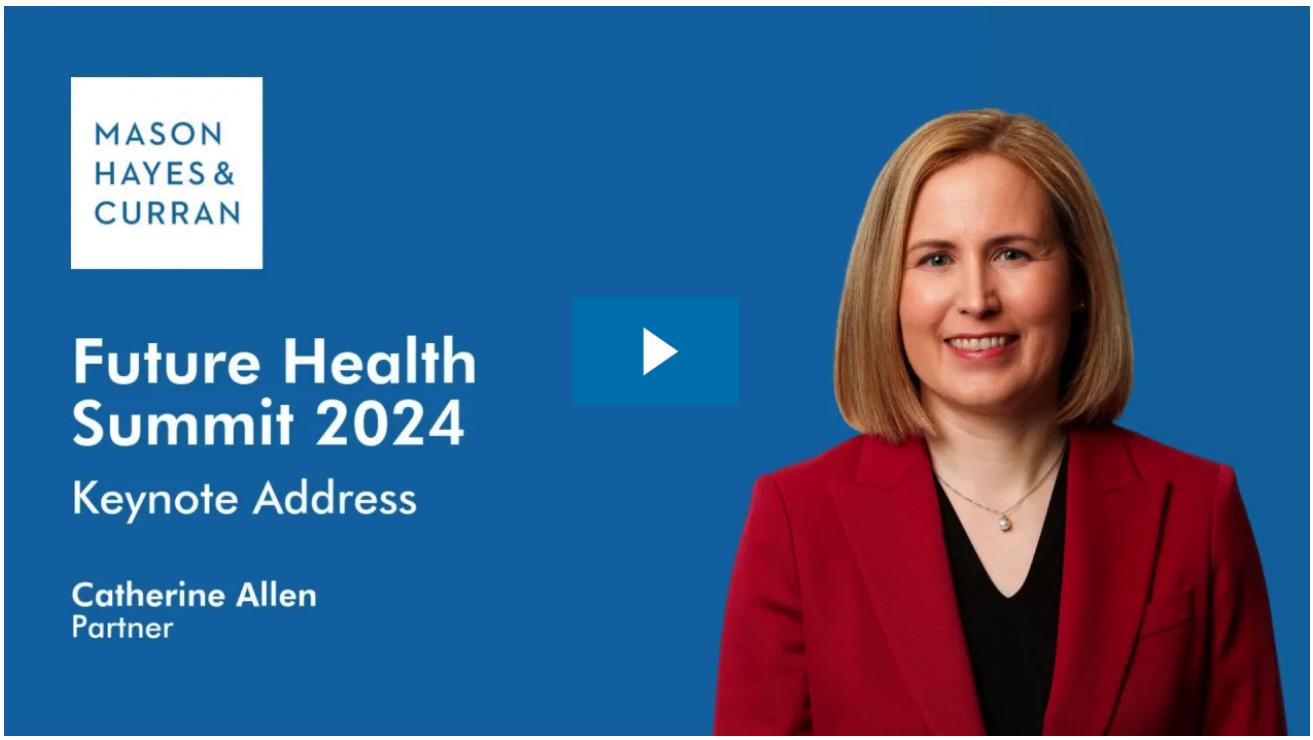
MASON HAYES & CURRAN

# Healthcare Sector Update

## In Brief

Summer 2024

# Welcome




Welcome to the summer edition of our Healthcare Sector Update In Brief series. In this issue, we examine a selection of topics and trends impacting our clients.

First up, in the above video, Catherine Allen, Partner and Head of our Public, Regulatory & Investigations team, recently delivered a keynote address at Future Health Summit 2024. Catherine spoke as part of the Governance session, with a focus on good governance in healthcare investigations.

Other popular insights featured in this edition include:

- Key Aspects of the Statutory Home Support Scheme
- Medical Claim Statute Barred Before Expert Report Received
- Work to Commence Patient Safety Act Continues
- AI and Digital Health Products: EU Product Liability Reform

## Key Contacts

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# Key Aspects of the Statutory Home Support Scheme

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The ageing nature of Ireland's population has created increasing demand for home support services. In Ireland there is no statutory entitlement to receive formal homecare or home support. However, the Health Service Executive (HSE) does provide publicly funded home support services and commissions external or private providers to provide these services. While there is no statutory regulation of home support services in Ireland, legislation is progressing in this area. The General Scheme of the Health (Amendment) (Licensing of Professional Home Support Providers) Bill 2024 was published in May of this year.

## Compliance under the new legislation

The Health Information and Quality Authority (HIQA) will be charged with monitoring compliance by public, private, and not-for-profit home support providers. When introduced, the new legislation will require home support providers to hold a licence from HIQA before they can operate. Those holding a licence will also need to comply with Ministerial regulations which are due to be made under the legislation, and with national standards of care to be developed by HIQA.

The Department of Health projects that, once the Bill is enacted, it will take three years for the new system to become fully operational. This three-year implementation period includes a 12-month commencement period and a 24-month transitional period. During this period, Ministerial regulations and HIQA's national standards will be developed and formalised. HIQA expects to go to public consultation on these standards later this year.

Further details regarding the new legislation are provided for in the Scheme. The following elements form the core of the legislation and should be considered carefully by relevant operators and stakeholders:

- **Registration requirements:** In order to be granted a licence, it is intended that the Chief Inspector of HIQA will need to be satisfied, among other things:
  - With the applicant's fitness to provide a home support service
  - That the applicant can meet the cost of the appropriate policy of insurance, and
  - With the applicant's financial capability to provide home support services
- **Licencing:** HIQA may attach conditions to a licence. Licences will remain valid for three years, after which point they will need to be renewed.
- **Inspections:** The Scheme allows for the inspection of home support service providers to assess compliance with regulations and standards and for the service of a compliance notice as may be required.
- **Appeals and Enforcements:** The Scheme also allows for appeals and enforcements of certain decisions of HIQA.

## Industry concerns

Stakeholders have raised concerns about how this statutory home support scheme will be supported, including:

- **How it will be funded:** The Minister for Health stated in March 2024 that the Department of Health was examining a range of funding options. These options are based on reports that the Department commissioned from the Economic and Social Research Institute (ESRI) and the European Observatory on Health Systems. Home & Community Care Ireland (HCCI), the national membership organisation for managed home support providers, in a report published in April 2024, considered a range of options. These included full state funding through general taxation, co-payments from service users, and long-term care insurance.
- **Recruitment and retention of staff:** HCCI has proposed that social welfare law be amended to incentivise more workers to enter the sector. This approach would also aim to incentivise those already in the sector to work more hours per week, without fear of losing their social welfare benefits.
- **Exclusion of certain types of home support service:** Stakeholders who responded to a survey by the Institute of Public Health indicated their concern that home support services provided by individuals directly employed by a service user, among other types of arrangements, are excluded from regulation. Similar concerns were expressed during pre-legislative scrutiny of the General Scheme of the Bill on 19 June 2024. The Department of Health explained that a balance needed to be struck between regulation and the exclusion of a small number of arrangements that were felt inappropriate for regulation, or where regulation would be too onerous.

## Comment

While the anticipated home support legislation is not yet in force, there have been some recent developments and continued engagement from the wider sector. Stakeholders and Government officials are considering the practical challenges facing the new statutory scheme, including funding and recruitment. The recent pre-legislative scrutiny of the General Scheme of the Bill allowed many of these concerns to be discussed. It will hopefully inform the development of the Bill as well as the associated Ministerial regulations and HIQA national standards.

# Medical Claim Statute Barred Before Expert Report Received

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TA recent judgment in a case before the High Court has reaffirmed that *"a court has to consider what a plaintiff did or did not know on a given date"*[1] in deciding whether a case should be statute barred. Recent caselaw provided that parties were allowed to advance their proceedings by relying on the date of expert reports as their "date of knowledge".

However, *Monaghan v Molony*[2] indicates that this is not always the case. Here, the High Court found that Mr Monaghan had the knowledge he needed to maintain the proceedings before securing an expert report. It also found that the content of the expert report was materially the same as the information already available to him.

## Background

Mr Monaghan sustained an injury in May 2015 to a major chest muscle. He attended his GP on three occasions before being referred for surgical intervention. He underwent a direct repair operation in January 2016 which was unsuccessful. However, an allograft procedure had to be carried out which allegedly caused significant injuries.

Importantly, in October 2015 Mr Monaghan was advised by a treating orthopaedic surgeon that a delay in referring him for surgery was likely to cause the direct repair surgery to fail.

Mr Monaghan issued proceedings outside of the normal two-year statutory timeframe in May 2018, based on an expert report from January 2017. This report essentially stated that the GP's delay in diagnosis and subsequent referral for surgery caused the failure of the direct repair surgery and the need for an allograft procedure to be carried out.

The GP argued Mr Monaghan's claim was statute barred as proceedings should have issued within two years of his date of knowledge. The GP argued that his date of knowledge was long before he issued proceedings[3]. This knowledge involved:

- When he knew the identity of the defendant
- That he suffered an injury
- That his injury was significant, and
- That it was caused by the GP's inaction

1. *O'Sullivan v Ireland [2020] I IR 414 Finlay Geoghegan J. at para 104*
2. *Monaghan v Molony [2024] IEHC 284*
3. *Section 2 Statute of Limitations (Amendment) Act 1991*

## Arguments put forward

Mr Monaghan's contentions included that his date of knowledge ran from the date of his 2017 report or from a subsequent expert report he obtained.

The GP relied on correspondence between Mr Monaghan and his former lawyers and with the Medical Council. This highlighted that Mr. Monaghan:

- Was informed by an orthopaedic surgeon in October 2015 that significant injury was caused by the delay in his operation
- Intended to take legal action in November 2015 as he knew that the delay impacted on the direct repair surgery
- Gave them an account of why his injury from his surgery in 2016 was due to the delay, and
- Highlighted concerns he raised with his former lawyers about his claim becoming statute barred

## Court decision

Ultimately, the High Court found that Mr Monaghan's expert reports did not provide him with a new date of knowledge. This was because the key information was already available to him when he attended the orthopaedic surgeon in October 2015.

In addition, the correspondence with the Medical Council and Mr Monaghan's former lawyers proved that he knew of his injury, the time constraints around issuing proceedings, and he didn't need expert advice to know this. All of these factors meant his claim was statute barred.

## Conclusion

The case highlights that legal practitioners must exercise caution as an injured patient may not be able to rely on the date of their expert report to avoid their claim being statute barred. While it appears that gaining access to correspondence involving a party's former lawyer and the Medical Council is somewhat unique in this case, it also highlights the importance of thoroughly investigating the date of knowledge issue. Lawyers defending these claims should diligently interrogate the facts including seeking access to ancillary information which might suggest an injured patient held the requisite knowledge prior to securing their expert opinion.

# Work to Commence Patient Safety Act 2023 Continues

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Today marks the one-year anniversary since the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 was signed into law on 2 May 2023. We discussed the key features of this legislation in a previous article available online.

Since this legislation was enacted, the Minister for Health launched a National Open Disclosure Framework to complement the Act. The Framework sets out a system-wide approach for public and private health and social care providers to follow, when engaging in open disclosure following notification of a patient safety incident[1].

The Government also advised, in November 2023, that a number of preparatory steps were to be implemented before setting a commencement date for the Act. These steps include:

- Necessary updates to the National Incident Management System (NIMS)
- Roll-out of open disclosure training policy to all HSE staff, and
- The finalisation of the communications programme to be put in place for patient-requested reviews in cancer screening services

The intention is to commence the Act as soon as possible, once these steps have been completed.

HIQA stated in its Overview Report, published in December 2023, that it is expected the commencement of the Act will increase the number of services to be monitored by HIQA. It is also expected that HIQA will require additional resources to manage the volume of patient safety incidents being reported by health service providers[2].

HIQA also launched a public consultation process on amending the scope of the National Standards for Safer Better Healthcare[3]. This process was open for feedback from the public and health service providers during March-April 2024. The aim was to allow them an opportunity to share their views on the inclusion of private hospitals within the scope of these standards. The standards have been utilised by HIQA since 2012 to inspect, monitor and investigate healthcare services provided by the HSE. Effecting this change will allow HIQA to monitor private hospitals upon the commencement of the Act.

## Comment

It remains to be seen whether the Act will be commenced during 2024. While it may present challenges for those working within the health services, the Framework should assist in a consistent approach being adopted to embed a culture of open disclosure resulting in a better, safer care experience for patients and their families.

In the meantime, it is important that health service providers familiarise themselves with their mandatory obligations and put appropriate systems in place to ensure compliance with the Act once commenced.

1. *National Open Disclosure Framework (2023)*
2. *HIQA Overview Report – Monitoring and Regulation of Healthcare Services 2021-2023 (December 2023)*
3. *HIQA – National Standards for Safer Better Healthcare (Draft version 2 for public consultation – March 2024)*

# 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.

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Legal 500, 2024

### Our Healthcare Team

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Chambers & Partners, 2024