Bristows

Biotech Review of the Year

Issue 13

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Dear reader,

Welcome to the 13th edition of our Biotech Review of the Year. We are pleased to present a collection of articles that reflects the breadth of legal, regulatory and commercial issues that businesses and institutions in the biotech sector are navigating today. This edition brings together perspectives from our specialist teams, offering insights into innovation, investment, regulation and dispute resolution at a time of continued change for the industry.

We open this issue with a focus on **investment and growth**, beginning with an exploration of the current outlook for the cell and gene therapy sector. The article looks at a market characterised by extraordinary scientific promise alongside significant volatility, examining how companies are responding to shifting investor sentiment, regulatory complexity and the realities of commercialisation. We then turn to a different, but equally pressing, challenge: the persistent women's health data gap in clinical research.

Practical considerations for companies at earlier stages of development are addressed next in our top 10 considerations for early stage and spin-out biotech companies. We highlight the importance of making foundational decisions early, from equity structuring to people strategy, in order to support future growth and investment. This theme is complemented by our Tax team's analysis of the UK Government's Budget 2025, which examines the key tax measures intended to support science and innovation and assesses what they mean in practice for life sciences businesses operating in the UK. We wrap up our focus on investment and growth with an article addressing the increasing scrutiny by competition authorities of so-called 'killer acquisitions', and what this evolving enforcement landscape means for biotech companies pursuing transactions.

Next we turn our attention to the **changing legal frameworks** shaping the sector. Our Regulatory team examines the European Commission's proposal for a European Biotech Act, considering whether it has the potential to unlock growth and competitiveness for the health biotech industry across the EU. Our Data Protection colleagues focus on clinical research, analysing how the lack of harmonisation in data protection law across Europe is hindering clinical trials and, in turn, innovation and patient access. The section concludes with a piece looking at decentralised medicines manufacturing in the UK, which traces the regulatory and practical implications of bringing manufacturing of innovative medicines closer to patients.

Our third section focuses on **litigation and arbitration** in the sector. Our Patent Litigation colleagues consider whether biotech litigation has entered a new era, reflecting on the impact of increased biosimilar competition, phase III waivers and recent uptake of UPC and cross-border litigation, and what this signals for future disputes in the sector. We also explore whether 2026 will finally deliver greater clarity on SPC manufacturing waivers, an issue of continued importance for innovator and generic companies alike. Finally, our Commercial Disputes team examines the complexity of assessing loss in life sciences disputes, where scientific uncertainty and long term value creation can make quantification particularly challenging.

Finally, we are very pleased to share with you insights from our Q&A with Stuart Casey, Associate General Counsel – IP Strategy & Innovation at Touchlight, a pioneering cell-free DNA manufacturer. We thank Stuart for taking the time to share his thoughts on challenges and changes in the biotech industry, as well as his tips for anyone stepping into an in-house counsel role in a biotech company.

We hope this edition of Biotech Review provides both practical guidance and strategic insight for those operating across the biotech ecosystem. We would like to thank all of our contributors for their expertise and collaboration and would be delighted to hear from you with any thoughts, comments or questions on the topics addressed.

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Contents

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Cell and gene therapy: all aboard the rollercoaster ride...

Over the last few years, arguably no other part of the global life sciences industry has shown as much promise, and yet faced as many challenges, as the cell and gene therapy (CGT) sector. CGTs were first conceptualised over half a century ago and have been in development for several decades. However, it was only comparatively recently that Glybera became the first gene therapy to receive approval in Europe in 2012, with Kymriah becoming the first FDA approved CAR T-cell therapy in the US in 2017.

Around this time, the CGT market was undeniably the "hot new thing" and tipped to be the shining light of the life sciences industry, promising long-term patient benefits and even potential cures. However, following the excitement after a flurry of regulatory approvals, a significant number of commercialisation hurdles have, to differing extents, somewhat derailed the sector's progress. This article explores the current state of the global CGT market (including some of the key challenges faced when bringing such therapies to market) and what its future may hold.

The state of the current CGT market

Claight's market research valued the global CGT market at about $21.43bn in 2025 and forecasted an approximate value of $139.83bn by 2034. Unsurprisingly, the US is the leading market for CGT, with the same research finding that of the more than 1,000 companies worldwide operating in the CGT space, over half of them are based in the US. Leading players in the global CGT market include, among others, Amgen, Novartis, Alexion Pharmaceuticals (a subsidiary of AstraZeneca) and Genetix Biotherapeutics (previously known as bluebird bio). However, not to be underplayed, the UK has also long been a pioneering force in CGTs with notable UK success stories including the likes of Autolus Therapeutics, Orchard Therapeutics and Oxford Biomedica.

Generally speaking, the global CGT market is projected to grow significantly over the next decade – fuelled by both government and private venture funding (albeit acknowledging the turbulent and challenging times for capital markets, and funding for CGTs specifically, over the last few years), supportive regulatory environment and, ultimately, a growing demand for these innovative therapies. Notably, there is a growing awareness that the CGT pipeline is no longer as niche as before, with a focus expanding beyond rare diseases, resulting in an ever-increasing amount of clinical trials for CGTs. To demonstrate this, the American Society of Gene & Cell Therapy reports that there were over 3,000 CGT clinical trials underway globally during 2025. Despite these positive signs and the projections for growth, it is impossible to ignore the many hurdles which biopharma companies face when it comes to commercialising CGTs, which unfortunately threaten the uptake of CGTs and overall success of this industry.

Commercialisation challenges

Typically, major challenges for CGT companies arise after obtaining the relevant regulatory approval for their therapy, whereas for many other medicines, this is when the programme is significantly de-risked.

In some cases, CGTs have been withdrawn, or faced narrowing labels or "black-box" warnings, due to safety concerns. An obvious recent example is Elevidys, which was developed by Sarepta Therapeutics, for the treatment of Duchenne muscular dystrophy. In July 2025, Sarepta temporarily suspended shipments of the therapy due to the death of two patients from liver failure following treatment, and then significantly narrowed its label to reduce the types of patients who could receive the treatment.

Aside from safety concerns, the other challenges typically faced by CGT companies are commercial and operational hurdles – particularly manufacturing difficulties and supply chain issues, struggles in agreeing reimbursement deals with relevant paying authorities and sometimes also, quite simply, relatively low patient uptake. One of the earliest signs of these challenges for the CGT market was seen in the case of Provenge, a personalized, cell-based immunotherapy used to treat certain types of advanced prostate cancer, which was developed by Dendreon Pharmaceuticals and was, following approval by the FDA, one of the most widely anticipated launches of 2010. However, ultimately this therapy failed due to many of the challenges described above, such as suffering from a complex manufacturing process (which was difficult to scale) and the associated costs of the therapy making it nigh on impossible to obtain reimbursement at a level which the company would consider commercially sustainable. Similarly, a decade on, Zynteglo, which entered the market with a price tag of $1.8m, was withdrawn by bluebird bio (as it was then known) from Europe in early 2022 after failure to agree reimbursement negotiations with German health authorities.

As a result of these challenges, in recent years, we have seen a number of biopharma companies voluntarily withdraw marketing authorisation for CGTs. A 2024 comparative pharmacovigilance study of CGTs found that, by 30 June 2024, the EMA had approved 26 CGTs, of which seven had been withdrawn – highlighting that withdrawals are now a recurring feature of the European CGT landscape and noting that, as mentioned above, most are attributable to commercial/operational hurdles, rather than solely as a result of product safety issues. The same study noted that while withdrawals are not as commonplace in the US, there has been a general pattern of post-marketing challenges, such as label changes, boxed warnings and trial holds, all of which had a negative impact on the commercialisation of CGTs in

the US market. Some companies have even suffered from considerable competition from hospitals which have produced their own cheaper versions of the therapies, taking advantage of hospital use exemptions (or equivalent exceptions) under their local regulatory regime.

In light of this landscape, some biopharma companies have scaled back their CGT programmes or even exited the CGT sector entirely. For example, in February 2025, Pfizer stopped marketing Beqvez (its hemophilia B gene therapy) and said, at the time, that it no longer had any active gene therapy programmes. Similarly, the likes of Novo Nordisk and Takeda have also fundamentally exited the CGT space in recent times and many companies have pivoted away from CGT to double-down on other promising programme areas such as GLP-1 and antibody drug conjugate programmes. Some younger or specialist CGT companies have gone into liquidation or made a voluntary decision to wind down, and many earlier stage biotech CGT companies, particularly those with assets in Phase III trials or approaching commercialisation, have failed to secure further investment.

However, all is not lost as many large biopharma companies remain committed to the CGT industry and its undoubted potential. To name just a few, Novartis, Astellas Gene Therapies and Alexion have all demonstrated significant expenditure, and success, in new CGT programmes and show no signs of stopping any time soon. Interestingly, many companies in the space appear to be de-risking, and pooling efforts and resources, by way of prioritising partnership deals for CGT programmes. See for example Astellas Gene Therapies' headline-making deal with AviadoBio in 2024 for AVB-101 (an AAV gene therapy for frontotemporal dementia), which saw reported payments of around $20m equity, up to $30m upfront and potential $2.18bn in milestones. Therefore, while it has no doubt been a challenging few years for the CGT sector, there is a certainly hope for the future – with many biopharma companies (and investors) backing themselves and the industry to overcome these challenging commercialisation hurdles.

Hope for the future

Amidst the increasing predictions of a generally improving investment climate in the future, there appear to be a few specific trends or opportunities which offer hope for the CGT industry.

As with seemingly every other industry at the moment, the use of AI offers a seismic opportunity to revolutionise CGTs, particularly in terms of manufacturing, to enable faster, more efficient and ultimately scalable processes. In particular, AI is likely to help automate batch recording and quality control, offer the ability to analyse vast datasets almost instantaneously to better understand complex biological processes and process parameters and, of course, help to identify potential new CGTs earlier and thus expedite the time-consuming and expensive clinical development process.

Alongside the use of AI, there is an increasing interest in the use of decentralised manufacturing for CGTs. Given the short shelf life of CGTs and the severity of critically ill patients, decentralised models will help simplify logistics and bring manufacturing closer to the patient. The UK's new decentralised manufacturing framework is addressed by Hugo Kent-Egan on page 36 of this publication.

More generally, the landscape of contract development and manufacturing organisations (**CDMOs**) in the CGT space is rapidly evolving and expanding. While there are many CDMOs now operating successfully in the CGT space, up until recently, only a

limited pool of those could boast of genuine experience of manufacturing for Phase III trials or commercial launch of CGTs. However, over time, one would expect this market up-skilling to occur and ultimately offer biopharma companies greater choice (and, thus, cost efficiencies) when it comes to outsourcing the manufacturing process. We have previously explored the key strategic considerations when partnering with CDMOS for CGT programmes.

As touched on earlier, many CGTs have failed as a result of reimbursement issues given the unparalleled high costs of bringing these therapies to market. Creative payment models are being developed to help address this issue. For example, we have seen annuity-based models (spreading the cost over several years in a pre-agreed payment plan) and outcomes-based models, whereby reimbursement payments are conditional upon the patient reaching specific clinical outcomes by deadlines – although collecting the data on those outcomes can be difficult and costly in practice. However, over the next few years, we expect to see better infrastructure for collecting this data and other creative payment models to emerge and become customary for CGTs - for example, the use of a subscription style model for certain CGTs that allows paying authorities to pay a lump sum for unlimited access to treatments over an agreed period of time. Therefore, greater access to reimbursement coupled with the possibility of reduced costs, arising from efficiencies and growing patient demand, is another source of hope for the CGT sector.

As well as creative solutions to maximise the efficiency and affordability of existing therapies, *in vivo* cell therapy has the potential to be a complete paradigm shift for the CGT sector. Traditional *ex vivo* engineering (whereby a patient's cells are modified outside the body and reinserted) is labour intensive, costly, complex, time-consuming and requires access to specialised facilities – thus, ultimately, contributing to the cost issues detailed above. However, *in vivo* therapies, where genetic material or modified cells are delivered directly inside the patient's body, have the potential to reduce these complexities (and costs) and ultimately expand the scope and availability of CGTs.

However, a word of caution, while much progress is being shown in this promising area, it is widely acknowledged that a number of technical, safety and regulatory challenges will need to be addressed before *in vivo* therapies are widely available. Nevertheless, *in vivo* CAR T-cell therapy, in particular, is rapidly becoming a very hot area for investment, exciting VC investors and large pharmaceutical companies alike. In the last 18 months, companies such as Eli Lilly, Kite Pharma, AbbVie and AstraZeneca have been snapping up companies with *in vivo* platforms.

Lastly, for US and European biopharma companies, exploring other territories (in particular China) also offers a new source of hope. In recent years, China has become an increasingly influential market for CGT development, particularly as it is widely viewed as offering quicker and more cost-effective clinical development pathways. Many CGTs are being first evaluated under China's investigator-initiated trial system, which allows academic centres to run first in-human studies before formal IND/sponsor trials – a trend which is seemingly becoming increasingly popular.

To conclude, even those with an optimistic outlook would have to acknowledge the difficulties that the CGT sector faces, especially when it comes to commercialisation. However, as we have highlighted, there remain clear reasons to be hopeful for the success of the industry in the future. One thing is for sure, the continued evolution of the global CGT market is set to be a rollercoaster ride for all involved.

Half the population, half the data: addressing the women's health gap in clinical research

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Historically, women have been underrepresented in clinical trials. This is due in large part to the 'male by default' approach that has been taken in research and medicine. Additionally, even when women have been included in clinical trials, results have rarely been disaggregated by sex, meaning there has been a lack of consideration as to how conditions and treatments can affect women differently.

This has contributed to the gender health gap, which refers to disparities in health outcomes between sexes, and the gender data gap, which highlights the lack of sex-specific research and analysis. These gaps have profound consequences, ranging from misdiagnosis and ineffective treatments to increased adverse drug reactions among women.

Closing these gaps requires systemic change in research design, regulatory frameworks, and funding priorities. In this article, which focuses on the UK, we explore the causes and implications of the gender health and data gaps and the steps that are being taken to close them.

Causes of the gender health gap

The gender health gap has arisen for a number of different reasons, one of which is a historic lack of research and clinical trials either specifically focussed on women's health issues, or including a representative sample of women.

A 2025 study conducted by the MHRA and the University of Liverpool analysed the data on all 4,616 clinical trials submitted to the MHRA between 2019 and 2023. This analysis shows that there were 67% more male-only studies than female-only studies (making up 6.1% and 3.7% of all trials respectively). Further, reproductive and childbirth related trials constituted only 2.2% of all clinical trials submitted to the MHRA.

Although 90% of clinical trials in the MHRA study included participants of both sexes, this figure does not tell the whole story. Women with child-bearing potential were only included in 33.1% of the trials. There was particular underrepresentation of pregnant women (only 1.1% of participants) and breastfeeding women (only 0.6% of participants). Therefore, merely including both sexes does not mean that the trial is representative of the overall population.

Additionally, unless researchers analyse and report results by sex, the results will not necessarily capture the differences between men and women. Where trials are not split up by sex, it can be impossible to know the extent to which sex disparities have an effect.

The UK's Health Research Authority confirms there is currently a lack of standardised guidance for researchers in the UK on how to adequately account for sex and gender differences in clinical studies. This contrasts with the approach in other areas of the world. For example, the EU's Clinical Trials Regulation requires that the age and gender of subjects in clinical trials must be justified. The EMA is also publishing guidance aimed at closing the data gap, including a 2025 guideline for consultation on inclusion of pregnant and breastfeeding individuals in clinical trials. In the US, the National Institute of Health has required investigators to consider sex as a variable in vertebrate animal and human studies since 2016. The Canadian Institutes of Health Research (Canada's federal funding agency for health research) expects all research applicants to adhere to policies on integrating sex and gender into health research.

Consequences of the gender health gap

The consequences of the gender health gap are wide-reaching, spanning not only healthcare delivery and outcomes but also workforce composition and economic prosperity. A 2024 report by McKinsey states that closing the gender health gap could boost the global economy by an estimated $1tn annually by 2040, through improving the health outcomes of women and, in turn, optimising their economic participation.

On a national level, the Women's Health Strategy for England policy paper published in August 2022 outlines a ten-year strategy for England to improve the health of women and girls. The report notes that while women typically live longer than men, women spend a greater proportion of their lives living with ill health and disability. One reason for this could be that women's health research primarily focuses on diseases with high mortality such as ovarian, cervical and uterine cancer, rather than conditions affecting women's day-to-day health such as polycystic ovary syndrome and endometriosis.

The reluctance to include pregnant and breastfeeding women in clinical research has been shown to have tragic effects on women's health outcomes. A BMJ study found that confusing messaging around vaccination during pregnancy was likely to have contributed to the deaths of 27 women in the UK during the pandemic. The EMA notes exclusion of these populations from clinical research has also resulted in product leaflets lacking details about the benefits and risks of a medicine during pregnancy and breastfeeding, contributing to the difficulty these women and their healthcare providers may face when making treatment decisions.

Furthermore, women's safety is impacted by a lack of clinical trials considering sex difference in drug responses. The 2024 McKinsey report notes that "since 2000, women in the US have reported adverse events from approved medicines 52% more frequently than men, and serious or fatal adverse events 36% more frequently." In particular, women experience some asthma and cardiovascular disease treatments differently to men. As also highlighted by the 2024 McKinsey report, an analysis of the most used clinical interventions found that 64% of them disadvantaged women (because of limited access, lower efficacy or both). In comparison, this figure was only 10% for men.

A 2022 paper on the results of a Phase III clinical trial for Alzheimer's drug lecanemab reported a 27% reduction in cognitive decline among participants. While the trial did not analyse results by sex, data relating to subgroups contained in the paper's supplementary materials suggested that for male participants the rate of slowing decline was actually 43% compared to only 12% for their female counterparts. As the trial was not designed to examine sex differences, it is unclear whether this discrepancy is in fact caused by underlying sex differences. However, these results highlight the gaps that can arise when clinical research does not account for sex differences.

Women's health also impacts GDP and productivity. The effects of the gender health gap are most prevalent during women's working years and this, in turn, is responsible for around 80% of the estimated impact on GDP. Addressing the gap can ensure women are able to work and be productive at work. For example, the 2024 McKinsey report highlights that approximately 80% of women experiencing menopause say it interferes with their lives, and that menopause has been linked to departing the workforce prematurely. The report concludes that addressing menopause and endometriosis alone could add up to $130bn to global GDP.

Women's personal finances are also affected by the gap. A 2024 report by Deloitte found that working women in the UK spend £1.5bn more per year on healthcare than men. On average, this equates to women's out-of-pocket spending on healthcare being 50% more per year than that of men, with the most significant difference – around 250% – seen in fertility, menopause, and menstrual health spending. However, across areas affecting both sexes more generally, women still spent 25% more on general healthcare and private counselling or other mental health support than men and 10% more on medical diagnostics and wearables.

Solutions

Government and public body initiatives

There are currently no legal requirements in the UK to include women in clinical trials or disaggregate data by sex. This will continue even after the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 comes into force on 28 April 2026. This is despite the fact that the UK Government's response to the 2022 consultation stated it would take forward a number of changes to support greater diversity in clinical trials.

However, governments and public bodies in the UK are putting in place guidelines and policies to address key causes of the health gap. The Medical Science Sex and Gender Equity (MESSAGE) project was set up in response to research showing that in 2021 no UK research funders or their major regulators had a policy requiring consideration of sex or gender of research participants or sex or gender disaggregation of data in analysis or reporting. The project designed a sex and gender policy framework and accompanying toolkit, which provides a best practice policy for UK research funders on accounting for sex and gender in biomedical, health and care research. While voluntary, as of December 2023, 29 organisations had published a statement of intent to support the project. These signatories from across the UK medical

research community contribute £4.1bn per year to UK medical research. With influential organisations such as the Medical Research Council and the BMJ, as well as regulators including the MHRA, publicly supporting the initiative, it is hoped that further organisations will follow.

Additionally, the UK Government announced in October 2025 that the Women's Health Strategy will be renewed in 2026 to address specific barriers in access to healthcare. While there is no mention of how clinical trial disparities might be addressed, a commitment to remove barriers suggests implementing guidelines to R&D in the UK could form a central part of the strategy.

Funding opportunities

Outside government and regulator strategies, private funding provides grant opportunities for women's health research. There are limited funding opportunities in the UK. However, at a global level, in August 2025, the Gates Foundation announced a $2.5bn investment to fund innovation in maternal, menstrual, gynaecological, and sexual health for women. Also, under Horizon Europe and its predecessor Horizon 2020, the EU invested over €2bn in projects focused on women's health. Further, all research projects under Horizon Europe must integrate a gender dimension, unless the topic description explicitly specifies otherwise.

AI and synthetic data

Despite these strategies taken by governments and regulators to combat the gender data and health gaps, there will inevitably be a delay between the implementation of these measures and the gaps closing. As biotech continues to transform with the use of AI, there is potential for AI and synthetic data to help to fill the gender data gap in the meantime.

Synthetic data is artificially generated data that mimics statistical properties of real-world data, and can be used to increase diversity and representation in training datasets. Synthetic data can also mitigate bias from real-world data, for example by removing gender-based discrimination.

In September 2024, the MHRA published its Data Strategy 2024-2027, which notes that while randomised controlled clinical trials are the gold standard for demonstrating efficacy, the data gathered is often not representative of the safety and efficacy of products across all potentially exposed patients. The Strategy discusses the importance of real-world data and notes the Clinical Practice Research Datalink (the MHRA's RWD research service) has already been used to develop synthetic datasets. Therefore, the MHRA may be open to accepting use of synthetic data in the approval of products.

There are however still risks associated with using synthetic data, as AI models trained on limited datasets can amplify data gaps or exhibit bias. For example, research from LSE found that some AI tools used in social care settings downplay women's physical and mental conditions in comparison to men. To balance addressing gender data gaps with the need to ensure data is free from bias, it is clear that UK regulators will need to provide researchers and innovators with comprehensive guidance around the use of AI and synthetic data in healthcare and clinical trials.

Final thoughts

Bridging the gender health and data gaps through inclusive research has the potential to transform women's health and positively impact the economy (both in the UK and globally). While recent initiatives in the UK are a step in the right direction, continued progress depends on commitment from regulators and funders to prioritise gathering data specific to women's health. Solutions such as the use of synthetic data could help bridge the gap until the effects of such initiatives become tangible, but will require clarity from the regulators.

Top 10 corporate, tax and employment considerations for early-stage and spin-out biotech companies

Launching and scaling a biotech company offers immense potential to drive meaningful changes to the health and lives of patients, but founders must navigate complex corporate, tax and employment challenges for their business to thrive. Companies can set themselves up for success by making key corporate and commercial decisions at an early stage. By prioritising strategic people practices – from equity incentives to global talent mobility – early-stage and spin-out ventures can also build resilient foundations for growth, fundraising, and long-term value creation.

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Here are our 'top 10' dos and don'ts for early-stage biotechs to consider.

1. Founding equity

Allocating founding equity as between founders and any research institution contributing IP is a critical early decision. Equity allocation should reflect each founder's expertise alongside past and anticipated contributions, including time commitment and ongoing involvement with the company. Founders should engage with the relevant technology transfer office early, to understand the research institution's expectations. Founders should also consider adopting bespoke articles of association or a shareholders' agreement to prevent founders from selling their shares to third parties and reclaim equity from founders who leave the company early or otherwise decrease their contribution below the levels initially anticipated. These legal structures help 'lock up' the company and protect its long-term integrity.

2. Tax considerations on incorporation / spin-out

The Employment Related Securities (**ERS**) tax regime can trigger employment tax charges when founders who are (or will become) directors or employees acquire shares at a discount to market value. Income tax (and potentially National Insurance contributions) arises on the discount at the time the shares are issued. Future employment tax charges can also arise if a founder's shares are subject to 'clawback' provisions or other restrictions affecting the value of the shares. To mitigate future tax liabilities (at a time when the shares could be very valuable and the resulting tax liability very high), it is possible to elect to be taxed 'upfront' on the value of the shares as if no restrictions apply. As a result, it is generally advisable for founders to acquire shares early – ideally at incorporation – and to enter into a 'Section 431 Election' within 14 days of the shares being acquired. Academic founders involved in developing the underlying IP may benefit from academic spin-out relief, which excludes the value of the IP from any ERS charge that is triggered on acquisition of shares or on a later increase in the value of the academics' shares when the IP is acquired by the company. However, it is important to note that this relief does not apply to non-academic founders.

3. Navigating the investment climate

Securing investment is increasingly difficult, so founders must present realistic, grounded business plans to build investor confidence. Founders should prepare for investor scrutiny and be ready to provide warranties in the transaction documents in relation to their business plan. Be prepared for delays in the fundraising process due to stakeholders' internal approval cycles and negotiation timelines. Staying organised – especially with key documents like equity investment documents, collaboration agreements, employment and consultancy agreements – can streamline the due diligence process. A disciplined approach to planning and documentation can significantly improve fundraising outcomes.

4. Implement attractive employee incentives

Early-stage biotech companies often struggle to match the salaries of larger corporates, making equity incentives a powerful alternative. Share options and growth shares can attract top talent by offering a stake in the company's future success, fostering alignment and long-term commitment. These schemes can be tax-efficient and scalable if properly structured and compliant with Enterprise Management Incentive (**EMI**) or Company Share Option Plan (**CSOP**) rules. Beyond equity, offering unique benefits – like flexible work, wellness support, and enhanced leave policies – can differentiate a company in a competitive market. Post-pandemic, candidates increasingly value holistic benefits that support work-life balance.

5. Consider employment status

Biotech start-ups often rely on flexible arrangements with consultants and advisors, but it's crucial to correctly classify employment status. Misclassification can lead to significant tax liabilities under the UK's IR35 regime, especially if contractors are effectively working as employees. Diverse models – such as freelance contracts, internships, and job sharing – can provide agility without overcommitting resources. However, companies must ensure contracts and working practices align with the intended status to avoid legal and tax risks. Tools like HMRC's Check Employment Status for Tax (**CEST**) can help, but must be used with care and supported by clear documentation.

6. Protect business interests early

Safeguarding intellectual property and commercial interests from the outset is essential for biotech start-ups. Contracts with employees and consultants need to be clearly drafted and should include robust intellectual property assignment and confidentiality provisions, alongside appropriate restrictive covenants. Equity schemes should also include leaver provisions to distinguish between 'good' and 'bad' leavers, protecting the company's cap table and incentivising loyalty. For example, a 'bad' leaver may forfeit all equity, ensuring only active contributors benefit. By putting these safeguards in place early, companies can protect their IP and equity structure, preserving stability as the business expands.

7. Governance and compliance

Post-investment, companies must comply with investor rights, undertakings, and potential veto powers, each of which require structured internal workflows. Reminding directors of these rights and restrictions during board meetings helps avoid procedural missteps. As operations expand, especially into clinical phases, governance demands will intensify, particularly around patient data. Both existing and future investors expect robust compliance systems, so budgeting for legal and operational support is crucial. Proactive governance builds credibility and ensures alignment with regulatory requirements.

8. Evolving people practices

Whether a biotech company is starting out, scaling or preparing for exit, ensuring that HR practices evolve alongside the company is key to sustainable growth. Clear and considered employment policies and procedures reduce legal risk, attract talent, and support any subsequent due diligence process. For example, as the workforce grows, companies should introduce effective anti-bullying and harassment, sexual harassment, whistleblowing and anti-bribery and corruption policies. Family leave policies that offer enhanced pay should also be considered as a useful talent attraction and retention tool. Aligning people strategies with business goals builds a resilient culture and boosts investor confidence. Companies should plan for future talent needs, not just current demands, to maintain momentum. A forward-looking approach to workforce planning ensures readiness for both growth and transition events.

9. Leveraging success

A biotech company's success no longer hinges solely on the traditional path of taking a candidate through clinical trials and exiting via IPO or acquisition – alternative strategies are also gaining traction. Out-licensing early-stage assets is increasingly viable as pharma companies seek out opportunities to invest in earlier-stage technologies. For companies that are developing multiple technologies, spinning out one or more of these separate technologies can attract targeted investment and unlock additional value. Monetising royalty streams from out-licensed IP offers another path to liquidity and growth. Founders should remain agile and explore diverse routes to maximise commercial potential.

10. Think global mobility

Tapping into international talent pools can give biotech companies a vital edge in innovation and growth. Accessing global expertise enables cross-border collaboration and accelerates scientific progress. Companies should adopt inclusive immigration policies and flexible mobility frameworks to attract top-tier talent. Equity incentives must be tailored to work across jurisdictions, especially as UK companies increasingly adopt US-style share schemes. Embracing global mobility signals a commitment to excellence and positions companies for success in a competitive, international market.

Closing remarks

Successfully navigating the early stages of a biotech venture requires founders to make deliberate decisions across equity structuring, tax planning, governance and employment strategy. By addressing these foundational considerations, companies can mitigate risk, attract investment and foster a culture of innovation and compliance. Strategic people practices and global talent engagement further enhance resilience and position start-ups for long-term success. With the right frameworks in place, early-stage and spin-out biotechs can confidently pursue growth, impact and exit opportunities.

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Budget 2025: the key tax measures supporting science and innovation

On 26 November 2025, Rachel Reeves delivered her long-awaited second Budget. In addition to raising an additional £26bn in tax revenue by 2030/31, Reeves also included several references to the UK's Modern Industrial Strategy.

First published in June 2025, this strategy sets out the UK Government's 10-year plan to increase business investment and grow the strategically important industries in the UK, including a package of reforms and investment intended to make the UK one of the world's top three life sciences economies.

This was further developed in July 2025 when the UK Government published its Life Sciences Sector Plan, with a focus on:

1. enabling world-class R&D;
2. making the UK an outstanding place in which to start, grow, scale, and invest; and
3. driving health innovation and NHS reform.

Against this backdrop, this article highlights the tax measures in the 2025 Budget intended to drive growth. It considers how these measures support the Modern Industrial Strategy and how they will impact on the life sciences sector in particular.

1. R&D tax relief advance clearances

The availability of R&D tax relief has historically been pivotal in boosting the UK's life sciences sector. However, the regime has been the subject of significant change in recent years. The extent of this change, together with the large number of HMRC enquiries and a substantial backlog in claims, has created serious challenges for UK biotechs.

HMRC currently offers a limited voluntary advance assurance scheme. This gives certain first-time R&D relief claimants the chance to send HMRC details of R&D work before claiming tax relief via a Company Tax Return. However, HMRC's research has shown that only a small proportion of companies actually use this service. This has been partly attributed to the eligibility criteria for the scheme being too restrictive and the process being inflexible, with long turnaround times.

The Budget included an announcement that HMRC plans to pilot a new targeted R&D advance assurance service in Spring 2026. This pilot is intended to offer companies an accessible and focused assurance process providing certainty in relation to complex or high-risk aspects of tax relief claims.

Unlike the current advance assurance scheme (which is only available to first-time claimants), any SME planning to claim R&D relief will be able to apply to take part in the pilot.

The pilot will offer assurance on four issues:

1. whether a project meets the definition of 'R&D' for tax purposes;
2. whether overseas expenditure qualifies for relief;
3. which party is able to claim relief for contracted-out expenditure; and
4. whether a company qualifies for an exemption from the PAYE/NICs cap.

In last year's Biotech Review, we highlighted the challenges of the changes to the R&D regime in relation to points 2 and 3 above. We anticipate that this pilot may prove particularly helpful to companies still getting to grips with these changes.

In a sign of their commitment to driving improvement in the R&D tax relief landscape, HMRC's consultation response also sets out that a "Research and Development Expert Advisory Panel" has already been assembled. This panel brings together independent experts in subjects such as AI, life sciences and advanced manufacturing, and will provide both guidance and insight into cutting-edge R&D across specific sectors. The panel's work is intended to develop HMRC's understanding of innovation and development in specific sectors so it can better engage with businesses.

2. EMI options

The Enterprise Management Incentive (**EMI**) scheme is a tax-advantaged employee share option scheme. EMI offers qualifying companies the ability to provide highly tax efficient share-based remuneration to employees.

In order to qualify to grant EMI options, companies must meet certain strict qualifying criteria. The application of these limits currently means that companies can out-grow EMI very quickly, blocking them from offering this attractive form of incentive to their employees. This is a particular challenge for biotechs in their growth phase competing with large US salaries and reward packages for an often globally mobile and highly skilled workforce.

In a welcome development, the Budget included an announcement that from April 2026, certain limits will be increased as shown in the table, meaning that a far greater proportion of growth companies will become eligible to grant EMI options and will be able to incorporate this form of employee equity award into their remuneration strategy for a longer period of time.

Criteria	Current Limit	Limit from 6 April 2026
Company maximum gross assets (being all assets as they would appear on a balance sheet, without any deduction for liabilities)	£30m	£120m
Company maximum number of full time employees	250	500
Maximum value of aggregate EMI options awarded by a Company (calculated at the date of grant)	£3m	£6m

The time limit for exercising EMI options will be increased from the current maximum of 10 years to 15 years and existing EMI contracts can be amended without losing the tax advantages, provided any amendments are in line with the updated EMI legislation.

Each of these changes should be good news for growth companies in the life sciences sector who typically need significant funding and a longer timeline to exit, helping them to recruit and retain talent in a highly competitive environment.

3. EIS and VCT scheme changes

The Enterprise Investment Scheme (**EIS**) and the Venture Capital Trust (**VCT**) scheme are both forms of tax-advantaged venture capital investment schemes.

- The EIS helps businesses raise money by offering tax reliefs to individual investors who subscribe for new shares in qualifying companies.
- The VCT scheme provides income tax relief for individuals who invest in a quoted vehicle which in turn invests in the debt and equity of a spread of unquoted smaller companies.

A number of conditions apply under each scheme before the generous EIS and VCT tax reliefs can be obtained. The Budget materially increased (broadly doubling) a number of limits that apply under the schemes, significantly expanding the scope of companies that can qualify to raise EIS and VCT finance and increasing the amount that can be raised, as shown in the table below:

Criteria	Current Limit	Limit from 6 April 2026
Annual Company Investment Limit (the maximum amount a company can receive by way of qualifying investment under the schemes in a single year)	£5m (£10m for "knowledge-intensive" companies (**KICs**))	£10m (£20m for KICs)
Lifetime Company Investment Limit (the maximum amount a company can receive by way of qualifying investment under the schemes in total)	£12m (£20m for KICs)	£24m (£40m for KICs)
Company maximum gross assets (being all assets as they would appear on a balance sheet, without any deduction for liabilities)	£15m before the EIS/ VCT share issue £16m immediately after the EIS/VCT share issue	£30m before the EIS/ VCT share issue £35m immediately after the EIS/VCT share issue

Whilst the above is very welcome news for UK biotech companies who have historically rapidly run out of headroom to raise finance under the EIS and VCT regimes, this good news must be weighed against a reduction in the amount of income tax relief available to VCT investors. This is being cut from 30% to 20% in order to better balance the amount of upfront tax relief offered by the VCT scheme compared to EIS, where dividend relief is not available.

The UK Government has predicted that the changes to venture capital reliefs should lead to around £100m per year of extra investment into the most successful UK scaling companies. However, when the amount of VCT income tax relief was previously reduced in 2006/07, the level of VCT investment dropped markedly. It therefore remains to be seen how investors will respond to the overall package of changes to these schemes.

4. Tax Support for Entrepreneurs: Call for Evidence

Worth around £9bn in 2025, the UK's venture capital market is one of the top three in the world, alongside the US and China. Although the UK's ecosystem is comparatively strong, the Treasury has acknowledged that the UK's finance and tax systems can sometimes result in businesses feeling constrained as they seek to scale up in order to realise their full potential.

Building on the other measures we discuss in this article, the UK Government issued a Call for Evidence in late 2025 seeking views on how the tax system could better support growing businesses. The consultation closed on 28 February 2026, and the responses are now under consideration. The intention is that this feedback will drive development of ideas to use the tax system to improve, rebalance and better target support for businesses in their scale-up phase.

Final thoughts

As highlighted by the BioIndustry Association, outdated limits on venture investment tax incentives and EMI share options were widely viewed as holding back the scale-up of life science companies in the UK, so the extension of these limits is very positive news for the sector.

However, with many companies still grappling with the myriad of changes to R&D tax relief and the significant additional NICs costs imposed in the previous Budget, and with no mention of Business Rates reform to help cushion the rising costs of laboratory space, it remains to be seen whether the Chancellor has done enough to build a tax system to support the UK's position as a leading life sciences economy.

If you would like further information in relation to any of these measures, please contact a member of our tax team.

Competition authorities in Europe target 'killer acquisitions' – what biotech companies need to know

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Competition authorities are increasingly targeting so-called 'killer acquisitions' in the life sciences sector, where established firms acquire innovative biotech start-ups to eliminate future competition. We examine the latest regulatory and enforcement developments in Europe and key considerations for biotech companies seeking to manage compliance risks while sustaining innovation-driven growth.

Summary

The life sciences industry, propelled by fierce competition in innovation, is under heightened scrutiny from competition authorities. The spotlight is on 'killer acquisitions' – transactions where a dominant, established company acquires a smaller, often pre-revenue start-up with the aim of potentially eliminating the competitive threat posed by its innovative R&D.

The vast majority of acquisitions of start-ups by established market leaders are not carried out with any improper intent, nor do they necessarily give rise to competition concerns. Many start-ups view acquisition as a preferred exit strategy, so restricting such deals could reduce incentives for innovation. Historically, these deals have often fallen below EU or national merger control thresholds due to the target generating little or no turnover. However, recent case law indicates that competition authorities now apply both merger control and abuse of dominance rules to examine these transactions.

Competition authorities have faced strong criticism for potentially overlooking the 'killer acquisition' theory of harm, for example the European Commission's (**EC**) review of Facebook's acquisition of WhatsApp in 2014. Facebook paid $19bn, despite WhatsApp's annual turnover being less than $10m. This sparked questions about the strategic motives behind such a significant investment. As a result, competition authorities have reassessed their approach in innovation-heavy sectors such as biotech, taking robust and swift action to preserve competition in innovation.

'Killer acquisitions' are likely to be blocked, unwound, or require divestment, all of which can be highly disruptive to business. In addition, a finding of abuse of a dominant position can also result in fines of up to 10% of global turnover.

'Killer acquisitions' under focus

Competition authorities have become increasingly concerned that mergers and acquisitions in concentrated markets such as biotech and pharmaceuticals – where firms compete on innovation – can impact not only prices but also the pace of invention. One key focus is the 'loss of potential competition', which underpins the 'killer acquisition' theory. This describes established companies buying start-ups to eliminate future threats, often by halting competing projects before new products reach the market.

In November 2024, the EC published a final report analysing the effectiveness of the EC enforcement mechanism in identifying 'killer acquisitions' in the pharmaceutical sector. The report concluded that the EU merger regime has generally been effective in identifying potential 'killer acquisitions' in notified transactions, but that below threshold transactions remain more difficult to capture, given the limited enforcement tools available to the EC. For instance, the EC is limited either to: Member States referring below-EU-threshold transactions to the EC under Article 22 EU Merger Regulations[1] (**EUMR**, discussed further below), or a complaint under Article 101/102 Treaty on the Functioning of EU (**TFEU**) for anti-competitive behaviour and abuse of a dominant position.

Global trend to expand merger jurisdictional thresholds to catch 'killer acquisitions'

Most merger regimes rely on jurisdictional thresholds based on target turnover which presents challenges where start-ups are pre-revenue. Some countries have adopted transaction value thresholds such as Germany, Austria, the US, and India. Others have broadened 'call-in' powers to allow the review of below-threshold mergers that raise competition concerns, including Denmark, Hungary, Ireland, Italy, Latvia, Lithuania, Slovenia, and Sweden.

On 1 January 2026, Australia implemented a mandatory notification regime based on acquirer-focused turnover thresholds targeting 'killer acquisitions' and roll-up strategies in sensitive biotech, pharmaceutical, and technology sectors.

UK introduces new merger thresholds to catch 'killer acquisitions'

The UK operates a voluntary merger review regime for transactions that meet either the 'turnover' test or the 'share of supply' test. Historically, the UK Competition and Markets Authority (**CMA**) has been granted broad discretion by the courts to interpret the 'share of supply' test flexibly and expansively. This has enabled the UK to review transactions involving targets with minimal or no UK turnover, including including Illumina's acquisition of GRAIL in DNA sequencing (discussed further below), Roche Holdings, Inc.'s acquisition of Spark Therapeutics, Inc. in gene therapy and Thermo Fisher's proposed acquisition in 2018 of Gatan from Roper Technologies in the field of electromagnetic microscopes.

In 2025, the Digital Markets, Competition and Consumers Act 2024 (**DMCCA**) introduced significant changes to the UK jurisdictional thresholds, specifically addressing 'killer acquisitions'. Under the new test, a transaction may qualify for review even if the target has no UK turnover and the parties do not have overlapping activities, provided:

- the acquirer has more than £350m in revenue and more than 33% share of supply in the UK; and
- the target has a UK nexus (this is interpreted broadly, such as having a UK branch, owning UK IP rights, or conducting preparatory

1 Council Regulation (EC) No 139/2004

activity towards supply in the UK with no turnover required).

This new test is particularly relevant in the biotech and pharmaceutical sectors as it captures vertical mergers between suppliers and customers and conglomerate mergers where parties are active in complementary markets.

However, at the same time, the DMCCA also introduced changes aimed at reducing the regulatory burden for start-ups. Under the updated 'turnover' test, the target turnover threshold has increased from £70m to £100m. The revised 'share of supply' test now contains a small business exemption: a transaction is only caught if the parties have a combined 25% UK share of supply, and either party has turnover exceeding £10m. This means combinations between start-ups which do not raise killer acquisition risks are considered to have pro-growth effects and are not subject to merger reviews. In the context of the CMA's growth strategy published in November 2025, we expect the CMA to refocus its enforcement efforts on transactions that have a clear UK nexus and raise *prima facie* competition issues.

Limitations of Article 22 EUMR to refer below-threshold transactions to the EC

Under Article 22 of the EUMR, Member States may refer transactions that do not meet the EUMR thresholds to the EC for substantive competition assessment.

In 2020, Illumina, the global leader in DNA sequencing technology, sought to acquire GRAIL, a developer of an early cancer screening test, for $7.1bn. As with Facebook/WhatsApp, concerns arose that GRAIL's competitive importance was not reflected by its lack of turnover compared to the high purchase price. Several Member States referred the case to the EC under Article 22 as they were concerned that Illumina would foreclose GRAIL's competitors by restricting access to, or increasing the price of, DNA sequencing. The EC eventually prohibited the acquisition following an in-depth Phase 2 merger review and required Illumina to divest GRAIL. The EC also fined Illumina for illegally closing the deal prior to gaining clearance. Illumina appealed both the gun-jumping and the prohibition decisions to the European courts.

In a subsequent judgment[2] in September 2024 relating to Illumina's completed acquisition of GRAIL, the European Court of Justice (**ECJ**) held that an Article 22 referral is possible only in relation to transactions that meet the national merger thresholds. This ruling was a set-back for the EC as it has significantly curtailed the EC's primary route for catching below-threshold 'killer acquisitions' before they close.

Revival of Article 102 TFEU to plug enforcement gaps

Due to the limitations of Article 22 EUMR and national merger regimes mentioned above, the EC's primary enforcement route for challenging 'killer acquisitions' has shifted back to Article 102 TFEU, which prohibits dominant companies from abusing their market power to the detriment of consumers. This strategy is based on the 2023 *Towercast* ECJ judgment[3] which confirmed that acquiring a competitor to eliminate it (a 'killer acquisition') could constitute abuse of dominance under Article 102 TFEU, even if the deal did not meet standard merger thresholds.

The French Competition Authority was the first national authority to apply the *Towercast* principle to the healthcare sector. In November 2025, it fined an online medical booking platform €4.67m for eliminating its competitor following an acquisition in 2018. The transaction was below threshold and therefore not notified for review.

In March 2024, the EC opened its first Article 102 inquiry into the termination of an advanced pipeline product subject to third-party rights. The investigation concerns a US-based veterinary medicine company that, as part of a larger transaction in 2017, acquired a

2 Joined Cases C-611/22 P and C-625/22 P
3 Case C-449/21

competing late stage pipeline asset which was subject to a commercialisation agreement with a third party. In 2019, the acquirer unilaterally decided to terminate development of the competing pipeline drug to concentrate on its own existing pipeline product for the same clinical indication.

The EC is not challenging the acquisition of the pipeline product itself (as it was below the jurisdictional thresholds), but rather the post-acquisition decision to halt its development and refusal to transfer it to the third party that held exclusive commercialisation rights in the EU for development.

The EC received a complaint from the third party rightsholder in 2020 and opened an investigation in 2021. There is currently no deadline for the EC to issue a final decision. Complex Article 102 cases can take three to five years (or even longer) to conclude but much sooner if the EC decides to close the case.

These cases show that, despite the current limitations of merger control rules described above, the EC and national regulators have not been deterred from scrutinising acquisitions where the target has little or no turnover (as is generally the case with pre-clinical or clinical stage biotech companies). With this in mind, we set out below a high level list of points for parties involved in acquisitions in the life science sector to bear in mind.

Checklist for acquirers

- Competition authorities have broad powers to obtain internal documents, including emails, texts and Teams/ WhatsApp messages. 'Smoking gun' documents can be used by authorities to initiate enforcement actions. Regular compliance training will ensure dealmakers are aware that they should only cite legitimate reasons in communications about potential transactions.
- Any dominant firm must ensure that the strategic rationale for acquiring a small innovator is clearly documented, with a focus on genuine synergy, the acceleration of innovation, and supporting scientific evidence, rather than aiming to eliminate a competitive threat.
- Post acquisition, dominant firms should be aware that decisions to terminate overlapping pipeline projects may attract customer or competitor complaints and prompt authorities to investigate under abuse of dominance rules. Clearly documenting commercially sound reasons for any such termination and seeking competition law advice will mitigate the risk.
- For companies competing for targets, consider whether a rival acquirer could be pursuing a 'killer acquisition' strategy. Bear in mind that any complaint to competition authorities must be supported by evidence that the transaction is harmful to consumers.

Checklist for sellers/targets

- Don't assume that target company is too small for merger clearances to be required, even where target is an early stage pre-revenue biotech company.
- Sellers/targets are unlikely to be aware of any intention by the acquirer to deploy 'killer acquisition' strategies. If such concerns do arise, the matter should be escalated to the legal team and all communication with the acquirer should be paused until further advice is obtained.
- When assessing multiple acquirers/bidders, sellers should evaluate whether merger clearances are required, as any review carries risks (for example the transaction could be blocked or require undertakings to remedy any competition harms). Review processes can be lengthy and demanding on management time; the need (or not) to obtain merger clearances could be a key factor which distinguishes between different bidders.
- If merger clearances are required, or if sellers believe there is otherwise a prospect that the acquisition may prompt scrutiny from a competition regulator, the sellers should negotiate upfront how far the buyer must go to secure clearances and who bears the risk if regulators require remedies.

Changing legal frameworks

Proposal for a European Biotech Act: will the Commission's proposal unlock the potential of the health biotech industry in the EU?

December of 2025 was an exciting month for the life sciences sector in terms of legislative updates in the EU. In addition to a political agreement being reached by the EU institutions on the so-called "EU pharma package", the Commission published its Proposal for a Regulation to establish measures to strengthen the Union's biotechnology and biomanufacturing sectors (European Biotech Act).

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Introduction

Health biotech, one of the fastest growing innovative industries in the EU, is strategic and central for the EU's competitiveness, autonomy and innovation leadership. However, despite having world-leading biotech science, the Commission itself recognises that the EU faces structural barriers in clinical development, regulation and manufacturing of biotechnologies. Too often EU start-ups end up growing, employing and placing products on the market outside the EU, thus creating value elsewhere. The reasons for this are multiple: limited access to risk capital and other sources of funding, skill shortages, processes that slow down the development of biotech innovation, and fragmented and complex legal frameworks. The reality is that the EU is losing ground to other regions with increasingly agile regulatory and financial systems, namely the US and China.

It is therefore welcome news that, to address this competitiveness gap, the Commission has proposed a European Biotech Act focused on the health dimension of biotechnology, health biotech. This refers to the application of biotechnology for the promotion, protection or restoration of human health and biotech applications relevant to animal health, plant health, veterinary public health, and food safety. The proposed Regulation will apply to the entire life cycle of health biotech products and services, including related research, access to funding, development, testing, validation, manufacturing, placing on the market, and use activities.

Below are some of the tools proposed by the Commission to make it easier to bring biotech products from the lab to the factory and then to the EU market, while maintaining the highest safety standards for the protection of the EU population and environment.

Health biotech strategic projects, high impact health biotech strategic projects, and access to funding

The Commission's proposal introduces the concepts of "health biotech strategic projects" and "high impact health biotech strategic projects", and establishes a framework for their recognition and support aimed at strengthening the EU's industrial biomanufacturing capacity and value chains.

Health biotech strategic projects would serve as targeted instruments to mobilise public and private investments through coordinated action among the EU, Member States, industry, research communities and other stakeholders. In particular, they should contribute to the EU's biotech objectives by strengthening industrial capacity and value chains, scaling up critical research and technology infrastructures, accelerating innovation and technology deployment, or advanced data and digital platforms. Health biotech strategic projects with the potential to contribute to the EU's objectives in biotech in a systemic and multiplier manner would constitute high impact health biotech strategic projects. These projects would have to act as catalysts for cooperation between academia, industry and the public sector, and be key for the development of regional biotech clusters and innovation ecosystems across the EU Member States. They would be given particular consideration for EU funding, priority access to administrative support and fast-tracked procedures at Member State level.

Whereas a designated competent authority at Member State level would assess and verify whether a particular project fulfils the conditions for recognition as a health biotech strategic project, the recognition of a high impact health biotech strategic project would be assessed through a two-tier process, involving the national assessment and that of the Commission.

The proposal also establishes an EU health biotech investment pilot in partnership with the European Investment Bank Group and other implementing partners, which would bring together equity instruments and venture-style debt tailored to biotechnology-specific risk profiles in order to mobilise private investment into the sector. It remains to be seen whether this will be sufficient to attract the necessary private investment required to develop complex infrastructures for the success of health biotech businesses.

SPC extensions

One of the most exciting tools to incentivise the development and placing on the EU market of health biotech in the form of medicinal products for human use is the proposed introduction of a 12-month extension to supplementary protection certificates (**SPCs**) for medicinal products developed by means of biotech processes and for advanced therapies medicinal products (**ATMPs**). This provision aims at incentivising the development of products using innovative biotech technologies which will bring a therapeutic advantage to patients.

SPC extensions would be reserved for products with a marketing authorisation granted by the EU for a medicine developed by means of biotech processes or an ATMP provided that the following conditions are met:

1. the medicine contains a new active substance "distinctly different" from that of any authorised medicine in the EU;
2. the medicine has a "distinctly different" mechanism of action and shows a level of safety and efficacy which is at least equivalent to that of any authorised medicine in the EU for the same disease;
3. the efficacy clinical trials supporting the marketing authorisation are conducted in more than two EU Member States; and
4. at least one manufacturing step, excluding packaging, quality testing and certification, is performed in the EU.

The respective requirements that the new active substance and the mechanism of action should be "distinctly different" introduce a degree of uncertainty and discretion that seems unnecessary and could tarnish what otherwise is an excellent proposal. Absent the "distinctly different" requirements, the conditions for obtaining this new extension should not be difficult to meet for biotech products for human use. Needless to say, the degree of "distinctiveness" required to obtain the incentive would require clear guidance from the EMA.

Just like with the paediatric SPC extension introduced by the Paediatric Regulation (EC) No 1901/2006, the EMA would be responsible for assessing compliance with the conditions for obtaining the extension and issuing a compliance statement. This compliance statement would then be submitted along with the application for an SPC which is lodged with the competent industrial property office of the Member State that granted the basic patent.

The Commission proposes the introduction of a second SPC extension concerning biotech medicinal products for veterinary use treating zoonoses (that is, diseases which can be transmitted to humans from animals) developed and authorised in the EU. For marketing authorisations granted by the Commission for a veterinary medicinal product developed by means of a biotech process that is intended to diagnose, treat or prevent zoonotic diseases, a 12-month extension of the SPC would be possible when the same conditions as the above-mentioned ones for medicines for human use are met. The EMA would also assess compliance with the conditions and issue the corresponding statement.

Making clinical trials easier and faster

Conscious of the need to bring simplification and shorten the timelines for biotech innovations to reach the EU market, the Commission considers it necessary to accelerate clinical trials in the EU to attract more clinical research in the EU. In this context, the Commission proposes to make changes to the Clinical Trials Regulation (EU) No 536/2014.

Amongst the many changes proposed, some stand out. In particular, the Commission wants to streamline and speed up the authorisation process for multinational clinical trials. It wants to give a stronger leading role to the reporting Member State and strengthen the principles of mutual trust and reliance. The assessment by the reporting Member State, including the ethical aspects of the clinical trial, would serve as a reference for the other Member States concerned. These should complement the assessment only when necessary. Another important proposed change is the involvement of ethics committees in the assessment of ethical aspects of Part I of the application dossier, so that the ethical perspective is

integrated in the assessment report by the reporting Member State. The aim is to ensure that the ethical review is conducted in a more harmonised and transparent manner. These changes should be welcome news to sponsors as they would reduce divergent approaches.

The Commission also wants to shorten authorisation timelines for multinational clinical trials from 106 to 75 days, including validation and ethical review (with further reductions when there is no request for information to the sponsor). For ATMPs, the additional 50 days for assessing these products would be eliminated. The assessment period for substantial modifications would also be shortened (from 96 to 47 days, with further reductions when there is no request for information to the sponsor) and, importantly, parallel submissions for substantial modifications would be permitted going forward, as long as they relate to different parts of the dossier.

The introduction of a single, core dossier for investigational medicinal products (**IMPs**) would simplify clinical trials using the same IMP. Simplifications for low-interventional clinical trials would be further supported by the introduction of a new category of "minimal-intervention" clinical trials. These would be clinical trials with authorised IMP(s) used in accordance with the terms of the marketing authorisation, and where the additional diagnostic or monitoring procedures do not pose more than a minimal additional risk or burden to the safety of the subjects compared to normal clinical practice in any Member State concerned. These minimal-intervention clinical trials would only require an ethical review before they could begin.

Two proposed changes that are likely to have the biggest impact on the resources that sponsors have to allocate when setting up clinical trials are (1) the introduction of mandatory EU harmonised templates, and (2) the introduction of a single assessment process for combined studies involving the investigation of a medicine together with a medical device or an *in-vitro* diagnostic. The latter in particular will be welcome news, as currently sponsors wanting to generate data for novel therapies that use different technologies have to deal with up to three stand-alone legal frameworks.

Last but not least, the Commission proposes the harmonisation of the lawful basis for processing personal data in clinical trials and the allocation of responsibility between sponsors and investigators. The Clinical Trials Regulation (EU) No 536/2014 would be amended to clarify that the legal basis for processing of personal data is the existence of a legal obligation where it is necessary for sponsors and investigators to comply with the legal obligations imposed on them to ensure the safety and efficacy of the IMP. Member States would not be able to introduce further conditions such as requiring consent for the processing of personal data, including genetic data or data concerning health. It would also be clarified that sponsors and investigators would both be controllers under the GDPR. Finally, Clinical Trials Regulation (EU) No 536/2014 would be amended to allow for secondary uses of clinical trial data for scientific research purposes without a new or additional GDPR consent.

Regulatory sandboxes and other proposed changes

The term "regulatory sandbox" is perhaps one of the most repeated in the legislative proposal, as there are numerous types of regulatory sandboxes that are being proposed. Firstly, the Commission proposes the establishment of regulatory sandboxes for health biotech products which are at a very early stage of development and do not fall within the scope of existing regulatory sandboxes, like the one that will be in place when the new EU pharma law package

finally becomes a reality. It also foresees the possibility of creating regulatory sandboxes at national level for food and feed biotech products, although not for novel foods. Another regulatory sandbox is foreseen to harness the benefits of disruptive and innovative approaches to clinical trials, including the use of AI in clinical trial design, data collection, analysis and participant interaction. Other sandboxes are proposed in the context of the development of innovative technologies, methods or products related to veterinary medicinal products, and for substances of human origin that cannot yet be developed in full compliance with the requirements of Regulation (EU) 2024/1938 on standards of quality and safety for substances of human origin, the so-called SoHO Regulation.

There are plenty of references to AI in the proposed Regulation. Whereas the EU AI Act provides harmonised rules for the placing on the market or putting into service and use of AI systems and models in the EU, which the European Biotech Act would not amend, a new Advisory Group on Biosecurity, reporting into the Commission, would be created to monitor the capabilities of AI models in biological applications.

The Commission's proposal is packed with other changes, including (1) the establishment of an EU-wide Regulatory Status Repository that would compile relevant opinions, recommendations, decisions and guidance in the area of health biotech to determine the regulatory status of a product, (2) a new framework for preventing the misuse of biotech products of concern, (3) the enhancement of competitiveness in biosimilars, (4) the creation of both the EU Health Biotechnology Support Network to help developers navigate regulatory pathways and the Foresight Panel for Emerging Health Innovation to provide regulatory, scientific and technical expertise on emerging science and technology to the Commission, the EMA, other EU advisory bodies and national competent authorities; and (5) amendments to general food law, the legal framework for veterinary medicinal products and the framework that applies to substances of human origin, to name a few.

Conclusion

As the proposed regulation follows the EU's ordinary legislative procedure (with the European Parliament and the Council acting as co-legislators), we will have to wait for the final text before the Regulation is enacted.

More than ever, we need a strong life sciences ecosystem in the EU. With the end of the hiatus and uncertainty caused by the lengthy process to agree on the reform of the EU pharma package, the Commission's proposal is an exciting tool to support the development, funding, testing, manufacturing, marketing and use of health biotech in the region.

Trial by name, trial by nature: how lack of data protection harmonisation is hindering European clinical trials

Europe's ability to leverage its world-leading academic institutions, healthcare systems, access to funding and fiscal incentives have long positioned it as a powerhouse for clinical research. However, divergences in the interpretation and enforcement of data protection law within the EEA are undermining Europe's position, with adverse consequences for patients and medical innovation in Europe.

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Clinical trials are crucial in the development of new and improved ways to detect, prevent and treat health conditions. While Europe remains a global hub for clinical research, analysis of available evidence points to a geographical shift away: between 2013 and 2023, the number of clinical trials initiated worldwide rose by over 38%, yet the EEA's share halved over the same period. This decline means fewer European patients are gaining early access to potentially life-saving treatments.

According to the same research, data from clinical trial repositories indicates that 60,000 fewer people participated in clinical trials involving an EEA country in 2023 compared to 2018. The adverse consequences of this for patients, healthcare systems and the broader R&D ecosystem in Europe are substantial:

- participation in clinical trials can translate into better health outcomes for European patients, particularly for those with rare diseases for whom trials may be the only option for treatment;
- clinical trials are a revenue source for hospitals and centres that conduct them, generating funds that can be invested in healthcare provision; and
- clinical trials foster collaboration between academia, industry and healthcare providers, strengthening R&D and fast-tracking innovation in Europe.

What is going wrong?

There is evidence to suggest that lack of regulatory harmonisation, rather than the overall weight of regulation, is a key factor. Over two-thirds of clinical trials in the EEA involve sites in multiple countries. As a result, divergence in interpretation and enforcement of data protection rules matter. National healthcare laws and data governance practices (including with respect to ethics committees) means sponsors are faced with the prospect of implementing different operational processes between EU Member States to comply with different national approaches.

This creates challenges for processing clinical data in relation to both:

- the specific clinical trial and any subsequent regulatory approval of the medicine or medical device (primary use); and
- purposes outside of the clinical trial protocol (secondary use).

All collection and use of personal data requires a valid legal ground under Article 6 GDPR (lawful basis). Additionally, any processing of health data and genetic data can be undertaken only if one of the pre-defined conditions under Article 9 GDPR (Article 9 condition) applies.

The appropriate lawful basis and Article 9 condition typically depend on the data in question and the purpose for which it is processed. For example, some processing within a clinical trial is required to obtain pharmacovigilance data as part of the sponsor's safety-related obligations under the EU's Clinical Trials Regulation (**CTR**). This processing is therefore carried out under the lawful basis of 'compliance with a legal obligation' (Article 6(1)(c) GDPR), an approach endorsed by the European Data Protection Board (**EDPB**), the independent body responsible for consistent application of the GDPR.

Conversely, processing of clinical trial data for other purposes typically requires different lawful bases and Article 9 conditions. Processing for the same purposes should be carried out under the same lawful basis regardless of whether it is taking place in one Member State or another. In reality, however, different lawful bases are used between Member States as a result of continuing divergences in law and interpretation across the EEA.

The EDPB sought to achieve harmonisation with respect to primary use of clinical trial data in its Opinion issued in 2019. Save for clinical trials conducted in the public interest pursuant to a legal mandate, sponsors are encouraged to rely on:

- the lawful basis of 'legitimate interests' (Article 6(1)(f) GDPR) – that is, to undertake the processing on the basis that it is necessary for the objectives of the clinical trial, and these purposes are sufficiently legitimate to override the privacy interests and fundamental rights and freedoms of the trial participants; and
- the Article 9 condition that provides for processing that is necessary for 'scientific research purposes' (Article 9(2)(j) GDPR).

In the EDPB's view, this approach is both pragmatic and provides an appropriate level of data protection. This is because reliance on the 'legitimate interests' lawful basis requires the sponsor to perform a balancing test to ensure that the processing is justified, with the implementation of additional safeguards where the test indicates these are necessary for the processing to be lawful. The EDPB Opinion is not binding, but it is highly persuasive on Member States.

However, not all Member States adopt this approach, notably Austria, Germany, the Netherlands, Hungary, Ireland, Italy and Portugal. Instead, these countries typically rely on:

- the lawful basis of 'consent' (Article 6(1)(a) GDPR) – that is, the processing is carried out on the basis of participants' consent to the use of their personal data; and
- the corresponding Article 9 condition of participants' 'explicit consent' to the processing (Article 9(2)(a) GDPR).

This divergence is due to:

- national laws or mandatory Informed Consent Form (**ICF**) and Participant Information Sheet (**PIS**) templates in some Member States that require the sponsor to rely on consent, such as in Germany and Belgium;
- national regulatory guidance in some Member States that strongly favour consent; and
- ethics committees in some Member States that effectively make ethics approval of a clinical trial conditional on reliance on consent - despite the fact that it is for the sponsor (and sometimes the trial site) as the controller of the processing to determine the lawful basis, not a third party.

The EDPB considers that consent obtained in the context of a clinical trial is typically not valid under the GDPR due to the pressure that participants may face to take part, stemming from their health status, institutional expectation, or social and economic factors.

Matters are complicated further by the lack of a single EU-wide interpretation of the concept of secondary use of clinical trial data. Some Member States interpret it to constitute use of the data for an entirely new purpose; others take the more narrow view that it means any purpose that is not compatible with the original purpose of data collection per Article 5(1)(b) GDPR, which could include use of the data for other clinical research, for example. There is also variation in whether secondary use warrants its own lawful basis or if the lawful basis for the primary use can be relied upon. The European Commission takes the former approach, but has stated that the lawful basis may be the same as that of the primary use. Some Member States, such as Spain, allow sponsors to obtain 'broad consent' for processing for scientific research generally. Others, including Italy, require fresh consent for secondary use, which can be tricky to obtain in practice, particularly if the secondary use takes place years or decades after the primary use, or is by a different controller.

Why does all this matter?

As things stand, if sponsors adopt the position endorsed by the EDPB, they may struggle to obtain ethics approval and may breach national laws that mandate consent. However, if they rely on consent instead, they may be considered to be in breach of the GDPR in some Member States. Attempts to reconcile these conflicting requirements often require sponsors to modify the trial protocol, ICF and PIS, and can impede trial progression.

The differing national requirements also mean that clinical trial data cannot necessarily be co-mingled, depriving the data of its full value both for primary use and secondary use.

For example:

- reuse of the data, which may otherwise avoid the need for further clinical studies, is hampered;
- opportunities to improve the methodology for future clinical trials may be lost; and
- there is a risk of blocking other avenues for innovation, such as use of the data for training AI models for predictive modelling and drug discovery.

What can be done?

The European Federation of Pharmaceutical Industries and Associations (**EFPIA**) has sought to tackle some of the issues highlighted in this article by developing a GDPR Code of Conduct on Clinical Trials and Pharmacovigilance (**Code**). The objective of the Code is to provide greater certainty for stakeholders and reduce administrative burden by promoting a consistent interpretation of key GDPR provisions for application to pharmacovigilance and clinical research and clarify how the GDPR interacts with sectoral legislation such as the CTR.

After nearly four years, however, the Code has still not been approved. In January 2022, EFPIA announced that the Code had reached the final review phase by data protection authorities before submission to the EDPB for approval. The most recent official update before this article was published was in July 2025, confirming that the Code has now been submitted to the Belgian Data Protection Authority for formal assessment. While it is hoped that the EDPB will be relatively quick to approve the Code on receipt due to prior review by multiple data protection authorities, this is by no means assured.

This seemingly leaves us, for now, at an impasse. In November 2025, the European Commission introduced a proposal for simplification of EU digital regulation in the form of the Digital Omnibus. Early indications are that key aspects of the Digital Omnibus proposal will be hotly debated between the European Commission, European Parliament, and Council of the European Union. This will likely occupy a substantial portion of the legislative agenda at the EU level in 2026. Meanwhile, and erroneously in our view, a more targeted fix to harmonise data protection rules for clinical trial data in the life sciences sector appears to have been sidelined.

From factory to bedside: decentralised medicines manufacturing in the UK

The stated aim of the UK's regulator for medicines, the MHRA, is to make the UK the best country in the world to deploy healthcare innovations safely and for the benefit of patients.

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As a part of this focus on innovation, new legislation was introduced in July 2025 that redefines how innovative medicines can be manufactured and delivered to patients in the UK. The new decentralised manufacturing framework moves medicines manufacturing closer to patients and offers the potential to unlock access to complex and innovative personalised therapies.

Background and drivers

Regulatory frameworks dictate how medicines are manufactured. Conventional pharmaceutical manufacturing relies on a small number of large, centralised facilities producing medicines for global distribution. This model is very efficient for mass production of typical medicines but is unsuitable for:

- personalised therapies that require patient-specific preparation, including many cell and gene therapies;
- ultra-short shelf-life products that cannot survive long transport times; and
- therapies that need to be supplied rapidly in response to an urgent need, such as pandemic vaccines.

Decentralised manufacturing seeks to address existing barriers in the medicines regulatory framework that hinder patient access to these therapies.

Key features of the new framework

Two types of decentralised manufacture

The new regulatory flexibility is introduced through amendments to the UK's laws governing the regulation of medicines and clinical trials[1]. The amendments to these frameworks came into force on 23 July 2025 after a six-month implementation period.

The new provisions introduce a distinction between two models for decentralised manufacture of medicine: point of care (**POC**); and modular manufacture (**MM**). This distinction is fundamental to how the new rules operate.

POC medicines are products that are manufactured and supplied at the point where the patient receives care. This will usually mean that the medicine is manufactured in the hospital where the patient is being treated but it can also include home-based manufacture.

1 The Human Medicines Regulations 2012 and The Medicines for Human Use (Clinical Trials) Regulations 2004

MM medicines are products that are manufactured in a mobile, modular unit. These units could be prefabricated manufacturing units that are either self-contained or need to be connected to services at a clinical site.

Designation

The framework limits the new regulatory flexibility by limiting the POC and MM decentralised manufacture designations to only those medicines for which the need for decentralised manufacture can be justified based on clinical benefit. In this context, clinical benefit is assessed broadly and can incorporate elements of improved clinical outcomes, equity and timeliness of access. However, where the benefit is restricted to cost alone, this does not represent a suitable justification for decentralised manufacture.

The legislation provides that:

- POC designation will typically be granted to products with a short shelf-life, such that they "can only be manufactured" at or near the place where the product is to be used or administered; and
- MM designation will be granted to products requiring decentralised, relocatable manufacture that could otherwise be accomplished in a factory, but which is necessitated by "reasons relating to deployment".

Decentralised manufacture designation can be applied for in respect of products already the subject of a marketing authorisation or products in clinical development.

*Good manufacturing practice (**GMP**)*

Both POC and MM operate through a hub-and-spoke model, whereby a single control site (the hub) holds a manufacturing licence issued by the MHRA. This hub site must meet GMP standards in the way that it supervises and controls the manufacture or assembly of the medicines at the local spoke sites.

The hub site is also responsible for the master file associated with the POC medicine or MM medicine. The master file contains a detailed description of the arrangements for manufacture or assembly of the product.

Pharmacovigilance

The legal requirements for pharmacovigilance and the good pharmacovigilance practice (**GVP**) modules that apply to authorised decentralised manufacture products are the same as those that apply to other authorised medicines.

For POC and MM medicines, the manufacturing process used is as much a determinant of the product's quality as the substances within the product. Minor changes or differences in manufacturing steps at local sites can affect the product's quality and subsequently its safety and efficacy. This fundamental complexity creates specific pharmacovigilance challenges.

For these products, it is essential that products and batches can be traced continuously during clinical use. The local sites must be distinguishable so that emerging safety concerns are rapidly detected and evaluated. Traceability must be fully integrated across the different healthcare settings where the products may be administered.

Opportunities and challenges

This new framework provides a plethora of exciting opportunities, such as:

- The new manufacturing flexibility supports innovative technologies. The framework provides a clear, world-first regulatory pathway for novel manufacturing techniques.
- Therapies can be delivered to patients faster. By reducing reliance on traditional, lengthy supply chains, medicines, especially those with very short shelf-lives, can reach patients more quickly and efficiently.

- Supply chain issues can be mitigated. Manufacturing medicines closer to the patient helps to mitigate issues related to product shelf-life, storage, and logistics associated with centralised production and distribution.
- Clinical trials can be more flexible. The framework provides regulatory clarity for conducting clinical trials with decentralised Investigational Medicinal Products (**IMPs**), which may boost research and development by allowing for more flexible trial designs and potentially greater patient recruitment and retention.

There are also a number of challenges presented by the new framework, primarily in relation to quality assurance and financial viability.

As set out above, ensuring consistent product quality across a potentially large number of geographically distributed sites may be difficult. This requires robust quality management systems and high levels of automation and standardisation in equipment and processes to minimise variability and new risks emerging.

Although the new framework addresses regulatory barriers that existed previously, other barriers to patients accessing these products remain, primarily in relation to funding these medicines to make them available from the NHS. The high list prices of personalised medicines clash directly with the cost-effectiveness thresholds used by the National Institute for Health and Care Excellence (**NICE**). This is compounded by the small patient populations and the uncertainty in long-term clinical data, which makes demonstrating cost-effectiveness highly complex for NHS budget holders.

Conclusions

The MHRA's decentralised manufacturing framework marks a paradigm shift in medicine production. The world-first framework will be monitored closely by international regulators. The proposals for changes to the EU's pharmaceutical framework include a model similar to the one implemented by the MHRA. In the US, the FDA is also developing a comparable framework. By bringing manufacturing closer to patients, the UK is setting a new standard for agility, innovation, and patient-centric care.

Litigation & arbitration

Has biotech litigation entered a new era?

2025 was an important year for biotech patent litigation, in Europe and further afield. We saw not only a change in the volume of litigation but a change in its nature too, with a mixture of national disputes, cross-border disputes and disputes in the Unified Patent Court (UPC).

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It seems that biotech litigation is entering a new era, potentially fuelled by changing landscapes for biosimilars. Traditionally there have been fewer competitors for blockbuster biologics as compared to small molecule products, largely because it has been more expensive and complex to produce and market biosimilars than it is for small molecule generics. However, with an increased number of companies entering the biosimilar sphere from countries with lower manufacturing and development costs and an increased use of marketing partners, allowing entities to develop large molecules to co-market with companies with established marketing presence in other jurisdictions, we have seen the biosimilar field becoming more competitive.

European litigation

Much of the litigation in 2025 centred around aflibercept, a recombinant fusion protein marketed as Eylea® by Bayer and Regeneron. This medicine is approved for the treatment of wet age-related macular degeneration. In Europe, the supplementary protection certificate (**SPC**) protecting aflibercept expired in November 2025 and the focus of the litigation was on the patents that remained in force after that date, namely the formulation patents EP 2 364 691 (**EP 691**) and EP 2 944 306 (**EP 306**).

As is often the case for formulation patents, a key question in the court proceedings was whether the formulation used by the biosimilars infringed the patents. The biosimilars had developed formulations which were not the same as Eylea's but differed in certain aspects and were therefore variants of Eylea's formulation. The formulations are shown in the table on the next page.

Entity	VEGF antagonist	Co-solvent	Tonicity agent	Buffer	Stabilizer	pH
Regeneron/ Bayer (reflected in EP 691 and EP 306)	40 mg/ml	0.03% polysorbate 20	40mM sodium chloride	10mM sodium phosphate	5% sucrose	6.2 – 6.3
Formycon	40 mg/ml	0.03% polysorbate 20	40mM sodium chloride	10mM histidine	5% sucrose	6.2 – 6.3
Samsung Bioepis	40 mg/ml	0.03% polysorbate 20	~~40 mM sodium chloride~~	7.78mM sodium phosphate	8% sucrose	6.2 – 6.3

In English court proceedings[1] Regeneron and Bayer asserted infringement of EP 691 and EP 306 under the doctrine of equivalents. This doctrine allows patentees to allege that there is infringement of a patent even in the absence of a literal infringement. The test the English courts must consider when assessing infringement under the doctrine was laid down by the Supreme Court in *Actavis v Lilly*[2] in 2017. It requires an assessment of (i) whether the variant achieves substantially the same result in substantially the same way as the invention; (ii) if so, whether it would have been obvious to the skilled person at the priority date, knowing that the variant achieves substantially the same result as the invention, that it does so in substantially the same way; and (iii) whether, even if the variant achieves the result referred to above, the patentee nonetheless intended strict compliance with the wording of the claim.

EP 306 was found invalid for added matter by Meade J. EP 691 was upheld as valid but, when considering the facts of the case, the Judge found that it was not infringed by either biosimilar product. Applying the *Actavis v Lilly* test for equivalence, Meade J had little doubt that the variant did not achieve substantially the same result in substantially the same way as the invention (the first limb of the test). Relevant to this decision was the fact that the patentee had chosen to assert a narrower, dependent claim directed to a preferred embodiment in the specification (claim 5). Accordingly, the inventive concept of the claim was found to be narrow and the biosimilar products were found to fall outside it. The Judge also determined that strict compliance with the literal meaning of the claim was intended by the patentee (the third limb of the test) on the basis that the specification had disclosed a number of possibilities but had only claimed some of them.

1 *Formycon & Samsung Bioepis v Regeneron & Bayer* [2025] EWHC 2527 (Pat)
2 *Actavis UK Limited and others v Eli Lilly and Company* [2017] UKSC 48

The English court's findings can be contrasted with the decision of the Munich Regional Court, which not only found EP 691 to be infringed, but also granted a cross-border permanent injunction against Formycon in 20 EU Member States. Although the same patent (**EP 691**) was asserted in the German action, Regeneron and Bayer asserted claim 1, which was wider in scope than the claim asserted in the UK, providing for a range in the values and alternative excipients. Following an assessment under the doctrine of equivalents in each jurisdiction where injunctive relief was sought, the Munich Court found that each jurisdiction would likely find claim 1 infringed where the 'variant' used a histidine buffer rather than the claimed sodium phosphate buffer, as is the case for Formycon's product. As we entered 2026, the Munich Regional Court also granted a cross-border preliminary injunction against Advanz Pharma under EP 691 covering 21 jurisdictions. Both decisions relied on the CJEU's decision in *BSH v Electrolux*[3] to grant cross-border relief. Moreover, preliminary injunctions were granted in Germany against three further biosimilar manufacturers: Stada, Hexal and Celltrion. The decisions demonstrate that the option to seek relief using long-arm jurisdiction will be a powerful tool in this new era of biosimilar litigation. Choice of venue may also be critical, although the fact that different claims were asserted in the UK and German proceedings means that the decisions are not directly comparable.

Although aflibercept patents have not been litigated in the UPC, a centralised court system that handles patent litigation across 18 EU Member States in Europe, this forum will be an important consideration for future biotech litigation. There have been comparatively few biotech cases to date, but as the court develops its body of case law, this is likely to change. One notable biotech dispute in the UPC is the originator dispute between Amgen, Sanofi and Regeneron in relation to PCSK9 inhibitors. There are various patents at issue in UPC proceedings, with decisions shaping future considerations for biotech companies, including the UPC Court of Appeal setting out a 'holistic' inventive step test[4] and the Düsseldorf local division addressing the infringement of a second medical use patent on the basis of a product's Summary of Product Characteristics.[5] Despite the willingness of the German courts to issue cross-border injunctions - once a powerful selling point of the UPC - we expect more companies to utilise the UPC in the next few years to attempt to centrally revoke European patents that are not opted out of the system and to seek quick decisions on the merits, which the court aims to provide within 12 months. It will be interesting to see if the UPC and the EPO align on validity issues, which may determine the focus of future litigation.

Global litigation

Europe was not the only jurisdiction to see a wave of Eylea® litigation in 2025. In the United States, Regeneron secured injunctions against nearly all biosimilars - except Amgen - based on its formulation patents. In South Korea, the courts upheld the validity of the patents and granted an injunction against Samsung Bioepis, preventing manufacture of its biosimilar, though relief was denied against Celltrion. In Japan, the dispute took a different form: Samsung Bioepis pursued an unfair competition claim, alleging that Regeneron had acted improperly by notifying regulators that Samsung Bioepis's biosimilar might infringe its patents. The claim was dismissed, affirming Regeneron's right to inform authorities of its intellectual property rights.

3 (C-339/22)

4 UPC_CoA_528/2024, Decision of 25 November 2025
5 UPC_CFI_505/2024.,Decision of 13 May 2025

The future of biosimilar litigation strategies

The landscape of biosimilar litigation is entering a period of accelerated evolution. Both innovators and biosimilar manufacturers will need to reassess longstanding approaches to loss of exclusivity planning. The assertion of different claims against different biosimilars in different jurisdictions needs careful alignment. The challenge for biosimilars to assess which changes to make to a formulation which may lead to a non-infringing product is a delicate line to tread.

A series of regulatory and legislative developments across major jurisdictions will also reshape the opportunity and timing in biosimilar market entry strategies. The new EU Pharma Package and proposed Biotech Act (covered on page 27 in an article by Xisca Borrás) is one such example. Regulatory developments in the United States are moving in a similar direction too. The FDA has recently issued draft guidance indicating that comparative clinical studies will not always be required to demonstrate biosimilarity, with such studies becoming necessary only in limited circumstances. Should this guidance be adopted, it would significantly reduce the cost and duration of biosimilar development in the US, potentially accelerating market entry.

Alongside these changes, several other major authorities, including the EMA, MHRA and WHO, have expressed support for waiving Phase III clinical studies for biosimilars. The publication of guidance across these organisations reflects a growing consensus that Phase III data are often unnecessary for biosimilar approval, further reducing development burdens and shifting the litigation landscape by altering the timing and nature of regulatory submissions.

The SPC manufacturing waiver in Europe will also continue to influence strategic behaviour. The most recent decisions and the outlook in Europe is discussed by Luke Norton in the next article in this publication.

Taken together, these developments signal a future in which biosimilar litigation becomes more front-loaded, more international in scope and more closely intertwined with evolving regulatory frameworks. Innovators and biosimilar manufacturers alike will need to adapt quickly, reassessing the timing of patent challenges, the role of patents, and the interplay between regulatory and litigation strategies in an increasingly competitive biologics market.

2026: A year of clarity for the SPC Manufacturing Waiver Regulation?

Between 2024 and 2025, there were multiple cases across Europe addressing the scope of the SPC Manufacturing Waiver Regulation. The courts have diverged, with different interpretations across the EU and the UK. Through 2026 and 2027, it is hoped that further judgments and the European Commission's consultation will help to clarify its scope.

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Introduced in 2019, the SPC Manufacturing Waiver Regulation[1] was provided to remedy a competitive disadvantage that EU-based generic and biosimilar manufacturers (**makers**) faced, particularly in relation to manufacture for: (i) export to 'third countries'[2] during the lifetime of a supplementary protection certification (**SPC**); and (ii) entry into the EU market on SPC expiry. Typically, during the period an SPC is in force in the EU, any unlicensed manufacturing activities in the EU would be an infringement of that SPC, whereas makers would be free to manufacture and service markets where there is no SPC (or equivalent rights) protecting the relevant product.

The SPC Manufacturing Waiver Regulation allows makers to manufacture in the EU in circumstances where:

i. the product will be exported to a third country during the SPC period; or

ii. in the final six months of the SPC term, the product will be stockpiled to enable launch in the EU on the day after the expiry of the SPC.

In order to protect the SPC holder, the SPC Manufacturing Waiver Regulation contains various conditions, including labelling requirements and supply chain due diligence. The maker is also required to notify the competent industrial property office and the SPC holder with prescribed information no later than three months before making or the first related act.

1 Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products
2 Countries outside the European Union

The SPC Manufacturing Waiver Regulation was adopted and amended by the UK post-Brexit through the Intellectual Property (Amendment etc.) (EU Exit) Regulations 2020 (certain amendments were necessary, not least because the UK is now itself a third country). The UK version of the waiver permits manufacturing for export to countries outside both the UK and the EU.

In essence, the disputes across Europe and the UK have related to one piece of prescribed information required by Article 5(5)(e) of the SPC Manufacturing Waiver Regulation:

> *"The notification must include the following:*
>
> ...
>
> e. *for medicinal products to be exported to third countries, the reference number of the marketing authorisation, or the equivalent of such authorisation, in each third country of export, as soon as it is publicly available."*

The courts have been asked to decide whether a notification which does not contain the relevant marketing authorisation (**MA**) number is valid such that it starts the three-month notice period (the interpretation advanced by generic and biosimilar companies), or if the clock for the three-month notice period only starts once the MA number is provided in any subsequent update (the interpretation advanced by SPC holders).

In addition to this main argument, various sub-arguments have been raised to support one interpretation or another. In particular, courts have heard arguments on whether the SPC Manufacturing Waiver Regulation also protects other rights in the relevant export countries - in other words, can the maker avail itself of the export waiver if the SPC holder also has relevant rights in the export country?

This is relevant to the main argument, as SPC holders have argued that the MA number must be provided sooner rather than later so that they can confirm the relevant country of export is free of rights.

Previous cases – a divergence emerges

The first decision relating to the scope of the SPC Manufacturing Waiver Regulation was *Janssen v Formycon*.[3] The Munich Court, having considered evidence from both parties, awarded Janssen (the SPC holder) a preliminary injunction. The court held that Formycon's notification was not valid as the maker must provide the MA number in at least one country of export or confirm the country of export in its notification.

After the Munich decision was handed down, cases were also heard in the Netherlands[4] and Belgium,[5] where similar arguments were raised. However, in these cases the Dutch and Belgian courts held that:

i. a notification which does not include an MA number is valid (and starts the three-month period), but must be updated once the MA number is publicly available;

ii. the country of export does not need to be provided to the SPC holder; and

iii. the relevant export country does not have to be "rights-free" for the SPC waiver to be used.

One of the key considerations in the Belgian and Dutch decisions was the protection of maker's confidential information. This was based on submissions relating to the "*travaux préparatoires*" and the recitals of the SPC Manufacturing Waiver Regulation.

3 *Janssen v Formycon* Munich District Court (case no. 21 O 12030/23)
4 *Janssen v Samsung Bioepis*, District Court of The Hague (case no. C/09/657817), upheld by the Dutch Court of Appeal in *Janssen v Samsung Bioepis* (case no. 200.337.844/01)
5 *Amgen v Samsung Bioepis*, Court of Appeal of Brussels (case no. 2024/QR/44), *Amgen v Samsung Bioepis*, Dutch-speaking Brussels Enterprise Court (case no. A/24/02113) and *Regeneron v Sandoz*, French-speaking Brussels Enterprise Court (case no. A/24/02427)

As recital 15 states, the information provided to the SPC holder should: "*... be limited to what is necessary and appropriate for the certificate holder to assess whether the rights conferred by the certificate are being respected,* ***and should not include confidential or commercially sensitive information***" (emphasis added).

In the UK, the first decision on the SPC Manufacturing Waiver Regulation was handed down on 24 November 2025.[6] Consistent with the Belgian and Dutch decisions, the Patents Court confirmed that the requirement to provide the MA number in the notification "*as soon as it is publicly available*" means that a notification which does not contain an MA number can still be valid and, therefore, three months after that notification, the maker may begin manufacturing. However, the UK judgment differed from the Dutch and Belgian decisions as the court concluded that rights in third countries might be relevant and that, to police compliance with the waiver conditions, the SPC holder is entitled to request information from the maker, which may include confidential information.

Therefore, by the end of 2025, across Europe and the UK three divergent approaches to the SPC Manufacturing Waiver Regulation notifications have emerged. For a notification to be valid:

1. the MA number (or country of export) must be provided (the German approach);
2. the MA number does not need to be provided, but third-country rights might be relevant and the SPC holder can request further information from the maker even if it is confidential information (the UK approach); or
3. the MA number does not need to be provided, and confidential information such as the country of export need not be disclosed to SPC holder (the Belgian and Dutch approach).

2026/2027

Janssen has appealed the Dutch Court of Appeal's decision to the Dutch Supreme Court. Therefore, it is anticipated that in 2026 there will be a decision in Europe from a final appeal court, which may help to clarify the requirements and scope of the SPC Manufacturing Waiver Regulation, although the Dutch Supreme Court decision will not bind other courts in Europe. Elsewhere, an appeal remains possible against one of the first instance decisions in Belgium[7]. In the UK, the deadline to appeal the first instance decision has now passed and there has been no indication that the decision has been appealed to the Court of Appeal. As the parties to the German case settled following the court's ruling, this first instance decision will not be reviewed by a higher court either. However, considering the divergence in different courts' approaches, a possible reference to CJEU is also anticipated in 2026. We expect that there will also be fresh litigation on this issue in the coming years.

In addition to further litigation and judgments, the European Commission announced a public consultation calling for evidence for its initiative evaluating the SPC Manufacturing Waiver Regulation and assessing whether its objectives have been achieved. The date at which the consultation is due to open has not yet been confirmed, but the amending measures are due to be implemented in the fourth quarter of 2027, so the public consultation is expected to open soon.

6 *Regeneron & Bayer v Alvotech & Fisher* [2025] EWHC 3050 (Pat)

7 *Regeneron v Sandoz* (case no. A/24/02427)

Conclusion

On its face, the SPC Manufacturing Waiver Regulation appeared to be a win-win for SPC holders and generic/biosimilar manufacturers. It gives makers more options to manufacture in the EU/UK in jurisdictions they may be more familiar with. Practically, due to the global nature of manufacturing and supply chains, without the SPC Manufacturing Waiver Regulation, makers were able to manufacture or utilise contract manufacturing organisations in jurisdictions without SPCs (or equivalent rights) and therefore SPC holders had no visibility over the actions of generics/biosimilars. In exchange for allowing makers the ability to manufacture in the EU/UK during the SPC term, SPC holders are given more visibility over makers' activities.

However, the current murky picture regarding the SPC Manufacturing Waiver Regulation's interpretation is leading to litigation and increased costs for both SPC holders and makers. This could mean that fewer generics/biosimilars utilise the waiver, leaving SPC holders in the dark as manufacture occurs outside the EU/UK. It is hoped that the scope and requirements of the SPC Manufacturing Waiver Regulation will be clarified and settled in 2026/2027 so that both SPC holders and generics/biosimilars will be able to rely fully on the mutual benefits.

Commercial disputes in the life sciences sector: the complexity of assessing loss

Commercial disputes involving life sciences businesses are common but resolving them can be tricky because the sector's unique features can make assessing loss difficult. In this article, we look at some of the areas where commercial disputes most typically arise and we examine some of the features of the sector that tend to complicate damages analyses.

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What kinds of disputes crop up in life sciences?

Many of the disputes commercial disputes lawyers see in life sciences arise out of the IP-rich transactions that are the hallmark of the sector. From collaboration agreements with research institutes or academia to co-development agreements, licensing deals, joint ventures and so on, the transactions that enable innovation can also become fertile ground for dispute. Commercial disputes in life sciences come in a number of flavours:

- **Disputes about development or diligence obligations:** For example, a party may allege that a counterparty has failed to comply with clauses requiring each party to use a certain level of effort or care – perhaps "commercially reasonable efforts", "best endeavours" or "reasonable care and skill" – to achieve a project's goals, for example to develop a drug candidate diligently or to maximize sales of a product or reach a specific milestone, such as to achieve regulatory approval. *Innovate Pharmaceuticals Ltd v University of Portsmouth Higher Education Corporation*[1] is a good recent example. A university was found to have breached a research agreement by failing to exercise reasonable skill and care in performing a research programme into the properties of IP1877B, a drug for the treatment of brain tumours.
- **Financial terms:** These disputes are extremely common and run the gamut of contractual payment obligations – from license fees and milestone payments (which may be tied to R&D or regulatory milestones) to royalty rates on sales and profit-sharing formulae. Disputes about indemnity provisions also frequently arise. These

1 [2022] EWHC 1681 (TCC)

disputes may also throw up technical issues because payment provisions are often tied to the way "products" are defined. There are several recent examples in the English case law. See, for example, *Astrazeneca UK Ltd v Tesaro Inc*[2] (which considered whether royalties were payable on particular sales of a PARP inhibitor called niraparib) and *Eteboxagu AB v Cycle Pharmaceuticals Ltd*[3] (which considered the appropriate royalty base for sales of a drug called NITYR, used in the treatment of a rare metabolic disorder called Hereditary Tyrosinemia Type 1).

- **Disputes about termination and exit:** These often arise where performance is at issue – e.g. where allegations are made of material breach. These are highly risky situations and require extremely careful thought, even more so where termination relies on issues of technical fact and time is of the essence to find an alternative supplier.
- **Disputes about licences and assignments:** Given that IP is the core asset for many life sciences businesses, it is unsurprising that disputes about the scope of one party's permission to exploit another's IP are also common. For a recent example, see *Dr Vanessa Hill v Touchlight Genetics Limited*[4], in which Bristows successfully defended the Touchlight group from claims that it was not entitled to its core synthetic DNA manufacturing technology, including on the basis that the technology had not been assigned to Touchlight from the claimant.

Beyond core R&D and licensing deals, life sciences companies rely on a complex web of supply chain agreements to bring products to market. Manufacturing agreements for raw materials or APIs, supply agreements, distribution agreements and logistics contracts for transportation, warehousing and packaging services are also all ripe for disputes. Common problems include:

- **Quality and compliance issues:** For example, when a manufacturer delivers product that does not meet required specifications or quality standards. We often see conflicts over batches that fail testing or GMP standards, or ingredients that do not meet purity specifications.
- **Delayed delivery or product shortfalls:** Supply chain timing is critical. Disputes frequently occur if a supplier or CDMO misses delivery deadlines or cannot supply the agreed quantities. These disputes can be particularly sensitive because maintaining a commercial relationship is often a priority.
- **Distributor performance and termination:** Where a distributor underperforms (e.g. fails to hit sales targets or fails to expand the market), suppliers will likely have a right to terminate. Likewise, disputes also often arise over territory and channel restriction, for instance, a distributor selling outside its territory or selling competing products. Managing underperformance can be fraught with difficulty and clients need to be astute not to waive their rights inadvertently by failing to assert them.
- **Pricing and payment disputes:** Common examples include disagreements on price increases for ingredients, currency fluctuation clauses, or late or non-payment for delivered goods. More recently, rebates payable by companies to central governments (such as VPAG in the UK) have increased dramatically and so these definitions have come under increased scrutiny.
- **Regulatory compliance failures:** In a highly regulated sector, if a partner fails to obtain or maintain required approvals, this will cause issues throughout the supply chain. A manufacturing partner losing a regulatory certification or failing an inspection can halt production. A product not being registered or approved in a target market on time can cause substantial loss.

2 [2024] EWCA Civ 78
3 [2023] EWHC 462 (Comm)
4 [2025] EWHC 107 (Pat)

Why can calculating loss be particularly difficult in life sciences cases?

When assessing loss from a breach of contract, English law starts from a simple proposition: damages are intended to put the claimant in the position it would have been in had the contract been performed. In practice, this requires the decision maker – the judge or a tribunal – to compare what actually happened in the real world (the "breach" situation) with what would have happened if the breach had never occurred. The difference between the two is the starting point for the damage a claimant has suffered. The obvious difficulty is that the non-breach counterfactual is entirely hypothetical – because it never happened! – but it must still be proved.

A practical way to approach the analysis is to ask three questions:

1. What would the claimant have done?
2. What would the defendant have done (assuming they had performed under the contract)?
3. What would third parties have done?

Once those questions have been answered, claimants can start to estimate what they might have lost. Counterfactual analysis becomes both interesting and complex where, as in many cases, the counterfactual depends on the convergence of a number of hypothetical acts from the claimant, the defendant and third parties. The trick is to present the simplest story possible to a decision maker, which means that working with expert advisers who know the sector is essential.

Of course, this is far easier said than done when uncertainty is a key feature of the industry. Drug development is long-term, high-cost and high-risk. Even where a candidate enters clinical trials, failure remains extremely common, including at late stages. Damages models therefore demand that decision makers ask: were it not for the defendant's breach of contract, would the programme have succeeded? Would approval have been obtained? Would launch have occurred on the claimed timetable?

Regulation adds further uncertainty. A regulator's decision-making behaviour is outside the parties' control and depends on complex data. A product may need to navigate multiple regimes, each with different evidential requirements and timelines. For on-market products, reimbursement policies can be fragmented and subject to change, complicating modelling of pricing and uptake across territories.

Manufacturing can be a major source of further uncertainty. In biologics, supply constraints, yield variability and quality issues can dominate the counterfactual. Assumptions of uninterrupted supply and rapid scale-up need to be tested against the technical record: deviation history, capacity limits, validation timelines and the availability of key inputs.

Moreover, decision makers have to make findings about quantum, i.e., how much has been lost, and not just answer binary questions around whether a launch would have occurred at all. In this regard, life sciences products have pronounced lifecycle dynamics that the counterfactual must account for. For patented products, there is usually an introduction period with heavy investment, a growth phase as prescribing becomes routine, maturity as the product becomes established, and then decline following patent expiry or the arrival of new therapies. Timing therefore becomes decisive where a breach is said to have caused a missed window, whether that is first-to-market for a new product or first-mover advantage for a generic or biosimilar.

Competition also rarely arrives smoothly. Price erosion around generic entry may cause rapid initial adjustment followed by periods of relative stability as the market absorbs new entrants. Models that assume linear price decline or immediate full substitution are vulnerable unless grounded in evidence about how the relevant market behaves. Timing also affects business realities: a delay that pushes launch close to loss of exclusivity may make continued development materially less attractive, which changes what parties plausibly would have done in the non-breach world. In other words, a claimant may not have bothered commercialising a product at all.

Life sciences markets are also noisy. Performance may be affected simultaneously by regulatory developments, competitor launches, changes in reimbursement, supply shortages, evolving standards of care, new clinical data and wider economic conditions. Damages assessments therefore often turn on isolating the incremental effect of the breach from unrelated forces.

Conclusion

Damages cases are won and lost on clarity. Judges and tribunals are more than capable of following complex models but they need a coherent narrative that links the breach, the consequences and the numbers. Quantum evidence is most persuasive when it is anchored in the technical and factual evidence, rather than running on a separate parallel track. Scene-setting matters, particularly where the decision maker is not steeped in the science or in the sector itself. The key takeaway is that litigants and their advisers need to advance a case theory that accounts for the peculiarities and complexities of the life sciences sector and be able to carry the decision maker along with them.

Industry insights

Q&A with Stuart Casey, Associate General Counsel (IP Strategy & Innovation), Touchlight.

Q&A

We spoke with Stuart Casey, Associate General Counsel - IP Strategy & Innovation at Touchlight.

Touchlight is a UK-based biotechnology company that develops and manufactures synthetic DNA using a cell-free enzymatic process to support the development of genetic medicines, including mRNA, viral vectors, vaccines and non-viral gene therapies.

Q: What do you see as the main challenges facing the biotech industry in the last 12 months?

It has been a turbulent time for the industry since the COVID-19 pandemic, and biotech companies today are facing various challenges, many of which are funding related. At Touchlight, we are among the largest DNA manufacturers in the world and many of our clients are international. So, from my perspective, the greatest challenge at the moment is geopolitics. Geopolitical developments and uncertainties are impacting our clients and influencing key decisions relating to investments and pipeline development, in some cases resulting in the delay or cancellation of programmes or reluctance to initiate new programmes. In particular, uncertainties around tariffs and other market protection policies have a significant impact on the resilience of global supply chains. When companies are having to constantly concern themselves with where the next policy changes may take the industry, it makes it difficult for companies to plan and make decisions. As a result, we are generally seeing a more risk averse approach from many of our clients.

Aside from geopolitical issues, another challenge facing the industry is the flock of capital towards AI. This has led to a contraction of available funding for other sectors, including biotech. With geopolitics driving risk averse behaviour, and with less funding being available overall, the biotech industry is currently faced with two substantial challenges.

Q: What do you contemplate making the biggest difference to the way biotech companies work in the next five years?

With biotechs becoming leaner and more focussed, the seemingly obvious answer might be the emergence of AI, but within the next five years I don't think this will be the most significant factor influencing how biotech companies work. AI does have the potential to be an amazing tool for businesses, particularly in relation to repetitive tasks, data crunching and presenting information in a digestible natural language format. However, AI is still very much in its infancy and I believe we cannot be as confident in the answers it generates as we would like to be.

Instead, I think that quantum computing could have the most transformative effect on the industry in the next five years. Quantum computing will enhance our ability to do molecular modelling and solve problems that historically have been too difficult and would take too long using traditional computing. This in turn should make a huge difference in speeding up drug discovery and generally allow us to take a more predictive approach to drug development and move away from what is still largely a bench science with a test-and-see approach.

Q: Given the challenges and changes we've discussed, do you think collaborations and partnerships will become even more important for the biotech industry in the future?

As an industry, biotech is already very open to collaborations – there is an understanding that different companies will have different expertise and resources which can be leveraged through partnerships. I don't necessarily think that we will see an increase in collaborations in coming years, but that's primarily because I think the capacity that businesses have for partnerships is already near its maximum. Generally, the ability of companies to enter into partnerships in the biotech industry is not so much limited by the amount of funding available, but by resource constraints, particularly the availability of people. Even big companies don't have infinite resources for each area of opportunity from a personnel perspective. That being said, I think what you do see in our industry is big companies leveraging external capabilities and entering relationships with specialist companies rather than themselves always hiring in new personnel. This allows companies such as Touchlight, in its capacity as a CDMO, the opportunity to get involved in many different areas, including non-viral gene therapy, viral gene therapy, gene editing, RNA vaccines, and many more. There is an enormous range of opportunity within this industry.

Q: Do you foresee any changes to the way biotech companies collaborate and partner in the future?

I do think that we're likely to see partnerships outside of traditional areas. Rather than just collaborations between biotech companies, I think that as the industry becomes more data driven, we're bound to see more collaborations between biotech and big tech. The emphasis will be on technology to support the bio-industry, rather than biotechnology, particularly in relation to drug development and discovery. In the same way that big pharma seek out partnerships with small, agile biotech companies who provide specialist expertise, from a data perspective, big pharma is likely to leverage the capabilities of big tech companies.

Q: What are the key things that you would tell someone now stepping into the role of in-house counsel for a biotech company?

It is a fascinating time to be involved in this field of science. In addition to the emergence of innovative technologies, what we are now seeing is a game-changing shift where we are moving away from broad one-size fits all medicine to genuinely personalised medicine within our lifetime. This is medicine specifically tailored to the individual, leveraging innovation such as neoantigen immunotherapy with the capacity to target an individual's own specific cancer cells.

When you are a lawyer in private practice, you don't always get to see a matter all the way through from beginning to end. On the other hand, being in-house you get to be involved with a matter from start to finish and can help to direct its progression throughout. This means your sphere of influence is much greater and you are often called on to provide both commercial and legal advice, so a real understanding of the business is crucial when you're working in-house. This does not mean that you need to have worked in pharma or biotech for your whole career to be successful though. I moved into the biotech industry a few years ago having previously had a background in fast-moving consumer goods. While at first that may seem quite different to biotech, fundamentally, Touchlight is still a business which makes products for customers - our product just happens to be DNA.

Bristows & life sciences

It's been a really busy year for our Life Sciences practice, with our lawyers participating in a wide range of innovative initiatives, industry and governmental bodies, training sessions, campaigns and market leading thought leadership pieces.

Please find a selection of our sector and legal insights over the past year, in case you have missed them.

London Life Sciences Week 2025

On Wednesday 19 November, we hosted a cocktail reception at The Baptist Bar, L'oscar London, as part of London Life Sciences Week 2025.

The evening brought together leaders from across the global life sciences ecosystem in an elegant, relaxed setting. It was a fantastic evening of conversation with experts, entrepreneurs and innovators from pharma, biotech, AI, charities, cell and gene therapy, universities, digital health and women's health. It was great to hear from those shaping the future around the world and benefiting patients.

Bristows partners with WHW Europe 2025

We were delighted to partner with Women's Health Week Europe 2025, supporting discussions on emerging therapies, technologies and solutions aimed at closing the gender health gap.

During the conference, Bristows' Alex Denoon moderated a session on "*What are you wAIting for? The benefits of implementing AI into your women's health business*", where he facilitated conversation with leading experts in the space.

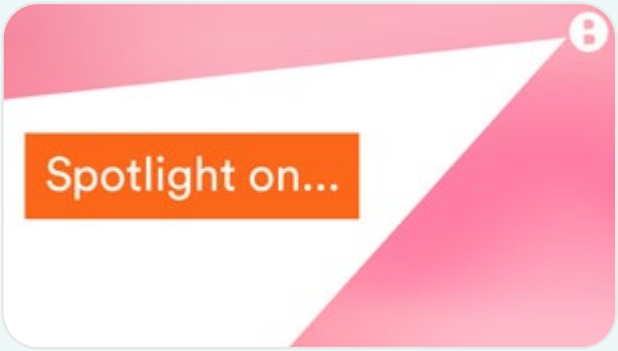
Women's health & innovation

We are proud to support innovation in women's health, helping clients navigate the legal, regulatory and commercial challenges of bringing new therapies and technologies to market.

From femtech start-ups to global pharma and academic spin-outs, our team advises across the full lifecycle of women's health innovation, offering specialist expertise in IP, data protection, regulatory strategy, funding and compliance.

Visit our dedicated women's health & innovation page - a central hub for all our insights, articles and resources exploring the evolving women's health landscape.

Spotlight On: Women's Health & Innovation



As part of this initiative, we also launched a dedicated podcast and article series, where our experts explore topics including:

- GDPR challenges in women's health
- The benefits and pitfalls of AI in femtech
- Early-stage funding for femtech companies
- Key licence terms in university spin-out deals
- Patenting trends in the women's health space

Publication: UPC Review of the Year

Our second UPC Review is now live, highlighting the key developments from the past year, from claim construction and inventive step to the doctrine of equivalents, intermediary liability, cross border issues and preliminary injunctions.

We also recap major procedural updates, including preliminary injunctions, inspection and preservation orders, expedition, stays and bifurcation.

Read the full publication here

The 12 days of UPC

Revisit our 12-part video series breaking down notable UPC decisions in 2025 and their practical implications.

Watch the series here

Podcast series: You, me & the UPC

Stay up to speed with the latest UPC developments through our *You, Me & the UPC* podcast series, where our lawyers unpack trends shaping European patent litigation, alongside *Case by Case*, our succinct expert summaries of recent UPC decisions and their practical impact.

Listen now

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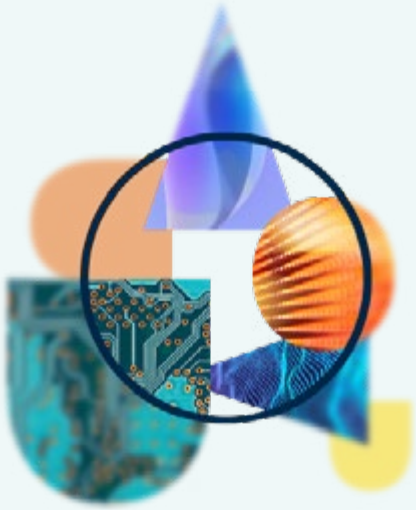
Bristows' tool for patent litigation insights

Irides is Bristows' global patent litigation resource, built on decades of specialist experience. It provides practical guidance, strategic solutions and jurisdiction-specific insight, including the UPC, to help you manage patent portfolios and litigation more effectively.

As part of this offering, our *Irides Weekly Update* delivers a concise round-up of key patent litigation news and developments from around the world.

To learn more about *Irides* and subscribe to global patent litigation insights, click here.



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Talent in the life sciences sector

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About Bristows

Embedded in the life sciences sector

We are one of the largest, dedicated life sciences teams in Europe sitting under one roof. Our full-service practice offers a seamless, integrated service across IP, commercial, regulatory, competition, digital, data protection, corporate, tax and dispute resolution.

We support a wide variety of clients across the life sciences ecosystem, acting for global biotech, pharma and medtech companies, digital health developers, consumer healthcare brands, specialist investors, universities and research institutes and government-funded bodies. Our clients also include many leading tech companies now entering the sector as "convergence" between tech and life sciences takes hold.

Many of our lawyers have diverse technical backgrounds across biology, chemistry, biochemistry, molecular and cellular biology, microbiology, nanotechnology, genetics, neuroscience, physics and engineering. Our in-depth scientific knowledge allows us to quickly identify the key issues at play, even in the most complex and technical of matters, and deliver pragmatic, commercial advice that will work in practice.

What our clients say

"The Bristows team have a lot of experience and a deep understanding of the life science sector, and they bring a wealth of experience."
Chambers and Partners 2026

"Excellent team with strength in depth in the life sciences and tech space. Strong market knowledge. Responsive and solution-focused."
Legal 500 2026

"Very knowledgeable and very commercial; always delivering pragmatic, risk-based advice to support our business."
Legal 500 2026, Life Sciences

Tier 1 - Life Sciences and Healthcare
Legal 500 2026

Band 1 - Life Sciences: IP/Patent Litigation
Chambers and Partners 2026

Meet the new co-heads of our life sciences sector group

We are delighted to announce our new co-heads leading our integrated, commercial team of life sciences experts:

Rachel Mumby
Partner, Patent litigation
Visit profile

Marek Petecki
Partner, Corporate & financing
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Meet the editors

Charlie French

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Charlie is an experienced IP litigator, focusing predominantly on patent disputes in the pharmaceutical and biotechnology sectors. In addition to her experience in the courts of England & Wales, she coordinates multinational patent litigation strategies for clients and has a particular interest in the Unified Patent Court (UPC).

Ellen Lambrix

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Ellen specialises in advising on commercial and IP transactions, particularly in the life sciences sector. Her clients range from multinational companies to start-ups and research organisations. She has significant experience advising on high value transactions including IP licensing, R&D collaborations and IP settlements.

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Erik advises on a broad range of commercial agreements involving innovation and intellectual property, with a particular focus on structuring and negotiating complex partnering arrangements. He works closely with clients in the life sciences sector, from early-stage ventures to global organisations, on transactions and agreements that underpin the development and commercialisation of novel therapies and products.

Aida Tohala

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Aida is a patent dispute specialist, working predominantly in the life sciences sector. As well as experience in the courts of England and Wales, she has significant experience in life cycle management coordinating litigation across many diverse jurisdictions. Aida greatly enjoys assisting clients with the development and execution of cross-border litigation strategy.

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