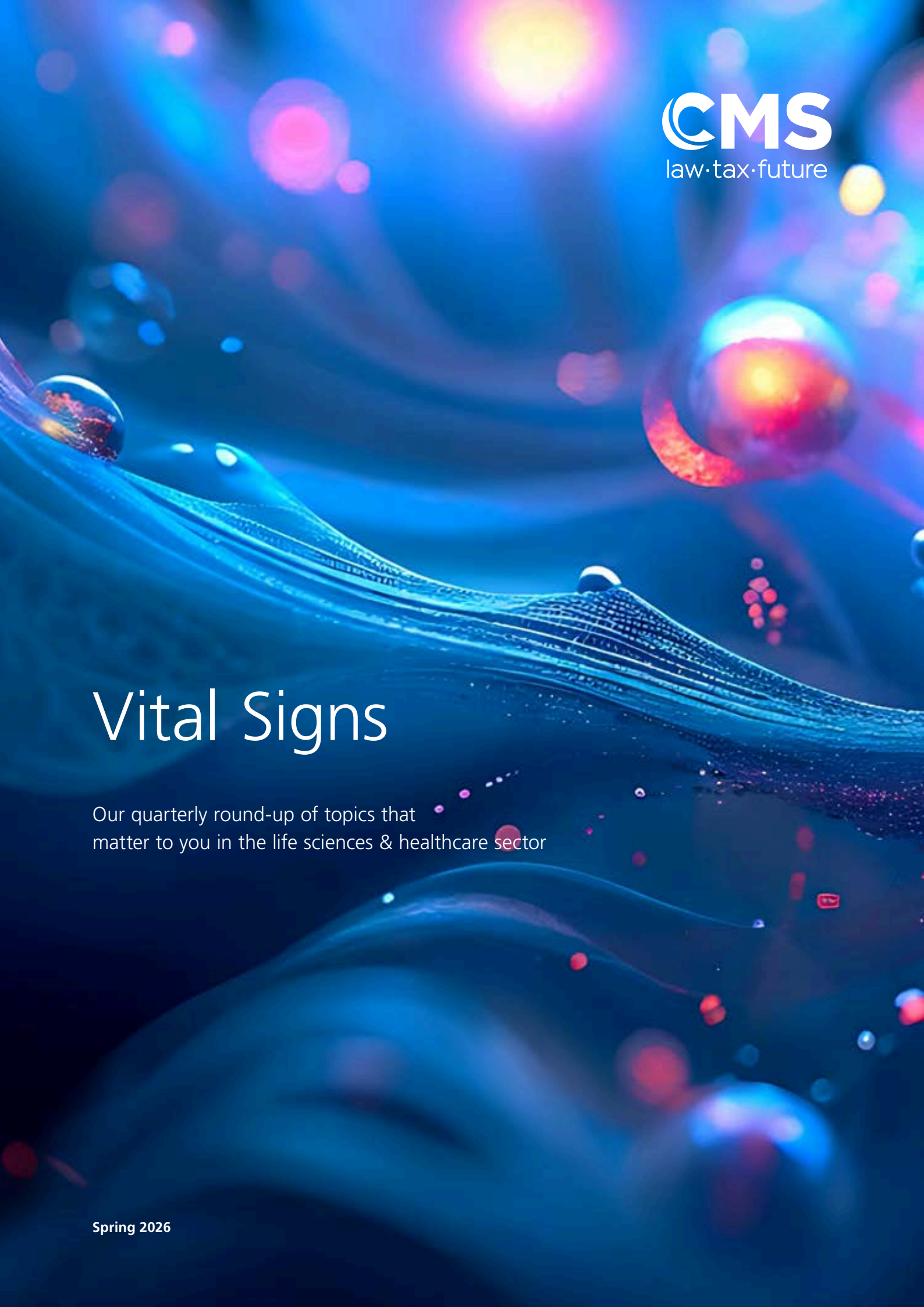


Vital Signs

Our quarterly round-up of topics that matter to you in the life sciences & healthcare sector

Spring 2026

Contents

Introduction

As the life sciences and healthcare sectors continue to evolve at pace, this Spring edition of Vital Signs brings together timely insights on some of the most pressing legal and regulatory developments shaping the landscape.

In this issue, we explore the growing complexity of public procurement in healthcare, where shifting policy priorities and heightened scrutiny are redefining how services are commissioned and delivered. We also examine the implications of the latest market study into private dentistry, highlighting emerging competition concerns and what they may signal for future regulatory intervention.

Collective redress remains high on the agenda, and our feature on class actions considers the increasing litigation risks facing healthcare providers, pharmaceutical companies, and associated stakeholders in an era of greater claimant coordination and funding.

We also consider the intersection of artificial intelligence and patient data – an area of both immense opportunity and significant legal challenge. As AI-driven innovation accelerates, questions around data governance, privacy, and ethical use are becoming ever more critical.

Finally, we turn to medical device regulation in Great Britain, reflecting on the MHRA's February 2026 consultation and what its proposals could mean for the long-term recognition of CE marking, the role of UKCA, and future routes to market for higher-risk and innovative products.

We hope this edition provides valuable perspectives to help you navigate these developments with confidence. As always, our team remains on hand to discuss any of the topics covered.

David Bridge
Partner, Solicitor Advocate,
Co-Head Life Sciences & Healthcare
T +44 20 7367 3021
E david.bridge@cms-cmno.com

CMA Launches Private Dentistry Market Study

The Competition and Markets Authority ("**CMA**") has formally launched a market study into the private dentistry market in the UK. The study covers the provision of private dental services – including preventative, clinically necessary and cosmetic treatments – in the United Kingdom and is due to conclude with a final report by 4 March 2027. The study follows announcements made towards the end of last year and will examine whether features of the market are not working well for consumers.

Scope of the study

The CMA intends to investigate five key areas: consumer choice between practices and treatments; the nature and extent of competition between dental practices; whether practices engage in unfair or anticompetitive conduct; the effectiveness of the regulatory framework (noting its developed nature across the UK); and pricing and profitability, including how prices have moved relative to inflation and how different financing structures, corporate ownership models and business models affect profitability.

Process and possible outcomes

The CMA has set out a roadmap as to how it intends to carry out the market study and has said it intends to move at pace, in line with its "4Ps" framework (pace, predictability, proportionality and process). The launch triggers a statutory 12-month deadline for publication of a market study report setting out findings and any proposed actions. Notably, the CMA has indicated it may take enforcement action – including consumer or competition enforcement – before the study concludes.

Possible outcomes include recommendations to governments to change aspects of regulation, direct CMA enforcement action (as already trailed), and new guidance to help ensure businesses better understand their obligations. The review may also inform future policy across different nations of the UK.

Lessons from the veterinary services investigation

The dentistry sector has been on notice for some time, so the launch of the market study should come as no surprise. There are obvious parallels to the CMA's market investigation into veterinary services, which has now concluded with a wide-ranging package of remedies likely to fundamentally change how the market is structured and operated. Among other things, the CMA's final decision imposes remedies including mandatory written complaints processes, access to mediation, and a prohibition on unreasonably long termination periods in out-of-hours contracts. The CMA has also recommended that government establish a replacement statutory regime and has required an enhanced monitoring role for the RCVS, funded by a levy on veterinary businesses. Proposed remedies will be implemented through a legally binding Order, to be made within six months of the final decision report.

How should the sector engage?

The immediate next steps involve information gathering and market engagement by the CMA. The CMA has issued calls for evidence from consumers and dentist professionals and will be looking to engage with dentistry practices themselves, their investors and owners, and insurance providers and other businesses engaged in the sector.

The scale and breadth of the CMA's final remedies package in the veterinary services investigation underscores the importance of early and proactive engagement with this process. In the veterinary investigation, the CMA adjusted a number of its remedies in response to stakeholder feedback - for example, simplifying certain requirements and extending implementation timescales for smaller independent businesses. Many businesses and industry bodies were supportive of the changes the CMA imposed, and those that engaged constructively were able to influence the design of remedies.

Stakeholders with an interest in the market - including those in the wider healthcare supply chain - should consider engaging proactively with the process to help shape its direction and any resulting recommendations.

Class Action Exposure in the Life Sciences Industry

The UK and European life sciences sector is increasingly having to navigate a reality previously the preserve of the United States – burgeoning and costly class action and group litigation risks. Our class actions specialists, in combination with Portland, a public and corporate affairs consultancy, consider the implications for businesses in this sector.

The stakes for pharmaceutical, biotech and medical device firms are uniquely high, where litigation brings with it not just financial risk, but can fundamentally undermine a business' reputation, regulatory relationships and market access.

At the same time, it is important to recognise that many types of group claims – especially those focused on product liability and personal injury – face substantial hurdles, including proof of defect and causation, and the predominance of individualised issues that often make such claims ill-suited to class wide resolution.

The total value of class actions in the UK has soared to an estimated £155 billion as of 1 July 2025, according to the latest edition of the CMS European Class Action Report. That growth is also being seen in Europe, particularly in the Netherlands and Portugal.

The life sciences sector is not immune from the risks of this growing area of legal redress. The findings of Portland's 2025 Reputation and Accountability Report are that healthcare is the top industry that the British public would support a class action against.

A combination of factors is driving this growth, including new procedural mechanisms, innovative and aggressive claimant law firms (including US ones) that have entered the UK market, and technology and social media techniques that assist with bookbuilding. There is also an increasingly sophisticated litigation funding sector that has fuelled growth. The growth in class actions is likely here to stay, and as well as being a legal trend, it is now a critical business risk.

Why life sciences?

In this new landscape, life sciences companies face a perfect storm that makes them attractive class action targets:

— **High-value, high-profile claims:** because of the breadth of their consumer bases, claims against life sciences companies, including for product liability, have the potential to involve thousands of claimants and therefore be high value to claimant law firms and litigation funders. To the extent the claim relates to matters of human health, it may also generate intense media scrutiny that can be leveraged by claimant law firms and build settlement pressure. This, combined with the fact that life sciences companies are often perceived as having substantial financial resources, makes them attractive targets for claimant firms and litigation funders seeking significant returns. Faced with such a claimant

onslaught, defendants in life sciences matters will often have to rely on the inherent difficulties faced by claimants of establishing loss and causation, including on a class wide basis.

— **High public engagement and willingness to participate:** Portland's latest data indicates that, of those surveyed, 65% said they would be willing to join a class action if given the chance – a figure which has been steadily rising over the past three years. The emotive nature of health-related issues, combined with sophisticated social media campaigns, further fuels public engagement. In the context of an opt-in regime in the UK for all class actions (save for those within the scope of the Competition Appeal Tribunal ("**CAT**") regime), the greater the public's readiness to join such actions, the more likely it is that claims will attract substantial numbers of claimants, increasing both the financial and reputational exposure for companies.

— **Sensitive data at stake:** the sector's management of vast amounts of sensitive personal data makes it a prime target for data breach claims. 23andMe's $30 million settlement in the US, following a breach affecting 6.9 million users, is a stark warning of the potential scale and cost of such claims. Balanced against the risk is the fact that, in the UK, the procedural rules for group actions have hampered data protection claims. The landmark Supreme Court judgment in *Lloyd v Google*, a claim in which it was alleged that Google had secretly tracked the internet activity of iPhone users, held that the "*same interest*" requirement for representative action was not satisfied, because the entitlement to compensation under the Data Protection Act 1998 required individualised assessment. It followed that it was impossible for a single judgment to bind the entire group, and the claim could not continue as a representative action. That said, it is widely recognised that *Lloyd v Google* has not entirely closed the door on data protection class-action claims.

The new litigation landscape

The growth of opt-out mechanisms
The direction of travel in the UK and EU is firmly towards greater availability and use of opt-out mechanisms, which have the power to increase litigation risk by automatically including 100% of potential claimants. Currently, opt-out procedures are only available via the representative action procedure in England & Wales (which has seen limited use) and the UK-wide Competition Appeal Tribunal ("CAT") for competition law breaches. However, the position is not static – the UK government has launched a consultation exploring whether its collective actions' opt-out regime is fit for purpose.

The evolution of Group Litigation Orders
Outside the CAT's regime, group actions are generally managed through Group Litigation Orders ("**GLOs**"), an opt-in mechanism by which the court jointly manages individual claims giving rise to common or related issues of fact or law. The GLO mechanism has developed significantly over the last 18 months, driven largely by the Diesel Emissions GLOs – litigation of unprecedented scale involving some 1.2 million claimants. That experience has necessitated sophisticated case management strategies and innovative approaches, and the increased certainty as to how a GLO will progress has in turn increased the appetite of claimant law firms and funders, who can now more reliably predict the likely costs and duration of group actions.

Product liability reform
New product liability regimes in the EU and the recently announced Law Commission review of UK product liability law may further facilitate group claims, increasing the risk that life sciences companies face coordinated, cross-border litigation. The EU Product Liability Directive ("**EU PLD**"), now being implemented across the EU, maintains the "no-fault" liability regime while expanding the categories of compensable harm, introducing presumptions as to defects and causation, and imposing new disclosure obligations, all of which have the potential to increase the appetite for class actions. Of particular concern is the EU PLD's introduction of a presumption of defectiveness for product recalls.

Cross-border contagion
The global nature of the life sciences industry means that class actions initiated in one jurisdiction – particularly the US and Australia – are increasingly being mirrored or exported to the UK and EU. The UK claim brought over talcum powder is a clear sign of this trend, and companies should expect cross-border coordination of group litigation to become the norm rather than the exception.

Beyond Damages: the true cost of class actions

For life sciences companies, the consequences of class actions extend far beyond financial damages. The impact can extend to:

— **Regulatory relationships:** litigation can undermine trust with the very bodies responsible for approving and procuring products, threatening long-term commercial viability.

— **Reputation and brand:** in a sector where safety and trust are paramount, reputational damage can be swift, severe, and difficult to repair – impacting not only patients and consumers, but also investors and commercial partners.

— **Operational disruption:** defending a class action is resource-intensive, diverting key personnel from core business activities and placing significant strain on internal teams

Proactive risk management

Companies that anticipate and address class action risks are better positioned to manage the commercial and legal risks that flow from those claims, reassure regulators, investors and the public, and maintain their licence to operate. A proactive strategy could include elements such as:

— **Mapping global litigation risk:** identify potential exposure across all jurisdictions, as claims and legal strategies are increasingly international. Staying with or ahead of legal, regulatory and consumer sentiment developments enables the business to better identify and manage risks proactively.

— **Developing crisis communication plans:** prepare protocols for communicating with regulators, public health bodies and the public to ensure a rapid, coordinated response. In class actions in particular, the battle can be fought in the press and online as much as in the court room. You can expect the claimants to build a strong public narrative, rooted in corporate accountability and access to justice, in some instances even before a claim is formally filed. Those who prepare early, and plan holistically, will be best placed to preserve their reputation, brand image and consumer trust outside and beyond the claim.

— **Auditing public statements:** external communications can present a key source of risk and will be a focus for claimant law firms. Auditing statements made, and developing protocols for the making of statements going forward, can help identify and manage those risks.

— **Managing document production and privilege:** the documents you create, including relating to communications, may need to be disclosed in a class action. Putting in place robust and defensible protocols to control the production of documents and to protect privilege can prove vital.

— **Identifying an external team to manage a claim:** bringing external lawyers and communications experts on board early can help ensure that potential legal and reputational issues are identified and addressed before they escalate and reduce the likelihood of misstep that could lead to litigation or reputational harm. Having such experts on-hand also means they are up to speed, ready to move quickly and able to co-ordinate across multiple jurisdictions should a claim eventuate.

While class actions are a material, business-critical risk for the life sciences sector, there often remain significant hurdles for claimants to overcome. With the right preparation, life sciences businesses can reduce the likelihood of claims, narrow their scope, and manage proceedings on terms that protect their regulatory relationships, commercial objectives and brand – turning a significant threat into a manageable and defensible risk.

This article was written in collaboration with Portland.

Portland

Public Procurement: The Government's Response to Further Reform

In March 2026, the Cabinet Office published its response to the public consultation on further reforms to the UK public procurement rules, titled *Public Procurement: Growing British industry, jobs and skills.* The consultation, which ran from June to September 2025, forms part of the Government's wider ambition to use the £385 billion spent annually through public procurement to deliver its Industrial Strategy, foster a resilient economy and support British businesses. The consultation received approximately 860 responses, drawn from contracting authorities, including authorities in the health sector and the NHS, local and central government, as well as suppliers and other interested parties.

The proposals for further reform build on changes already introduced since the Procurement Act 2023 came into force in February 2025, including the new National Procurement Policy Statement and the requirement for central government departments to exclude suppliers from major contracts if they cannot demonstrate prompt payment of invoices within an average of 45 days. The consultation sought views on a range of further measures, including mandating SME procurement spend targets, increasing transparency reporting, strengthening social value requirements and, of particular interest to suppliers, introducing a prompt payment exclusion ground.

Prompt payment: strong support for exclusion

The consultation proposed requiring all contracting authorities to exclude suppliers from bidding on major contracts (those valued at over £5 million per annum) if they cannot demonstrate prompt payment of invoices to their supply chains within an average of 60 days. This proposal attracted significant support, with 73% of respondents agreeing or strongly agreeing - the highest level of support of any proposal in the consultation.

Suppliers particularly highlighted the damaging knock-on effect late payments can have on businesses' ability to manage their cash flow and plan for growth. SMEs, while supportive, argued that 60 days was too long and that a 30-day threshold would provide greater security - a view echoed by the majority of strategic suppliers. Local government and industry bodies broadly agreed with the principle but emphasised that implementation must not generate disproportionate red tape for businesses. Some local government respondents also raised concerns about the risk of legal challenge if the measure is treated as a discretionary exclusion ground, noting that suppliers may present mitigating factors for delays which contracting authorities may find difficult to assess.

What happens next?

It is important to note that these reforms are not yet a certainty. The Government has stated that any future legislative proposals would be dependent on securing parliamentary time. Nevertheless, the consultation response provides a useful indication of the direction of travel. The strength of support for a prompt payment exclusion ground - across contracting authorities, suppliers and other stakeholders - suggests that this is an area where we can expect to see further reform.

Prompt payment is already an issue that many suppliers in the life sciences and healthcare sector are having to address for the purpose of public sector contracting, and the Government appears focussed on flowing prompt payment requirements down and through the supply chain. Businesses in the sector bidding for contracts over £5 million would be well advised to review their payment practices now, so that they are prepared should these proposals be taken forward.


TREND TABLE
LARGE NUMERICS
ALARM HISTORY
BED-001
ADULT
85
CHECK ELECTRODES
115/ 63
(70)
100

AI Under the Microscope: Memorisation Risks in Clinical Models

New research by MIT[1] has highlighted a growing challenge for machine learning in clinical settings: some large models trained on de-identified electronic health records ("**EHR**") may unintentionally memorise elements of training data in ways that, under certain prompts, could reveal sensitive patient attributes. Even when data is anonymised, rarity and uniqueness can raise identifiability and increase the risk that sensitive attributes are inferred, leading to a risk of leakage of confidential patient information. For life sciences organisations, including pharmaceutical companies, clinical research organisations ("**CROs**"), and medical device manufacturers, this poses significant compliance and reputational risks, particularly where AI tools are deployed in clinical trials or real-world evidence generation.

The study's finding

The MIT study proposes a practical testing framework for assessing memorisation in healthcare foundation models and validates it on a publicly available EHR model trained on de-identified data. The framework includes six distinct tests (T1–T6) designed to measure memorisation at both the embedding and generative levels, and to distinguish between beneficial model generalisation and harmful memorisation of individual patient data. In simple terms, the study found that the more specific details about a patient are used to question the AI, the more likely it is to reveal sensitive information, such as a real diagnosis. In contrast, simple questions using only basic demographic information did not cause this leakage of private data. This means that the more an individual trying to misuse the AI already knows about a patient, and the more targeted their questions are, the higher the risk of sensitive information being exposed. Critically, the study identified instances where questions without clear medical context still revealed private health information, a finding of particular concern for life sciences organisations processing special category data such as health data, genetic data, and biometric data in clinical research settings.

Context and risk assessment

Despite the risk of data leaks, the study highlights the importance of context. If someone attempting to misuse the AI already has detailed information and uses it to obtain special category data, the additional damage might be limited. However, the authors also pointed out specific, worrying instances where questions without clear medical context still revealed private health information. The study's additional tests (T5–T6) help distinguish between the AI truly remembering individual patient details and merely generalising from broader population data. This distinction is critical when assessing whether a data breach has occurred and its potential impact on identifiable individuals. For clinical trial sponsors and CROs, this contextual analysis is essential when evaluating the privacy risks of deploying AI tools that have been trained on, or have access to, patient-level clinical trial data.

Implications for life sciences organisations under the UK GDPR

For organisations in the UK, especially those operating across borders in multinational clinical trials or collaborative research arrangements, this research directly impacts their compliance with the UK GDPR, potential contractual risks with third parties processing personal data on their behalf, and how the Information Commissioner's Office ("**ICO**") and other regulators might view their data governance practices.

Under the UK GDPR, if individuals can be reasonably identified from an AI model or its output, then training and using these models constitutes processing of personal data. Where the data in question relates to health, genetic information, or biometric data used for identification purposes, it will also constitute special category data under Article 9 of the UK GDPR, requiring organisations to identify both a lawful basis for processing under Article 6 and a separate condition for processing under Article 9. This places significant legal obligations

[1] Xu, G. et al., "An Investigation of Memorization Risk in Healthcare Foundation Models", OpenReview (2025), available at: https://openreview.net/forum?id=NMvMYtRjkg

on data controllers and data processors. Life sciences organisations must carefully consider their roles in the processing chain: sponsors may act as controllers (or joint controllers) whilst CROs typically act as processors, necessitating robust data processing agreements that address AI-specific risks. If a data leak occurs, providers and users could face regulatory enforcement action by the ICO, legal claims from affected data subjects, and serious reputational damage in a sector where trust is paramount.

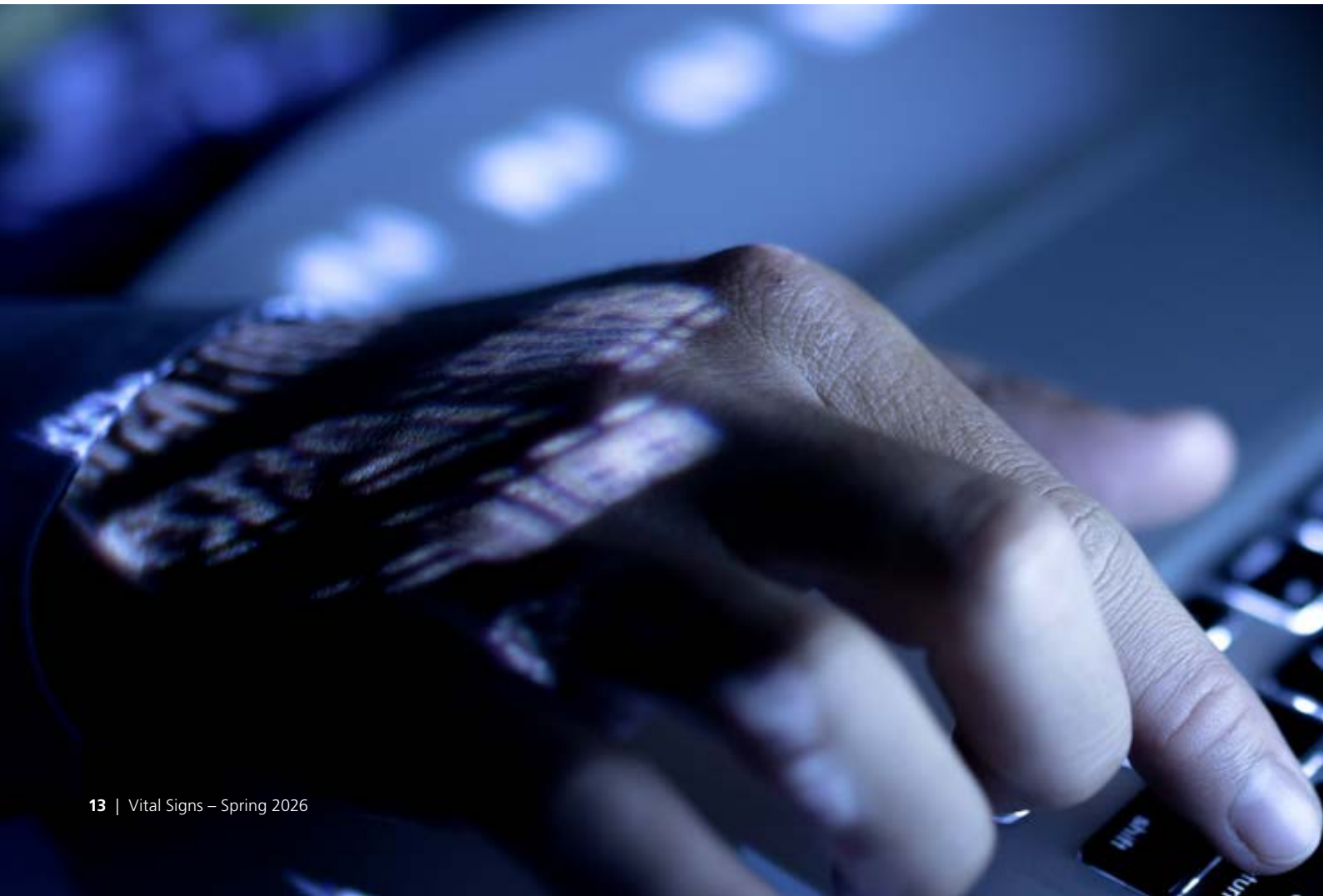
Horizon scanning and regulatory developments

With new laws such as the EU AI Act and the UK's own AI regulatory framework on the horizon, regulators will likely expect thorough assessments of data governance and privacy risks for high-risk clinical AI systems. Under the EU AI Act, AI systems used in healthcare contexts may be classified as high-risk, requiring conformity assessments, risk management systems, and human oversight measures. Although the UK is developing its own approach to AI regulation, the ICO has already signalled its expectations around transparency, fairness, and accountability in AI systems that process personal data. The study's framework provides a valuable tool for auditing and demonstrating that these privacy risks have been addressed before a model is released. Life sciences companies developing or deploying AI-enabled clinical tools (whether for drug discovery, clinical decision support, or pharmacovigilance) should consider integrating such testing frameworks into their pre-market governance processes and ongoing post-market surveillance activities.

Practical takeaways for life sciences organisations

In light of the MIT study's findings, organisations in the life sciences and healthcare sector should consider the following practical steps:

1. **Conduct Pre-Deployment Privacy Assessments:** Before deploying AI models trained on patient data, carry out a Data Protection Impact Assessment ("**DPIA**") under Article 35 of the UK GDPR. The DPIA should specifically assess memorisation risks using frameworks such as those proposed in the MIT study, including testing whether targeted prompts can extract sensitive information from the model.



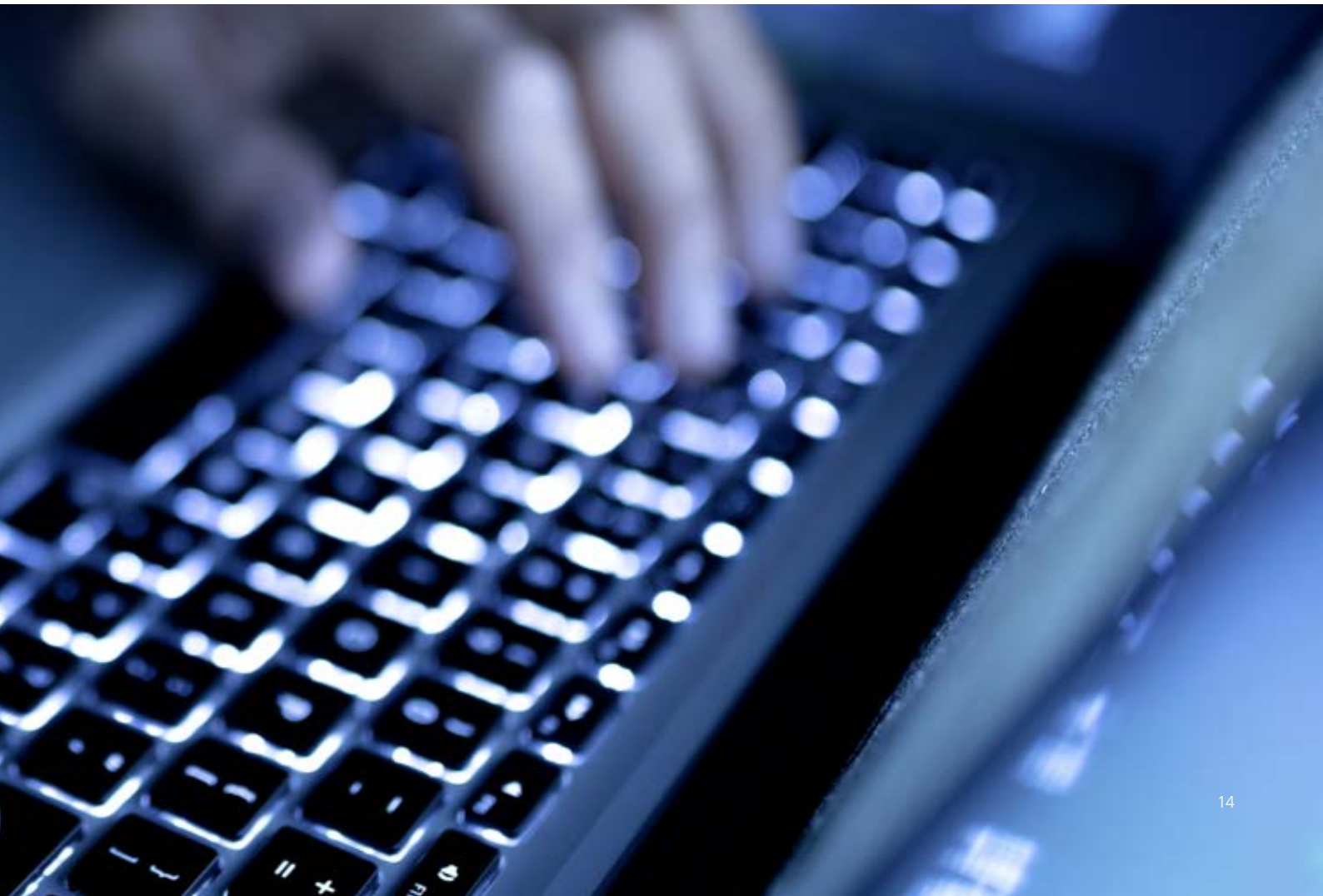
2. **Implement Robust Contractual Protections:** When engaging CROs, AI vendors, or other data processors, ensure that data processing agreements include specific provisions addressing AI-related risks, including: (a) representations regarding memorisation testing and mitigation; (b) audit rights to verify AI governance practices; (c) clear liability allocation for breaches arising from model memorisation; and (d) requirements for ongoing monitoring and testing of AI models to identify potential vulnerabilities.

3. **Assess Vulnerable Subgroups:** The MIT study highlights that certain patient populations, such as those with rare diseases, elderly patients, or individuals with unique medical histories face elevated privacy risks from AI memorisation. Life sciences organisations should identify vulnerable subgroups within their datasets and implement enhanced safeguards, such as differential privacy techniques or targeted retraining to reduce memorisation of sensitive samples.

4. **Develop Data Subject Request Procedures:** Ensure that procedures for handling data subject access requests ("**DSARs**") under Article 15 of the UK GDPR account for AI-specific considerations. Where AI models may contain memorised patient data, organisations should be prepared to explain to data subjects how their information has been used in model training and what safeguards are in place to prevent disclosure of their personal data through model outputs.

5. **Integrate Testing into AI Governance:** Consider adopting the MIT study's testing framework as part of pre-market AI governance. Document the results of such testing to demonstrate accountability to the ICO and other regulators.

6. **Monitor Regulatory Developments:** Stay abreast of evolving AI regulation in both the UK and the EU. The EU AI Act's requirements for high-risk AI systems, including those used in healthcare, will have implications for life sciences companies operating in or supplying products to the European market. Similarly, the ICO's guidance on AI and data protection should be considered and incorporated into compliance programmes.



CE Marks in Great Britain: The End of Uncertainty?

From the outset, the post-Brexit regulatory path for medical devices was always going to be difficult. Layering a new domestic conformity assessment regime on top of the already formidable demands of the EU Medical Devices Regulation was a prospect that few in the industry relished. Six years on, after a series of transitional extensions, the direction of travel has shifted markedly. In February 2026, the Medicines and Healthcare products Regulatory Agency (the "**MHRA**") launched a consultation proposing indefinite recognition of CE-marked devices in Great Britain.

How we got here

The UKCA mark was introduced after Brexit as the domestic replacement for the CE mark across England, Scotland, and Wales. The scale of the challenge was clear from the start: roughly 90% of medical devices on the Great Britain market carry the CE mark, and requiring manufacturers to undertake a wholly separate conformity assessment process alongside their EU obligations was widely regarded as unworkable. Transitional extensions followed, first to 2025, then to mid-2028 or mid-2030, depending on device classification and applicable EU legislation. Each extension bought time, but none offered a permanent answer.

The MHRA's latest consultation, open until 10 April 2026, attempts to do exactly that. It set out three proposals and taken together they point in a very different direction from the one originally charted.

CE recognition without an expiry date

The main proposal is to recognise CE-marked devices compliant with the EU Medical Devices Regulation ("**EU MDR**") or the EU In Vitro Diagnostic Medical Device Regulation ("**EU IVDR**") on the Great Britain market indefinitely. The key features of the proposal are:

— Registration with the MHRA would still be required, but there would be no need for a separate assessment by a UK-approved body.

— The MHRA asked whether indefinite recognition should cover all EU MDR- and EU IVDR-compliant devices, or only those classified in the same or a lower risk class under the UK Medical Devices Regulations 2002. For manufacturers sitting on the boundary between the two classification systems, the practical consequences could be significant.

What about higher-risk devices?

If the MHRA limits indefinite recognition to same- or lower-risk devices, a second proposal would bridge the gap:

— Devices classified at a higher risk level under UK rules than under their EU equivalents would not get automatic recognition, but nor would they face a blank-sheet approval process.

— Instead, a UK-approved body would review the device through an "international reliance" pathway, drawing on the manufacturer's existing EU MDR or EU IVDR assessments before deciding whether the device can access the Great Britain market via an international reliance route.

— The MHRA says this would affect only a small proportion of devices - the divergence between EU and UK risk classifications is, in reality, fairly narrow.

— For manufacturers of affected devices, however, the distinction between automatic recognition and a streamlined-but-separate review is a meaningful one, and the consultation is worth engaging with on that basis, not least because the detail of how this route works in practice remains to be settled.

Legacy devices and the MDD timeline

The third proposal deals with a more immediate problem. Certain devices still certified under the older EU Medical Devices Directive (**EU MDD**) can currently be placed on the Great Britain market until 30 June 2028, depending on device type and certification status. The MHRA wants to push that deadline out by six months to 31 December 2028, matching the EU's own timeline for transitioning from the MDD to the EU MDR. The rationale is straightforward: if these devices remain available across the Channel until the end of 2028, aligning the Great Britain timeline avoids an unnecessary divergence.

Reading between the lines

Step back from the specifics and a bigger picture emerges. The MHRA is not just patching a transitional problem, it is rewriting the post-Brexit regulatory story for medical devices. Several broader themes are worth noting:

— The UKCA mark is not being scrapped, but it is being recast. Rather than serving as the mandatory gateway for all devices, it will likely be repositioned as a specialist route for first-in-market innovative products, including AI-enabled medical devices.

— This thinking may also intersect with forthcoming work on AI-enabled medical devices, including the National Commission into the Regulation of AI in Healthcare, due to report this summer, which could help shape how a specialist UK route operates in practice and position the UK as more than a jurisdiction duplicating EU regulatory assessments.

— The shift is consistent with what the Government has already done for other manufactured goods, where continued recognition of CE marking is now settled policy.

— The consultation fits neatly within the broader ambitions of the Life Sciences Sector Plan and the 10-Year Health Plan, both of which target the UK becoming a leading country for MedTech access by 2030.

— The MHRA's Chief Executive, Lawrence Tallon, has said that long-term certainty over CE recognition was "the number one request" from the industry, and these proposals are plainly a response to that pressure.

What comes next?

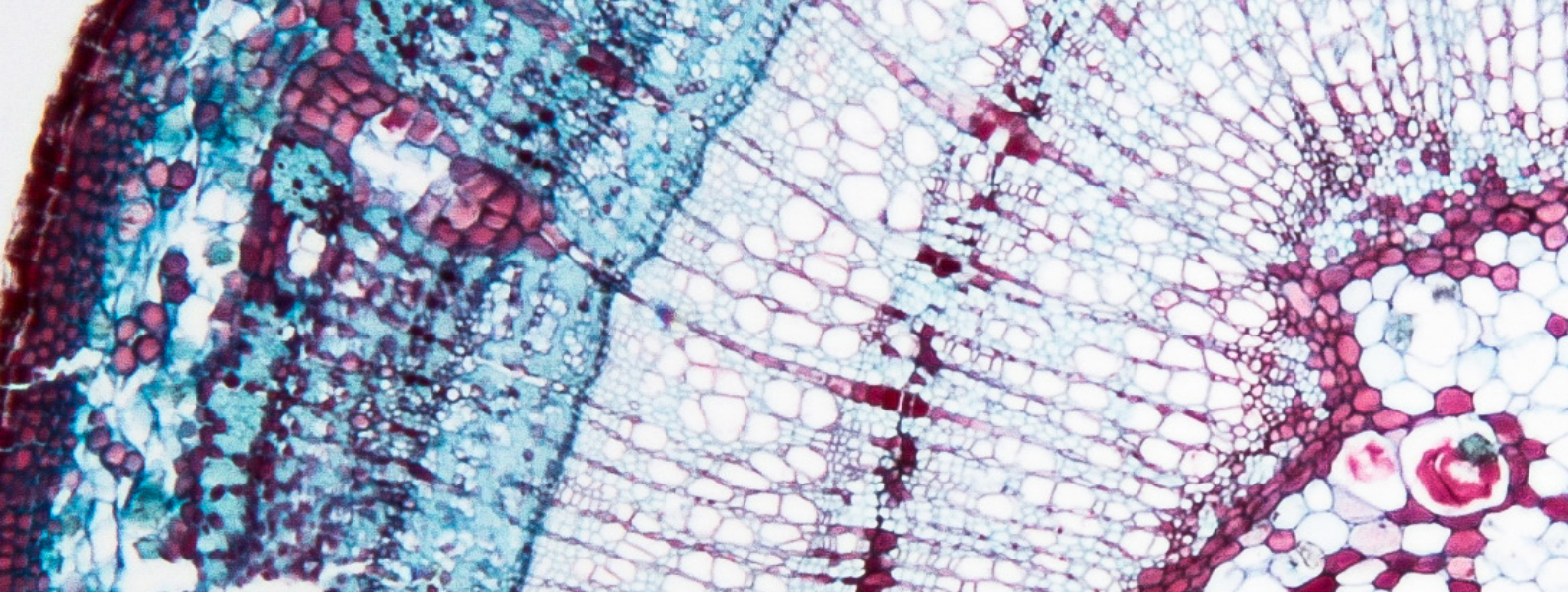
The consultation closed on 10 April 2026. Manufacturers, approved bodies, UK Responsible Persons, healthcare professionals, and patient groups will be watching closely for the MHRA's response. What is on the table was not another six-month extension or a holding measure, it is a reshaping of how the UK controls access to its medical device market. Stakeholders would be well advised to:

— Review how their devices are classified under both the EU and UK frameworks, particularly where risk classifications diverge.

— Assess whether the international reliance route, if adopted, would affect any of their products and plan accordingly.

— Engage with the consultation directly, whether as manufacturers, approved bodies, UK Responsible Persons, healthcare professionals, or patient groups.

The overarching message from the MHRA is clear: the era of temporary fixes is over. What comes next will be permanent, and for many in the industry who have long pressed for a pragmatic approach to CE recognition, the direction of these proposals will be a welcome, if overdue, development.



Contacts

We hope you have enjoyed reading this spring briefing, if you would like to discuss any of the subjects in this publication with us, please do reach out to our Life Sciences & Healthcare Sector Co-Heads or the authors of the articles below.

David Bridge
Partner, Co-Head Life Sciences & Healthcare sector
T +44 20 7367 3021
E david.bridge@cms-cmno.com

Candice Blackwood
Partner, Co-Head Life Sciences & Healthcare sector
T +44 20 7524 6726
E candice.blackwood@cms-cmno.com

CMA Launches Private Dentistry Market Study

Graeme Young
Partner
T +44 20 7367 2906
E graeme.young@cms-cmno.com

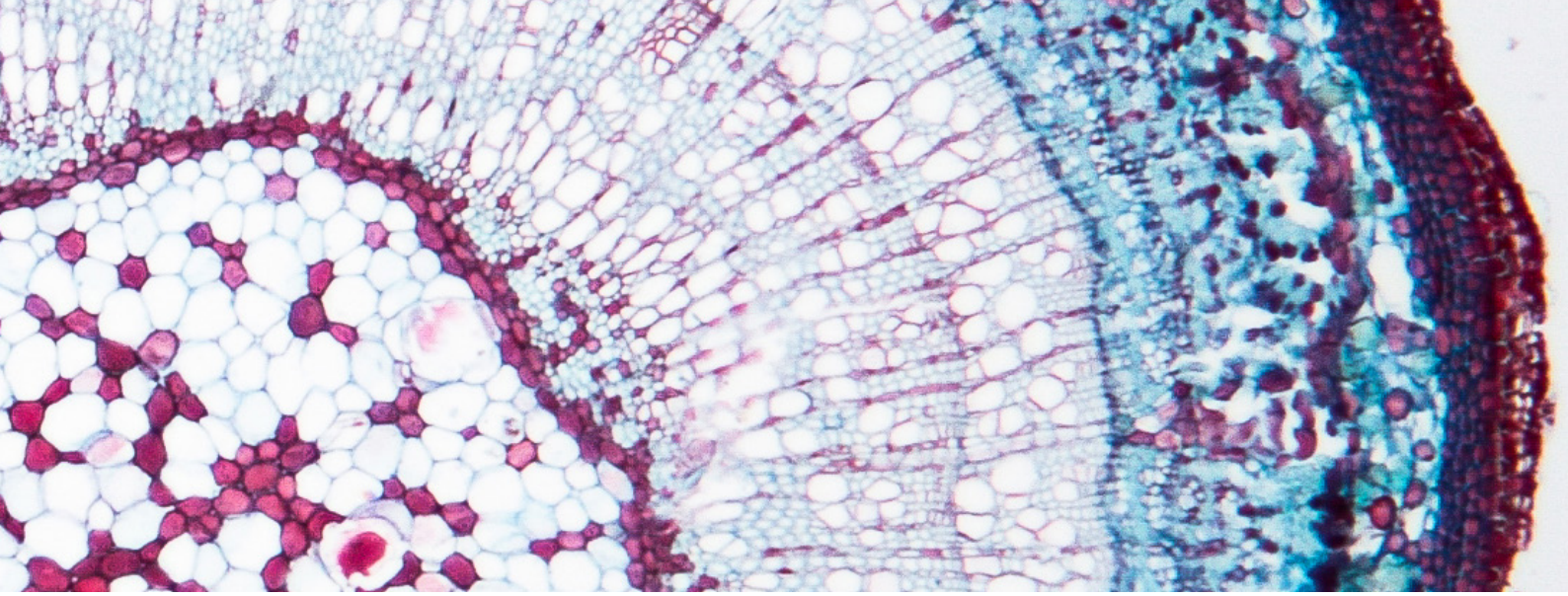
Neil Baylis
Partner
T +44 20 7067 3457
E neil.baylis@cms-cmno.com

Helena Siebenrock
Trainee Solicitor
T +44 131 200 7503
E helena.siebenrock@cms-cmno.com

AI Under the Microscope: Memorisation Risks in Clinical Models

Sam De Silva
Partner & Global Co-Head Commercial Practice Group
T +44 20 7524 6223
E sam.desilva@cms-cmno.com

Gemma Watson
Trainee Solicitor
T +44 20 7367 2302
E gemma.watson@cms-cmno.com



Class Action Exposure in the Life Sciences Industry

Louise Boswell
Partner, Solicitor Advocate
T +44 20 7367 3725
E louise.boswell@cms-cmno.com

Nicholas Quirke
Senior Associate
T +44 20 7067 3375
E nicholas.quirke@cms-cmno.com

Simon Pugh (Portland)
Partner
T +44 7762 657 280
E simon.pugh@omc.com

Megan Lambert (Portland)
Senior Executive
T +44 7768 132 394
E megan.lambert@omc.com

Public Procurement: The Government's Response to Further Reform

Wendy Nicolson
Partner
T +44 20 7367 3725
E wendy.nicolson@cms-cmno.com

Emma Blundell
Senior Associate
T +44 131 200 74707
E emma.blundell@cms-cmno.com

CE Marks in Great Britain: The End of Uncertainty?

Amélie Chollet
Partner
T +44 20 7367 2907
E amelie.chollet@cms-cmno.com

Shaina Haria
Trainee Solicitor
T +44 20 7367 2289
E shaina.haria@cms-cmno.com

Victoria Mitchell
Graduate Solicitor Apprentice
T +44 20 7367 2935
E victoria.mitchell@cms-cmno.com

CMS Legal Updates subscription service

Sign up now for the free online email alert service delivering commentary, analyses and insights from CMS experts on the legal issues affecting your business, directly to your inbox.
cms.law/subscription

CMS Cameron McKenna Nabarro Olswang LLP
Cannon Place
78 Cannon Street
London EC4N 6AF

T +44 (0)20 7367 3000
F +44 (0)20 7367 2000

2605-0207933-5