Life sciences – what to watch in 2025

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We asked more than 200 Freshfields lawyers – across geographies and practice areas: ***what are the 1–2 issues top of mind for you and your clients going into 2025?***

Here are the ten topics most frequently identified as areas to watch in 2025.

1 Antitrust – maintained levels of heightened scrutiny and enforcement.

Impact of new US administration on merger control and antitrust enforcement

Despite what some may call conventional wisdom that a Republican administration may take a less aggressive approach to antitrust enforcement, we expect to see some degree of continuity between the Biden administration and the second Trump administration. Members of the Democratic and Republican Parties have aligned in embracing populist themes and supporting scrutiny of mergers in recent years. In particular, bipartisan support for the Federal Trade Commission's (FTC) heightened enforcement in the life sciences sector is likely to continue.

We do, however, expect to see some departures from the approach taken by the Biden administration including a pivot from merger challenges premised on more novel theories of harm (e.g., portfolio effects in *Amgen/Horizon*, potential competition of early-stage drug development in *Sanofi/Maze*) to those that conform to more traditional theories (e.g., horizontal overlaps in *Novant Health/CHS* and *IQVIA/Propel Media*). Relatedly, the FTC under the second Trump administration is expected to place greater weight on rigorous economic analysis. More merger remedies likely will be accepted, and fewer litigated merger challenges will be brought when settlement is possible.

Evolving scope of EU and UK jurisdiction to review transactions

In recent years, there has been a concerted effort across competition authorities, particularly in the EU and UK, to stretch the boundaries of jurisdiction in cases where authorities are interested in reviewing a deal – even where the nexus to the relevant jurisdiction is marginal or non-existent.

In the EU, the *Illumina/Grail* judgment of the European Court of Justice temporarily put an end to the European Commission's (EC) practice of accepting and encouraging referrals from Member States in cases which are not notifiable either at EU or Member State level. Broadly, the European Court of Justice (ECJ) held that the EC may now only review below-threshold mergers referred by Member States where the referring Member State itself has jurisdiction under its own national merger control rules.

However, this "win" for legal certainty was short-lived – with an increasing number of EU Member States having introduced the power to "call in" below-threshold transactions – encouraged by the EC to introduce such powers to ensure that transactions of this type can continue to be referred to the EC.

The surrounding political climate is in flux. There have been calls for a more relaxed approach to merger

control which would allow more consolidation and the creation of "European Champions" who could better compete with their US and Chinese merger control counterparts. In her first speech since taking office, the new EU Competition Commissioner Teresa Ribera, has signaled that she may be more open to a "policy-driven" enforcement agenda, although not at the cost of competition. She has also identified the "enforcement gap" left by *Illumina/Grail* as a key priority which she intends to tackle during her term.

Increased patent misuse/enforcement litigation

In the US, under a Food and Drug Administration (FDA) dispute process, the FTC continues to challenge the FDA's Orange Book listings, questioning the accuracy and relevance of patents with claims that such patents can delay entry of lower cost generic alternatives. The FTC challenged more than 100 patent listings in 2023 and extended its challenge to an additional 300 patents in April of 2024.

In the EU, the EC noted in its 2024 update that access to affordable medicines – a key policy goal of the EC – is hindered by companies misusing patent procedures. Recent enforcement decisions have further highlighted this focus: in October of 2024, the EC fined Teva for misusing the European Patent Office's rules on divisional patents to extend the patent protection of its multiple sclerosis drug, Copaxone. Teva allegedly staggered divisional filings, enforced these divisionals against competitors, and then strategically withdrew them before validity challenges. The EC deemed this a misuse of patent procedures and an infringement of EU antitrust rules.

Continued focus on role of PBMs in US healthcare system

In 2024, the FTC targeted pharmacy benefit managers (PBMs) for what is perceived as their role in driving out-of-control drug costs. In July of 2024, the FTC issued an interim report – where they describe PBMs as "powerful middleman [who] may be profiting by inflating drug costs and squeezing Main Street pharmacies." A few months later, in September of 2024, the FTC filed a complaint in its administrative court against the largest 3 PBMs (CVS Caremark, Express Scripts, and Optum) alleging the PBMs' rebate schemes have artificially inflated the price of insulin. In response, Express Scripts filed a defamation lawsuit against the FTC based on allegations in the report, and the PBMs have now lodged a concurrent constitutional challenge to the agency's authority to bring claims in its administrative court.

Going into 2025, the escalating scrutiny of PBMs will be an area to watch as the FTC changes guards in a second Trump administration and as Republicans gain control of both the House and the Senate. Though incoming FTC Chair, and current commissioner, Andrew Ferguson, largely supported the release of the report, his fellow Republican commissioner, Melissa Holyoak, was strongly opposed. Both Republican commissioners were also recused from the FTC's litigation against CVS Caremark, Express Scripts and Optum.

On the legislative side, in December of 2024, House Republicans launched an investigation into whether CVS Caremark violated antitrust laws by steering independent pharmacies away from using services that facilitate efficient distribution of high-cost specialty drugs because the services could potentially compete with the PBM. Time will tell how the executive and legislative branches will approach enforcement efforts and scrutiny of PBMs moving forward.

Impact of new US Hart-Scott-Rodino Act (HSR) rules

The final rules for the new HSR form (Final Rules) were published on October 10, 2024, and are currently scheduled to become effective February 10, 2024. If they go into effect, the Final Rules will substantially increase the amount of data and information parties must provide to the regulators in connection with mergers and other transactions, with a commensurate increase in the time, cost, and burden associated with preparing an HSR filing and closing transactions. The Final Rules include several new features that will have an outsized impact on the burden of preparing HSR filings in the life sciences sector. First, the Final Rules introduce new disclosure requirements for known planned (versus existing) products and services that overlap between the parties. The Final Rules also include a new section on "supply relationships" where parties must disclose whether they have existing licensing arrangements between them. We expect the FTC to use this newly available information to facilitate continued scrutiny of life sciences deals.

Recent developments could lead to a delay in the effective date of the Final Rule. First, in early January the US Chamber of Commerce, joined by the American Investment Council and business groups, filed a complaint in the Eastern District of Texas to, among other things, enjoin enforcement of the new HSR rules and issue a declaratory judgment that the new HSR rules are "arbitrary and capricious" in violation of the requirements of the Administrative Procedure Act. Second, on January 20, 2024, President Trump issued a request to freeze pending regulations for 60 days. While the FTC has not yet announced whether the freeze will apply to the Final Rules, if the freeze were to apply it would stay the effectiveness of the Final Rules until March 21, 2025. Whether the Final Rules go into effect as scheduled will be closely watched by dealmakers as we head into what is expected to be an increase in life sciences M&A in 2025.

Status of US federal ban on non-competes

In April of 2024, the FTC finalized its rules banning nearly all post-employment non-compete agreements, but the rule is embroiled in litigation and has not come into effect. Private plaintiffs filed 3 separate challenges to the rule in the Northern District of Texas, the Eastern District of Pennsylvania, and the Middle District of Florida. The Texas court reached its decision first and ordered a stay of the FTC's rule, finding that the text, structure, and history of the FTC Act do not support the FTC's authority to issue the rule and that the rule is arbitrary and capricious, in violation of the Administrative Procedure Act.

The status of the FTC's rule remains uncertain. On October 18, 2024, the FTC filed an appeal challenging the Texas court's order staying the rule. That litigation is ongoing, but it is still unclear whether the second Trump Administration will pursue the rule. The rule was published on a partisan, 3-2 vote by the FTC. And while federal agencies under the first Trump administration showed an interest in protecting workers' rights, critics of the FTC's rule have argued against its breadth and potential for commercial harm.

While we expect the second Trump administration to abandon efforts to bring the non-compete ban into force, life sciences companies should keep apprised of the rule's status and watch for follow-on legislation at the state level.

2 Global protectionism – trend of increased restrictions to continue?

Foreign direct investments

Recent years have shown increased scrutiny and stricter approaches by governments to investments by foreign entities (so-called "foreign direct investments" or FDI) in sensitive sectors – apart from China, which has notably relaxed restrictions on FDI. Following the COVID19 pandemic, the life sciences sector has become a key area of concern for national regulators in numerous jurisdictions due to its relevance for public health. While governmental review has so far been limited to M&A, regulators have been vocal about subjecting other contractual agreements to FDI review. This may include R&D agreements and agreements which could otherwise lead to the sharing of data and information between companies from different countries. Going forward, it is therefore key to consider potential FDI implications at an early stage of transactions and collaborations in the life sciences sector, to regularly monitor changes in the relevant rules (and the political climate) and to engage with the relevant regulators whenever a transaction may be viewed to have an impact on public health.

Pending US BIOSECURE Act

The US BIOSECURE Act, a draft of which was passed in the House and is now pending before the Senate, would have a substantial impact on the global life sciences sector if successfully enacted. The Act would restrict any entity (domestic or foreign) that receives federal funding from the US government (including, potentially, in the form of Medicare reimbursement) from contracting with certain "biotechnology companies of concern" with a central focus on certain Chinese companies currently providing a broad swath of biotechnology R&D and manufacturing services to pharma and biotech companies across the industry. BIOSECURE has received bipartisan support in Congress and endorsement from industry trade groups. In anticipation of its passage, many pharmaceutical companies have already begun to shift their supply arrangements and contract research services to ex-China entities. While the proposed legislation currently contemplates that existing contracts with affected entities can be maintained without penalty until January 1, 2032, the impact on pharmaceutical supply chains may be extensive. In response, WuXi, one of the Chinese biotech companies explicitly named in the BIOSECURE Act, has already started to divest assets to limit its reliance on the US market and mitigate the risk to its business ahead of the Act being enacted.

Changes to China's human genetic resources regulations

In recent years, restrictions on access to and the export of human genetic resources (HGR) information and patient data from China have presented challenges in cross-border licensing and other drug development transactions with Chinese counterparties. Reports suggest that the Chinese government plans to amend HGR regulations in 2025. We anticipate additional guidelines and clarifications regarding the scope of HGR data, which are aimed at streamlining the HGR approval process.

Despite these challenges, 2024 saw significant growth in China's local biotech sector, with a marked increase in out-licensing deals. To facilitate potential M&A structures in addition to licenses, many Chinese biotech companies have opted to house the IP and other assets relating to their products in separate subsidiaries to keep acquisition as an alternative.

3 Drug pricing – ongoing refinement of government programs.

US – Inflation Reduction Act (IRA)

Since passage of the IRA in 2022, the life sciences sector has been vocal in expressing its discontent with the drug pricing provisions, arguing that they are not only unlawful but also disincentivize innovation. Several high profile drugmakers reportedly plan to ask the second Trump administration to pause negotiations until the process can be fixed. While we anticipate some policy shifts under the second Trump administration, since both sides of the aisle have been focused on perceived high drug prices, some variant of the drug pricing negotiation provisions of the IRA will likely endure. In a final act to further the implementation of the IRA, in early January, the Biden administration named the next 15 drugs to be the subject of price negotiations under the IRA, including several of the blockbuster GLP-1 drugs.

UK – reform of statutory and voluntary schemes for branded medicine pricing

In the UK, branded medicines are subject to price negotiations with the National Health Service (NHS) under the so-called "statutory scheme," unless manufacturers opt-in to the alternative "voluntary scheme." Since the introduction of a new 5-year voluntary branded medicines pricing, access, and growth scheme (VPAG Scheme) in 2024, both (i) public data, and (ii) reforms to the statutory scheme to align it more closely with the VPAG Scheme, suggest that the VPAG Scheme is the preferred scheme for branded medicine suppliers due to its greater predictability and stability. Given that the reforms to the statutory scheme are expected to take effect in 2025, we expect that the differences between the schemes – and the risk that more changes will be made to the statutory scheme in the future – will encourage more branded medicine suppliers in 2025 to sign up to the VPAG Scheme to give them better stability and predictability through the end of 2028. It will also be interesting to see whether industry positivity towards the VPAG Scheme continues.

EU – regulatory reforms impacting pricing

A package of proposed reforms to pharmaceutical laws is currently making its way through the EU legislative process, which we expect to be finalized in 2025 or 2026. The package touches on 3 areas of interest. First, the proposal would reduce the regulatory data protection period from 8 years to 7.5 years, but would give marketing authorization holders (MAH) the ability to increase the baseline period by 6 months to 1 year under certain circumstances (e.g. if the drug is deemed to address a particular unmet medical need or the MAH conducts a significant share of R&D within the EU in collaboration with public bodies). Second, the proposal would expand the so-called "Bolar Exemption," which allows generic or biosimilar manufacturers to make use of patent rights for an innovative medicinal product when preparing a corresponding marketing authorization application, to include pricing and reimbursement activities. Finally, the proposal would generally reduce the availability of orphan market exclusivity (OME), changing it from the current scheme in which an MAH receives a 10 year period of exclusivity each time a new indication is approved for an orphan drug, to a single period of exclusivity available on a per-MAH/active substance basis, with the OME period ranging from 4–11 years depending on which of 3 categories the drug falls into. These reforms, if implemented, will indirectly impact drug pricing in the EU. We expect negotiations on the reforms to be complex and expect modifications before they are formally adopted. Innovators will want to keep a close eye on their progress during 2025 and keep in mind any potential impact on their R&D pipelines and on-market portfolios.

4 US litigation – increased focus on diligence clauses.

Diligence or "commercially reasonable efforts" clauses stipulating a required level of efforts to be expended by buyers or licensees in M&A and licensing transactions to achieve milestones and sales thresholds have long been the source of disputes between deal counterparties. Recently, however, many of these cases have not simply been resolved quietly through settlements or confidential arbitration but through litigation. In 2024, there were 3 important cases in the Delaware Court of Chancery interpreting "commercially reasonable efforts" (CRE) clauses in life sciences contracts: *Himawan/Cephalon, Fortis Advisors/Johnson & Johnson* and *Shareholder Representatives/Alexion*. While having arisen in the context of M&A deals, they are instructive for licenses or any other transaction with a diligence clause.

Cases involving diligence clauses tend to be very fact specific, but some trends emerged from these cases that are instructive for life sciences companies. All 3 cases involved so-called "objective" CRE standards under which the required level of efforts is determined by reference to similar companies developing similar products. Importantly for these types of clauses, in both *Himawan* and *Alexion*, the courts established that in interpreting an objective standard, courts will not necessarily look at actual existing companies faced with similar circumstances but will consider a "hypothetical company approach," defining commercially reasonable effort as those efforts a similarly situated company "would expend under the circumstances at hand."

Other themes that arose included whether a buyer or licensee is entitled to consider the payments owed to its counterparty in determining the required level of efforts and whether, apart from the diligence clause, the contract expressly gives the buyer or licensee full discretion over future development of the relevant product, highlighting the advisability of expressly addressing these points in the contract whenever possible.

Companies should be aware of these cases and the likely continuation of the increase in litigation in this area and consider how to mitigate the risk of disputes both in current deals and future contract negotiations.

5 EU litigation – changes and uncertainties.

New claimant-friendly Product Liability Directive (PLD) adopted in the EU

The new EU PLD, formally adopted in late 2024, significantly overhauls the regime governing claims by consumers for compensation where a product causes them harm. The new rules are patient-friendly and are designed to ease the way for plaintiffs to pursue legal action, in particular in complex cases. We expect a profound impact on defendants operating in the EU, in particular in the life sciences sector. Although the overall framework is similar to the old Directive (e.g. "strict" or "no fault" liability remains), there are important changes including:

- Expansion of the scope of the definitions of "product" (to include, for example, software) and of compensable "damage" (to include medically recognized psychological harm);
- broadening the list of potential defendants to include additional stakeholders in the supply chain;
- creation of rebuttable presumptions as to defect and causation to help claimants prove their case – essentially shifting the burden of proof to the defence in many circumstances;
- extending the expiry (or "longstop") period from 10 years to 25 years in cases of latent harm – with all the document-keeping and evidential issues that presents; and
- important procedural changes, including the introduction of requirements to produce documents and other evidence to plaintiffs, which will be largely unfamiliar in some EU jurisdictions.

Member States must now implement these changes into their national laws by December 2026.

Continued uncertainty in EU patent enforcement before the Unified Patent Court

Following the successful launch of the Unified Patent Court (UPC) in June of 2023, the supra-national court has provided an extra dimension to the EU patent litigation landscape. Although its goal is to streamline EU patent litigation, we see its presence as increasing the uncertainty in developing (and protecting against) patent enforcement strategies. We are seeing patentees opt into the UPC system with only a portion of their portfolios, with the others remaining within the national systems of specific countries. This means that, at least in the medium-term, we are likely to continue to see a mixture of related proceedings in both the UPC and the national courts (particularly Germany).

As to proceedings in the UPC itself, it remains to be seen how substantive decisions on validity and infringement will be treated on appeal and the extent to which the various local divisions of the UPC will ensure consistency among them. This goes also to procedure, where local divisions are already developing their own perspectives (e.g., Munich is considered pro-patentee) and standards. 2025 may bring some consistency from the Court of Appeal, but we are sure to see further legal creativity from users of the relatively new system.

Growing influence of US class action culture on European claims

The influence of US class action culture on claims in Europe is becoming increasingly evident. The claimant bar is expanding and strengthening its international connections, with US-headquartered plaintiff law firms seeking to establish themselves in key European markets such as London, Germany, and the Netherlands. These claims are further fueled by the proliferation of available capital from litigation funders, with the EU funding market expected to grow by more than 8 percent annually over the next 3 years. These funders, often international, assist claimant firms in replicating successful targets and tactics across different jurisdictions.

The growth of claimant firms is also accompanied by increased activity from NGOs and consumer and patient advocacy groups. These groups are likely to leverage the rules under the Representative Actions Directive, also known as the "Collective Redress Directive" (CRD), which mandates that all EU member states must have at least one procedural mechanism allowing consumer organizations, regulators, and other "qualified entities" to initiate representative actions on behalf of consumers. It is likely that the life sciences sector will be an early target of such claims.

6 EU/UK regulatory oversight – ongoing reform.

Changes to UK Medical Devices Regulation

Reform of the medical devices regulatory regime in the UK has been long-awaited post-Brexit, and 2 key pieces of legislation are now taking shape.

First, the draft Medical Devices (Post-Market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024 were laid before Parliament in October of 2024. These regulations are intended to amend and add to the existing post-market surveillance requirements in the Medical Devices Regulations 2002 to: (i) require medical device manufacturers to comply with more prescriptive rules around post-market surveillance (PMS) systems and plans; and (ii) publish a PMS report every 3 years, as well as a periodic safety update report for high-risk devices every 1 to 2 years. They also further develop serious incident reporting requirements as part of the Medicines and Healthcare products Regulatory Agency's (MHRA) goal to foster a foundation of patient safety whilst supporting innovation in this sector. The legislation is expected to go into effect in the second half of 2025.

Second, the MHRA has also consulted on further updates to the regulatory framework for medical devices placed on the UK market. Additional legislation arising out of this consultation process is expected, likely to address matters such as conditions for access to the UK market for CE-marked devices and those approved under regimes in other trusted markets such as Australia, Canada and the US, and new rules for the classification of in vitro diagnostic devices.

Changes to UK Clinical Trials Regulation

During 2022–2023, the MHRA consulted on a new legislative framework for clinical trials in the UK, with a view to creating a streamlined, proportionate, and flexible regulatory environment that prioritizes patient safety.

Following the consultation, new regulations were proposed in December of 2024, marking the first significant overhaul of the regime in 2 decades. The new legislation is intended to support more streamlined regulation of clinical trials and remove unnecessary administrative burdens on trial sponsors, while protecting the interests of trial participants. It includes: (i) proposals for a single route of approval for clinical trial applications; (ii) requirements for publishing notice and results of clinical trials; and (iii) a requirement to retain medical files of trial participants for 25 years (as opposed to five years currently).

If enacted, the MHRA expects the new regulations to enter into force in early 2026, following a 12-month implementation period.

Changes to EU Medical Devices Regulation

In July of 2024, EU regulations applicable to medical devices (MDR) and in vitro diagnostic medical devices (IVDR) were amended. Among other changes, the transitional provisions for certain in vitro diagnostic devices were extended and an obligation for manufacturers to provide information in case of interruption or discontinuation of supply was introduced and applies from January 10, 2025.

Meanwhile, calls for more fundamental changes to the MDR and IVDR are increasing. Following a resolution of the EU Parliament in October of 2024, calling for urgent revisions to address supply shortages and to reduce regulatory burdens, the Council of the EU echoed these concerns during a meeting in December of 2024, emphasizing, among other things, the need for reduced bureaucracy, clear and transparent certification process timelines, and better market access for niche products. The new EU Commission has now brought forward a targeted evaluation to assess the effectiveness of the MDR/IVDR by 2 years and is seeking public feedback by March 21, 2025.

It remains to be seen, when and to which extent, legislative measures for a revision of the MDR/IVDR will follow. However, reportedly, certain non-legislative measures might be taken earlier, including addressing delays in market access for orphan medical devices, particularly in pediatric care.

7 MedTech – ongoing expansion and evolving legal issues.

In 2024, we saw the continued rapid expansion of the MedTech industry. As AI technologies have increasingly been adopted, the scope of associated global collaborations and complexity of applicable regulations has continued to grow. In 2025, we expect AI to continue to drive advancements in diagnostics, drug discovery, administration, and clinical trials, offering new opportunities for precision medicine and other therapeutic innovations. The adoption of virtual care and direct-to-consumer models will continue to expand, with companies increasingly leveraging digital platforms to improve patient engagement and streamline access to medications. Cybersecurity will remain a critical focus, with stricter data privacy regulations in response to rising cyber threats. We also expect global regulators to intensify oversight of the deployment of new technologies, particularly to enhance safety, transparency, and accountability in AI-centered offerings. Amid these shifts, MedTech companies must navigate evolving antitrust scrutiny, particularly around AI-related mergers and data-sharing practices, while seizing opportunities to collaborate with other digital health innovators to meet growing demand in a dynamic global market.

8 Deal-making – recent trends in biopharma.

M&A

2024 was generally considered to be a disappointing year for biopharma M&A. According to the EY Firepower report, while the number of deals remained steady relative to 2023, biopharma M&A deal value was down over 50 percent compared to 2023. The fourth quarter was particularly quiet as we didn't see the spate of deal announcements leading up to the JP Morgan Healthcare conference (JPM) that we often see.

Citing a more flexible regulatory environment under the second Trump administration and widely reported patent cliffs facing the industry, many pundits have been predicting a significant uptick in M&A activity for 2025. And, in fact, day one of JPM saw 3 $1bn-plus deals announced – Johnson & Johnson's acquisition of Intra-Cellular Therapies (neuroscience) for $14.6bn, Eli Lilly's acquisition of Scorpion Therapeutics (oncology) for up to $2.5bn and GSK's acquisition of IDRx (oncology) for $1.0bn. However, apart from these transactions, JPM came and went without any further significant deal announcements, leaving dealmakers wondering how quickly the biopharma M&A market may in fact pick up.

Count us at Freshfields among those expecting a much better year for biopharma M&A deals, particularly if the IPO market is slow to recover and the recent trend toward venture capital investors consolidating their investments in a small number of biotechs through so-called "mega" financing rounds of at least $100m continues. This lack of available financing for many may leave cash-strapped biotechs looking for an exit through M&A.

We also expect contingent value rights (CVRs) to continue to play a significant role in helping bridge value gaps between buyers and sellers for public biotechs. Going in the other direction, time will tell whether we see more acquisitions of private biotechs for 100 percent cash at closing. While historically virtually all these deals had a milestone component, we are starting to see aggressive buyers put all their money on the table to win hotly contested auctions.

China

There has been a huge increase in innovative products coming out of China, leading to a significant growth in licensing deals by Chinese licensors. While this trend wasn't widely reported until recently, it's been happening for a while. The number and average value of licensing deals involving drugs discovered in China reached record levels in 2024 according to data published by Jefferies, and pharma companies are now sourcing a significant portion of external innovation from China (1/3 of license deals done in 2024, according to a report by Stifel). This rise is largely fueled by a shifting of sentiment by US and EU drugmakers that, unlike in the past, products coming out of China are now innovative and catching up in terms of novelty, reliability, and safety —whereas, previously, deals originating out of China tended to target "me too" drugs or involved companies providing drug manufacturing or R&D services. Whether this trend continues remains to be seen, but in the near term, we continue to see a steady stream of innovative deals coming out of China.

Traditional M&A terms influencing licensing and collaboration agreements

Recent years have seen increasing fluidity in life sciences deal structuring, with parties often transitioning between M&A and licensing models well into due diligence, as well as conducting parallel financing and strategic transaction (whether M&A or licensing) processes. This approach has caused a reevaluation of some of the traditional differences between M&A and license deal structures in several areas, but particularly around risk allocation during the period between signing and closing of licensing deals. One key difference has typically been the absence of robust closing conditions in licensing deals relative to those in M&A deals.

Heightened antitrust scrutiny of the life sciences sector, regardless of the transaction structure, has increased the risk of licensing deals not being cleared by regulators or being significantly delayed, causing stakeholders to focus more on allocation of risk during the interim period between signing and closing. Licensees are looking for greater protections during this interim period and are increasingly negotiating for M&A-style closing conditions, including "rep bringdowns," absence of material adverse change and other conditions. We expect this trend to continue in 2025 as market practice for M&A and licensing deals around risk allocation continues to merge.

9 ESG – increasing regulation in life sciences sector.

Reform in the environmental risk assessment (ERA) process

In 2025 in the EU, negotiations are set to continue on a package of measures to reform the general pharmaceutical legislation, including proposals for major changes to the ERA process, aimed at enhancing the evaluation of potential environmental impacts. Such proposals would: (i) require evaluation of environmental antimicrobial resistance risks across a medicine's entire manufacturing and supply chain (inside and outside the EU), including identification of risk mitigation measures; (ii) strengthen the consequences of non-compliance with the ERA requirements, including, at the extreme, refusal or revocation of marketing authorizations or withdrawal of medicines from the market; and (iii) require the European Medicines Agency to identify medicines authorized prior to 2006 that are "potentially harmful to the environment" to undergo ERA for the first time.

Exponential growth in global ESG disclosure obligations for corporates

While for many years voluntary and more targeted carbon reporting has been required in certain jurisdictions, we have recently seen an explosion in mandatory ESG reporting around the world. The EU has been at the forefront with its Corporate Sustainability Reporting Directive (CSRD). Other jurisdictions are now looking to introduce similar sustainability-related disclosure regimes by reference to the International Sustainability Standards Board standards. Moving forward, we expect this proliferation of mandatory reporting to continue, despite anti-ESG sentiments in the US and elsewhere. Although no additional EU corporate-level ESG disclosure rules have been proposed, the new Corporate Sustainability Due Diligence Directive (CSDDD) is due to take effect in 2027. The CSDDD, in addition to introducing new human rights and environmental due diligence requirements and further disclosure obligations, will also require in-scope organizations to prepare and report on a Paris-aligned climate change transition plan. These new disclosure regimes (and, in particular, the CSRD) create a material regulatory burden, as well as present real legal and commercial risks for an organization. In practice, appropriate governance frameworks (and often significant amounts of time and resources) are needed to manage these regulatory obligations and related risks. Following widespread criticism of the CSRD, CSDDD and the EU Taxonomy, the EU Commission is currently working on a possible proposal to make these expansive and ambitious regimes more workable. Although any simplification and streamlining of these EU regimes will be welcome news, this should not distract or delay companies from gearing up on their preparedness for ESG reporting during 2025.

Impact on deal execution

As carbon, environmental, human rights and supply chain issues become more mainstream from an ESG disclosure and transparency perspective, deal executives should factor certain risks and opportunities (e.g., legacy liability concerns, environmental impact of pharmaceuticals, waste, decarbonization, emission controls, restricted substances, affordable access to medication, resource use, water, circular economy and supply chain human rights challenges) into their diligence efforts and decision making. Additionally, deal executives should consider: (i) a target's preparedness for sustainability reporting and ESG governance more generally; (ii) whether a potential transaction aligns with their organization's sustainability goals and strategy; and (iii) how a potential transaction would impact ESG performance and credentials going forward. In 2024, we saw deal documents evolve in some cases to include provisions addressing ESG liabilities, including a range of ESG covenants, information rights and performance provisions. We expect to continue to see these types of provisions in the year ahead.

10 US public health agencies – landscape under the Trump administration.

Changes to role and funding of US public health agencies

The second Trump administration has recently announced its appointees to lead key US public health agencies, which include (i) Robert F. Kennedy, Jr. as Secretary of the Department of Health and Human Services (HHS), (ii) Jim O'Neill as Deputy Secretary of HHS, (iii) Dr. Martin Makary as Commissioner of Food and Drugs, i.e., the top official of the Food and Drug Administration (FDA), and (iv) Dr. Jay Bhattacharya as Director of the National Institutes of Health (NIH). If these leaders are confirmed by the US Senate, and based on their recent works, writings, and other public commentary, we would expect HHS, the FDA, and NIH to seek to implement several measures intended to revamp US drug development by reducing inefficiencies, expediting approval processes, and promoting innovation in the US. Specifically, we would expect these measures to potentially include some or all the following:

- Increased consideration of clinical trial data generated, and comparability studies conducted, outside of the US in connection with drug approval decisions, with the intent of making drug development faster and less expensive. Notably, these measures have been supported by Vivek Ramaswamy, the founder of a US biotechnology company and—briefly—the co-chairperson of Department of Government Efficiency, a Trump administration advisory commission.
- Reorganization and reallocation of US federal funding, including through (i) conversion of some of NIH's grant budget into block grants which would be provided to state governments, (ii) allocation of increased R&D funding to small businesses through the Small Business Innovation Research and Small Business Technology Transfer programs, and (iii) provision of additional funding towards investigator-based grants to encourage innovation.
- Reduced regulation by the FDA of certain products which have been regulated as medical devices, such as laboratory-developed tests with mathematical algorithms that never touch patients.
- Lowering of efficacy standards that must be met for new pharmaceutical products to be approved, so long as their safety is sufficiently demonstrated.

Of course, the extent that these measures are implemented will depend on several factors, which we will be actively monitoring now that the second Trump Administration has formally entered the White House.

New policies around use of "march-in" rights for US government funded IP

In 2024, the US National Institute of Standards and Technology (NIST) proposed a framework to expand the use of "march-in" rights applicable to government-funded inventions under the Bayh-Dole Act. Such rights allow the government to provide patent licenses to permit third parties to commercialize products based on government-funded inventions if the originator does not comply with certain statutorily-imposed requirements. Specifically, the proposed framework would expressly allow the government to consider pricing as a factor when determining whether to exercise its right to "march-in"—a change supported in a public comment by the current FTC.

If implemented, this policy shift could have far-reaching implications within the life sciences sector, providing the government with an additional mechanism to combat price increases for pharmaceutical products. However, the draft framework is still undergoing public comment. The future of the NIST's proposed framework could be in jeopardy as the first Trump Administration signaled reluctance to allow the government to consider pricing as a factor in exercising march-in rights.