MASON HAYES & CURRAN

Digital Health Mid-Year Review 2024

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Welcome to Mason Hayes & Curran's Digital Health Mid-Year Review 2024

As EU policymakers strive to foster innovation while ensuring high levels of patient safety, data privacy and cybersecurity, and health systems continue to invest in technologies that will allow them to provide care to growing populations of patients with complex and changing needs, we cover various key legal developments from the last 6 months:

- The European Commission has proposed a package of reforms to adapt EU product liability rules to the digital age and AI, including through the revision of the Product Liability Directive. We highlight some important connections between these frameworks which developers of software medical devices that will be regulated as AI systems should be mindful of
- We provide key takeaways from the ICO's new guidelines on transparency for health data processing, emphasising the need for clear privacy information to build public trust and ensure compliance. We identify the potential harms which could arise from lack of transparency, and the recommended methods for effectively conveying privacy information
- We discuss a recent small claims tribunal decision from Canada, as a cautionary reminder of the risks of chatbot errors and the need for companies to be aware of potential liabilities, in light of the recently adopted AI Act
- We also outline the EU's progress with the "Head Office Tax" (HOT) proposal, aimed at simplifying corporate tax rules for SMEs expanding across Member States, addressing concerns about its scope and potential tax planning opportunities, and recommending monitoring of developments by life sciences SMEs with establishments in other EU Member States

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

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Michaela is Head of our Products practice and is Head of Life Sciences. She advises clients in the pharmaceutical, healthcare, medical device, digital health, cosmetic, 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.

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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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AI and Digital Health Products: EU Product Liability Reform

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As part of its holistic approach to AI policy, the European Commission has proposed a package of reforms to adapt EU product liability rules to the digital age and AI, including through the revision of the Product Liability Directive 85/374/EEC (the PLD). As discussed in our previous article on the PLD, this revised Directive is intended to be complementary in nature to current EU product safety frameworks, such as:

- The EU Medical Devices Regulation (EU) 2017/745 (MDR)
- The In-Vitro Diagnostic Medical Device Regulation (EU) 2017/746 (IVDR), and
- The recently adopted AI Act

These interlinked frameworks give rise to a complex new legislative environment that stakeholders must navigate with care. We highlight some important connections between these frameworks that developers of software medical devices that will be regulated as AI systems should be mindful of.

Broader scope of the PLD

The PLD seeks to update the EU's strict liability regime applicable to products, including software and by extension, AI systems. Accordingly, claims for damage allegedly caused by AI-enabled digital health products and services will fall within the scope of the PLD. This is because the PLD expands the definition of a 'product' to include software:

"'product' means all movables, even if integrated into, or inter-connected with, another movable or an immovable; it includes electricity, digital manufacturing files, raw materials and software".

While the term 'software' is not defined in the PLD, the recitals to the PLD make clear that it applies to software of all kinds, including:

- Operating systems
- Firmware
- Computer programmes
- Applications, and
- AI systems

It also acknowledges that software is capable of being placed on the market as a standalone product and may subsequently be integrated into other products as a component. Accordingly, software will be a product for the purposes of applying no-fault liability under the PLD. This applies 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.

Insofar as an AI system qualifies as a 'product' and 'software', it is proposed to fall within the scope of the PLD. At a high-level, this will mean that the PLD will apply to most, if not all, consumer or public-facing systems, or systems that are components of hardware that qualify as a physical 'product'. Accordingly, digital health products and services delivered using AI-enabled technologies such as wearable devices, telemedicine platforms and health apps will be affected.

Two noteworthy exclusions regarding the scope of the PLD are as follows:

- The new product liability rules contained in the PLD will apply to products placed on the market or put into service 24 months after its entry into force. The current Product Liability Directive 85/374/EEC will be repealed with effect from 24 months after the PLD's entry into force. However, it will continue to apply to products placed on the market or put into service before that date.
- The PLD will not apply to pure information, such as the content of digital files or the mere source code of software. It will also not "apply to free and open-source software that is developed or supplied outside the course of a commercial activity" unless it is subsequently integrated by a manufacturer as a component into a product in the course of a commercial activity.

Defectiveness

Under the PLD, the criteria for determining the defectiveness of a product, including an AI system, will be expanded. Some of these additional criteria, which are non-exhaustive in nature, are particularly relevant to AI systems and link back to AI Act requirements:

- In the first instance, the PLD provides that a product will be considered defective "*if it does not provide the safety that a person is entitled to expect or that is required under Union or national law*". Consequently, an AI system may be deemed defective for the purposes of a product liability claim by virtue of being non-compliant with requirements under the AI Act, the MDR and/or the IVDR.
- Additional defectiveness criteria specified under the PLD include a product's interconnectedness, self-learning functionality and safety-relevant cybersecurity requirements.
- In reflecting the relevance of product safety and market surveillance legislation for determining the level of safety that a person is entitled to expect, the PLD also provides that, in assessing defectiveness, interventions by competent authorities should also be taken into account. This includes "*any recall of the product or any other relevant intervention by a competent authority or by an economic operator as referred to in Article 8 relating to product safety*".

Accordingly, an AI-enabled product's compliance with requirements under the AI Act, the MDR and/or the IVDR and interventions by competent authorities in respect of same, will weigh in the balance in terms of assessing the 'defectiveness' or otherwise of an AI system.

Rebuttable presumption - defectiveness

Under the PLD, the burden remains on a claimant to prove:

- The defectiveness of the product
- The damage suffered
- The causal link between the injury or damage sustained, and the allegedly defective product

These elements must be proven in accordance with the standard of proof applicable under national law in the relevant Member State(s). The PLD acknowledges, however, that injured parties are often at a disadvantage compared to manufacturers in terms of accessing and understanding information about how a product was produced and how it operates, particularly in cases involving technical or scientific complexity. Accordingly, the PLD introduces a rebuttable presumption of defectiveness where:

1. The claimant demonstrates that the product does not comply with mandatory product safety requirements laid down in Union law or national law.
2. The claimant demonstrates that the damage was caused by an "*obvious malfunction*" of the product during "***reasonably foreseeable***" use or under ordinary circumstances.
3. A defendant fails to comply with a court order to disclose relevant evidence at its disposal.

In the context of AI systems, the rebuttable presumption of defectiveness triggered under the PLD by a product's non-compliance with mandatory product safety requirements laid down in Union law or national law could therefore be triggered by an act of non-compliance with requirements under the AI Act, the MDR and/or the IVDR.

Rebuttable presumption - causation

The PLD also provides for the presumption of a causal link between a product's alleged defectiveness and the damage suffered, where it has been established that the product is defective, and the damage caused is of a kind typically consistent with the defect in question.

A rebuttable presumption will arise where a national court must presume a product's defectiveness or the causal link between its defectiveness and the damage suffered, or both, where, despite the disclosure of evidence by a manufacturer, and taking all relevant circumstances into account:

- The claimant faces excessive difficulties, in particular due to technical or scientific complexity, in proving the product's defectiveness or the causal link between its defectiveness and the damage, or both, and
- The claimant demonstrates that it is likely that the product is defective or that there is a causal link between the defectiveness, the damage, or both.

On the interpretation of 'excessive difficulties', Recital 48 of the PLD refers to AI systems specifically. It provides that in determining technical or scientific complexity, national courts must do this on a case-by-case basis, taking into account various factors, including:

- The complex nature of the technology used, such as machine learning.
- The complex nature of the causal link such as a link that, in order to be proven, would require the claimant to explain the inner workings of an AI system.

It further provides that, in the assessment of excessive difficulties, while a claimant should provide arguments to demonstrate excessive difficulties, proof of these difficulties should not be required. For example, in a claim concerning an AI system, the claimant should neither be required to explain the AI system's specific characteristics nor how those characteristics make it harder to establish the causal link.

Manufacturer's control

The PLD introduces various new provisions that recognise that, in the case of technologically sophisticated products, a manufacturer's responsibilities do not necessarily crystallise at the factory gates. This is particularly significant for connected products, where the hardware manufacturer retains the ability to supply software updates or upgrades to the hardware by itself or via a third party.

The PLD provides that the developer or producer of software, including an AI system provider, should be treated as a manufacturer. While the 'provider of a related service' is recognised as an economic operator under the PLD, related services and other components, including software updates and upgrades, are considered within the manufacturer's control where they are integrated, inter-connected or supplied by the manufacturer or where the manufacturer authorises or consents to their supply by a third party.

A 'related service' is defined in the PLD as "a digital service that is integrated into, or inter-connected with, a product in such a way that its absence would prevent the product from performing one or more of its functions". For example, where a manufacturer consents to the provision by a third party of software updates for its product or where it presents a related service or component as part of its product even though it is supplied by a third party. However, a manufacturer isn't considered to have consented to the integration or interconnection of software with its product merely by providing for the technical possibility to do so, or by recommending a certain brand or by not prohibiting potential related services or components.

Additionally, once a product has been placed on the market, it is considered within the manufacturer's control insofar as it retains the technical ability to supply software updates or upgrades itself or via a third party.

This means that manufacturers of products with digital elements may be liable for damage arising from changes to those digital elements that occur after the physical product is placed on the market. This is a significant shift to more of a 'lifecycle' approach. This aligns with the approach adopted under various pieces of EU product safety legislation, including the MDR, where manufacturers must continuously evaluate the impact of software updates and upgrades in products on the market. The consequence for manufacturers of AI-enabled products is that greater attention will need to be paid to:

- The degree of control it exercises over its products once placed on the market.
- Where its products remain within its control, the extent to which changes like software updates and upgrades impact on not just safety but also product liability exposure.
- What 'related services' form part of its products and the level of control exerted over these 'related services', including the nature of the relationship with any third-party providers of related services and the potential consequences of same from a product liability perspective.

Substantial modification

The PLD maintains the general limitation period of 3 years for the initiation of proceedings for the recovery of damages. This limitation period runs from the day on which the injured person became aware, or should reasonably have become aware, of all of the following:

1. The damage
2. The defectiveness, and
3. The identity of the relevant economic operator that can be held liable for the damage.

The PLD contains two modifications to the current 10-year longstop provision in the existing Product Liability Directive. First, an extension to 25 years in certain cases involving latent personal injuries unless the injured person has, in the meantime, initiated proceedings against a potentially liable economic operator. Second, where a product has been 'substantially modified', the calculation of time runs from the date that the substantially modified product has been placed on the market or put into service.

In that regard, the PLD defines 'substantial modification' as the modification of a product after it has been placed on the market or put into service:

1. That is considered substantial under relevant Union or national rules on product safety, or
2. Where relevant Union or national rules do not provide such a threshold, that:
    - Changes the product's original performance, purpose or type without being foreseen in the manufacturer's initial risk assessment, and
    - Changes the nature of the hazard, creates a new hazard, or increases the level of risk.

What amounts to a 'substantial modification' can be quite case specific. However, the reference in the definition to modifications that are "considered substantial under relevant Union or national rules on product safety" engages the AI Act. This is because it contains references to substantial modification in the context of 'high-risk AI systems', i.e. most software medical devices regulated as AI systems owing to the application of MDR, Annex VIII, Rule 11 and Article 6 of the AI Act. One such example is high-risk AI systems that continue to learn after being placed on the market or put into service.

Where no thresholds are provided under the relevant Union or national rules on product safety, for example in cases involving regulated AI systems that are not high-risk under the AI Act, the threshold is assessed by the extent to which the modification changes the product's original intended functions or affects its compliance with applicable safety requirements or changes its risk profile.

We expect that the practical application of these concepts in the context of AI systems will require complex and case-specific analyses on liability exposure and mitigation.

Irrespective of which threshold criteria is applicable to a specific AI-enabled product, AI system providers and providers of products with AI components, will need to carefully track how relevant AI systems are changing and the legal consequences of those changes.

Conclusion

On one hand, digital health stakeholders of products regulated under the MDR and/or the IVDR may be uniquely well-placed to adapt to these changes given their experience of complying with the sophisticated EU medical device regulatory framework. On the other hand, however, the move to bring the EU product liability regime up to speed with updated product safety legislation is likely to give rise to increased litigation risks that will require careful management, particularly for liability exposure in respect of software as a 'product' for the purposes of product liability claims. To prepare for these incoming changes, digital health stakeholders with products on the EU market should carefully consider their potential liability exposure under the PLD.

We would recommend that they carefully analyse their existing product portfolio to:

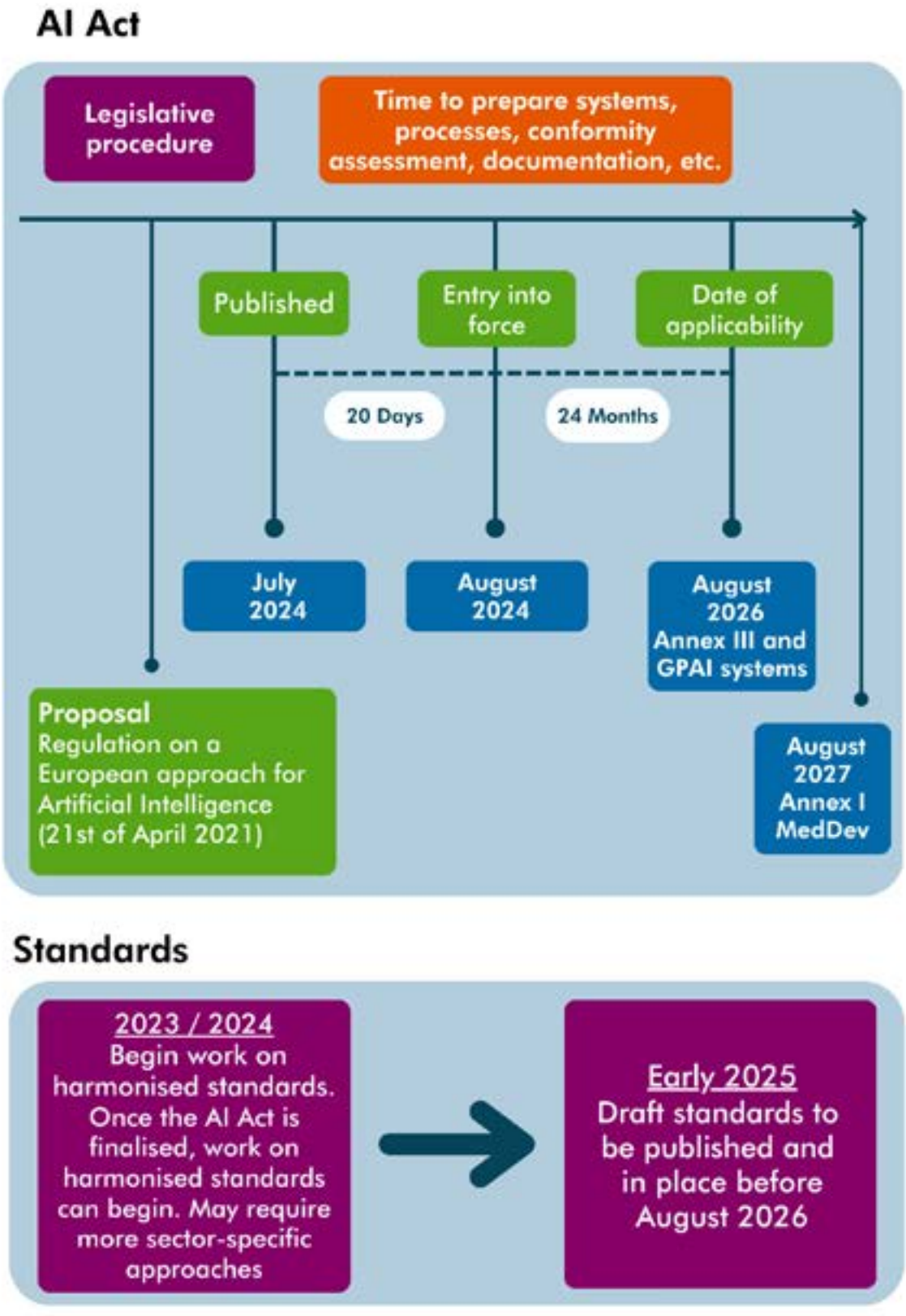
- Identify what products would fall within the scope of the PLD, including a review of third-party software and 'related services', i.e. digital services embedded in their hardware products.
- Review the warnings and disclaimers provided to users relating to risks or potential harm associated with using their products and related services, particularly having regard to the extended definition of damage.
- Incorporate the necessary screens and protocols into their product roadmaps in order to identify and mitigate EU product liability exposure.

Digital health stakeholders should also review their:

- Product liability insurance to ensure, amongst other things, that their coverage includes all damage envisaged under the PLD. Specifically, they should ensure that coverage extends to destruction or corruption of data and medically recognised damage to psychological health and to ensure that related services are also covered.
- Contractual arrangements with other economic operators to ensure there are adequate liability and indemnity provisions in place. This is particularly important given the new provisions in the PLD around service providers and what is considered to be within the manufacturer's control – even if a third party is carrying out certain tasks or services on their behalf.

For more information, contact a member of our **Product Regulation & Consumer** team.

Timeline for Compliance with AI Act for Medical Devices



Regulating Medical Devices in the EU and UK

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The regulatory landscapes governing medical devices within the European Union (EU) and the United Kingdom (UK) have seen significant developments in recent years. With the EU's implementation of a Medical Devices Regulation and In-vitro Diagnostic Medical Device Regulation, and the UK's regulatory transition post-Brexit, industry stakeholders must now track separate and diverging requirements in these markets. This article provides an overview of the regulatory frameworks in both jurisdictions, highlighting key amendments, areas of divergence, and their implications for stakeholders.

European Union's regulatory landscape

Within the EU, medical devices are tightly regulated to ensure their safety and performance throughout their lifecycle, from pre-market evaluation to post-market surveillance.

The regulatory framework for medical devices prior to 2021 consisted of three directives:

- Directive 93/42/EEC, (the MDD)
- Directive 90/385/EEC (the AIMDD), and
- Directive 98/79/EC (the IVDD)

These Directives have been replaced by Regulation (EU) 2017/745 (the MDR), which covers both general and active implantable devices, and Regulation (EU) 2017/746 (the IVDR), which covers in vitro diagnostic medical devices, or IVDs. The reform followed a series of safety issues associated with certain medical devices, such as metal-on-metal hip implants and PIP breast implants.

United Kingdom's regulatory transition

The MDR was originally due to enter into application on 26 May 2020, but its date of application was postponed one year until 26 May 2021 due to the COVID-19 pandemic. The UK was a member of the EU when the MDR was drafted and had actively participated in the shaping of the regulations before Brexit. However, the delayed implementation of the EU MDR meant that it did not form part of the UK's "retained EU law" at the end of the Brexit transition period, which concluded on 31 December 2020. As a result, medical devices continue to be regulated in the UK using the Medical Devices Regulations 2002, SI 2002/618, which effectively implemented the previous EU MD Directives.

The Medicines and Healthcare Products Regulatory Agency (MHRA) launched a Delivery Plan in 2021 to reform the UK regime for medical devices. This plan covered all parts of medical device regulation from pre-market approval, supply of medical devices to the market and post-market monitoring. The UK government envisages that the new regime would run in parallel with current EU rules, which continue to apply in Northern Ireland. This is required in order to maintain the UK government's approach on the movement of manufactured goods into Northern Ireland.

The MHRA released a roadmap in January 2024 outlining future reform, to provide clarity and outline opportunities for medical device providers and the industry as a whole. Many of the proposed amendments to the current UK regime outlined in the roadmap align with the MDR/IVDR. However, the MHRA aims to learn from the challenges faced during the implementation of the EU MDR regime in the EU, and possible areas of divergence include:

- Adopting the Global Medical Devices Nomenclature (GDMN) as medical device nomenclature for the UK system while the EU has adopted the European Medical Device Nomenclature (EDMN).
- Removing rarely used routes such as batch verification, product quality assurance and type-examination. Options to strengthen and clarify the conformity assessment requirements are also proposed.
- Adding obligation on economic operators to inform the MHRA of any issues affecting the supply of medical devices on the UK market.
- Specific regulation for software as medical device (SaMD) is proposed as a key area of divergence.
- On implantable devices: expanding the scope, introducing more stringent pre-market requirements, more controlled access and reducing the relevance of equivalence criteria. The UK Government has decided to maintain the existing scope.
- Expanded requirements for re-manufacturing of single-use devices.

MHRA Work Programme: Software and AI as a medical device

In conjunction with these reforms, the MHRA launched a consultation on the future regulation of medical devices in the UK. In particular, Chapter 10 of the consultation proposal provides the possible changes that would be specific to, or have implications for, SaMD.

These changes include, for example:

1. Defining software
2. Modifying the definition of 'placing on the market' to clarify when SaMD is deployed on websites, app stores and via other electronic means, and
3. Defining specific requirements for AI as a Medical Device (AIaMD).

The intention of the MHRA's work programme is that it will set a benchmark for the development of regulation for medical device software in the UK. The work packages aim to ensure that:

- The requirements for software and AI as a medical device provide a high degree of assurance that they are acceptably safe and function as intended, thereby protecting patients and the public.
- The requirements are clear, supported by both clarificatory guidance and streamlined processes that work for software, as well as bolstered with the tools to show compliance, for instance, via the designation of standards.
- Friction is taken out of the market by working with key partners like the National Institute for Health and Care Excellence and NHSX to align, de-duplicate, and combine requirements, ultimately providing a joined-up offer for digital health within the UK. The NHSX is a joint unit bringing together the Department of Health and Social Care, NHS England and NHS Improvement to drive digital transformation of care.

The MHRA's work programme includes eleven work packages across two workstreams:

1. Key reforms across the SaMD lifecycle, and
2. Further challenges that AI can pose to medical device regulation.

It is anticipated that much of the reform required to meet the objectives in the work packages will be in the form of clarification-based guidance, standards, or processes rather than secondary legislation.

Some key elements of the eleven work packages are:

- **Qualification** - Ensure that medical device regulations are broad enough to capture relevant software and protect patients and the public.
- **Classification** - Ensure that classification rules can closely track the risk that SaMD poses, but also impose proportionate safety and performance requirements and incorporate enough flexibility to address novel devices.
- **Pre-market** – Ensure that SaMD is safe, effective and of requisite quality before being placed on the market, that any pre-market requirements are sufficiently clear and appropriate for SaMD, and that there are appropriate registration requirements for a robust post-market surveillance system.
- **Post-market** – Ensure a robust post-market surveillance system with a clear safety signal to efficiently deal with, and thoroughly capture, adverse SaMD incidents is in place. Ensure SaMD functions as intended via use of real-world evidence, maintains performance and clearly outlines change management requirements and processes.
- **Cyber Secure Medical Devices** - Articulate how cybersecurity issues can translate to SaMD safety issues and ensure this is adequately reflected in both SaMD pre-and post-market surveillance requirements. Cooperate with other relevant bodies, for example, the Connected Medical Devices Security Steering Group for consistency of approach.
- **Mobile Health, and Apps** - Collaborate across government via other work packages to ensure that the SaMD market provides further safety, effectiveness, and quality assurance.

Further announcements

More recently, the MHRA has also announced a suite of further initiatives designed to set the UK apart from the EU as a home for the development and commercialisation of innovative healthcare technologies. These initiatives include:

- **AI Airlock**: Announced in October, this regulatory sandbox aimed at understanding and mitigating risks associated with AIaMD prior to placing on the market will include four to six projects to test regulatory issues in clinical settings. The objective is to identify challenges and share findings to aid regulatory and funding efforts. MHRA emphasises collaboration and transparency, with no guarantee of regulatory conformity. Applications will open after a webinar in June 2024, with an associated pilot programme involving partners like Team AB and the NHS intended to ensure consistent regulatory interpretation.

- **Impact of AI on regulation**: The MHRA published a policy paper in April 2024 outlining the potential impact of AI on medical products regulation. The paper states that many low-risk AI products will be reclassified for greater scrutiny, enhancing user safety. The paper also outlined MHRA plans to use machine learning to streamline document assessments, allowing human experts to focus on critical evaluations.
- **International recognition**: The MHRA recently announced plans to incorporate approvals from third countries and MDSAP certificates alongside UKCA marking until June 2030. A Comparable Regulator Countries framework would tap into global regulatory expertise, including the FDA, EU member states, Health Canada, and the Australian TGA. Reliance on other regulators' assessments would provide for faster UK approvals, focusing MHRA resources on innovation. Different risk classifications and documentation formats would need to align with UK regulations, and operational details would be developed with industry input. Certain product categories would be excluded from this framework, transitional arrangements for UKCA marked devices would be developed and the regulatory status of products on the market in Northern Ireland would remain unaffected.

Comment

It is clear that the MHRA is seeking to position the UK as a leader in the regulation of high-tech healthcare products by establishing a streamlined yet robust regulatory framework. Once planned changes are eventually enacted, it will be interesting to see how, or if, the future regime on the regulation of this sector in the UK differs to that in the EU. While the EU and UK share common objectives of enhancing medical device safety and fostering innovation, disparities will now exist in their regulatory approaches. Key areas of divergence include naming conventions and standards, conformity assessment procedures, and specific regulations for AI-driven devices. However, both jurisdictions recognise the importance of transparency, patient safety, and regulatory collaboration in shaping the future of medical device regulation.

As the regulatory landscape continues to evolve, stakeholders must navigate the complexities of compliance and stay abreast of regulatory updates. Ultimately, a harmonised approach to medical device regulation, balancing innovation with safety, will benefit patients, healthcare providers, and industry stakeholders alike.

Required Reading: Key Digital Health Documents

1. **MDCG 2024-3:** Guidance on content of the Clinical Investigation Plan for clinical investigations of medical devices (March 2024)
2. **MDCG 2024-5:** Guidance on the Investigator's Brochure content (April 2024)
3. **MHRA Roadmap** towards the future regulatory framework for medical devices
4. **MDCG 2024-1 Guidance** on the vigilance system for CE-marked devices
5. **IMDRF Guidance:** Principles of Labelling for Medical Devices and IVD Medical Devices (IMDRF/GRRP WG/N52 FINAL:2024 (Edition 2))
6. **WHO Publication:** Benefits and Risks of Using AI for Pharmaceutical Development and Delivery
7. **Position Paper:** Digital Europe Executive Council for Health's recommendations for EU digital health policy (2024-29)
8. **UK Guidance:** Software and artificial intelligence (AI) as a medical device
9. **MHRA Policy Statement:** International recognition of medical devices
10. **Press Release:** MHRA to launch the AI-Airlock, a new regulatory sandbox for AI developers

ICO's Guidelines on Transparency When Using Health Data

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The Information Commissioner's Office (ICO) has recently published guidelines on transparency in health and social care. This builds on the existing transparency guidelines. The guidelines are directed towards any organisations, public, private or third sector, that process health data, including for research.

The ICO sees transparency as necessary for data protection compliance and building public trust. In that vein, the guidelines are focused on:

- Privacy information - which the organisation must provide in order to comply with the data protection law, and
- Transparency information - which the organisation should provide to comply with the transparency principle and improve the effectiveness of the transparency material.

Key takeaways

Harms arising from lack of transparency

The ICO identifies the following harms as ones that could affect data subjects:

- Psychological harm - this can result in fear, anxiety, and embarrassment where data subjects do not understand how their data is being used
- Loss of control of personal information - where complex information is provided and users are deterred from reviewing the information. As a result this can cause them to lose control over their personal data as they do not understand how it is being processed
- Lack of trust in services - where organisations are not transparent, data subjects can be reluctant to continue using the service. This could in turn impact their health where they are not forthcoming about information about themselves

The identification of harms is important where organisations are considering what mitigations they can put in place as part of carrying out a data protection impact assessment, where one is needed. Increasingly, we have seen privacy data protection authorities focus on loss of control as a harm when looking at how organisations process personal data.

Methods for conveying transparency and privacy information

The ICO states that it is important to understand the data subject's needs when providing transparency information. For example, where the data subjects are not engaging with the organisation in a non-digital form, then the transparency information should be provided in a non-digital form.

The information can be provided to a larger audience or more directly one-on-one, such as by way of letter, depending on the context. Direct forms of communication are not always necessary or appropriate. When considering whether a direct form of communication is necessary, the organisation should consider:

- The impact the information will have on the data subject, and
- The public expectations around the information provided.

Presenting information effectively

Similar to the existing guidance on transparency, the ICO encourages the use of layered privacy information. The most important pieces of information should be prominently displayed in the first layer, with the second and even third layers providing additional details. The first layer should include:

- A brief overview of how the organisation will use the data subject's information and for what purpose
- Highlighting any choices or actions available to data subjects about how their information is used, and
- Signposting data subjects to areas where they can find out more detailed information in the additional layers.

Transparency checklist

The ICO has provided a transparency checklist to help organisations assess whether they are complying with the transparency requirements.

Conclusion

The guidelines expand on many of the existing transparency concepts but highlights the importance of thoughtfully approaching transparency for health and social care data. Organisations should consider how their approach to transparency complies with the guidelines, including whether they are using the best method and presenting information effectively, and whether they can make any changes going forward.

For more information and expert advice, contact a member of our **Privacy & Data Security** team.

Potential Liability for Chatbot Hallucinations?

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As well as now being the regular first point of contact for customers communicating with companies about technical support, payments and routine customer service issues, chatbots are now being deployed in more and more medical settings to deliver efficiencies and reduce costs. While the adoption of the EU's AI Act has attracted most attention for the regulation of chatbots, a recent 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 European Commission's proposed revised Product Liability Directive. The revised Directive will enter into force in 2024 and the new rules will apply to products placed on the market 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, e.g. 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. TThe AI Act has now been formally adopted and will come into force 20 days after its publication in the Official Journal of the EU (OJEU). Member States will, however, have two 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 strongly resist 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.

For more information, please contact a member of our **Artificial Intelligence** team.

Tax Update: EU Continues to Progress with HOT Proposal

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A proposal for the taxation of cross-border branches known as "the head office tax" or "HOT" system is currently making its way through the EU legislative process. The HOT proposal is aimed at simplifying corporate tax rules for micro, small and medium enterprises (SMEs) during their early stages of expansion. It appears to be generally supported by the European Parliament and is seen by the EU as complementary to the more controversial BEFIT proposal aimed at large companies.

Both proposals require unanimous approval at the European Council and therefore their adoption remains uncertain.

What types of life sciences companies is this proposal relevant to?

The HOT proposal is relevant to SMEs who are expanding across EU Member States through branches, referred to as permanent establishments, rather than subsidiaries. SMEs are defined under EU rules as including companies which have fewer than 250 employees and either have an annual turnover not exceeding €50 million or an annual balance sheet total not exceeding €43 million. The vast majority of domestic Irish businesses fall within this definition.

As currently drafted, the HOT system does not apply to companies that are or have subsidiaries. Concerns have been raised that this will exclude a significant number of companies so it is possible that there will be some relaxation of this restriction.

There are additional conditions to qualify for the regime including that for the previous two fiscal years:

- The combined turnover of the branches must not exceed double the turnover generated by the head office, and
- The head office must be resident for tax purposes in the head office Member State during that period

What is the current system for the taxation of permanent establishments?

Under the current rules, companies with permanent establishments in several Member States must comply with a different set of tax rules for calculating, filing and paying corporate tax in every Member State in which they have a taxable presence.

For example, an Irish SME company with branches in France, Spain and Germany must file corporate tax returns and pay corporate tax liabilities in each of those Member States. To calculate the taxable profits in each Member State, the Irish company needs to apply the different national rules on matters such as depreciation, amortisation, tax deductibility of expenses and losses, treatment of interest, bad debts, fines, etc.

How would the HOT system operate?

Under the proposed system, an Irish company with branches in one or more EU Member States would be able to file a single tax return with the Irish tax authorities. Using the above example, this would cover both its own activities in Ireland and the activities of each permanent establishment in other Member States, i.e. France, Spain and Germany. In a significant simplification, the taxable profits of the permanent establishments would be computed in accordance with the tax rules of Ireland. However, the tax rate applicable to the taxable profit of each permanent establishment would be the rate applicable in France, Spain and Germany, respectively.

The company would pay the tax liabilities arising from its own activities and those of its permanent establishments to the Irish tax authorities who would then transfer the tax arising from the profits of each permanent establishment to their respective tax authorities in France, Spain and Germany.

Therefore, the company would only deal with the Irish tax authorities for both the corporate tax return filing and payment of tax.

Will the HOT system be optional?

It is proposed that the HOT system will be optional for SMEs. However, once adopted by a company, the HOT rules will generally apply to all of its permanent establishments for a period of five fiscal years.

Current status of this proposal?

Members of the European Parliament adopted a resolution which is generally supportive of the HOT proposal on 10 April 2024. They have proposed some amendments including extending the scope of the Directive to cover situations where SMEs operate in other Member States with up to two subsidiaries. They also recommend that transposition of the proposed Directive should be required by 1 January 2025.

Concerns

Specific concerns have been raised with the EU Commission by a number of Member States. These include that permanent establishments operating in the same Member State could be taxed differently, depending on where their respective head offices are located. This might lead to tax planning opportunities, with deliberate relocations of head offices towards countries with the most favourable corporate tax regimes. In addition, the exclusion of SMEs who are part of a corporate group has also raised concerns that the proposal would benefit only a small number of SMEs.

Conclusion

We recommend that life sciences SMEs with permanent establishments in other EU Member States monitor developments in relation to this proposal over the coming months. If implemented, the HOT proposal may be an attractive option for SMEs that are within the scope of this new system. This is because it will reduce complexity for them in dealing with corporate tax compliance for their EU branches. However, the key to the success of the system is likely to be dependent on the possible widening of the scope to include companies that have subsidiaries, so that a greater number of companies can benefit from the system.

Due to the requirement for unanimity at the European Council, it will be necessary to resolve the concerns of all Member States to achieve the required support and pave the way for the adoption of the proposal as an EU Directive. Significant work will be required if this is to be achieved in advance of the transposition date proposed by the European Parliament of 1 January 2025.

For more information and expert advice on all relevant taxation matters impacting your business, contact a member of our **Tax** team.

Injuncting a UK Approved Body

Key principles from a recent case

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In a significant judgment for public authorities and regulatory bodies, the Court of Appeal of England and Wales allowed the appeal in *British Standards Institution v RRR Manufacturing PTY Ltd*. The Court considered the principles applicable to interim relief applications against public authorities. While this is a decision of the English and Welsh courts, it is still important and of potential persuasive authority in Ireland. This is due to the shared common law tradition with England and Wales. The judicial review application was taken by the British Standards Institution (BSI) to challenge interim relief obtained against it by RRR Manufacturing PTY Ltd (RRR). By prohibitory and mandatory orders, BSI was (a) prevented from suspending the UKCA certification for RRR's small portable defibrillator medical device (the device) and (b) required to renew the UKCA certificate at a later date, irrespective of its concerns about the device's safety and performance.

The facts

BSI is an 'approved body' in the UK appointed by the Medicines and Health Regulatory Agency (MHRA). It has the power to award, suspend and revoke UKCA certificates under the UK Medical Devices Regulations 2002[1].

The device had both CE and UKCA certification permitting it to be sold in both the EU and UK markets. However, following concerns raised by the MHRA regarding the device's safety, BSI initiated a technical surveillance review of the device's UKCA certificate. In its subsequent decision, BSI identified a number of major and minor non-conformities with the device to be addressed through corrective action plans (CAPs). RRR exercised a right of internal appeal to BSI. This appeal was dismissed. Subsequently, BSI issued a further decision justifying its conclusion. Based on these two decisions, BSI decided to suspend the device's UKCA certification.

RRR applied for judicial review challenging BSI's decisions. It sought an expedited hearing to prevent BSI from withdrawing its UKCA certificate. The grounds for its application for interim relief were that suspending the device's certificate, on the basis of allegedly unlawful decisions, would cause serious and potentially irreversible harm to RRR, both in the UK and in other jurisdictions.

The judgment

RRR's four grounds of claim were:

- Illegality
- Procedural unfairness
- Irrationality, and
- Fettering of discretion

1. *Whereas the EU Medical Devices Regulation (2017/745) (MDR) is now applicable in EU Member States and Northern Ireland, the UKCA requirements for medical devices regulated under the UK Medical Device Regulations 2002 are based on requirements derived from the MDR's predecessor, Directive 93/42/EEC on medical devices (MDD).*

In considering the balance of convenience, the judge applied the principles governing the grant of interim relief in judicial review proceedings as set out in *American Cyanamid Co v Ethicon Limited*[2] modified as appropriate for public law cases. In doing so, she concluded that the balance of convenience favoured maintaining the status quo. She directed that BSI be restrained from suspending or withdrawing the device's UKCA certificate until after a decision on the substantive claim. She also directed that BSI maintain the device's certification, which was shortly due to expire and for which renewal was not automatic, pending determination of the claim.

In reaching her decision, the judge acknowledged that public health and safety is of paramount concern. However, she found no evidence that the device was a current risk on health and safety grounds. She also noted that the MHRA had the power to investigate the device if it was shown to be a risk to public health and safety. The judge further noted that news of the suspension would spread quickly and that RRR would suffer considerable commercial and reputational harm as a result. The judge refused BSI's permission to appeal.

Grounds of Appeal

BSI appealed the decision on the following three grounds:

- The judge misunderstood both the burden of proof under the relevant regulations, and what it was that had to be proved. BSI argued, amongst other things, that the judge was wrong to decide that there was no evidence that the device was a current risk on health and safety grounds. It further argued that it was not for BSI to satisfy the court that the device was unsafe. Rather, it was for RRR to satisfy BSI that the device was safe and met all the essential requirements
- The judge was wrong to grant a mandatory injunction requiring BSI to renew the device's UKCA certification at a future date. BSI argued, amongst other things, that a public authority should not be restrained from discharging its functions in good faith. This was particularly relevant in the context of a mandatory order. BSI contended that such an order would require it to act in a way it considers unsafe and contrary to the public interest
- The judge should have reserved the costs of the interim application until the outcome of the claim was known

Court of Appeal judgment

The Court of Appeal held that all three grounds of appeal should be allowed. Accordingly, the Court of Appeal set aside the prohibitory order restraining suspension of the UKCA certificate. The Court of Appeal also set aside the mandatory order requiring BSI to renew the UKCA certificate at a later date. Additionally, the costs order was set aside.

In her leading judgment, Lady Justice Laing outlined the underlying principles which should have been applied to the facts of the case as follows:

- First, that great weight must be given to the protection of public health
- Second, in accordance with the medical device regulatory framework, the manufacturer must satisfy the approved body that a device is safe and effective
- Third, the court should also give great weight to the assessment of the relevant material by the expert regulator

2. *[1975] AC 396*

In light of those considerations, the Court of Appeal affirmed that, in determining where the balance of convenience lies in a public law case, two important factors are that:

- The court will not readily restrain a public authority from exercising its powers in good faith. Even if a claim passes the threshold test of raising a serious issue to be tried, if there is not a strong *prima facie* case on the merits, this will be a significant factor in the balance of convenience against the grant of an injunction
- Maintenance of public health is a very important objective and must carry great weight in the balancing exercise

Conclusion

This judgment reaffirms the principles to be applied in interim relief applications against public authorities. It confirms that, in the absence of a strong *prima facie* case, the courts should be slow to grant interim relief against a public authority that is exercising its powers in good faith. It also confirms that the courts should afford significant weight to the protection of public health and safety in determining the balance of convenience. While this is a decision of the Court of Appeal of England and Wales, it is still important and of potential persuasive value in Ireland as a common law EU jurisdiction. This is particularly so given that the underlying principles and legal tests applied in this instance are largely the same as those that would be applied in an Irish law context. The judgment can be found online.

Recent MHC Events, Articles & Publications

Events & Webinars

- MedTech Summit 2023: Medical Device Software and AI Medical Devices – Liability through a wider lens
- RAPS Euro Convergence, Berlin
- Future Health Summit 2024
- IBA World Life Sciences Conference, Madrid
- HealthTech Ireland Breakfast Briefing Series: The AI Act and what it means for your organisation
- RAPS Ireland: Substantiation, Advertising & Promotion for Medical Devices
- Technology Conference – Technology and Digital Disruption

Publications

- Mondaq in Association with Mason Hayes & Curran | Product Liability Comparitive Guide 2024
- A question of liability: Who is responsible when an AI medical device leads to patient harm? (Journal of Medical Device Regulation - November 2023)
- Medical Devices: Sources of Regulation (Thomson Reuters Practical Law Series)
- Product Liability Law in Ireland (Lexology Getting the Deal Through Series)
- Medical Devices and the Risk of Trademark Infringement
- Decentralised Clinical Trials in the EU
- The EU AI Act – Imaging and Diagnostics

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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.

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