. They highlight the criteria for whether a processing activity is "genuinely" scientific research and set out particularly relevant consent mechanisms and issues. They also touch on storage limitation rules and erasure obligations when looking to future research projects.

Our Data & Technology team explores why organisations involved in scientific research should review the guidelines carefully, as they clarify how research-related data processing will be assessed and what safeguards may be needed to ensure GDPR compliance.

What you need to know

- The EDPB outlined six key-indicative factors for determining whether a particular processing activity counts as scientific research processing.
- Additional processing of data initially processed for a particular research purpose, even if for further scientific research, may trigger obligations.
- Data collected for scientific research may be stored under certain circumstances for specific, reasonably foreseeable future projects.
- Consent may present unique issues in scientific research, and choosing the appropriate mechanism depends on the project's structure.
- Safeguards, such as anonymisation/ pseudonymisation, are particularly applicable and important in many scientific research scenarios.

The European Data Protection Board (EDPB) adopted Guidelines 1/2026 in April 2026, clarifying how the General Data Protection Regulation (GDPR) applies to the processing of personal data for scientific research purposes, for public consultation.

What is "scientific research"?

The guidelines confirm scientific research can be conducted for profit by private entities. They identify six key-indicative factors to determine if data processing is "genuinely" for scientific research, including where it is:

1. Following a methodical and systematic approach
2. Adhering to ethical standards
3. Ensuring verifiability and transparency, e.g. peer review or publication
4. Maintaining autonomy and independence in the research environment
5. Having objectives that contribute to society's general knowledge, and
6. Showing the potential to apply existing knowledge in novel ways.

Activities meeting all criteria are presumed to be scientific research, but the EDPB notes that controllers who *"do not meet all factors"* may still *"be able to demonstrate why the activities should nonetheless be considered scientific research."* However, the examples referenced in the guidelines focus on expected cases and not the borderline use cases where guidance is most needed.

The guidelines explain that data need not be limited to a particular project but may be *"processed in a research data facility for the purpose of making the data available for future research projects within a specific area of research"* if the operations meet the six factors. *"Ancillary processing"* during tasks closely related to scientific research may also count under a case-by-case analysis. This might include, for example, processing contact details of potential research subjects.

GDPR Article 5 considerations

The EDPB clarified three topics related to GDPR Article 5:

- **Further processing:** If a controller collects personal data for a specific scientific research purpose, as the sole purpose or among several, scientific research is deemed a primary purpose. Processing that data for a different purpose, even another scientific research purpose, constitutes further processing. If data is originally collected for a non-scientific purpose, later processing for scientific research counts as further processing. If one controller provides personal data to a second controller for scientific research processing, the act of providing the data is deemed further processing if it was not originally collected under a primary purpose of scientific research. Further processing typically requires notifying data subjects, unless doing so would *"seriously impair the achievement of the objectives of a scientific research project"*, such as by introducing bias.
- **Presumption of purpose compatibility:** Further processing for scientific research is presumed compatible with the initial purpose under Article 5(1)(b), i.e. no compatibility test is needed. However, a compatibility test is required where the primary purpose, but not the further purpose, is scientific research.
- **Storage limitation:** Controllers may sometimes store personal data for further research, such as when results directly inspire future projects using the same data. Data may not be stored for "generic scientific research". However, it can be stored, with appropriate safeguards/regular review, for specifically identified potential research in a particular area for future activities reasonably foreseeable given the *"nature, scope, context, and purpose"* of processing.

Lawfulness and scientific research

The EDPB identifies four legal bases for scientific research processing:

1. Consent
2. Legal obligation
3. Public interest, and
4. Legitimate interest

Processing of special categories of personal data, including criminal convictions, is subject to additional special procedures. The guidelines highlight consent issues, e.g. the physical/mental state of clinical trial patients, and the usefulness of dynamic consent (initial consent given for known stages, and separate consent given for newly arising stages) for certain long-term research projects. They also discuss "broad" consent, a term recognised in Recital 33 GDPR, and the limited circumstances where it might be appropriate.

Right to be forgotten and scientific research

Article 17(3)(d) provides an exception to erasure obligations for scientific research, but it should *"only be applied in limited circumstances where erasure is likely to render impossible or seriously impair the achievement of the scientific research purposes".*

Safeguards and scientific research

The guidelines emphasise the importance of safeguards, naming anonymisation/pseudonymisation as particularly applicable for research requiring aggregate data, as opposed to studies tracking individuals over time.

Conclusion

The guidelines clarify many scenarios, but compliance when processing personal data for scientific research remains complex. This underscores the need for robust and adaptable governance frameworks that appropriately balance important research with the rights of data subjects.

03

Software update requirements to empower consumers

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Stricter requirements regarding software updates for digital products and green claims are coming into force in September 2026. The new requirements are part of the EU's wider legal framework for empowering consumers for the green transition. Our Planning & Environment team reviews why businesses selling digital products or making green claims should review their consumer-facing information now, as the new rules will increase scrutiny of how software updates, sustainability claims and product information are presented to consumers.

What you need to know

- New software update requirements will take effect from 27 September 2026.
- Withholding information on the negative effects of software updates will be prohibited.
- Presenting a software update as necessary, when it only enhances functionality features, will be prohibited.
- The minimum period during which software updates will be implemented will have to be provided to consumers at the point of sale.
- Other consumer protection measures are also being introduced to tackle false and misleading green claims.

Introduction

EU consumer protection law targets misleading "green" claims and promotes sustainable, repairable and long-lasting products. The legal framework at EU level includes the Empowering Consumers for the Green Transition Directive.[1] It aims to empower consumers for the green transition through better protection against unfair practices and through better information.

The Directive was transposed into Irish law by the ECGT Regulations[2] in April 2026. The Regulations will come into operation on 27 September 2026.

Software updates

An important feature of the Regulations relates to new, stricter software update requirements for digital products. The following two practices will be prohibited:

- Withholding information from a consumer about the fact that a software update will negatively impact on the functioning of goods with digital elements or the use of digital content or digital services, and
- Presenting a software update as necessary, when it only enhances functionality features. Verified information on updates must be provided to ensure that consumers have an accurate understanding of the necessity of the software update.

In certain circumstances, traders of products with digital elements, for digital content or for digital services, will be required to provide the following information to consumers:

- The minimum period during which the producer or provider of the product will provide software updates. The period will have to be expressed as either a period of time or by reference to a date.

This obligation applies to both on-premises and off-premises sales. The obligation will only arise in circumstances where the producer or provider of the product makes the information available to the trader.

[1] Directive (EU) 2024/825 of 28 February 2024 empowering consumers for the green transition through better protection against unfair practices and through better information
[2] S.I. No. 124/2026 - European Union (Empowering Consumers for the Green Transition) Regulations 2026

Green claims

Greenwashing is a voluntary claim about the environmental or social characteristics of a product or company that is misleading. Stricter international regulation and stakeholder scrutiny is increasing pressure to ensure that these claims are not misleading. Legislation aims to ensure that business' claims are accurate, verifiable and not misleading.

The Directive and ECGT Regulations prohibit the following types of claims from 27 September 2026:

- Unverified, generic claims such as that a product is "green" or "eco". Recognised standards are available to verify these claims before they are made.
- Carbon neutral claims are only permitted when they are based on the actual lifecycle of a product.
- Sustainability labels must be based on specified certification schemes.
- Claims that a product as a whole is sustainable if only one component meets the claim.
- Claims of compliance with legal requirements within the relevant product category on the EU market as a distinctive feature of the seller's offer.
- Future performance claims, e.g. climate neutral by 2030, must be based on clear, objective, publicly available and verifiable commitments, which are set out in a detailed and realistic implementation plan that includes measurable and time-bound targets.
- Irrelevant benefits. For example, making a claim about a particular product when it does not result from any specific feature of the product and is common to that type of product.

Conclusion

Stricter rules for providing information about software updates will be in place from 27 September 2026. Digital health businesses should ensure that they provide accurate details on any software updates. This includes being vigilant about not concealing information on the negative impact of a software update on goods that contain digital aspects. For example, when providing a software update, it will be important to communicate any potential negative effects of the update such as negatively impacting battery duration.

04

Medical technology creators face new EU assessment rules

Medical device conformity assessment timelines

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Medical device and in vitro diagnostics manufacturers have long complained about slow and uneven conformity assessments. The newly adopted Commission Implementing Regulation aims to fix that by imposing uniform rules on the notified bodies that carry out those assessments. The rules cover timelines, pricing transparency and re-certification and seek to ensure enhanced predictability for product planning without changing what devices need to prove to get certified.

What you need to know

- The European Commission has adopted Commission Implementing Regulation.[3] It sets uniform procedural and quality management requirements for notified bodies doing conformity assessments under the Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR).
- The Regulation was published in early May 2026 and is expected to apply from February 2027. Some reporting duties start later.
- The rules apply to all products requiring conformity assessment under both the MDR and IVDR.

Why the EU moved now

Under the MDR and IVDR, notified bodies play a central gatekeeper role. Yet practice has varied widely across the EU. Some manufacturers received fast, structured engagement. Others faced long delays and unclear fee estimates. The Commission has said these divergent practices harmed predictability and market access.

This measure sits alongside a broader reform effort. The Commission published a legislative proposal to amend both the MDR and the IVDR in December 2025, known as the Simplification Package. It proposes to:

- Reduce administrative burden
- Support digitalisation, and
- Improve certification efficiency.

It has not yet been adopted; it must pass through the European Parliament and the Council before becoming law.

The core change: deadlines for conformity assessments

The Implementing Regulation introduces maximum time caps for stages of conformity assessment work carried out by notified bodies. These caps are designed to reduce drift and improve planning for manufacturers.

Examples reported by specialist commentary include caps such as:

- 30 days for the notified body to issue a quotation following a complete application.
- 120 days for a quality management system audit.
- 90 days for technical documentation assessment and product verification.
- 20 days for final decision and certificate issuance.

[3] (EU) 2026/977

These are intended to bring structure to a process that has often lacked reliable timing. They should help manufacturers build more realistic launch plans and investor timelines.

The new framework does not mean every assessment will be fast. Timelines can be paused where:

- The notified body needs more material
- Non-conformities must be addressed, or
- Where other inputs are required.

This protects the integrity of the review. It also means poor file readiness will still create delays.

The second change: transparent pricing for safety checks

Cost uncertainty has been a major complaint, especially for SMEs. The Implementing Regulation addresses this by standardising how quotations are prepared and what they must contain.

Key features described in published analysis include:

- Notified bodies should only quote once they have a minimum defined dataset from the manufacturer
- Quotations must include an estimated overall cost, with more detail across key workstreams, plus an estimated timeline, and
- Where actual costs are expected to exceed the quoted estimate, notified bodies must inform the manufacturer and explain the reason.

The purpose is not to cap fees. It is to ensure manufacturers can see what they are paying for and can compare providers on a clearer basis.

What this means for device creators

- **Product planning should become more reliable:** Defined time caps should help teams map regulatory milestones against design freezes, validation, and supply chain readiness. That said, manufacturers should still plan for pauses where files are incomplete.
- **Better budgeting, but fewer excuses:** Clearer quotations should reduce “surprise” costs. However, manufacturers will likely face firmer expectations around dossier quality and responsiveness.
- **Notified body selection may become more evidence-led:** Once annual transparency reporting begins in 2028, manufacturers will have publicly comparable data on timelines and costs across notified bodies. Until then, selection will still rely largely on reputation and direct engagement.

What next?

If you are planning a CE mark submission, now is the time to recalibrate your assessment plan. A short readiness review can identify file gaps, set a realistic submission timeline, and improve cost predictability when you engage a notified body.

“Product planning should become more reliable: defined time caps should help teams map regulatory milestones against design freezes, validation, and supply chain readiness.

05

Promoting medicines on social media

Key takeaways from new HPRA guidance

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Businesses are generally aware that prescription medicines cannot be promoted on television or in print. What is often overlooked is that the same legal restrictions also apply to online activity. A post on Instagram, a LinkedIn article or a short-form video discussing weight-loss treatment may all fall within the legal definition of advertising.

The Health Products Regulatory Authority (HPRA) recently addressed this by publishing a dedicated webpage[4] to clarify that digital content is not treated differently. The new webpage clearly confirms the position: online content is subject to the same legal framework as traditional advertising.

What you need to know

1. Prescription medicines must never be advertised to the general public online.
2. Advertisements for non-prescription medicine must comply with strict national regulations.
3. Influencers and brand ambassadors are bound by the same strict advertising laws as traditional media.
4. Companies must ensure all marketing materials about a product must, among other things, align with the information in its Summary of Product Characteristics (SmPC).
5. The HPRA closely monitors all online medicine promotions.

What counts as advertising

The starting point is the definition of advertising under the Medicinal Products (Control of Advertising) Regulations 2007, as amended.[5] This definition is not limited to obvious promotional campaigns. Instead, it broadly covers any communication or activity intended to encourage the prescription, use, sale, or supply of a medicine.

In practical terms, this captures a wide range of content, including:

- Social media posts and stories
- Blog articles and website material
- Testimonials or user experiences, and
- Influencer or affiliate content

There is no requirement for a formal commercial link between the person making the communication and the product. Content can fall within scope simply because of its intended effect or purpose.

The rules also extend beyond direct references to medicines. Services that promote or lead to the prescription, supply, sale or consumption of a medicine may also be treated as advertising. This is particularly the case where the messaging encourages engagement with a specific treatment pathway.

[4] HPRA - Promoting medicines to the public on social media
[5] S.I. No. 541/2007 - Medicinal Products (Control of Advertising) Regulations 2007

The regulator's focus is broader than expected

The HPRA's guidance[6] is not directed at a narrow group of pharmaceutical manufacturers. Any person or business that promotes a medicine to the public in Ireland may fall within the regulatory scope. This includes:

- Online pharmacies
- Telehealth providers
- Wellness brands, and
- Individuals posting content

This approach reflects how medicines are now discussed and marketed. Social media, websites and digital services are treated as mainstream advertising channels rather than informal or secondary platforms. The regulator has also made clear that it will intervene where necessary, including requiring the removal of non-compliant content.

At a high-level, some of the key advertising rules include:

- **Unauthorised medicines:** Medicines that are not approved or registered in Ireland cannot be advertised.
- **Prescription-only medicines:** These must never be advertised to the public, in any format.
- **Free samples:** Medicines cannot be offered as samples to anyone who is not authorised to prescribe them.
- **Endorsements:** When medicines are advertised to the public, they must not include recommendations from healthcare professionals, scientists or celebrities.
- **Non-prescription medicines:** Certain non-prescription medicines may be advertised to the public. This is subject to certain restrictions. The content must be accurate and not misleading. It must also be presented in a balanced and objective manner. In addition, it must be based on the SmPC, which is the official document setting out the medicine's properties, indications and conditions of use. The advertising must also encourage the rational use of the medicine, present it objectively and without exaggerating its effects, and must not be misleading.

What this means for your business

The HPRA's new webpage is a strong reminder that their monitoring of social media for medicine advertising is both active and ongoing. Any business that mentions medicines online, should treat this as a prompt to review its current practices and ensure they comply with all rules for advertising to the public. Those in the sector should ask the following questions:

1. Do any of the medicines you reference online have prescription-only status in Ireland?
2. Does your content encourage people to seek, buy or use a specific medicine?
3. Are you working with influencers, content creators or affiliate partners whose posts refer to your products?

If the answer to any of these questions is yes, a compliance review is a sensible next step.

"A post on Instagram, a LinkedIn article or a short-form video discussing weight-loss treatment may all fall within the legal definition of advertising.

[6] HPRA – Guidance to Advertising Compliance

06

Distributor obligations and medical device classification under the MDR

Key takeaways from new HPRA guidance

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In a recent judgment, the Court of Justice of the European Union provided welcome clarification about distributor obligations under the Medical Devices Regulation. Specifically, the judgment delivered in *Dürr Dental SE v Cattani Deutschland Helmes GmbH & Co. KG* addresses a question of mounting practical importance.

That is, the extent of a distributor's duty under Article 14 of the MDR to verify that a product it places on the market has been correctly classified. This question is particularly relevant in instances where the manufacturer has CE-marked it as a machine rather than a medical device.

Our Life Sciences Regulatory team examines the judgment, which provides important guidance on the scope of distributor compliance obligations under the MDR.

Background

Dürr Dental SE manufactures oil-free dry-air compressors for dental treatment, classified as risk class IIa medical devices. Cattani Deutschland Helmes GmbH & Co. KG distributes comparable Italian-made compressors in Germany for the same purpose. Test purchases by Dürr Dental in 2020 and 2021 revealed that the Cattani compressors bore CE marking referencing only the Machinery Directive 2006/42, not the MDR, and lacked the four-digit notified body identification number required for class IIa devices. The manufacturer's instructions for use made clear the compressors were intended for use with dental treatment units in patient care.

Dürr Dental issued a cease-and-desist notice. Cattani Deutschland refused and consulted the manufacturer, which confirmed the product was not a medical device. Cattani Deutschland also contacted the German Federal Institute for Drugs and Medical Devices (BfArM), which concluded that no official measures were required. After mixed outcomes in the lower courts, the Bundesgerichtshof (the German Federal Court of Justice) referred five preliminary questions to the CJEU concerning Article 14 of the MDR, as follows:

- The extent of a distributor's duty to verify that a product it makes available on the market is a medical device, bears a CE marking as a medical device and is accompanied by the required EU declaration of conformity drawn up by the manufacturer.
- The relevance of how the device was CE-marked by the manufacturer, including whether it was CE-marked as a medical device or an accessory for a medical device, not CE-marked at all or instead, CE-marked by reference to the Machinery Directive.

- The scope of the distributor's verification obligations under the MDR, specifically whether they include verifying the product's risk classification, and where relevant, the requirement to be marked with a notified body identification number.
- The effect of a distributor being made aware of a product's potential non-compliance with the MDR through a competitor's letter of formal notice.
- The importance of the clarity of the letter of formal notice given its clear indication of an infringement of the law and of any assurances provided to the distributor by the manufacturer or public authorities that the objections in that notice are unfounded.

Decision

The CJEU addressed all five questions but grouped them into three sets of answers, as follows:

1. Verification of consistency

The CJEU held that distributors are not required to repeat the manufacturer's conformity assessment or independently verify the accuracy of the CE marking on each product. Primary responsibility for device conformity lies with the manufacturer. However, the obligation to act with 'due care' under Article 14(1) of the MDR, read with the third subparagraph of Article 14(2), requires distributors to carry out a 'verification of consistency' based on the information at their disposal. Relevant materials may include the EU declaration of conformity, the CE marking, the instructions for use, and the information on the manufacturer's website. A clear inconsistency might arise, for example, where a product plainly intended for medical use is CE-marked under the Machinery Directive. In these circumstances, the distributor must recognise and act on this. A breach of the distributor's due care obligation will arise only where the classification error is clear.

The CJEU held that it was a matter for the referring court to determine, in light of all the circumstances of the case, whether the distributor's efforts were sufficient to satisfy this obligation. In making that assessment, account should be taken of the basic knowledge of a medical device distributor, the content of the documents available to it and the technical complexity of the case.

2. The notified body identification number

A distributor is not obliged to verify the accuracy of a manufacturer's risk classification; that task requires technical expertise beyond what can reasonably be expected of a distributor, particularly a small and medium-sized enterprise (SME). However, where information available to the distributor indicates that the device has been classified in a risk class requiring notified body involvement (class IIa, IIb or III), the distributor's obligation to act with due care includes a formal check that the CE mark is followed by the four-digit notified body identification number, as required by Article 20(5) of the MDR. The CJEU held that this is a formal verification, not a substantive classification exercise.

3. Responding to concerns about non-conformity

The CJEU held that a formal notice from a competitor setting out factual and legal reasons for alleged non-compliance must be taken into account by the distributor as part of its duty to act with due care. However, it is for the distributor to assess whether that notice gives rise to a reason to believe that the device is not in conformity.

Where the distributor consults the manufacturer and the manufacturer considers the allegation unfounded, the distributor is not obliged to follow that opinion if it still has doubts. However, it will not breach its duty of due care by relying on the manufacturer's view, unless that view appears manifestly unfounded. Where the distributor has also informed the competent national authority, and that authority issues a clear and reasoned opinion rejecting the alleged non-compliance, any doubts on the part of the distributor about the product's conformity are fully dispelled by that opinion.

Impact

This judgment provides welcome clarity about the role and obligations of distributors under the MDR. It is particularly important for products on or near the boundary between non-medical and medical use.

It confirms that distributors are not expected to verify the classification of each product and repeat the conformity assessment carried out by the manufacturer. However, the obligation to act with due care requires that, before making a product available on the market, they verify the consistency of the CE marking with the applicable legislation based on the information available to them. If the declaration of conformity, instructions for use, website content or product presentation point to an obvious inconsistency, this cannot be ignored. The judgment also confirms that responsibility for correct classification remains with the manufacturer, while requiring distributors to identify clear warning signs and carry out basic formal checks where the product is presented as falling within a higher risk class. In practice, that is likely to require stronger onboarding procedures, clearer escalation channels and better record-keeping across the supply chain.

Lastly, the judgment provides clarity that a distributor may generally rely on the manufacturer's explanation unless it is plainly unsustainable. For manufacturers, especially those marketing borderline products under machinery legislation, the case highlights the need for a prompt review of classification decisions and supporting documentation.

07

Application of limitation periods under the PLD

LF v Sanofi Pasteur SA

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The Court of Justice of the European Union (CJEU) recently delivered a significant judgment in *LF v Sanofi Pasteur SA*.[7] The decision concerns the application of limitation periods and the coexistence of liability regimes for claims made under the Product Liability Directive[8] (the PLD). Our Product Liability team examines the decision which also confirms the validity of the 10-year "long-stop" period to claims involving progressive illnesses.

Background

The proceedings arose from litigation in France. The claimant was administered a vaccine manufactured by Sanofi Pasteur in 2003. She developed a range of progressive symptoms from 2004 onwards and was diagnosed in 2008 with macrophagic myofasciitis, a rare immune mediated muscle disorder. The claimant attributed this diagnosis to aluminium-based adjuvants contained in the vaccine.

The claim encountered difficulties relating to causation and, critically, limitation. In that context, the Cour d'appel de Rouen (Court of Appeal) referred a request for a preliminary ruling to the CJEU. It sought guidance on three issues under the PLD:

- The determination of the starting point of the three-year limitation period under Article 10
- The validity of the 10-year "long-stop" under Article 11 in light of Article 47 of the Charter of Fundamental Rights of the European Union (the Charter), and
- The extent to which claims under the Directive may coexist with national fault-based liability regimes in accordance with Article 13.

Decision

The CJEU's findings reinforce a strict interpretation of the Directive's procedural timelines to ensure legal certainty for producers while maintaining high standards of consumer protection.

1. The three-year limitation period (Article 10)

Article 10 requires that proceedings are brought within three years from the date on which the injured person became aware, or should reasonably have become aware, of:

- The damage
- The defect, and
- The identity of the producer

The CJEU clarified that *"awareness of damage"* does not require knowledge of the full or final extent of the harm. It also does not depend on the medical stabilisation or consolidation of the injury. The limitation period begins once the damage has definitively become apparent and can be linked to the product. The Court explicitly ruled that the progressive nature of an illness does not delay this start date. It further held that national rules that postpone the limitation period until a condition stabilises are incompatible with the Directive.

[7] C 338/24
[8] 85/374/EEC

2. The 10-year long-stop (Article 11)

Article 11 of the PLD provides that the rights conferred by the Directive are extinguished 10 years after the producer puts the product into circulation. This is the case unless proceedings have been instituted within that period. The referring court questioned whether this absolute long-stop is compatible with Article 47 of the Charter, the right to an effective remedy and to a fair trial, particularly in cases involving progressive illness.

The CJEU upheld the validity of Article 11. It reasoned that, given its interpretation of Article 10, claimants suffering from progressive illness are not, as a rule, deprived of effective access to a court. The three-year limitation period begins when damage has definitively become apparent and can be linked to the defective product, rather than when the injury stabilises. Therefore, injured persons will ordinarily be able to bring proceedings within the 10-year period.

The Court further distinguished progressive illnesses from cases involving latent injury, where harm may remain entirely unknowable for many years. It held that the exceptional approach adopted by the European Court of Human Rights in latent disease cases is not applicable in this context. Article 11 therefore remains a valid mechanism for balancing victim protection with producer predictability.

3. Coexistence of liability regimes (Article 13)

The Court confirmed that the PLD does not prevent an injured person from pursuing national fault-based claims alongside, or instead of, claims under the Directive. However, the Court drew a clear and important distinction. The Directive achieves complete harmonisation regarding strict, in other words "no-fault", liability for defective products. Member States are therefore precluded from maintaining or applying parallel no-fault regimes that duplicate the Directive's liability system on the same legal basis.

By contrast, Article 13 preserves the availability of other liability routes founded on a different legal basis, in particular national fault-based regimes. These claims are permissible where they require proof of specific wrongful conduct on the part of the producer. For instance, they include a failure to exercise appropriate vigilance, the continued marketing of a product despite known safety risks, or other breaches of a duty of care linked to product safety.

Where liability rests on such fault-based grounds, Article 13 does not prevent the claimant from relying on national law in addition to, or as an alternative to, the Directive.

Impact

For producers with products on the market in Ireland, this ruling is helpful. It clarifies important limitation issues under the PLD and the Liability for Defective Products Act 1991 (as amended), which transposes the Directive into Irish law

By its strict interpretation of these limitation periods, the CJEU has provided more certainty for businesses when managing long-tail statutory liability exposure. Crucially, the Court reaffirmed the application of the PLD's existing limitation periods to evolving injuries. It also rejected the expansive interpretation that time only begins to run once a claimant's condition has fully stabilised. This should support defendants and their insurers in pursuing limitation challenges under the PLD where proceedings are not issued within three years of an injury first becoming definitively apparent, regardless of subsequent evolution. The Court's validation of the 10-year long-stop further strengthens this position. By confirming that this provision is compatible with fundamental rights, the CJEU has reinforced the long-stop as a hard deadline for statutory strict liability claims. This provides a clear and predictable cut-off point. It also underscores the importance of maintaining accurate batch release and distribution records to evidence the *'date of circulation'*. However, the application of the long-stop provision will typically not provide a complete answer to product liability claims before the Irish Courts where concurrent fault-based claims under national law are to be expected.

Looking ahead

While this ruling solidifies the "old" regime, change is imminent. The new Product Liability Directive, which must be transposed by December 2026, will introduce a 25-year long-stop specifically for latent personal injuries. While this reform will give enhanced protection to claimants, it risks undermining the legal certainty under the current regime. Until then, *LF v Sanofi* confirms that for progressive illnesses, the 10-year rule remains the standard.

TOP 10

Digital Health recommended reading

01

MDCG: Guidance on classification of medical devices

02

MDCG: Manual on borderline and classification for medical devices under Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices

03

MDCG: Guidance on post-market surveillance of medical devices and in vitro diagnostic medical device

04

MDCG: Q&A Obligation to inform in case of interruption or discontinuation of supply

05

IMDRF: Playbook for Medical Device Regulatory Reliance Programs

06

Team NB: MDR/IVDR revision: impact on the sector

07

Team NB: Agreement related to the transfer of IVDR formal application and of appropriate surveillance of legacy devices

08

MedTech Europe: Position paper - MDR/ IVDR revision: Building a simpler, more predictable framework for patient access and innovation

09

MedTech Europe: Position paper - New EU rules: more business predictability and transparency in medtech conformity assessment

10

COCIR: Targeted revision of EU MDR Rule 11 for medical device software

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ABOUT US

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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