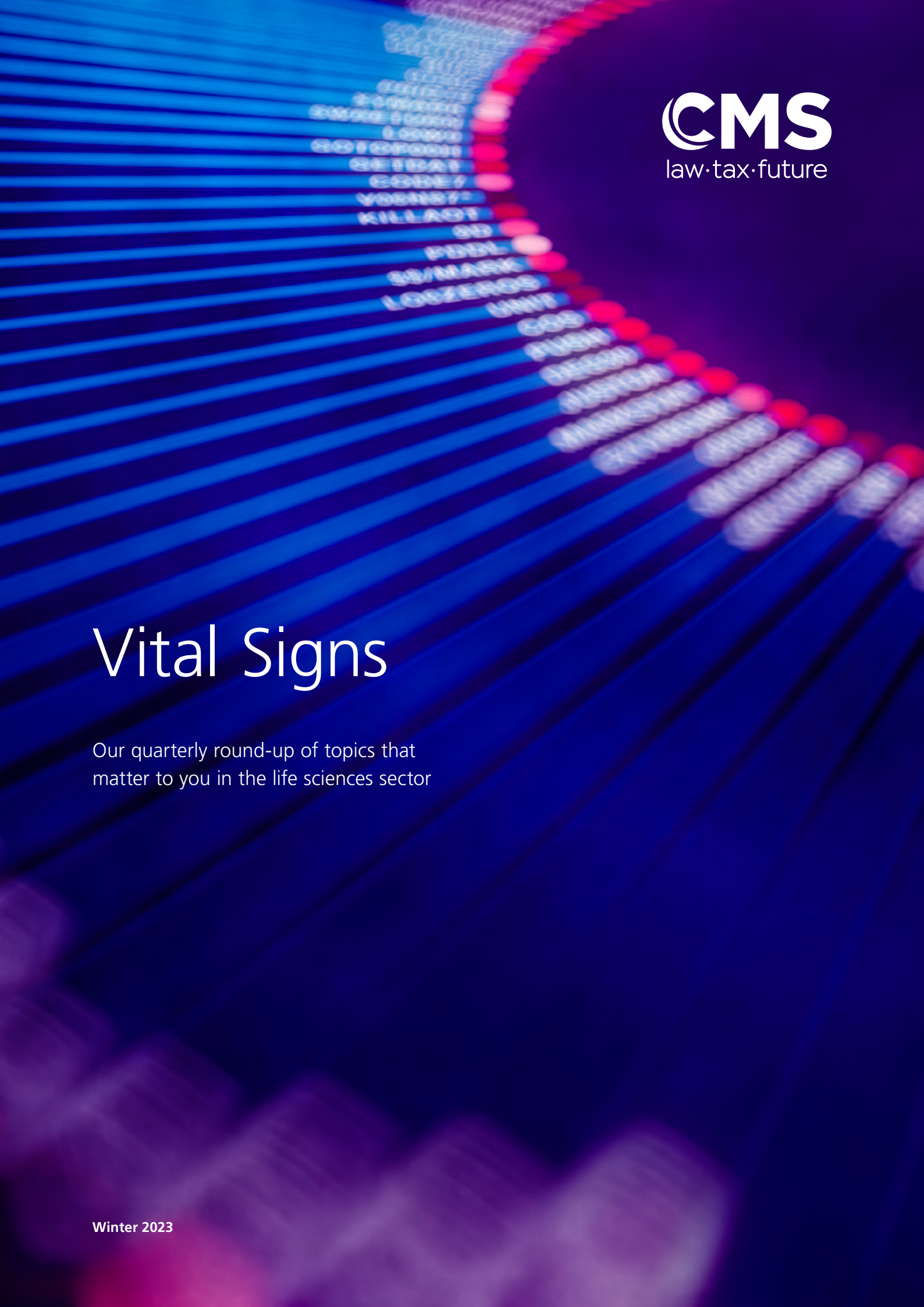

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# Vital Signs

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

**Winter 2023**

# Vital Signs

2023 has seen some significant legal developments impacting the life sciences industry, and as we look ahead to 2024, there are several important developments which we would like to keep our clients informed of.

In the UK, beginning in January 2024, the UK will roll out a new International Recognition Procedure for medicines approved in trusted jurisdictions. There are also new public procurement rules on the horizon as the Procurement Bill has been progressing through the Houses of Parliament, with the aim to make the UK's public procurement regime more efficient and transparent.

In Europe, the Unified Patent Court, which was opened in June 2023, has seen its first Infringement and revocation actions, and the first pan-European preliminary injunction was granted recently. In the regulatory sphere, a political agreement has been reached on the new Data Act, which will contain new rules on who can use and access data generated in the EU across all economic sectors.

If you would like to discuss these or any other developments, please get in touch. We would be delighted to talk about your interests and concerns.

> We always find them brilliant. They're very commercial, hugely responsive and know their onions.
>
> *Chambers & Partners, 2024*

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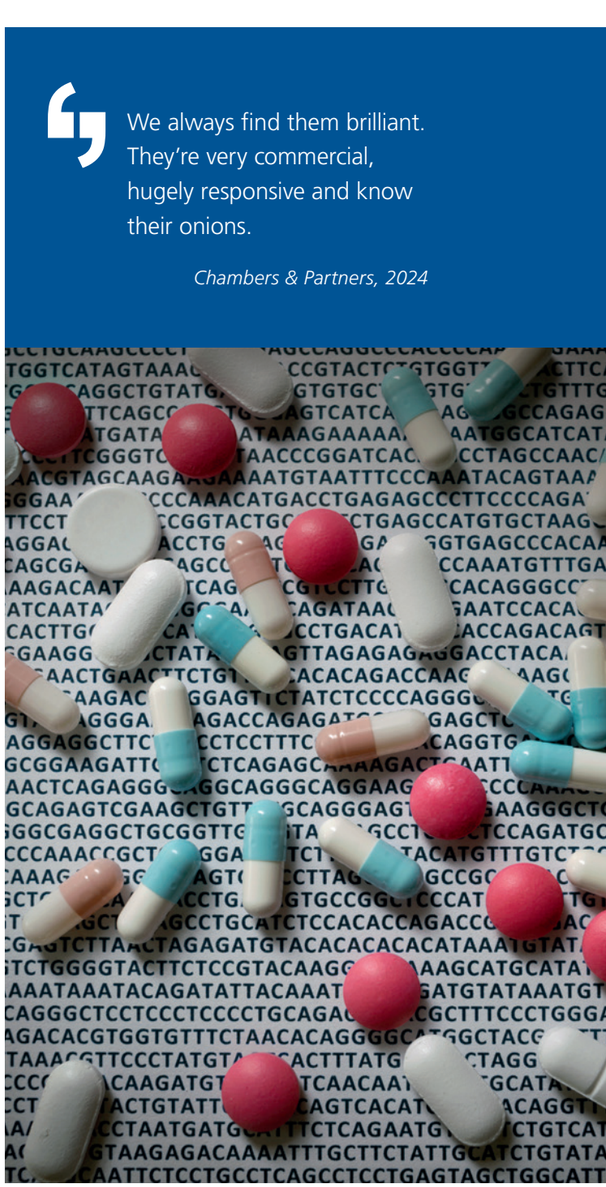


# Changes in the regulatory approval landscape for medicines and medical devices

## UK pharmaceuticals

— Following the Chancellor of the Exchequer's announcement in the Spring Budget, on 26 May 2023 the MHRA announced that new regulatory recognition routes for medicines will be established using approvals from Australia, Canada, the European Union, Japan, Switzerland, Singapore and the United States, meaning that in the future medicines already approved in these countries will benefit from "*rapid, often near automatic sign-off*" by the MHRA in the UK.

— The new regulatory recognition route, called the International Recognition Procedure ("IRP") is set to be implemented from 1 January 2024. This new procedure will replace the EC Decision Reliance Procedure ("ECDRP") and will also incorporate the Mutual Recognition/Decentralised Reliance Procedure ("MRDCRP"). Any submissions under ECDRP and MRDCRP received before this date will be processed as per existing practices, with the stipulation that for ECDRP applications, the Committee for Medicinal Products for Human Use ("CHMP") positive opinion should be received before 31 December 2023, but not necessarily the European Commission Decision.

— The IRP is designed for applicants who have already secured an authorisation for their product from one of the MHRA's specified Reference Regulators ("RRs"). Currently, the RR's are the regulatory authorities for medicinal products in Australia, Canada, Switzerland, Singapore, Japan, United States, and the European Union. To determine eligibility for the IRP, applicants are required to complete an online eligibility form six weeks prior to their planned marketing authorisation application ("MAA") submission date. There are two recognition categories within the IRP: Recognition A, for applications where the RR approval was granted within the last two years and the manufacturing process remains unchanged from that approved by the RR; and Recognition B, for applications where the RR approval was granted within the past decade and meets specific criteria, such as changes in the manufacturing process or the incorporation of novel technologies.

— A key aspect of the IRP is that while it allows the MHRA to leverage the expertise and decision-making of trusted regulatory partners, the MHRA retains the authority to reject applications if the evidence isn't sufficiently robust. This includes ensuring compliance with various regulatory standards, such as the need for a Risk Management Plan ("RMP") that aligns with MHRA requirements, an Environmental Risk Assessment ("ERA") assessed by the reference regulator, and a current GMP certificate for all manufacturing sites that meets MHRA standards.

— This procedure aims to streamline the authorisation process by considering the expertise of trusted regulatory partners, benefiting UK patients, while also ensuring that the products meet the stringent standards set by the MHRA.

## EU pharmaceuticals

On April 26, 2023, the European Commission (Commission) published its Pharmaceutical Review, intending to overhaul European Union (EU) pharmaceutical law for the first time since 1965. The Commission aims to achieve better access, affordability, and availability of medicines, improved industry competitiveness, compliance, combating antimicrobial resistance (AMR), and increased transparency. However, the industry has criticised the review for reducing intellectual property rights and neglecting the impact on industry's ability to develop innovative products.
Key changes in the Review:

> The CMS team has impressed in challenging circumstances with its flexibility, responsiveness and customer focus.
>
> *Legal 500, 2024*

— The Review examines regulatory data protection (RDP), market exclusivity for orphan medicinal products (OMPs), and supplementary protection certificates (SPCs) prolongation. The Commission aims to stimulate availability of products in all Member States and redirect investment toward unmet medical needs.

— The Review introduces conditional incentives, reducing the period of RDP from eight to six years, extendable in certain cases.

— These extensions include launching the product in all EU Member States, addressing an "unmet medical need", conducting comparative trials, and developing a new therapeutic indication with significant clinical benefits.

— Despite offering potential for slightly longer RDP, these mechanisms are complex and uncertain.

— To combat AMR, the Review provides a "voucher" of one year of RDP for developing a new antimicrobial, but the strict conditions may make this unworkable.

Orphan medicinal products:

— The Review proposes a "global orphan exclusivity" system, reducing baseline orphan market exclusivity from ten to nine years.

— This period can be extended by a year for products addressing high unmet medical needs, launching in all EU Member States, or introducing up to two more new therapeutic indications.

— This system potentially reduces exclusivity from 10 years to one year for subsequent orphan indications.

Other measures and risks:

— The Review streamlines and speeds up procedures, reduces the number of EMA committees, and introduces staged presentation of PIPs.

— However, it also includes strict new rules on shortages, reduced waivers for PIPs, and allows "pharmacy compounding" of unlicensed medicines.

— The Review introduces a new set of environmental risk assessment provisions, affecting the marketingauthorisation (MA) process.

— The Commission's Regulatory Scrutiny Board criticized the review for lack of analysis on the impact of incentive reductions on the EU industry's ability to innovate.

### Brand names for medicinal products (EU)

New guidelines from the EMA on naming medicinal products are expected to be published in Q1 2024, following the consultation which closed last year. The guidelines will apply to MA applications via the centralised procedure.

### UK medical devices

— On 19 September 2023 the MHRA introduced the pilot phase of the new Innovative Devices Access Pathway (IDAP), which is run in collaboration with the National Institute for Health and Care Excellence (NICE) and other partners, including the devolved administrations. IDAP provides innovators and manufacturers with a multi-partner support service including targeted scientific advice that brings new products to patients sooner.

— On 1 August 2023 the UK Government announced that it will recognise CE marking for placing most goods on the market in Great Britain indefinitely. However, there are different rules for medical devices. The UK Government will accept CE marked devices on the Great Britain market until, at the latest, 30 June 2030, depending on device type and classification.

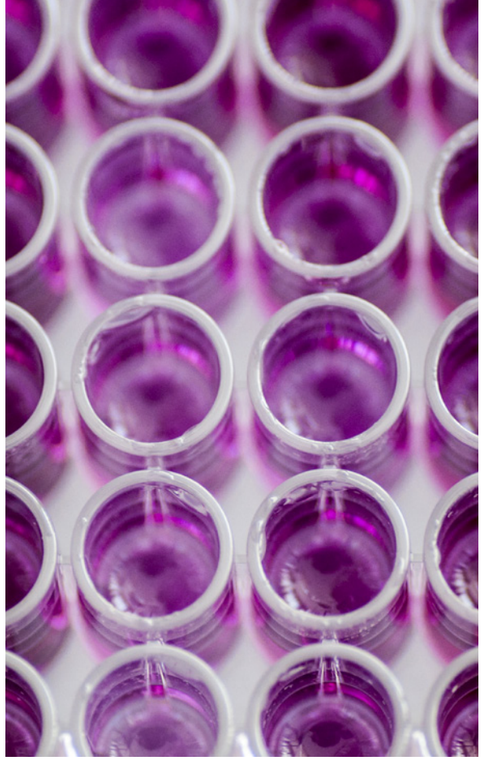
— On 27 July 2023 the UK Government announced that new post-Brexit UK Medical Device Regulations (replacing MDR 2002) are currently scheduled to apply from 1 July 2025, and will be closely aligned with the EU Medical Device Regulations 2017/745. The proposals include fairly generous transitional periods.

### Digital health

— On 28 June 2023 the EU Commission announced that a political agreement has been reached between the European Parliament and the Council of the EU, on the European Data Act, first proposed in February 2022. The Data Act will contain new rules on who can use and access data generated in the EU across all economic sectors.

— In the EU, the AI Act is making progress in the EU legislative procedure. This law will categorise AI applications into "risk levels", and create restrictions for AI systems which are categorised as "high risk". The AI Act will work alongside the new AI product liability rules laid out in the forthcoming Product Liability Directive and AI Liability Directive.

— For further information, please consult CMS's Expert Guide to digital health apps and telemedicine.



### UK clinical trials

— On 12 October 2023 the MHRA issued a press release announcing a streamlined notification scheme for the lowest-risk clinical trials. The press release explains that initial applications for the lowest-risk Phase 3 and 4 trials will be processed by the MHRA within 14 days rather than 30 days, provided the sponsor can demonstrate that the trial meets the MHRA's inclusion criteria.

— In March 2023 the UK Government published a response to the eight-week consultation on the future of clinical trial legislation in the UK, which began in January 2022. The response sets out high level goals regarding increasing the international competitiveness of the UK a competitive regulatory regime, especially following the introduction of the EU CTR. No timeline for draft legislation has yet been released, and this is an area CMS will continue to monitor.

### EU clinical trials

In October 2023, the EMA published revised transparency rules for the EU Clinical Trials Information system (CTIS), which has been compulsory since January 2023 for EU clinical trials. Under the new rules, the deferral mechanism which allowed sponsors to delay publication of certain documents to protect commercially confidential information has been removed. Sponsors will need to carefully consider their approach to protecting confidential information related to EU clinical trials and in particular how this may impact patent filing strategy.



# Risks and trends for commercial contracts in the life sciences sector

### Price increases

Inflation is slowing down but continues to drive prices up. We are seeing suppliers and service providers trying different ways to pass cost increases on to customers. For clinical research services, many CROs are reluctant to provide any fixed prices, only estimates. We predict this will continue this year.

### Digital transformation

The Covid pandemic, coupled with a rapid rise in computing power, has accelerated the adoption of digital technologies in the life sciences sector, such as artificial intelligence, cloud computing, data analytics, and telehealth. Companies need to invest in digital capabilities, foster a culture of innovation, and collaborate with external partners to stay competitive. Good contracts will be key to de-risking arrangements with digital service providers and ensuring that data from your other contracts can be used in your analytics to gain insights.

### Collaborations and acquisitions

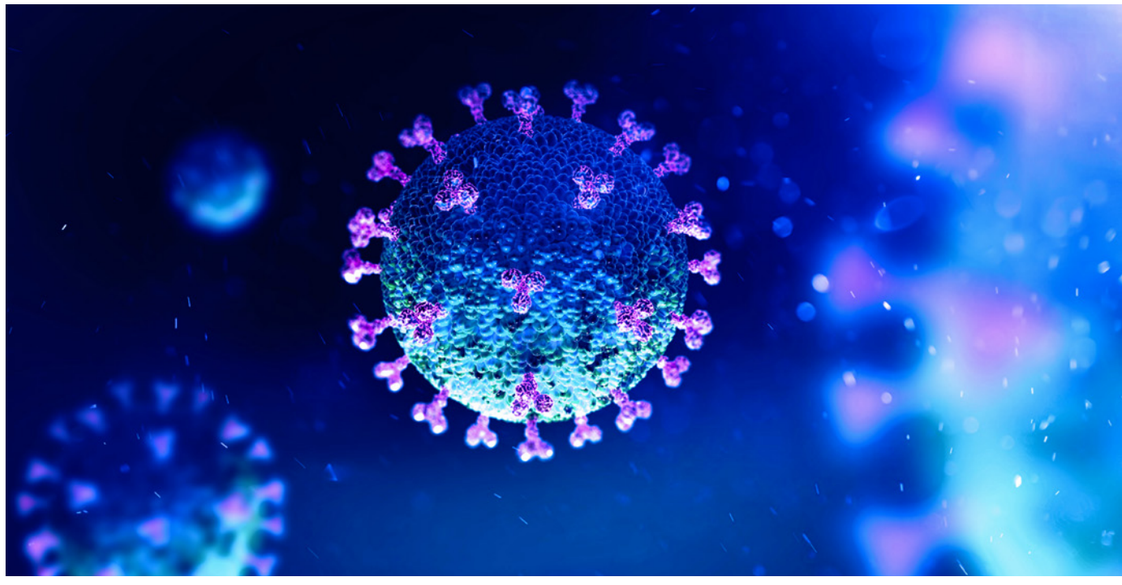
Fundraising remains difficult. Companies are turning to co-development and collaboration, including with companion treatments and diagnostics, to generate revenue and share risk. Larger companies remain active in seeking out licensing and acquisition opportunities, particularly to fill gaps in their product pipelines.

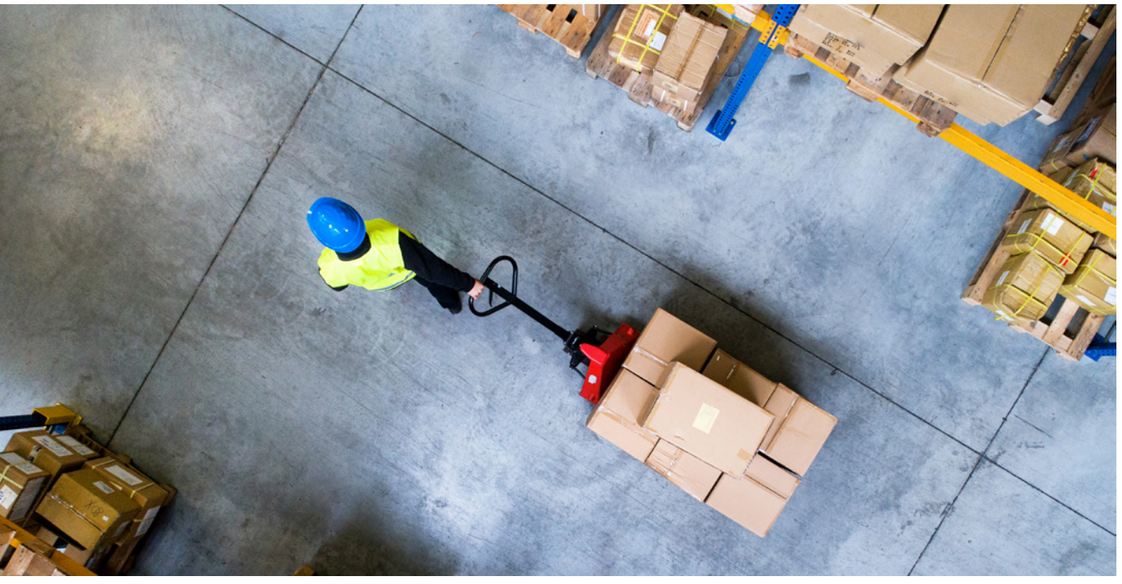
### Research grants

The UK has finally agreed its associate membership of the €95.5bn Horizon Europe programme. This will provide a boost of research funding that will benefit the UK life sciences sector. There may be an increase in collaboration agreements and sub-awards as UK researchers ramp back up their projects. Related contracts will need to take the Horizon funding terms into account, to the extent they "reach through" to the relevant arrangement, e.g. restrictions on IP ownership or use of funding.

### ESG

The life sciences sector is under pressure to demonstrate its contribution to environmental, social, and governance (ESG) goals, such as reducing carbon emissions, improving health equity, and enhancing patient centricity. Companies need to align their strategies and operations with ESG principles, as well as measure and report their impact. ESG clauses are increasingly appearing in contracts, especially around procurement. ESG can be difficult in the life sciences sector, especially in sub-sectors with high use of single-use plastics and international supply chains with large carbon footprints. However, planning, improving and monitoring ESG metrics will help differentiate companies from competitors and will become increasingly important in the future.





# Packaging and shipping products

### Windsor Framework

On 27 February 2023 the UK Government and the European Commission announced a political agreement in principle on the Windsor Framework, which will replace the Northern Ireland Protocol. This is a wide-ranging agreement covering multiple industries. With regard to medicines, the MHRA will be responsible for the approval of all medicines destined for the UK internal market, including Northern Ireland, and a single UK-wide marketing authorisation for medicines packaged "UK only" will allow medicines to flow freely between GB and NI. EU-wide marketing authorisations will no longer apply to NI. The Windsor Framework is currently going through the legislative process in the UK and the EU, and the parts applying to medicines will take effect from 1 January 2025.

The UK government has unveiled new guidance stemming from the Windsor Framework agreement, which is set to have significant implications for the labelling and packaging of medicinal products. Central to this guidance is the introduction of the 'UK Only' label, mandated for all medicines in the UK from 1 January 2025. This move aims to prevent the onward movement of these medicines into any part of the EU. Concurrently, the Medicines and Healthcare products Regulatory Agency ("**MHRA**)" will take on the responsibility of authorising all new medicines, including those in Northern Ireland that previously fell under the EU Central Authorisation Procedure. Another pivotal change is the discontinuation of the EU Falsified Medicines Directive (FMD) in Northern Ireland starting 1 January 2025. Companies should be aware of these changes, especially the requirement to notify the MHRA of any artwork modifications by 31 December 2024. Additionally, from 1 January 2025, joint EU/UK packs will no longer be permissible in the supply chain. As these changes loom, it's imperative for companies to adapt their operations and liaise with regulatory bodies to ensure a smooth transition and full compliance.

### Extended producer responsibility obligations in relation to packaging

Producers who meet the qualifying thresholds are currently required to collect and report their packaging data. Significant price changes are scheduled from 2024 where waste management fees will be calculated based on packaging previously reported as 'household packaging'. Furthermore, certain packaging will require labelling with the Recycle Now 'swoosh' and relevant wording by April 2026.



# Brand and IP asset protection

### Unified Patent Court

The Unified Patent Court (UPC) opened its doors on 1 June 2023. The UPC has jurisdiction over both Unitary Patents and European Patents which have not been opted out. Infringement and revocation actions are being filed regularly and the first pan-European preliminary injunction was granted recently. This new system brings with it complex considerations for patent holders in terms of patent prosecution and litigation strategy. For further information, follow our insights on the UPC and the Unitary Patent System on our dedicated homepage.

### Trademarks

— Courts and registries are beginning to differentiate between pure pharmaceuticals (regulated products) and products such as vitamins and minerals (unregulated). Indicating the regulatory status of a product could impact on trade mark status as well.
— Metaverse and NFT terms are being filed as standard now by most businesses and clients as part of their trade mark protection.

### Parallel imports and exhaustion

New regulations regarding the UK IP exhaustion regime were laid before Parliament on 16 October 2023. The aim of the new regulations is to maintain the current regime and ensure that there are no inadvertent changes as a result of the repeal of the Retained EU Law (Revocation and Reform) Act 2023. No decision has been made on any future IP exhaustion regime, but the government is continuing to engage with stakeholders in this regard.

### SPCs

The European Commission has published a series of proposed reforms to the Supplementary Protection Certificate (SPC) regime for medicinal products in the EU. Currently, SPCs are granted and enforced at a national level. However, the new proposals include amendments to the existing SPC Regulation to introduce a centralised examination procedure for SPCs, as well as new legislation creating a new unitary SPC to complement the new unitary patent. The new proposals are currently progressing through the ordinary legislative procedure. If enacted, they will have a significant impact on the procedure for obtaining, enforcing and revoking SPCs in the EU and will also impact decisions on appropriate marketing authorisation procedures.

### Compulsory licensing

The European Commission has published proposals for a new compulsory licensing regime to address future EU crises. If certain conditions are fulfilled, the Commission would be permitted to grant compulsory licences at an EU level to patents, published patent applications, utility models and SPCs without the rightsholder's consent in emergency situations, such as the COVID-19 pandemic. Fines of up to 6% of total turnover can be issued to licensees and rightsholders who fail to comply with the legislation. The proposed legislation is currently progressing through the ordinary legislative procedure.

### Trade secrets

Trade secret protection is rising up corporate agendas as another means of protecting valuable IP. Organisations should ensure that their policies, procedures and practices (including what happens 'on the ground' and also workforce training) are fit for purpose, especially in a hybrid working organisation. Alongside this and relatedly, there has been a rise in life science employee competition disputes. This is a major risk area for businesses in the sector and highlights the need to ensure employee contracts (as well as policies and procedures) are regularly reviewed and, where necessary, enforcement steps are taken.

# Litigation risks

### Sources of disputes in the life sciences sector

Disruption within the sector and external forces are likely to give rise to more disputes, particularly in the following areas:

— **M&A claims**. With the increased use of earn-out provisions, there will be more opportunities for parties to disagree on whether these have been triggered. Disagreements over adjustments to the purchase price have risen as buyers seek to realise more value post-acquisition, and an upward trend in this area is anticipated.

— **AI**. Disputes could stem from issues including ownership, data confidentiality and liability for AI defects or errors.

— **Intellectual property risk**. The inadequacy of existing risk management systems suggests that disputes will likely arise out of IP protection for new technologies. Current examples include challenges in obtaining patent protection in AI and digital health technologies. In addition, the lack of freedom to operate (FTO) and IP landscaping reviews, for example in the vaccine space, means that disputes arising out of the use of so called 'platform technologies' key to the pharmaceutical sector are likely.

— **Government intervention**. Although the sector is accustomed to a high regulatory burden, government interference in business activity reached new highs during the COVID-19 pandemic. At its peak, the push by some governments to make critical drugs widely and cheaply available, to the extent of overriding existing licensing arrangements and underlying patent protections, could lead to contractual breach claims as well as investor-state claims.

— **Data**. The lack of clarity around ownership of data generated from partnerships could lead to future disputes, particularly as big pharma increasingly partners with digital health companies for drug discovery and patient engagement and clinical trial automation.

— **Environmental, social and corporate governance**. It is expected that ESG scrutiny will increase over the next three years. This will lead to an increase in misrepresentation or breach of warranty claims, as well as claims grounded in material adverse change clauses in the ESG context.

### Shift towards arbitration

International arbitration is frequently expressed to be the preferred dispute resolution mechanism, but historically the uptake of arbitration by the life sciences sector has been lower compared to other industry sectors. However, due the increasingly global nature of the life sciences industry, in recent times the use of arbitration has been growing, and so has demand for arbitrators with specialist expertise and experience in the sector. Companies may wish to stay ahead of the game by carefully considering arbitration provisions from the outset of transactions, including whether it would be useful to stipulate that arbitrators should possess specific expertise or qualifications and provide for the arbitration to be administered by one of the major arbitral institutions that has access to specialists and is familiar with the types of cases most commonly arising in this sector.

### Class actions

The CMS European Class Actions Report 2023 details how class action risk in Europe continues to increase, driven by new class action procedures, the growth in litigation funding, a more active plaintiff bar – including more U.S. firms setting up in Europe, and the use of new technologies and techniques to facilitate large groups of claimants. Data in the report shows a relentless rise in class actions being filed in Europe: 55 in 2018; 72 in 2019; 119 in 2020; 120 in 2021 and 121 in 2022. With the Representative Action Direction now being implemented in the Member States, we expect these numbers to further increase in the years ahead. The key findings of the 2023 Report are:

— Europe and the UK continue to see record-high numbers of class actions, with 121 claims filed in 2022, up from 55 in 2018

— With the RAD's adoption in EU states, Europe expects a surge in consumer legal actions

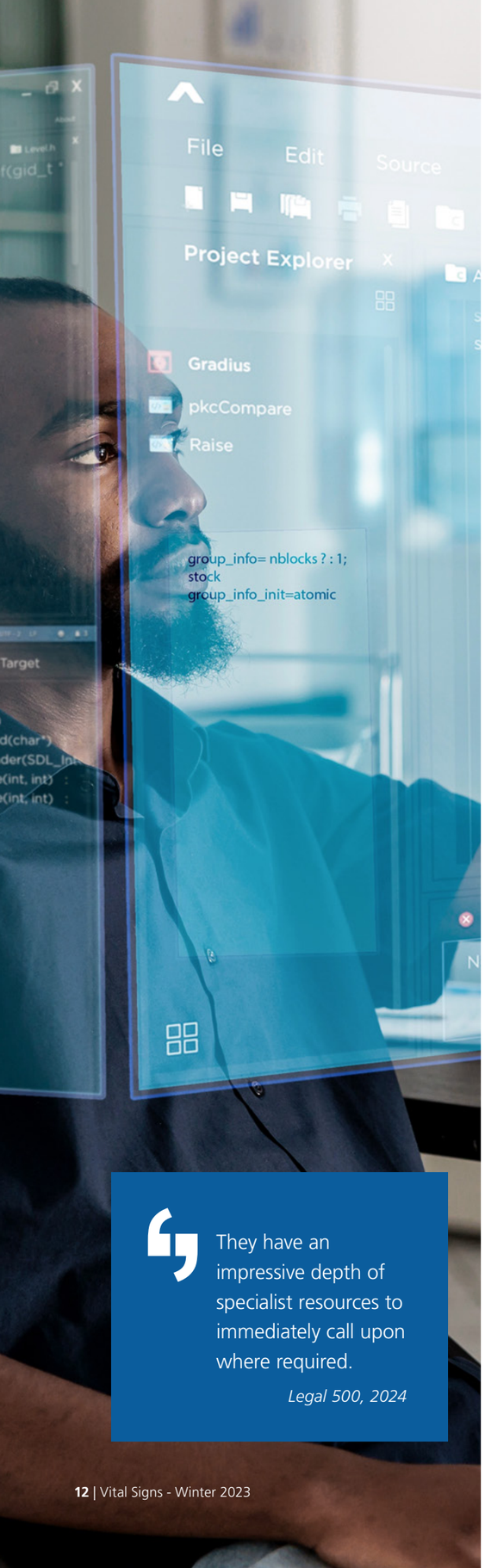
— There is no "safe" sector i.e., whether life sciences and consumer products, technology, financial products and professional services, all sectors are affected

— In the UK alone, we identified issued class actions seeking collectively in excess of €120bn

— UK, the Netherlands, Germany, and Portugal experience the most class actions (76%)

— The countries with the steepest growth in class actions are Germany, Slovenia, and Portugal

— Three key claim types: Product Liability (24%), Competition (26%), Financial Products/Securities (31%).




> They have an impressive depth of specialist resources to immediately call upon where required.
>
> *Legal 500, 2024*

# Risk of action by regulatory authorities

### Procurement

The Procurement Bill ("the Bill"), which is part of the government's attempt to "shake up our outdated procurement system", has been progressing through the Houses of Parliament and is expected to receive royal assent in the coming months. According to the UK Government, the Bill (which is expected to come into force in October 2024) will reform the UK's public procurement regime, making it quicker, simpler and more transparent.

The government has also announced the NHS Provider Selection Regime (the "PSR") which is a new set of rules that will replace the existing procurement rules for arranging healthcare services in England. The aim of the PSR is to move away from the expectation of tendering for healthcare services and it is expected to come into force on 1 January 2024.

If your business is involved with bidding for public sector contracts in the life sciences sphere, your business will be impacted by the changes to the procurement rules.

We have recently launched our Procurement Cube which will explore the new procurement rules through a lens of key sectors, including the Life Sciences & Healthcare sector. Please visit our Cube for sector-specific insights into UK procurement reform.

### Data protection

— From a UK perspective, the independent regulator of personal data processing (the Information Commissioner's Office or 'ICO') published its final guidance on Transfer Risk Assessments ('TRAs') in November 2022. TRAs are designed to accompany other appropriate safeguards, such as standard contractual clauses, in respect of international transfers of personal data and are a compulsory form of due diligence required to be undertaken by data exporters prior to undertaking international transfers to locations that are not covered by UK adequacy regulations. This follows the ruling of the Court of Justice of the European Union in Case C-311/18, Data Protection Commissioner v Facebook Ireland and Maximillian Schrems or 'Schrems II'. The ICO's approach is relatively pragmatic and it has published a TRA tool, that guides exporters through the assessment process. However, TRAs are not accepted in the EU and so where personal data is to be transferred from the EU on the basis of appropriate safeguards, then the exporter must instead conduct a Transfer Impact Assessment ('TIA'), which is a different type of risk assessment, based on EU-developed methodology. The ICO will accept either a TRA or a TIA and so a TIA can also be used when there are a combination of international transfers of personal data from the EU and the UK.

— The UK government's plans to reform data protection law in the UK through the introduction of the Data Protection and Digital Information (No. 2) Bill to Parliament are still ongoing. Although the aim of the Bill is to reform national data protection laws, the changes set out by the No. 2 Bill do not entirely reject the UK GDPR. Instead, they propose significant targeted reforms to the existing regime, impacting businesses that process personal data and are subject to UK data protection law. As at 10 October 2023, the bill is at the report stage and due to have its third reading in the House of Commons.

— The ICO is producing guidance on biometric data and biometric technologies. The first phase of the draft biometric data guidance is now available for public viewing and a consultation is open until 20th October 2023. The second phase of this guidance will include a call for evidence early in 2024.

— On 10th July 2023 the European Commission adopted an adequacy decision for the EU-U.S. Data Privacy Framework (DPF). The decision concludes that the US ensures an adequate level of protection (as compared with the EU) for personal data transferred from the EU, to US companies and organisations participating in the DPF, without the need to put in place additional data protection safeguards and conduct a TRA. The DPF has introduced binding safeguards to address concerns raised by the European Court of Justice in relation to how personal data treated in the US, including limiting access to EU data by US intelligence services only to what is necessary and proportionate, and establishing a Data Protection Review Court, to which EU individuals will have access.

— Finally, on 21st September 2023, the UK Secretary of State for Science, Innovation, and Technology took the decision to establish the UK-US 'data bridge' and issued adequacy regulations to this effect. The data bridge will be implemented in the form of a UK Extension to the DPF. This decision was made on the basis of the Secretary of State's assessment that the UK Extension to the DPF does not undermine the level of data protection for UK data subjects when their data is transferred to the US, and that the DPF maintains high standards of privacy for UK personal data. UK businesses and organisations will be able to use the data bridge to transfer personal data to DPF-certified organisations in the US, once the adequacy regulations come into force from the 12 October 2023. As with the DPF more generally, it will not be necessary to carry out TRA or TIA when making a transfer under the data bridge, and UK individuals will also have access the new Data Protection Review Court if they consider that their personal data has been accessed unlawfully by US authorities for national security reasons.

— To monitor enforcement of GDPR in Europe, please see CMS's GDPR Enforcement Tracker4.

### Advertising

Life sciences businesses should be aware of the increasing scrutiny that regulators in the UK and elsewhere are applying to environmental/sustainability advertising claims. So-called "green" claims must be clear and specific, and must cover the full life cycle of a product or service unless clearly limited in scope, and claims about environmental improvements, even if true, should not be "cherry-picked" to give a misleading impression of a business's overall environmental impact. With court action now a serious prospect in the UK, and new EU legislation on green claims on the horizon, businesses should consider auditing their environmental claims and their processes for creating and publicising them.

### Non-financial reporting requirements

The Environment Agency published regulatory position statement (RPS) 288, 'Reporting packaging data under Extended Producer Responsibility'.

RPS 228 effectively extends the deadlines until 31 May 2024 for large producers and compliance schemes to submit the first and second reports containing the data covered by the regulation. The deadline of 31 May 2024 also applies to Scotland and Northern Ireland, however the deadline for Wales (large and small organisations) is 1 April 2024.

### UK Sustainability Disclosure Standards

On 2 August 2023 the UK government published guidance on the framework to create UK Sustainability Disclosure Standards (UK SDS) by assessing and endorsing the global corporate reporting baseline of IFRS Sustainability Disclosure Standards. They will assess IFRS S1 and IFRS S2 for endorsement in the UK and aim to make an endorsement decision by June 2024. To assist with the assessment the government has set up the UK Sustainability Disclosure Technical Advisory Committee (TAC) and UK Sustainability Disclosure Policy and Implementation Committee (PIC). The TAC secretariat has published a call for evidence on IFRS S1 and IFRS S2, which closes on 11 October 2023. The responses to this call for evidence will be used to inform the UK Sustainability Disclosure TAC's technical assessment of IFRS S1 and IFRS S2.

# Corporate considerations

### Growing number of M&A-related disputes involving arbitration

According to the CMS European M&A Study 2023, across Europe, an arbitration clause was negotiated into 34% of deals. The current popularity of arbitration as a dispute resolution mechanism is consistent with its long-term popularity between 2010 and 2021, where the use of arbitration averaged 33%. In 2022, the application of national arbitration rules was frequently chosen for all deal sizes i.e. 65% of deals valued at more than €100m, 63% of deals with a value between €25m and €100m and 72% of deals below €25m.

The popularity of earn-outs experienced in 2021 was maintained in 2022, with their use modestly increasing by 1% to 27%. Given the sustained period of economic uncertainty, buyers are likely to use earn-out mechanisms in order to ensure that the price paid is measured over an extended period rather than by reference to financial years impacted by volatile economic conditions (e.g. inflation, interest rates etc.).

As buyers seek to realise more value post-acquisition, more disagreements over adjustments to the purchase price will emerge. We anticipate a greater number of disputes arising out of whether earn out clauses have been triggered across all sectors, particularly in the life sciences sector where earn out mechanisms are commonly used.

### Tax

— In recent years, concerns have intensified regarding non-compliance within R&D tax reliefs. HMRC's report from July 2023 highlighted that non-compliance levels were much higher than expected, particularly in the SME scheme, with error and fraud rates reaching 24.4%. Small claims and first-time claims also showed substantial non-compliance rates.

— To combat this, HMRC has implemented strategies such as increasing their compliance staff, utilising nudge letter campaigns, mandating digital claims submission with detailed information, and revising relief amounts in the SME scheme. Special attention is given to high-risk areas, including businesses less likely to qualify for reliefs, evidenced by the targeted nudge letters to care and nursing homes.

— Recent nudge letter campaigns reflect HMRC's behavioural strategy to guide compliance. One campaign focuses on the nursing and care home sectors, questioning the eligibility of R&D claims and cautioning against certain R&D agents. Another addresses the omission of Additional Information Forms in R&D claims, making such claims invalid and necessitating amended submissions.

— HMRC's approach, based on 'nudge theory,' aims to subtly steer taxpayers toward compliance. However, receiving a nudge letter should be taken seriously, prompting immediate professional consultation. Ignoring these letters could lead to severe consequences, including potential HMRC investigations under civil or criminal procedures. Early disclosure could help reduce penalties.

For more detail please see the CMS Autumn 2023 Tax Disputes Digest.

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