Life sciences report 2023: trends and future risks

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Kennedys

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Foreword

A challenging economic and geopolitical climate has not deterred life sciences businesses across the globe from producing innovative and ground-breaking medicines and technologies.

Notwithstanding an unprecedented period of uncertainty arising from Brexit and the COVID-19 pandemic – the impacts of which continue to be felt across all industry segments - life sciences businesses are emerging as resilient and forward thinking, working tirelessly to produce devices, treatments and therapies that will support global health in the years ahead whilst accounting for environmental, social and governance (ESG) priorities.

Advancements in medical technologies and the application of artificial intelligence have resulted in ground-breaking products and processes; new treatments and therapies have revolutionised the sector. Alongside this, the relationship between the life sciences industry and global businesses' ESG commitments continues to flourish.

Confidence in the capabilities of the industry is reflected in global investment and funding programmes. For example, the UK Government announced on 28 March 2023 that there will be £277 million in private and government investment that will help fund and advance manufacturing projects in medical diagnostics and human medicines.

In the EU, Horizon Europe, the EU's primary funding programme for research and innovation, which has a budget of €95.5 billion, continues to encourage research and collaboration whilst supporting breakthrough innovations through its European Innovation Council.

> As technology continues to drive innovation in life sciences at pace, law makers in the UK and EU are each carving out their own legislative paths. This requires a proactive approach to ensure that the legal and regulatory frameworks that govern life sciences products are fit for the risks and challenges arising in the modern world, as well as introducing, and managing, increasing ESG-related obligations.

Against this backdrop, this report highlights key legal and regulatory developments in the UK and the EU – and the related liability risks. Our experts also shine a spotlight on a number of priority topics for life sciences businesses, and their insurers, to consider as they plan for operational resilience in the months ahead.

Innovation

Digital technologies

Building upon the extraordinary accelerated development and use of digital technologies during the COVID-19 pandemic, digital transformation remains a priority for pharmaceutical, medical device and biotech companies who are joining forces with technology businesses to produce advanced digital health products and services, ranging from smart health applications and devices to digital therapeutics that can manage chronic health conditions.

Medical technology (MedTech)

The MedTech industry continues to produce ground-breaking technologies across a wide range of products, services and applications, including implants and prostheses, surgical devices, standalone software and mobile apps.

It also continues to attract significant investment. In 2022, MedTech Europe reported that the European MedTech market was estimated to be worth approximately €150 billion in 2021, with more than 500,000 products and services on the market.

In a post Brexit era, the UK is following suit, with MedTech accounting for 31% of life sciences turnover, consisting of 4,190 UK businesses and over £5 billion in exports. It is a high-paced area of innovation, with the UK having made 471 medical technology patent applications in 2021 alone.

The policy paper published by the Department of Health & Social Care on 3 February 2023 sets out the UK's medical technology strategy, which aims to "ensure the health and social care system can reliably access safe, effective and innovative medical technologies that support the continued delivery of high-quality care, outstanding patient safety and excellent patient outcomes in a way that makes the best use of taxpayer money".

> The modernisation of the UK and EU life sciences products regulatory regimes is, at least in part, a testament to rapid innovation in this space. Although AI and new technologies in the form of MedTech are at the heart of many reforms, actors in this space need to be aware of the broad reforms occurring to consider them strategically and holistically in order to future-proof their businesses.

Sarah-Jane Dobson, Partner, London

Regulatory and legislative developments

UK medical devices regulation
On 26 June 2022, the Medicines Healthcare and Products Regulatory Agency (MHRA) published its response to its consultation on the "future regulation of medical devices in the UK", which indicates future wide-reaching changes for the UK's future medical device regulatory framework. The new proposed framework aims to improve the safety of medical devices while being fit for the future, providing for the regulation of software and artificial intelligence as medical devices as well as promoting sustainability.

After much uncertainty as to when the UK's future regulatory framework will be published, life sciences companies will welcome the MHRA's announcement on 27 April 2023 that the government is aiming for core aspects of the future medical devices regime, as based on the consultation response, to apply from 1 July 2025. The MHRA's proposal to extend the transitional arrangements for CE marked devices will also offer comfort, enabling certain CE marked medical devices to continue to be placed on the GB market for longer.

Extension of the transitional periods for the EU Medical Device Regulation (EU MDR) and EU In-Vitro Diagnostic Regulation (EU IVDR)
Similar relief will be felt by life sciences companies operating in the EU following the European Commission (EC)'s publication, on 6 January 2023, of its draft legislative proposal to amend the transitional provisions provided for in the EU MDR and EU IVDR.

Once implemented, these proposals will provide more time to certify medical devices and mitigate the risk of device shortages, alleviating supply chain disruptions and ensuring patients will continue to have access to safe medical devices.

Artificial intelligence (AI)

Never before has there been so much focus on the capabilities of analytics-related technologies, such as artificial intelligence. For life sciences, the impact is colossal; from the diagnosis and identification of diseases to conducting clinical trials, in addition to the development of personalised medicines and the streamlining of manufacturing processes.

AI-enabled technologies continue to automate processes across the entire life sciences value chain, improving efficiency and saving costs.

Despite the enormous benefits to the industry, like other digital technologies, AI is at risk of malfunction or bias, giving rise to a myriad of liability risks, including in relation to product liability,

data privacy and discrimination. In recognition of these risks, there have been a number of regulatory developments in the EU and UK.

Regulatory and legislative developments

Whilst some existing EU regulations, including the EU MDR and EU IVDR, seek to address the safety challenges presented by AI, the EC considers it necessary to introduce AI-specific rules to address its unique risks and challenges.

An EU proposal for the regulation of AI, the Artificial Intelligence Act (the AI Act) which was published in April 2021, adopts a risk-based approach so that the 'riskiest' forms of AI are subject to the most stringent requirements and obligations.

For the life sciences industry, this means that high-risk products, such as AI-powered medical devices, will be subject to stringent obligations, including conformity assessments, human oversight and continued maintenance. On 11 May 2023, the EU's Internal Market Committee and the Civil Liberties Committee adopted the proposed AI Act, paving the way for a plenary vote in mid-June.

Although the UK Government has not produced draft legislation, the Department for Science, Innovation and Technology's (DSIT) White Paper on AI, published on 29 March 2023, states that it will be establishing a pro-innovation approach to AI.

The White Paper sets out five core principles including safety, transparency, fairness and accountability, to be issued on a non-statutory basis and implemented by existing regulators who will be able to provide guidance on the development and use of AI in their respective sectors. It is proposed that the regime will regulate the use of AI, not the technology itself, so as to avoid barriers to innovation. The UK does not intend to assign rules or risk levels to entire sectors or technologies; rather, regulation will be based on the outcomes AI is likely to generate in particular applications.

The White Paper accounts for the fact that some AI outcomes may require a higher standard of human-interpretability (the degree to which a human can readily understand the reasoning behind predictions and decisions made by the AI model), depending on the risks represented by an application. This is recognised by the MHRA's Project Glass Box, which is addressing the challenge of setting medical device requirements that take into account adequate consideration of human interpretability and its consequences for the safety and effectiveness for AI used in medical devices.

Key liability risks

As the laws and regulations governing digital technologies in the UK and EU continue to evolve and seek to keep pace with the speed at which the technologies are developing, legal claims in relation to product liability, AI and data privacy are increasingly key liability risks for life sciences companies and their insurers.

Product liability

Product liability claims have risen over the last decade, particularly in relation to medical devices and pharmaceutical products. This has driven high profile group litigation in the UK, EU and globally.

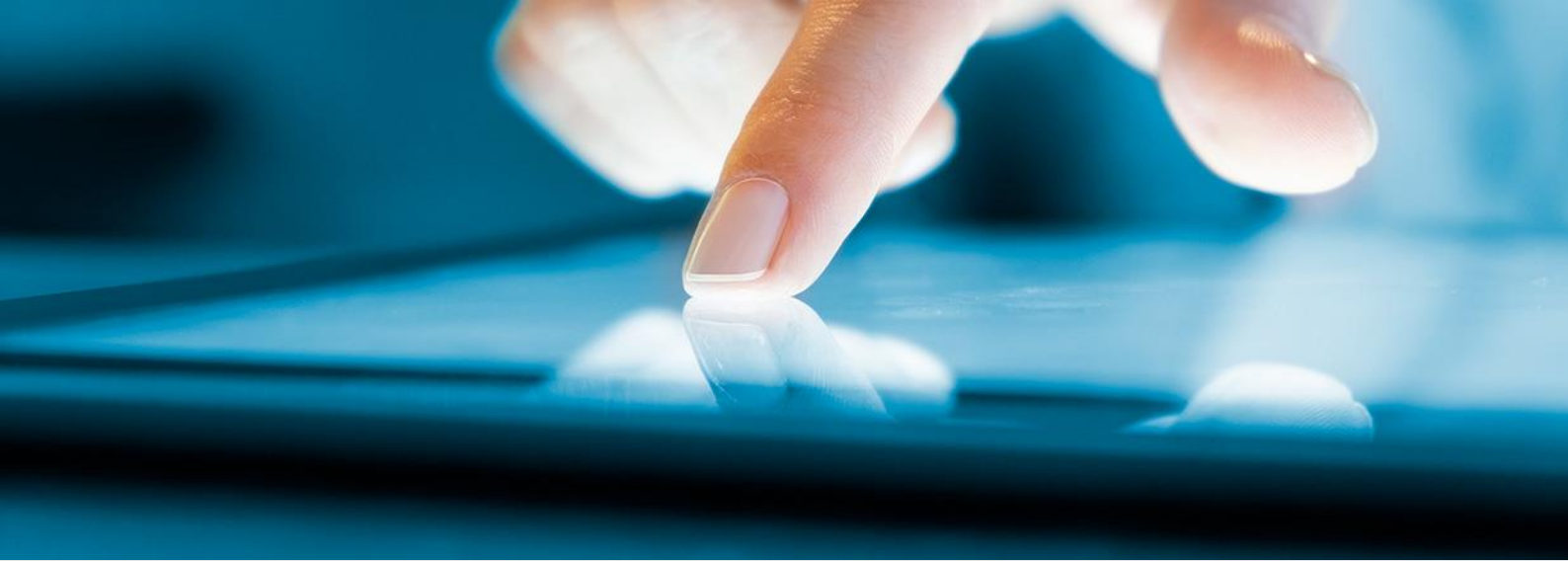
> Whilst the risk of such claims remain live, the potential product liability exposures in relation to new and emerging technologies are particularly significant. They include those that could arise from software vulnerabilities (e.g. in AI powered medical devices), affecting a large cohort of consumers across different jurisdictions, giving rise to group action risks.

This risk is expected to amplify in the EU in light of the proposed reform of the EU Product Liability Directive 85/374/EEC (PLD), the EU legislation governing liability for defective products. A draft legislative proposal, published on 28 September 2022, has potentially significant implications for manufacturers and suppliers of new technologies within the life sciences industry; it proposes a number of relevant amendments to the PLD:

- The alleviation of the burden of proof for claimants in product liability actions, particularly in relation to technical or scientifically complex products.
- The expansion of the definition of ‘product’ to cover intangible items such as electricity, software and digital manufacturing files. This will bring products such as connected/smart devices, IoT and 3D printing, all of which can be subject to automated software updates, within the scope of the PLD.
- AI systems and AI-enabled goods are also proposed to fall within the PLD’s scope, meaning that compensation would be available when defective AI causes damage, without the injured consumer having to prove fault on the part of the manufacturer.
- Increasing the number of potential defendants who may be liable under the PLD. In addition to manufacturers of tangible hardware, providers of software and digital services would also be liable.

The new PLD, once finalised, will potentially come into force in 2024, followed by a 12-month period for transposition into national laws by Member States.

In tandem with the proposal to reform the PLD, the EC also published a proposal for a civil liability regime for AI, known as the AI Liability Directive, which, when enacted, will enable individuals who have been harmed by AI to sue the AI 'provider'.



In stark contrast to the EU, the product liability risk in the UK arising from the use of digital technologies UK is less pronounced. Although the UK's Law Commission had previously consulted on proposals to make similar amendments to the Consumer Protection Act 1987 (CPA), the legislation that implemented the PLD into UK law, it confirmed on 16 February 2023 that it does not intend to introduce a new programme of law reform for the time being.

Accordingly, product liability litigation in the UK should remain relatively contained for the foreseeable future.

> The landmark product liability ruling in *Colin Gee v DePuy International Ltd* [2018] and the UK Supreme Court's decision in *Hastings v Finsbury Orthopaedics Ltd & Stryker (UK) Ltd* [2022] clarified the law on product liability, mostly in ways that have provided reassurance to producers, particularly those in the life sciences arena.
>
> With the CPA remaining untouched for now, these rulings should continue to reassure life sciences companies and their insurers that the courts will continue to recognise, and take into account, the importance of balancing consumer protection with the development of innovative technologies.
>
> Samantha Silver, Partner, London

Data privacy and cybersecurity

The potential of digital technologies continues to be harnessed through the increasing availability and use of 'real-world data', defined by the MHRA as "data relating to patient health status or delivery of health care collected outside of a clinical study".

Over the years, the internet, wearable and mobile devices and electronic health records have generated mass amounts of patient data which, coupled with artificial intelligence and machine learning techniques, are facilitating more efficient and improved health outcomes through streamlined product research and development, and supporting regulatory approvals and post-market surveillance.

Real world data which contains patient data is considered a “special category” of personal data subject to the requirements set out in the EU GDPR, the UK Data Protection Act 2018 and UK GDPR in the EU and UK. Breaches of these regulations, such as the unlawful collection and processing of such data, or the loss of such data, risks substantial financial penalties.

Regulatory and legislative developments

The UK
The Data Protection and Digital Information (No.2) Bill, which now comes under the responsibility of the DSIT, proposes to simplify the rules around the collection, sharing and use of personal data with a view to enabling businesses to grow and innovate whilst maintaining a high standard for data protection and privacy.

For the life sciences industry, the Bill should facilitate increased scientific research in the commercial sector as well as giving companies more flexibility over compliance with data protection rules, thereby promoting innovation.

The Bill provides that where the processing of personal data is for the purposes of scientific research, that research must be in the public interest. Scientific research would include research carried out for commercial purposes as well as non-commercial purposes. Providing this criteria is met, this increased flexibility would, for example, enable pharmaceutical companies to conduct scientific research based on personal data collated from clinical trial participants, without requiring the company to inform those participants that their data was being processed. However, this is subject to certain conditions being met, such as it being impossible for the information to be provided to the participants, or that it would involve a “disproportionate effort”.

The significance of barriers to data use in the context of clinical trials was highlighted in the DSIT’s Impact Assessment Study dated 13 March 2023, which reported that only 45% of requests for clinical trial data were successful.

The EU
Whilst significant volumes of data continue to be generated and collected by humans and computers, it is often not utilised to its potential due to conflicting economic incentives and technological barriers.

The EU’s Data Act, which is currently being considered by the EU institutions, proposes to make more data available for use and lays down rules on who can use and access what data and for which purposes, across all economic sectors in the EU.

Life sciences companies who manufacture and supply connected products (e.g. wearable health tech) and related services on the EU market will need to be aware of their obligations under the Act as non-compliance risks regulatory enforcement, including fines similar to the levels imposed by the EU GDPR.

The Act will work in tandem with other existing rules on the processing of personal data, including the EU GDPR, the EU Data Governance Act and the EU Digital Markets Act.

Treatments and therapies

Pioneering treatments and therapies continue to be a priority for life sciences companies. The development of a new life sciences innovation centre at the heart of Canary Wharf – a joint venture between Kadens Science Partner and the Canary Wharf Group – is testament to this. In addition to office space, the centre will provide capacity for fully serviced, flexible wet labs that will provide the means through which life sciences companies can drive innovation in healthcare.

Stem cell treatments

The development and use of personalised medicine has gathered pace in recent years, and 2023 is expected to present further opportunity for patients to receive medicines and treatments that are personalised to them.

Cell-based therapeutics in particular have gathered momentum in view of their potential to treat, and even cure, different diseases. To date, they have not been readily available due to regulatory barriers and manufacturing challenges although increased investment and funding, as well as proposed regulatory changes in the UK and EU, is expected to pave the way for them to become more mainstream in due course.

In November 2022, the biological medicines laboratories of the MHRA was granted access to funding of over £52,000 to facilitate collaboration across the MHRA together with a national and international network of stakeholders including scientists, clinicians companies and regulators to develop guidelines for microbiome therapeutics and diagnostics.

This is expected to bring confidence to the industry to invest in the development of new therapeutics in this area in the move towards personalised medicine.

Developments in this area are already being realised, with the MHRA announcing on 30 March 2023 that it is trialling a pioneering robot which grows stem cells, the CellQualia™ Intelligent Cell Processing System, that has the potential to bring safer and more cost-effective treatments to people with a wide range of diseases.

> The development of innovative cellular treatments to treat previously irreversible conditions could radically transform the healthcare landscape. Less invasive treatments, the opportunity to extend and save lives as well as the consequential cost reductions associated with chronic health conditions will have enormous social and economic impacts for the global economy.
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> For insurers, they may also reduce catastrophic injury claims spend through their potential to lessen, or even reverse, claimants' injuries, which could be particularly pertinent for spinal and brain injury claims.
>
> Alex Riley, Legal Director, London

Psychedelics

The pharmaceutical industry is investing billions into the study of psychedelics (also known as hallucinogens) for treating depression, alcohol use disorder, tobacco addiction, migraines, anorexia and other mental health disorders. Psychedelics are a class of psychoactive substance that produce changes in perception, mood and cognitive processes.

Many occur naturally, such as in trees, fungi, seeds and leaves, while others are made synthetically in laboratories. Examples include LSD, psilocybin, DMT, MDMA, and ketamine. Drugs based on psilocybin molecules, found in magic mushrooms, have shown promising results, including 'statistically significant improvement' in clinical symptoms of depression in studies.

> Although psychedelics are heavily restricted or prohibited in most countries based on their classification under illicit drug regimes, attitudes are changing and clinical trials are being closely monitored by governments, scientific communities and the pharma industry.

Europe's first commercial facility for psychedelic drug trials recently opened in London, with the goal of making the UK a global leader in psychedelics research and innovation. In February 2023, Australia broke the mould and became the first country to approve the legal use of MDMA and psilocybin for certain mental health conditions, setting the stage for other countries to follow suit.

> Psychedelics have been cited as being a potential solution to a global mental health crisis. However, as with any new product, psychedelics will give rise to a variety of potential liabilities, including those arising from clinical trials, treatment setting, inadequate warnings and serious adverse events identified during post-market surveillance.
>
> Nathalie Smyth, Partner, London

Regulatory and legislative developments

Reform of UK clinical trials regulation
The UK's current clinical trials regime, provided for by the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), which is derived from the EU's Clinical Trials Directive (2001/20/EC) (CTD), is set to be subject to reform.

Owing to the timing of Brexit, the EU's Clinical Trials Regulation (EU 536/2015) and Clinical Trials Information System, which reformed the existing framework under the CTD, did not apply in the UK.

On 21 March 2023, the MHRA published its proposal to update the existing regulatory framework following a consultation in 2022. The MHRA has proposed a series of new measures to make it faster and easier to gain approval and to run clinical trials in the UK, representing the biggest overhaul in UK clinical trials regulation in over 20 years. It endeavours to make the UK one of the best countries in the world to conduct clinical research.

The proposals provide for a proportionate, streamlined and flexible regulatory environment that will be as "future-proofed as possible", with the ability to respond to different types of trials and innovative designs – such as psychedelics - and supportive of new ways of carrying out trials, including decentralised trials.

Environmental, social and governance (ESG)

Innovation and ESG concepts are inextricably linked. From the development of the COVID-19 vaccine to the rapid development of novel MedTech products, breakthroughs within the life sciences industry continue to contribute significantly towards creating a safer and healthier society.

Looking ahead, the life sciences industry's drive for innovation must be carefully balanced with delivering on ESG commitments. With climate and environmental changes having the potential to significantly impact upon human health, ESG-related priorities are becoming a fundamental element to life sciences business practices, from developing ethical and greener drug discovery processes to producing sustainable and affordable products.

Whilst such practices are a step in the right direction towards a greener future, companies must not lose sight of the importance of transparency and trust. Increasing focus on corporate accountability and greater scrutiny of company ESG campaigns, underpinned by a rise in global climate activism, is expected to give rise to liability and reputational risks for life sciences companies in 2023 and beyond.

Environmental

Synthetic chemicals

According to published research, there are an estimated 350,000 different types of manufactured chemicals on the global market. In recent years, the spotlight has been on Perfluoroalkyl and Polyfluoroalkyl substances (PFAS), often referred to as 'forever chemicals' owing to their persistent

nature. PFAS are a complex and expanding group of man-made chemicals found in a variety of products used by consumers and industry, including medical devices. They have recently been under the scrutiny of various stakeholders across the globe, culminating in a series of international noteworthy legal and regulatory developments, because of their alleged impact on health.

EU national authorities from Germany, the Netherlands, Norway and Sweden submitted a regulatory dossier to the European Chemicals Agency (ECA) on 7 February 2023 proposing to ban the production and use of PFAS. The proposed ban will impact products across many industries, including the medical devices industry, and will mean that companies will have to look for alternative chemicals/substances for their products and production processes. The ban will also extend to EU imports of products containing PFAS. On 22 March 2023, the European Chemicals Agency opened a six month public consultation on the proposed PFAS restriction.

PFAS litigation in the United States and Europe is impacting chemical producers, as well as producers of the products that contain those chemicals. The claims relate to environmental damage and personal injuries including impacts on human health such as cancer and thyroid disease.

Escalating consumer activism and growing media attention, coupled with an increasing number of environmental class actions being brought before the English courts, is making future PFAS litigation in the UK, including by way of group actions, more likely, particularly if a more stringent regulatory regime is implemented. Life sciences companies that manufacture products containing PFAS are at risk of exposure to claims in this area. The development and outcome of legal cases in other jurisdictions should, therefore, be closely monitored.

Social

Diversity, equity and inclusion (DEI)

Bias and discrimination in product design, testing and clinical trials may result in some devices and medicines not being as effective on certain patient groups. This was reflected in the UK Government's response to its consultation on the future regulation of medical devices in the UK, published in June 2022. As a result, the MHRA pledged to provide extended guidance on how manufacturers of medical devices, including software and AI-enabled medical devices, can demonstrate and ensure the safety and efficacy of their products across diverse populations.

> With life sciences companies increasingly adopting AI-enabled technologies, they risk discriminating against certain patient cohorts if, for example, data sets are restricted. Potential causes of bias and discrimination include the inadvertent introduction of bias by developers, the use of flawed data when 'training' AI technologies, and/or testing the product on an insufficiently diverse population.

In 2021, the then Health Secretary, Sajid Javid, ordered a review into whether certain medical devices were equally effective regardless of patient ethnicity. This followed research that oximeters, which measure the level of oxygen in a patient's blood, had been overstating blood oxygen levels in people from ethnic minorities, impacting on the type of COVID-19 treatment received.

DEI-related lawsuits have already begun in the US. With shareholders increasingly holding organisations to account in respect of their DEI practices, life sciences companies in the UK and EU, including their directors and officers, are at an increasing risk of facing DEI litigation, not only in relation to their DEI practices but also in respect of the products that they sell.

Governance

Corporate sustainability

On 23 February 2022, the European Commission (EC) published its proposals for a Directive 2022/0051 on Corporate Sustainability Due Diligence (the CSDD). This provides a pathway for companies, in respect of their products' lifecycle and/or their business activities, to implement the necessary due diligence procedures to enable them to better identify, prevent, mitigate and bring to an end adverse impacts of their activities on human rights and on the environment that may occur within their value chains or operation structures, such as child labour, exploitation of workers and pollution.

The CSDD will place greater corporate responsibility on large EU and non-EU companies, including those operating in the life sciences sphere. EU based companies with more than 250 employees and a global turnover over more than €40 million, as well as parent companies with more than 500 employees and a global turnover of more than €150 million will be subject to due diligence requirements under the CSDD, with non-compliance proposed to attract significant financial penalties and civil liability.

The European Parliament's legal affairs committee adopted its position on the CSDD on 25 April 2023 and it will vote on its final negotiating position in May 2023.

Whilst the UK does not intend to introduce an equivalent legislation to the CSDD, life sciences companies are still at risk of being held to account in respect of human rights breaches across their supply chains through alternative legislation, including the Proceeds of Crime Act 2002.

The life sciences industry is also at risk of civil litigation, including group actions, in respect of alleged environmental and human rights breaches across their supply chains. The English courts are increasingly willing to entertain mass tort actions brought by claimants seeking to hold companies to account for harm, as exemplified in *Municipio de Mariana and Others v BHP Group PLC* [2022] in which foreign claimants are pursuing environmental claims against UK parent companies in respect of the actions of their foreign subsidiaries.

> Life sciences companies face distinct sustainability challenges across their entire value chain. From the sourcing of materials for drug development, to the manufacture of single use plastics for sterility, there is increasing pressure on companies to address current practices and implement effective sustainability strategies across all aspects of the business.
>
> As lawmakers seek to implement corporate sustainability practices, it is more important than ever that life sciences companies look beyond their own operations and undertake extensive due diligence to ensure that the sustainability practices of their contractors and suppliers are aligned with their own priorities and goals.
>
> Sarah-Jane Dobson, Partner, London

Greenwashing

Businesses across all industries are having to navigate the complex interplay between new and existing laws, regulations and policy initiatives that promote environmental sustainability, such as those governing packaging and waste. Breaches of these laws risk financial penalties or in some cases, criminal prosecution.

This evolving regulatory landscape, coupled with pressures to achieve a low or carbon neutral footprint and government led net zero targets, has inadvertently resulted in an increase in environmental misstatements known as ‘greenwashing’.

> In the UK, this prompted publication of the Competition and Markets Authority’s (CMA) Green Claims Code (the Code) which provides guidance for businesses on how to make responsible environmental statements. The Financial Conduct Authority (FCA) is also proposing a package of new measures to clamp down on greenwashing, with the final rules expected to be published by June 2023.

The EU is also seeking to crackdown on greenwashing. On 22 March 2023, the EC published a proposal for a Directive on substantiation and communication of explicit environmental claims – also known as the Green Claims Directive (GCD) - to provide consumers with clarity on environmental claims and labelling.

As sustainability continues to influence consumer decision making, there is an increased risk of enforcement action and litigation arising from misleading or false environmental statements (e.g. non-toxic), as evidenced by class action lawsuits filed against household brands in the US, including consumer health products. Life sciences companies and their insurers need to be alive to the growing risk of ESG-related litigation, with directors and officers being at a heightened risk as companies and senior management personnel are held to account.

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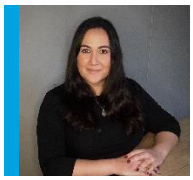

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