A&O SHEARMAN

Life sciences and healthcare *insights*

2026

Introduction

Welcome to our Life sciences and healthcare insights report, where our global team share their insights on the most important commercial, legal, and regulatory issues facing life sciences and healthcare companies around the world.

As innovation accelerates and geopolitical, technological, and policy pressures intensify, life sciences and healthcare companies are traversing an increasingly complex risk and opportunity landscape.

Matthew Appleton
Partner

Jim Ford
Partner

Marjan Noor
Partner

Clare O'Brien
Partner

SUMMARY

In this edition, we begin by placing shareholder activism under the microscope, exploring why life sciences and healthcare companies are attracting heightened activist attention and what boards can do to prepare and respond.

We then turn to the integration of AI into drug discovery and development, focusing on the critical issue of data provenance. As AI-driven partnerships, acquisitions, and collaborations gather pace, we examine how questions around data quality, consent, ownership, and regulatory compliance are becoming central to deal value and risk allocation.

Our third article explores China's growing role as a global engine of pharmaceutical innovation. We analyze the deal structures that Chinese innovators are using to expand internationally, alongside the regulatory, IP, and data-transfer considerations shaping these transactions.

We then assess the European Commission's proposed revisions to the EU Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR). We explain how these reforms aim to reduce regulatory burden, support innovation, and safeguard supply, while introducing new considerations around AI, cybersecurity, and post-market surveillance.

Next, we mark two years of the UPC and examine how it has reshaped European patent litigation, and what its growing body of case law means for life sciences companies navigating enforcement, risk, and cross-border strategy.

Finally, we examine how the European Union's expanding environmental and sustainability agenda is reshaping the regulatory and compliance landscape for pharmaceutical companies, often at significant cost.

This document contains elements that are interactive.

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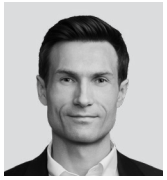
Under the microscope: shareholder activism in *life sciences and healthcare*

The life sciences and healthcare sector is a prominent target for shareholder activists. In 2025 a record 255 activist campaigns were launched worldwide, surpassing the previous high of 249 set in 2018, according to research from Barclays. Life sciences and healthcare companies were targeted in 31 of those campaigns, representing around 12% of the total. The sector's unique dynamics—high-cost, high-risk research and development, strict regulatory frameworks and heightened governmental and public scrutiny—create pressure points that activists are well-positioned to leverage. Here we explore the outlook for further campaigns in the months ahead, and what boards should be doing to prepare for potential activism interest

AUTHORS

Matthew Appleton
Partner

Claire Coppel
Partner



Matt Hamilton-Foyn
Partner

Dan Litowitz
Partner

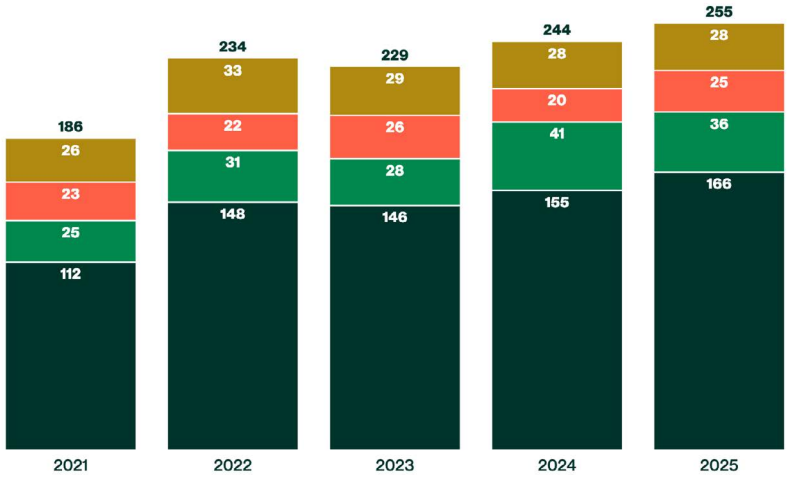
Derrick Lott
Partner

Aoife McDermott
Partner

Clare O'Brien
Partner

ACTIVIST ACTIVITY ON THE RISE

Number of campaigns (2021-2025)

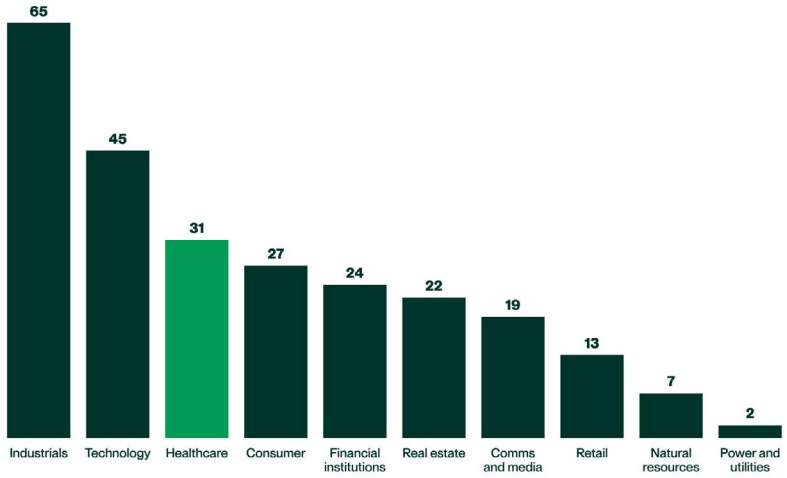


Size of target (market capitalization)

- USD500m-USD5bn
- USD5bn-USD10bn
- USD10bn-USD25bn
- USD25bn+

HEALTHCARE REMAINS AMONG THE MOST TARGETED SECTORS

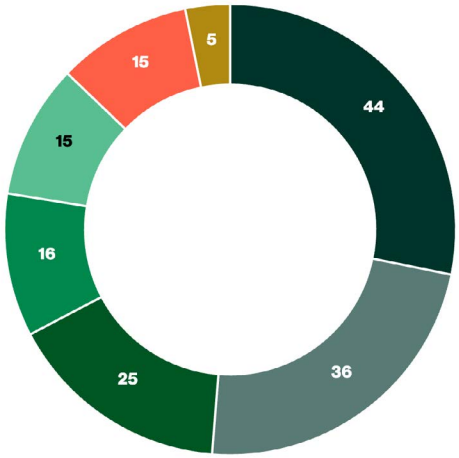
Number of campaigns by sector (2025)



Source: Barclays

M&A IS A KEY DRIVER OF ACTIVIST ACTIVITY

Proportion of campaigns pursuing different objectives (2025)



Campaign thesis

- M&A
- Board change
- Strategy and operations
- Capital return
- No public demands
- Governance
- Management change

Several characteristics of companies in the life sciences and healthcare sector provide ready avenues for activists to exploit.

Valuation disconnects and pipeline uncertainty are one of the primary drivers of activist activity. Many life sciences companies, particularly mid-cap biotechs and specialty pharma businesses, trade at valuations that shareholders believe undervalue their underlying asset base—whether clinical pipelines, intellectual property portfolios or commercial-stage products. Around one in six companies on the Nasdaq Biotechnology Index are currently trading below their cash reserves, with some investors pushing for capital to be returned as an alternative to continued allocation to less certain R&D investments. Patent cliffs—with USD47 billion in global pharmaceutical revenue at risk on average over the next four years according to the IQVIA Institute for Human Data Science—and pipeline failures can further depress share prices, creating another entry point for activist funds.

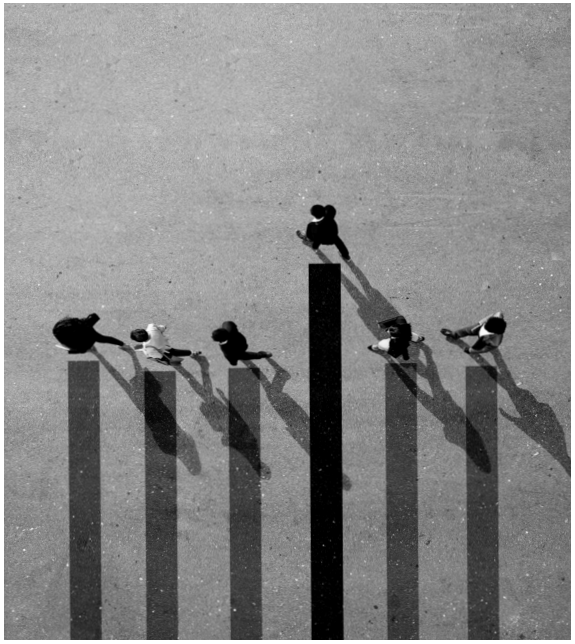
Encouraging or responding to M&A activity is another significant catalyst for activist campaigns (whether pushing for a sale or opposing an announced transaction) and is the most common campaign objective. Across all sectors globally, 44% of campaigns in 2025 had an M&A thesis (which is consistent with the four-year average) but this figure masked a dramatic shift across the year. M&A activism rose to 54% of campaigns in H2 and 64% in Q4, the highest proportion in five years, as transaction activity accelerated in the second half of the year. Looming patent expirations exert particular pressure on pharmaceutical companies to act through M&A to address this issue, as evidenced by the fact that more than half the transactions in 2024 by the largest pharma businesses targeted Phase 1 or earlier-stage assets.

Operational and margin pressure also creates vulnerabilities. Cost inflation (including as a result of newly imposed—albeit shifting—tariffs), competitive dynamics and pricing reform (notably in the United States, where the federal government has introduced policy measures designed to require pharma companies to price their products sold in the U.S. at levels that are no higher than those paid by consumers for similar products overseas are impacting margins.

In response, activists may argue for cost restructurings, portfolio rationalizations or divestitures of non-core assets in an effort to improve financial performance, focus management and increase share prices. U.S. policy dynamics—from the challenges of securing FDA approvals for new therapies to a reduction in public health funding—are creating an uncertain and unpredictable outlook, increasing the likelihood of further activist campaigns in the year ahead.

Meanwhile, the regulatory regime for shareholder communications and proxy contests in the U.S. is evolving. Reforms introduced by the federal government and the SEC—including an opt-in system that allows shareholders (other than registered investment advisors subject to fiduciary standards) to provide a standing instruction to automatically vote their shares in line with the board's recommendation, continuing efforts to impose restrictions on class-action lawsuits and executive orders aimed at curtailing the influence of "politically motivated" proxy advisers—aim to reduce the influence of proxy firms and large passive shareholders. Taken together, these measures are expected to result in a tilting of the balance in favor of boards and management teams.

Governance and capital allocation concerns round out the picture. Board composition, executive compensation, the rates of capital returned to shareholders and discipline over R&D spending provide governance-focused activists with a platform. E&S-related activism, including campaigns focused on drug pricing and access, can also play a role, particularly in the U.S. and Europe. Meanwhile, companies that benefited during the COVID-19 pandemic now face questions about their strategic direction as demand has normalized over recent years.



RECENT CAMPAIGNS: A SNAPSHOT

Several high-profile campaigns in 2025 illustrate these themes in action.

- Kenvue, the Johnson & Johnson consumer healthcare spinout, was targeted in 2025 by multiple activist funds (Starboard Value, Third Point, and Toms Capital Management) concerned that the company was underperforming its peers. In response, Kenvue agreed to appoint three new board members, including Starboard's Jeff Smith, and then agreed to be acquired by Kimberly-Clark in a transaction that valued the company at almost USD49bn.

- Becton Dickinson (BD) faced similar demands; Starboard urged the board to separate its life sciences division, leading to a recently completed USD17.5bn Reverse Morris Trust transaction that combined BD's biosciences and diagnostic-solutions business with Waters Corp.

- Pfizer was also a target for Starboard, which launched a campaign highlighting alleged failures in the company's R&D productivity and M&A strategy, as well as concerns over falling COVID-related sales and a declining share price. Here, Starboard ultimately refrained from nominating directors and eventually exited its position.

- At Medtronic, Elliott Management acquired a significant stake and, following what the company described as "constructive engagement", Medtronic added two independent directors to its board and created new board committees focused on, among other things, accelerating growth (including through tuck-in M&A), improving operational performance and potential divestitures.

- In Japan, Astellas was targeted by Farallon Capital, which acquired more than 3% of the company's shares and called for more aggressive cost-cutting and R&D restructuring, driven by concerns over significant M&A spending (over JPY1.5 trillion/USD10bn since 2016) and the expiry of the patent for its blockbuster cancer drug Xtandi, which lapses in 2027.

- In Denmark, Novo Nordisk saw activist hedge fund Parvus Asset Management build a stake following leadership changes—the chairman and six independent directors stepped down, while the CEO was dismissed—as the company's share price fell approximately 30% in 12 months amid slowing profit growth and competitive pressure from Eli Lilly in the U.S. obesity market.

- Notably, 12.2% of funds targeting healthcare companies went public with their demands globally in 2025, the highest proportion in five years, according to Barclays research.

WHAT SHOULD BOARDS BE DOING IN RESPONSE?

Proactive shareholder engagement, strategic discipline and clear and consistent communications are essential for boards in a more volatile activist environment.

KNOW YOUR SHAREHOLDERS

- It is critical that boards maintain a detailed understanding of their shareholder base and make sustained efforts to build rapport with individual fund managers at each of their primary institutional investors. Regular engagement is essential to gauge these managers' views on the company's business, management and strategy, and to assess how they might respond to activist demands such as calls for board changes, asset divestments or capital returns. Having this understanding allows boards to predict where an activist might find support for specific proposals, and to identify potential allies for the board among the company's existing investor base should they be required.

- Boards that do not engage proactively with their most important investors may find themselves on the wrong side of activist campaigns. If shareholders feel ignored, they may be more inclined to support activist proposals simply because activists are perceived as providing greater engagement. Regular outreach gives boards the best chance of ensuring their shareholders will not side with activists out of frustration with a company's lack of engagement, transparency or adherence to best practices.

CLEAR AND CONSISTENT STRATEGY IMPLEMENTATION

- Boards should evaluate their exposure to activist risk by assessing whether their company's share price reflects the company's intrinsic value, whether their portfolio is optimally configured and whether their governance arrangements meet current best-practice expectations. Conducting a regular "activist lens" review—essentially stress-testing the company's business plan assumptions, governance and stock valuation versus competitors—is advisable. The campaigns against Pfizer, Becton Dickinson, Novo Nordisk and Astellas were all triggered in part by share price underperformance relative to peers.

- Boards should ensure that the company's long-term value creation story, including its R&D pipeline strategy and capital allocation rationale, is communicated consistently to the market. Inconsistent or unclear messaging about strategy creates vulnerability; shareholders may become receptive to activist proposals if they do not fully understand the board's plans and therefore cannot measure the impact of strategic decisions on business performance.

- Where applicable, companies should be prepared to explain their capital allocation decisions; here, timely and robust disclosure can pre-empt investor concerns regarding the prudent use of their money and strengthen their confidence in directors' and management's ability to appropriately position the company for longer-term success.

- Boards should periodically assess and refresh their governance profile, evaluate their composition and performance and those of their management teams, as well as the company's compensation framework.

- Boards, together with their management teams and financial and legal advisers, should also regularly assess the company's mid- and long-term strategic plans, informed by credible management financial projections, with a view to deciding whether maintaining the status quo is in the best interests of shareholders and other stakeholders, or another course of action is advisable or even required.

BE READY—ENGAGE AND LISTEN

- Boards and management teams should have a pre-agreed response protocol in the event of an activist approach. This includes identifying external advisers (legal, investment banking, and communications), establishing a rapid-response team and ensuring the board has discussed and agreed on key strategic positions in advance. It is critical for a board and the company to speak with one voice in the face of an activist campaign. Activists and shareholders will seize on inconsistent messages or any indication that a company is not well organized or does not believe uniformly and with conviction in its own plan.

- Boards should not be pre-disposed to quickly dismiss suggestions simply because they are made by an activist. The "not invented here" response to proposals is generally shortsighted and counterproductive. Activists regularly spend significant time developing proposals for a company, which are often thoughtful and accretive. Boards should be open to constructive engagement where an activist's proposals could enhance value, while at the same time being prepared to defend their position (potentially publicly) where they believe an activist's thesis is flawed. It is important to make this determination after rigorous analysis of any proposals so as not to provide activists with ammunition that a board is entrenched and unwilling to consider new ideas.

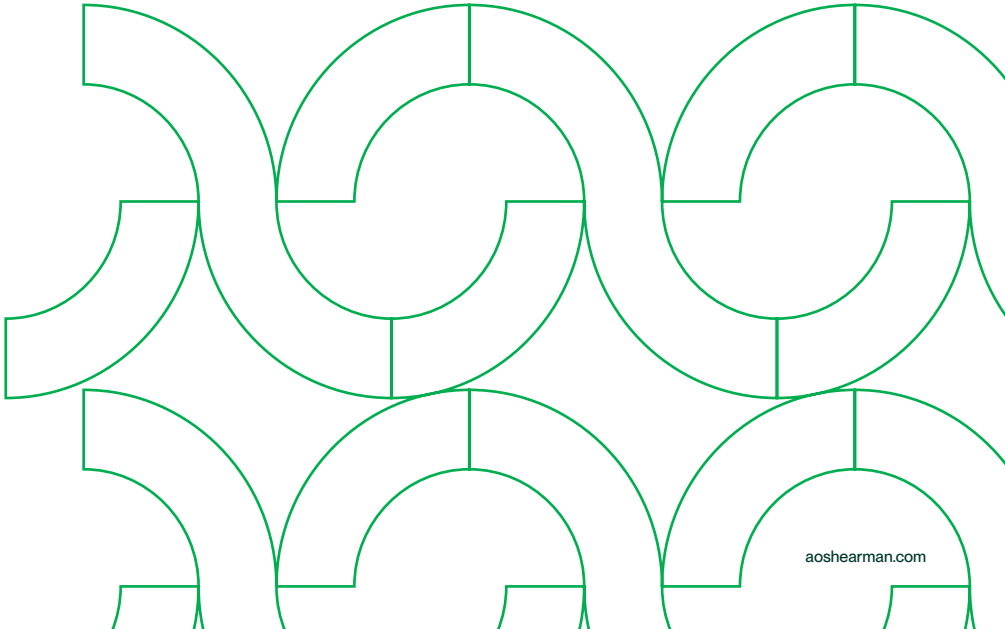
PREPARE TO LIVE WITH LONG-TERM ACTIVISTS

- We are seeing more activist funds taking stakes (occasionally up to 15 or 20% in smaller companies) and remaining as investors for several years, from where they seek to influence decisions and position companies for an eventual sale or other liquidity-driven transaction.

- Boards therefore need strategies not just for initial activist defense but also to manage ongoing relationships with activist shareholders who want to be involved in major decisions. Long-term activists may pursue incremental changes, such as nominating chairs or other directors, removing board members or blocking non-core acquisitions, which differs from the commonly held perception of their tactics (i.e., to take a position, push immediately for change and then exit their position when the share price rises).

Looking ahead, we expect the combination of significant M&A activity, ongoing valuation disconnects, pipeline uncertainty, a historic patent cliff cycle, U.S. policy dynamics (including tariff volatility, pricing reforms and reduced public health funding) and competitive pressures in the life sciences and healthcare sector will result in continued activist attention.

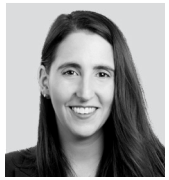
Boards that proactively address valuation mismatches, maintain open communications with their shareholders and articulate a convincing long-term strategy will be best positioned to navigate this more uncertain environment.



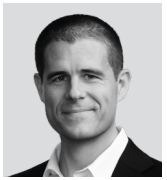
Q&A: Why data provenance is critical to *AI-powered drug discovery*

Pharmaceutical research and development is becoming more expensive and taking longer. Innovative AI scale-ups and platforms are addressing this by quickly accumulating vast datasets, but the larger companies that buy them need certainty those datasets are lawful, traceable, and defensible. Here we explain what major players need to know when entering into M&A, partnerships and collaborations with smaller innovators.

AUTHORS



Anna Rudawski
Partner



Alex Shandro
Partner

Life sciences companies are racing to deliver on an AI promise: faster identification of promising therapies, streamlined development, and novel treatments reaching patients sooner and safer.

Biotechs and pharma companies are integrating the latest generative AI models into their R&D systems: analysing vast volumes of data, identifying patterns to inform recommendations or predictions (such as whether a protein target or a candidate compound can bind to a given target), and optimizing clinical studies.

This may dramatically increase the efficiency—and reduce the cost—of drug development. This is particularly true in the rare and orphan disease space, where the cost of identifying and testing treatments can be astronomical.

However, realizing these benefits depends on factors less glamorous than the algorithms themselves: the quality and provenance of the data that feeds them.

This trend is driving transactional activity. We have advised on most of the highest-profile partnerships between AI biotechs and pharma companies for the deployment of AI to aid drug discovery.

These agreements raise complex and potentially existential issues around IP ownership, data usage rights, liability allocation, regulatory compliance and exclusivity.

The shape of these partnership arrangements is beginning to resemble a pure AI licensing model, with pharma companies now prioritizing the ability to take third-party model weights and fine-tune them using proprietary datasets on their own infrastructure.

There are obvious advantages to this approach, although it raises complex questions around the future ownership and usage rights for derived or modified models.

This dynamic holds a lot of promise, but it also carries risk. Fast-growth companies are scrambling to create the best models (with increasing specialization for a specific indication, therapeutic area or even specific protein), and to do so they must ingest huge volumes of high-quality data.

Depending on the model, this may include clinical trial data, real-world evidence, genomic data, electronic health records, and publicly available datasets. If this data is not “clean” (traceable, accountable, and compliant), it can introduce privacy and legal risk.

Another concern is secondary use, where AI models are trained on data collected from trials conducted before the technology existed—meaning the patient could not have explicitly consented to such use.

This raises difficult questions about whether original consent frameworks adequately cover the application of personal health data to train machine learning algorithms, particularly when those models may be commercialized or used in ways that were not contemplated at the time of data collection.

These concerns underscore the importance of data provenance—understanding where data comes from, how it was collected, and under what terms it can and can’t be used.

For companies on both sides of AI-pharma deals, rigorous data provenance practices are becoming essential to managing risk and ensuring long-term value.

WHAT DOES DATA PROVENANCE MEAN?

IBM defines data provenance as a historical record that details a data set's authenticity and integrity: who created it, the history of any modifications and who made those changes. In superhero terms, we might just refer to this as its origin story.

If the data is accurate and collected in compliance with all applicable laws at the time, it tends to meet legal and industry standards, while mitigating future use concerns. For data to be considered "clean" from a privacy standpoint, the data subject must have been provided the proper notice and consents.

These will vary by jurisdiction. In addition, the entire data handling chain must have been processed in accordance with applicable laws. That means appropriate records of processing, legal bases, and transfer mechanisms.

If data is later discovered to be "unclean"—as a result of improper collection or handling—researchers have a menu of unsavory options. The data can be permanently anonymized or de-identified, though this can render it useless for future research purposes.

Such anonymization may also be impossible with certain types of data, such as genetic data. In some cases, the only recourse has been to obtain new consents by locating patients and providing them with updated forms that explicitly describe data uses not contemplated in the original notice and consent documentation.

Intellectual property considerations also arise. Various types of intellectual property rights will protect the content used to train AI models. The processes involved in training an AI model will (absent the appropriate permission or an applicable defense or exception at law) amount to infringement of those rights.

Many pharma and biotech companies will have procured datasets from third-party providers, such as biobanks, research institutions or commercial data vendors.

These licensing arrangements may contain express or implied restrictions on some of the technical steps involved in developing or deploying AI models.

More existentially, the ownership and licensing provisions in those agreements require particularly careful consideration, as they may provide the data licensor with an argument to assert ownership over improvements and derivative works that are made using the licensed data. This would arguably include wider training datasets and even the resultant AI model itself.

These downstream complications underscore why thorough vetting of data provenance is critical during the due diligence phase. Undiscovered defects in data collection or handling (or their related consents and licensing terms) can significantly impair the value of a data asset, expose the acquiring party to regulatory risk, and necessitate costly remediation efforts that could have been identified and addressed previously.

WHAT IS 'SECONDARY USE', AND IS IT A CAUSE FOR CONCERN?

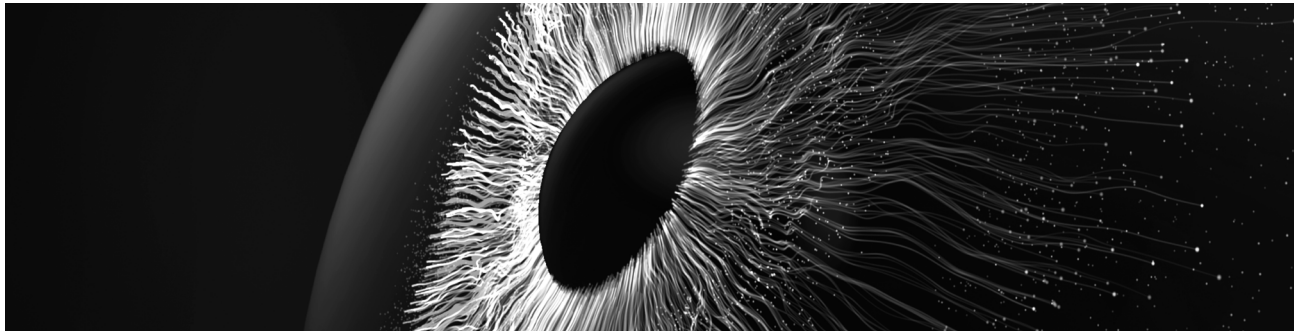
Most clinical trial consent forms include a standard disclosure authorizing secondary use, which is permission to use data for different but usually related future purposes, such as broader research applications.

The scope of this disclosure is relevant to assessing potential legal risks and compliance steps around use of data for AI purposes, whether as training data or as an input.

However, while such disclosures are standard, significant variation exists in how specific or broad they may be. We have observed that some early-stage and emerging growth companies sometimes take shortcuts on consent forms, relying on outdated, incorrect, or AI-generated templates.

The challenges are likely greater for older consent forms which would not have anticipated specific AI applications. While some of this data may be subject to public interest or research exemptions, these exceptions do not always provide enough comfort or latitude to use data in novel ways.

Following an acquisition, a buyer may need to locate patients to re-consent for secondary use, which can be time-consuming and uncertain.



GIVEN DATA PROVENANCE CONCERNS—WHAT SHOULD BUYERS ASK DURING DUE DILIGENCE?

Strategic buyers and investors should therefore vet data provenance when considering an acquisition or partnership.

During due diligence, they should probe whether the target has established robust privacy and AI governance processes around data collection and use. They should pay particular attention to data used to train AI models or that forms part of external databases from which the AI model can retrieve data to attach to a given prompt.

Key questions include whether the target has relied on publicly available datasets from bodies such as the FDA, which may carry fewer consent-related risks but still warrant scrutiny for accuracy and permitted uses; and, where the target has in-licensed data from third parties, the terms and scope of those licenses.

More broadly, buyers should also assess whether relevant data was collected in compliance with applicable laws (privacy and intellectual property) and whether AI models were trained on properly permissioned data.

It is important to understand whether the target has tracked risk exposure when models have ingested potentially unusable datasets; and considered the impact on model performance if corrupted or noncompliant inputs must be deleted.

Finally, buyers should evaluate whether appropriate cybersecurity measures are in place to protect models containing personal information, including access controls that limit both model access and output distribution to authorized personnel. This should be based on a detailed understanding of how the buyer intends to use the data after the acquisition.

The legal risks around AI are always driven by the use case. There is a big variation depending on the type of computational approaches that a buyer may intend to deploy, type of models, and type of development techniques. A buyer needs a legal team with deep understanding of AI technologies.

WHAT ABOUT DEALMAKING AND RISK?

Representations and warranties offer one mechanism for discovering specifics and possible shortcomings about data sets.

Purchase agreements should include representations confirming that the seller lawfully sourced or acquired the underlying data, holds all rights necessary to use that data in training AI models, and may transfer the data (and the corresponding model weights and code for the AI models) to the buyer.

Buyers should also seek confirmation that they may continue using the data for both intended and future purposes without obtaining additional consents or licenses.

Buyers can try to negotiate corresponding indemnities to further allocate risk, although these can be difficult to obtain. Indemnification provisions are particularly valuable where the target cannot fully substantiate data provenance.

Buyers may also consider whether escrow arrangements or purchase price adjustments tied to data quality—or contingent on completion of specified remediation steps—are warranted given the circumstances.

Buyers should recognize, however, that representations and warranties insurance may not provide complete protection, or any protection at all, for data-related defects. Coverage gaps are especially likely where representations are qualified by knowledge or materiality thresholds, or where disclosure schedules carve out specific data sets.

We are also seeing broad AI-related exclusions from policies, although the market is slowly moving to AI-specific cover. In practice, buyers should be prepared to undertake data remediation efforts post-closing and factor the potential cost of such efforts into their transaction analysis.

ARE THERE WORKAROUNDS WHEN IT COMES TO STRUCTURING A DEAL?

Sometimes you simply don't need the data. Some deals or agreements separate the intellectual property or assets from the underlying training data. While it's not always the case, it's worth exploring whether certain datasets are necessary to the overall value of the deal.

This approach may allow a buyer to purchase AI models or algorithms while leaving the underlying data with the seller, thereby reducing exposure to data provenance risks.

For instance, pharma companies are increasingly licensing AI models, but not the underlying data used to train the models. In principle, many AI experts argue that once a model is trained, it does not "store" the data.

This is a technical question at issue in multiple copyright lawsuits globally. EU privacy regulators have also addressed it, saying that the weights for an AI model can indeed be personal data to the extent they are a statistical representation of the underlying training data.

WHAT ARE THE MAIN REGULATORY FRAMEWORKS THAT APPLY?

Overlapping regulatory frameworks govern data use and protection, many of which predate the AI era and draw from established privacy principles.

There is increasing fragmentation globally, driven by geopolitics and diverse strategic objectives for different governments and policymakers.

The U.S. and the EU are now moving towards targeted AI-specific regulations and guidance, with early signs of harmonization.

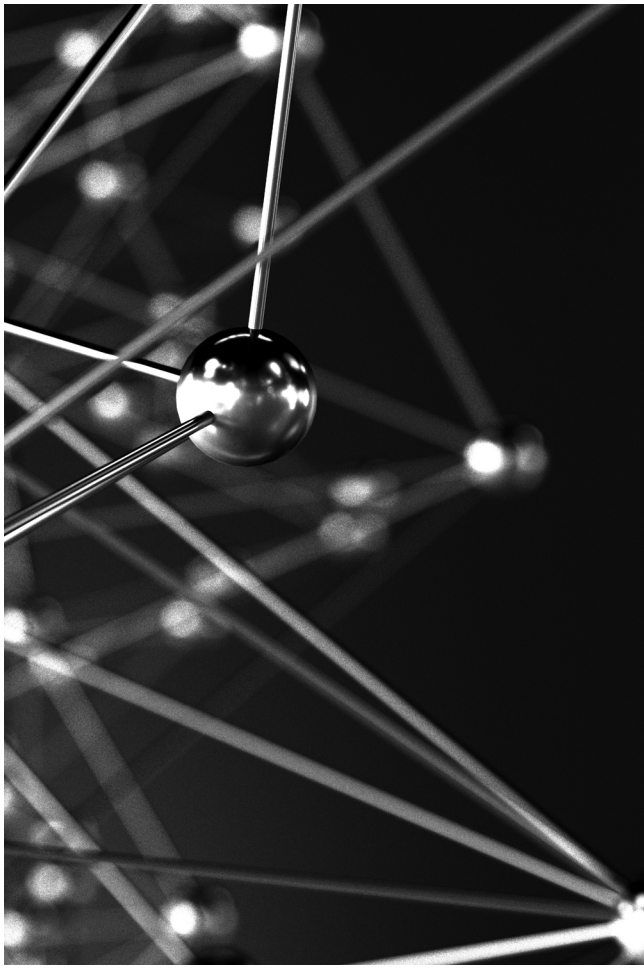
Accordingly, in January 2026, the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) jointly published Guiding Principles of Good AI Practice in Drug Development, which governs AI use from research to manufacturing as well as pharmacovigilance (drug safety monitoring).

Organizations operating in the U.S. must navigate an uncertain domestic landscape, complicating compliance.

At the federal level, legislative and executive priorities remain in flux and sometimes at odds—with one camp promoting AI dominance and another addressing safety concerns.

In the meantime, several states have enacted their own rules. The Trump Administration has signaled its intent to override or delay state-level AI regulations it views as obstructing national policy.

Historically, a significant portion of clinical trial data fell outside the scope of the Health Insurance Portability and Accountability Act (HIPAA), either due to how the trial was conducted or because an applicable exemption applied.



That calculus shifted as researchers increasingly turned to "real world" data sets derived from electronic health records, which fall under HIPAA. While such data can still be used, doing so requires additional processing—whether through de-identification, obtaining appropriate consents, or careful analysis of available exemptions.

Any such use of protected health information (PHI) to train AI models triggers the full suite of HIPAA obligations: the privacy, security, and breach notification rules all apply. Organizations deploying AI that touches PHI must execute a Business Associate Agreement (BAA) with their AI vendors, adhere to the "minimum necessary" standard, and implement robust technical safeguards such as encryption and access controls.

HHS will treat a vendor as a business associate based on the nature of the services it provides, regardless of whether a BAA is in place, and the covered entity bears most of the regulatory risk for failing to formalize the relationship.

In January 2025, the Food and Drug Administration (FDA) issued draft guidance outlining a risk-based framework for integrating AI and machine learning into drug development.

The guidance emphasizes several core principles: sponsors must clearly define the "context of use" for any AI model, conduct a structured risk assessment proportionate to the model's impact on regulatory decisions, and maintain transparency around model design and limitations.

Critically, the FDA underscores that data integrity remains foundational; organizations must be able to demonstrate that the data used to train and validate AI models is fit for purpose and sufficient to support claims of safety and efficacy.

The guidance makes clear that AI should augment, not replace, human expert judgment in drug development.

For dealmakers, this framework signals the types of documentation and validation processes that acquirers should expect to see (and diligence carefully) in any life sciences transaction involving AI-enabled research or development.

The EU AI Act represents the first effort to enact cross-sector harmonized AI-specific legislation, although its application to drug discovery is limited in practice. The EU appears to be loosening its most stringent AI rules in response to calls by the 2024 Draghi Report to boost Europe's global competitivity.

In any case, EU-sourced patient data is subject to GDPR, which remains the region's most relevant source of compliance requirements. This requires data controllers to have a lawful basis for processing personal data, which is not necessarily straightforward when originally collected for other purposes.

Health data is 'special category' data under the GDPR, requiring additional compliance measures, in particular under Article 9. This requires organizations to have secured explicit consent or demonstrate that it is necessary for research and statistics (narrowly construed) or public health.

Arguably the biggest GDPR hurdle is the purpose limitation, under which controllers are not permitted to use personal data for purposes that are incompatible with those for which the data was originally collected (secondary use).

Other key requirements include transparency (which raises complexities for some types of AI system or where the data has been aggregated with third-party data sources), data minimization (limiting the collection of personal information to what is directly relevant and necessary to accomplish a specified purpose), security, and strict cross-border transfer mechanisms.

The position under the UK GDPR is broadly equivalent, with nuances in the application and interpretation by local regulators.

To learn more about how EU and U.S. regulations impact M&A involving AI, please read this article.

TO WHAT EXTENT ARE REGULATORS THINKING ABOUT DATA PROVENANCE, AND IS THERE A RISK OF DISGORGEMENT?

In the U.S., disgorgement and data-destruction remedies are a growing risk for companies that improperly train AI models on healthcare data. While no regulator has yet imposed a major disgorgement penalty on a large-scale AI model, potential acquirers should consider this possibility.

The Federal Trade Commission (FTC) has applied disgorgement-style monetary penalties, substantial civil fines, mandatory deletion of improperly collected data, permanent prohibitions on sharing health information without explicit consumer consent, and injunctive relief.

Targets have included health-focused technology companies such as BetterHelp, GoodRx, Flo Health, and Kochava. The FDA has focused its own enforcement on product safety rather than data misuse, employing tools such as warning letters, injunctions, consent decrees, and product recalls.

It is unclear whether data provenance failures are insurable, though a buyer's representations and warranties may exclude or limit coverage for regulatory fines. If a target's executives were aware that data was improperly processed, acquirers could face difficulties recovering losses as well as fraud exposure.

In the cyber context, a hack could reveal shoddy data practices and require notification to authorities and data subjects. After an acquisition, this obligation often rests with the data owner, meaning an acquirer may need to contact data subjects with whom it has no relationship.

Regulatory risk can occur even without a data breach. In a worst-case scenario, models trained on unreliable, improperly weighted, or unlawfully obtained data could produce flawed outputs that inform clinical trial design or drug development decisions, potentially contributing to patient harm and product liability exposure.

ANY FINAL TAKEAWAYS?

Data provenance is a growing risk factor for large pharmaceutical companies seeking to acquire or partner with AI driven biotechs.

Smaller firms racing to scale datasets may rely on sources that lack full consent, robust documentation, or clear legal rights, which can leave a pharma company exposed to regulatory, operational, and reputational consequences.

Legal and compliance teams must learn the nuances of different AI technologies, frontier use cases and the factors that affect legal risk.

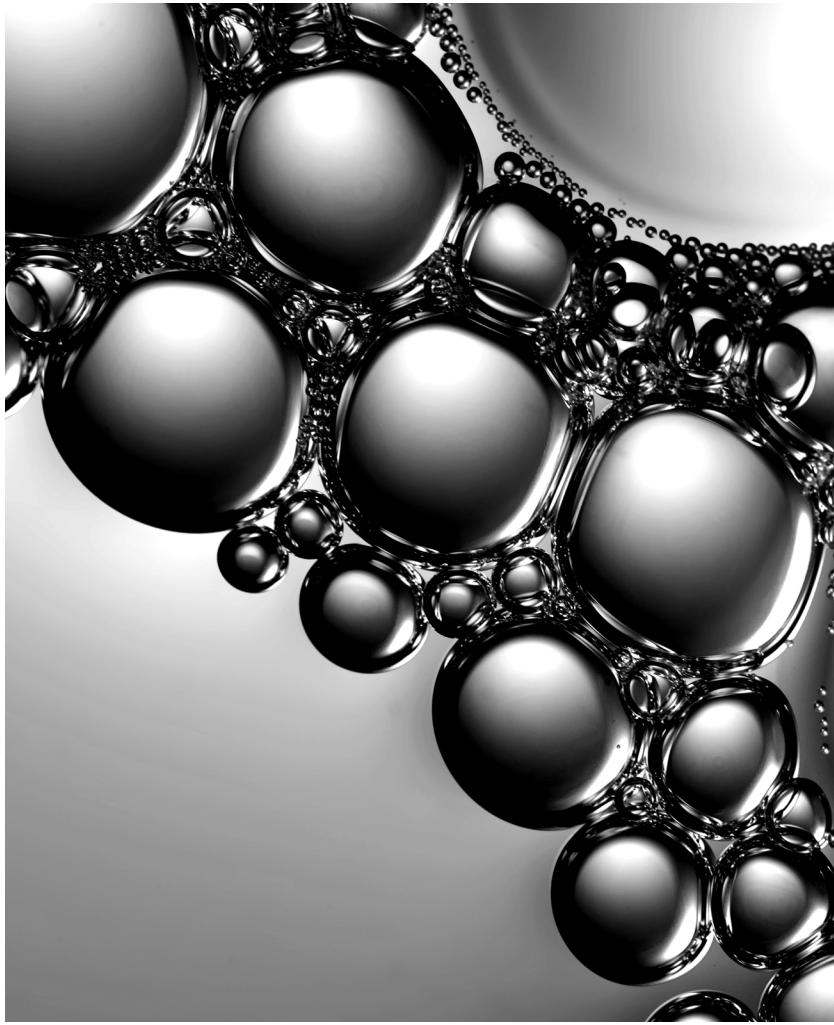
Depending on the model and use case, it may be appropriate to impose stringent provenance expectations during due diligence, scrutinizing sourcing and consent frameworks.

Strong AI-specific representations and warranties help to flush out information, and there is a growing toolkit of novel deal terms (including indemnities) to allocate data quality risks.

Our cross-practice and global AI Diligence Unit combines expertise in all relevant legal areas to deliver technology-led, efficient diligence on AI risks.

China's pharma innovators pursue a range of deal structures to *support global expansion*

Thanks to its scientific skills base, growing prowess in AI and a policy environment that supports rapid clinical trials, China has become one of the world's leading markets for pharmaceutical innovation. Here we explore how the country's pharma businesses are expanding internationally via out-licensing, partnership and NewCo deals—and the key legal and regulatory angles involved in these diverse transaction structures.



AUTHORS

Jill Ge
Partner

Paul Jing
Counsel

In recent years, Asia has emerged as a nexus of life sciences innovation. According to research, the region once known primarily as a manufacturing hub is now responsible for 43% of the world's innovative drug pipeline, up from 28% in just five years. In 2024 nearly two-thirds of biotech patents were granted in Asia, five times the proportion emanating from Europe.

MARKET DYNAMICS CREATE CONDITIONS FOR RAPID INNOVATION

At the center of this wave of innovation sits China, which now generates 29% of the world's innovative pipeline. The country's huge scientific skills base, dense patient pools, sophisticated network of contract research organizations (CROs) and contract development and manufacturing organizations (CDMOs), and favorable policy environment, underpin a drug development lifecycle that is significantly faster than the global average. China's growing prowess in artificial intelligence, supported by the state government's drive to deploy AI across industries through initiatives such as its AI+ Program and its 15th Five Year Plan provides further momentum for therapeutic discoveries.

WHY CHINA LEADS THE WORLD IN CLINICAL TRIAL VELOCITY

Amendments to China's Drug Administration Law established a 60-working-day implicit approval schedule for clinical trials (which had been further shortened for novel medicines) and set caps on the duration of regulatory reviews.

This, coupled with significant state investment—including in the country's Center for Drug Evaluation, part of China's National Medical Products Administration (NMPA)—has delivered dramatic results. China now conducts more clinical trials than the United States, while in 2024 the NMPA approved 83 new drugs compared with the 50 consents granted by the U.S. Food and Drug Administration (FDA). The time it takes to review a new drug in China fell from 663 days in 2017 to 105 days in 2024, far faster than the FDA average of 356 days.

The country's drug approval process—including in relation to clinical trial standards, the use of real-world evidence, electronic submissions and safety and efficacy protocols—has become more closely aligned with international standards since China joined the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) in 2017. The NMPA also supports China's involvement in multi-region clinical trials (MRCTs), further cementing its integration into the global pharma supply chain.

These developments have fueled Chinese innovation in therapeutic areas, including oncology—where it is a leader in the development of novel antibody-drug conjugates (ADCs)—immunology and metabolic disease.

DOMESTIC INNOVATORS PURSUE DIFFERENT OPTIONS TO FINANCE INTERNATIONAL GROWTH

While Chinese innovators have proved successful at generating promising new discoveries, the country's domestic capital markets have not been able to fully support their international expansion. As a result, Chinese pharma companies are increasingly pursuing strategic partnerships, joint ventures and out-licensing deals as a way to access new financing and build ties with global players who can support the development of their portfolios.

Asian businesses were responsible for almost 25% of global pharma out-licensing deals in 2024. Those originating in China generated USD800 million in advance payments, up from less than USD100m in 2020.

Chinese out-licensing transactions often involve molecules, early-stage drug candidates or discovery platforms, with the IP holder licensing to a foreign partner either the global or regional rights to further develop, manufacture and commercialize its innovations.

In return the licensor generally receives upfront payments to cover R&D costs and/or milestone payments and royalties on future ex-China sales, and in most cases retains its rights to commercialize the final product inside China. By going down this route, the licensor avoids the need to invest in production facilities, regulatory expertise and marketing capabilities outside its home market. Notably, a licensing deal with a reputable multinational can validate the licensor's science and pipeline, enhancing its reputation with investors and future partners both in and outside China.

PANEL: RECENT CHINESE OUT-LICENSING DEALS

DEAL	DETAILS
AstraZeneca/ Jacobio Pharma December 21, 2025	Jacobio will receive an upfront payment of USD100m and is eligible for additional development and commercial milestone payments of up to USD1.915bn, as well as tiered royalties on net sales achieved outside China. AstraZeneca will be responsible for all clinical development, regulatory submissions, and commercialization activities for JAB-23E73 (a pan-KRAS inhibitor) outside of China.
Novartis/Argo September 3, 2025	Argo will receive an upfront payment of USD160m and is eligible to receive potential milestone and option payments of a combined potential value of up to USD5.2bn, as well as tiered royalties on commercial sales. In addition, Novartis has expressed its non-binding intention to participate in Argo's next round of equity financing.
Merck KgaA/Biocytogen September 3, 2025	Biocytogen will provide proprietary, fully human antibodies derived from its RenMice platform for evaluation in Merck KGaA's antibody-conjugated LNP services. Merck KGaA has been granted an exclusive option to acquire rights to selected antibody assets in return for fees and royalties on sales and sub-licenses.
Sanofi/Visirna (a subsidiary of Arrowhead) August 1, 2025	Sanofi will acquire rights to develop and commercialize investigational plozasiran, Arrowhead's first-in-class RNA interference (RNAi) therapeutic candidate designed to reduce production of apolipoprotein C-III (APOC3) as a potential treatment for familial chylomicronemia syndrome (FCS) and severe hypertriglyceridemia (SHTG), in Greater China. Visirna will receive an upfront payment of USD130m from Sanofi. In addition, Visirna will be eligible to receive further milestone payments of up to USD265m upon approval of plozasiran across various indications in mainland China. Arrowhead is further eligible to receive royalties on net commercial product sales in Greater China as part of the Arrowhead-Visirna license which was assigned in part to Sanofi.

UPTICK IN STRATEGIC PARTNERSHIPS AND NEWCO DEALS

We are also seeing a rise in joint ventures (JVs) and collaboration deals between Chinese pharma companies and foreign parties, who share risk on co-development projects and cooperate to facilitate global clinical trials, among other things. When structuring these collaborations, parties would typically factor in geopolitical, regulatory and tax risks, and their impact on future supply chain stability and cost efficiency.

A third growth model involves mainland Chinese pharma companies incorporating NewCos outside the country—often in the Cayman Islands—into which they license ex-China intellectual property (IP) rights as a way to access international financing. This strategy, known as the "Spin-off NewCo" or "NewCo" model, has gained significant traction as a hybrid structure that sits between a traditional out-licensing deal and a full corporate spin-off. For companies with deep pipelines, the structure allows management to focus internal resources on priority programs while monetizing non-core or earlier-stage assets through external capital.

These arrangements often work best for larger businesses with extensive drug pipelines but can be more complicated in certain scenarios, for example if they rely on the parent company's platform technology.

The Chinese company will often retain an equity stake in the NewCo, with foreign venture capital firms, private equity investors, or licensees funding the development and commercialization of the in-licensed IP. This model offers advantages to the Chinese company over standard out-licensing deals, where royalties and milestone payments are contingent on the successful commercialization of products over which the originator has limited control. NewCo structures also offer Chinese companies that retain equity stakes the possibility of financial upside through an eventual strategic sale or IPO.

Here, Hong Kong listings are supported by Chapter 18A of the Hong Kong Stock Exchange (HKEX) listing regulations, which provides an established route for pre-revenue biotech companies to source equity financing. HKEX is now the second largest biotech funding platform globally, with more than USD17bn raised in 80 biotech IPOs since Chapter 18A was introduced in 2018.

PANEL: HKEX BIOTECH IPOS, SECONDARY PLACEMENTS AND DUAL LISTINGS

Insilico Medicine listed in Hong Kong in December 2025, becoming the first AI-driven biotech company to go public on the main board of the HKEX. The IPO raised a total of HKD2.27bn (USD291m) and was backed by investors, including Eli Lilly and Tencent.

Hengrui listed in Hong Kong in May 2025, raising HKD9.89bn (USD1.26bn). At the time, the deal was the biggest healthcare IPO in Hong Kong in nearly five years.

DualityBio debuted on the HKEX with a HKD1.64bn (USd211.4m) IPO in April 2025, making it one of the biggest offerings made under the HKEX's Chapter 18A regime since 2020.

Ascentage has been listed on the HKEX since 2019 and in January 2025 listed on the NASDAQ in a USD126.4m IPO.

3SBio raised HKD3.12bn (USD401m) in December 2025 through a new share placement. Funds raised from the sale will largely be used for research and development. The company is partnered with Pfizer in China.

Biocytogen listed on the Shanghai Stock Exchange STAR Market in December 2025. The listing followed the Company's flotation on the HKEX in September 2022 and established Biocytogen as the first "H+A" (i.e., Hong Kong and Mainland China) dual-listed global drug innovator.

WHAT DO PARTIES NEED TO CONSIDER IN CHINA-RELATED PHARMA DEALS?

The legal and regulatory framework surrounding China-related out-licensing, partnership and NewCo deals is complex. Where substantive pipeline assets are transferred outside of China in NewCo transactions, or in co-development deals where the parties may want to export improved technologies, China's technology export regulations may apply. Some tech exports are prohibited altogether (e.g., cell cloning and gene editing technologies applied to humans), while the export of "restricted technologies" requires a government license (though these are less relevant to biotech transactions). Notably, while the registration of agreements involving the export of "freely exportable technologies" is voluntary from a legal standpoint and not required for technology export purposes, PRC banks may in practice require evidence of a registered license agreement with the local Ministry of Commerce (MOFCOM) to process cross-border remittance of funds such as milestone payments and royalties. The registration process is relatively streamlined, though the specific documentary requirements for foreign exchange processing will depend on the practices of the relevant bank.

Chinese ownership of equity in foreign NewCo vehicles is subject to the country's outbound direct investment (ODI) framework, which requires approvals or filings with various government ministries, including the National Development and Reform Commission (NDRC). We have seen ODI processes suspended during tariff negotiations, while Chinese companies also need foreign exchange approvals to remit funds required for operations overseas.

CROSS-BORDER DATA TRANSFERS AND GEOPOLITICAL IMPLICATIONS

Data transfers are another important consideration. Cross-border life sciences transactions invariably involve the transfer of data during transactional due diligence and transition services, while such transfers will be ongoing in strategic partnerships.

Here, the global legal and regulatory environment is evolving rapidly and is heavily influenced by geopolitics. Countries including the U.S., the UK and certain EU member states have designated pharma supply chains as critical national infrastructure following interruptions to the supply of active pharmaceutical ingredients (APIs) and medicines during the COVID-19 pandemic and in response to more generalized geopolitical tensions. Against this backdrop, biotechnology, AI and health data are also now protected by many nations as a matter of national security. As a result, FDI and national security screening processes (such as that administered by the Committee on Foreign Investment in the United States) may apply, alongside other measures such as the U.S. government's America First Investment Policy, which imposes restrictions on U.S. outbound investments into China in areas including artificial intelligence and biotechnology.

NAVIGATING CHINESE EXPORT REGULATIONS ON HEALTH DATA AND HUMAN GENETIC RESOURCES

In the pharma sector, parties need to navigate the Chinese government's regulations on the export of clinical data and human genetic resources, among other things.

In NewCo deals where the intention is to eventually seek marketing authorization for drug sales in the U.S., a range of data will need to be made available to the U.S. authorities. If this information is held by the originator inside China, information sharing provisions between the Chinese company and the NewCo will need to be carefully constructed from the outset.

Exporting the personal health data of Chinese citizens requires either a security assessment arranged by the PRC's Cyberspace Administration or for the transfers to be conducted under contracts approved by the Chinese authorities. From a diligence perspective, the consent documentation underlying any cross-border data transfers should be reviewed and validated. For example, where a PRC licensor/target has obtained only generalized consent (such as consent to share data with unspecified overseas "partners") without expressly identifying the overseas recipient and providing the requisite information, the consent may be defective under PRC data regulations and may limit the foreign acquiror/licensee's ability to use the data.

Where human genetic resources (e.g., organs, tissues and other genetic materials) and related data (i.e., data generated by performing processes on human genetic resources, which includes genetic information, among other things) are involved, specific approvals/filings are required for exports.

In some instances, extra security reviews may apply, while data privacy regulations may also require parties to obtain additional consents from data subjects for cross-border transfers (which could be challenging to secure where clinical trial data is concerned). The time it takes to get the relevant authorizations needs to be factored in to deal strategy.

ROBUST INTELLECTUAL PROPERTY DILIGENCE IS A CRITICAL CONSIDERATION

Another key area of focus in China-related pharma deals is IP. When negotiating licensing deals, it is common for parties to focus their attention on IP licensing terms and the technical and commercial aspects of the underlying assets. However, IP ownership is equally important and sometimes overlooked.

Here, licensors may have jointly developed therapies or platforms with other parties and may also have jointly registered patents. And as Chinese innovators pursue different avenues to raise financing and commercialize their portfolios, the structure of their businesses may evolve rapidly. The implications of these reorganizations on IP rights require careful scrutiny.

More broadly, as China's pharmaceutical industry shifts from generics to innovative drugs, Chinese companies face increasingly severe challenges in IP protection and risk management. Many domestic innovators adopt a "fast follow" strategy, with products that closely resemble those of international leaders but lack sufficient differentiation. This not only weakens market competitiveness but also creates potential IP infringement risks that could ultimately prevent commercialization of products with considerable clinical promise.

As the volume of overseas deals involving Chinese innovative drugs continues to rise, disputes over new drug R&D are also on the up, with IP and compliance at the core of these challenges. Compared to mature multinational pharma businesses, Chinese drug companies lag behind in terms of patent strategy and IP risk management. This has led to frequent setbacks as they seek to expand overseas. In addition, trade secret disputes have become a major legal risk for Chinese innovators in the sector, particularly where key personnel have moved between competitors.

With this in mind, comprehensive due diligence on IP rights is vital to secure value in the deal. This analysis should be tailored to the assets and targets in question, which requires sophisticated in-market advice. Given these dynamics, it is prudent for potential investors and partners to pay close attention to patent and IP due diligence from the outset, and related risk assessments should be conducted holistically and thoroughly.

Medical devices— EU Commission proposes *MDR and IVDR revision*

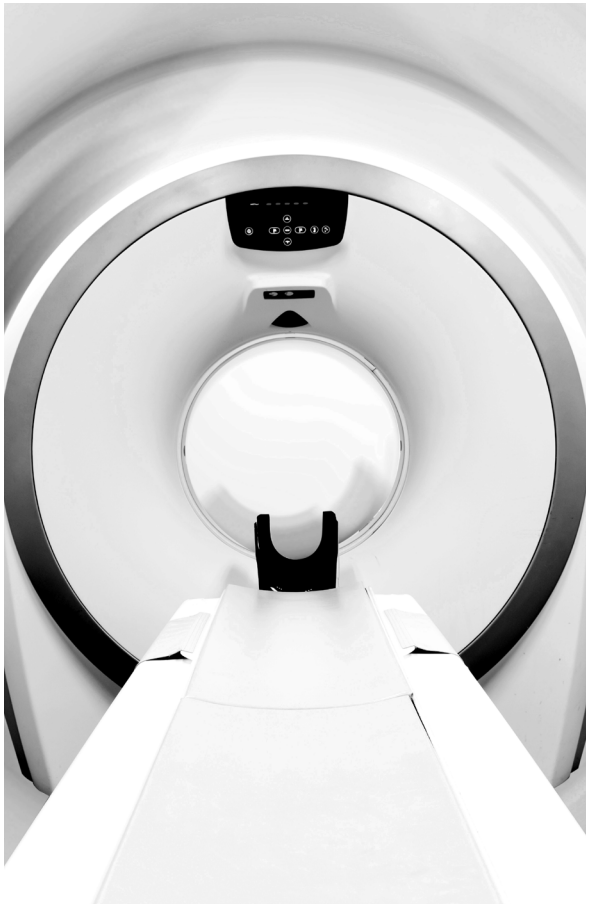
The EU Commission published its 170-page proposal on revisions of the Medical Device Regulation (EU) 2017/745 (MDR) and the In Vitro Diagnostic Regulation (EU) 2017/746 (IVDR) on December 16, 2025, which can be accessed here. After MDR and IVDR became applicable in 2021/2022, medical device manufacturers and Notified Bodies continued to struggle with the challenges resulting from the new regulatory framework. The transitional periods under the MDR and IVDR have been extended several times due to ongoing capacity bottlenecks of the Notified Bodies. This has not, however, been sufficient to tackle the remaining challenges.

AUTHORS

Eda Zhuleku
Counsel

Florian Preinfalk
Associate

The EU Commission's proposal aims to streamline and future-proof the regulatory framework for medical devices and IVDs in order to prevent supply shortages and products being taken from the EU market, while still maintaining a high level of public health protection.



KEY ASPECTS OF THE PROPOSAL INCLUDE:

Measures to simplify regulatory requirements and reduce administrative burden

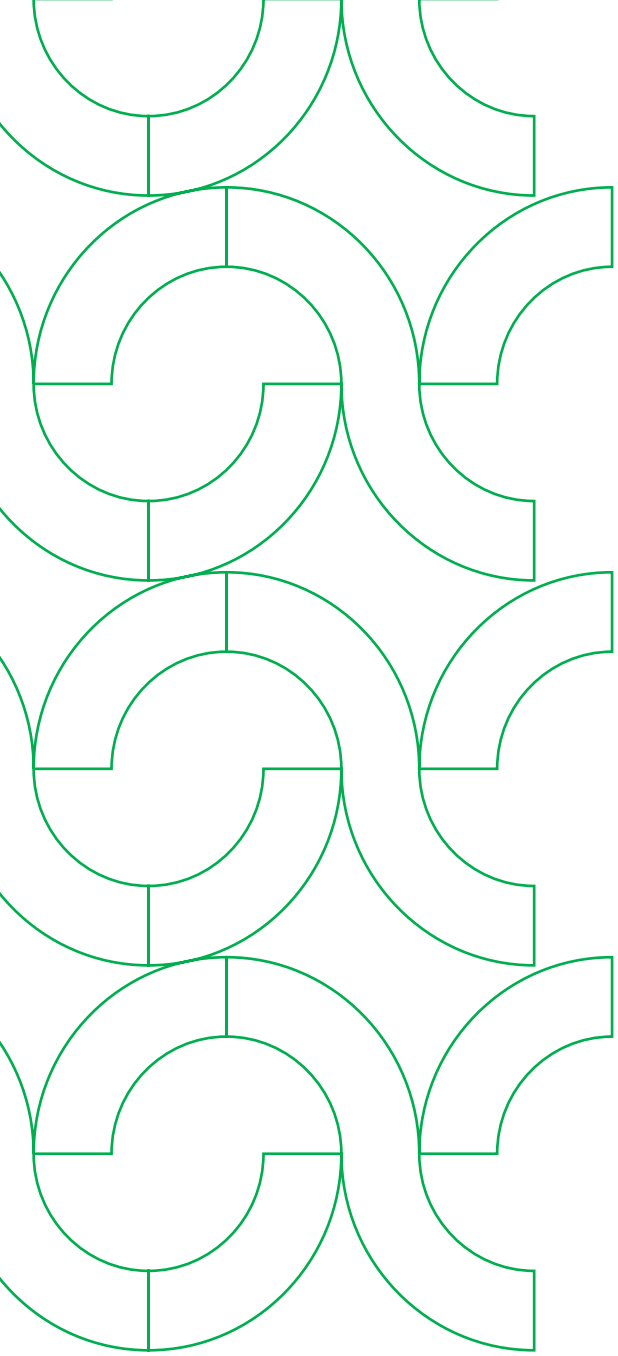
- **Validity of certificates**: The current maximum validity of Notified Body certificates of conformity of five years would be removed so that certificates are generally not limited in time. Notified Bodies would, however, still be entitled to define a maximum validity based on duly justified grounds and would carry out periodic reviews proportionate to the risk class of the respective device.

- **Classification rules**: The proposal includes changes to the classification rules under the MDR. For example, the proposal suggests that all reusable surgical instruments are classified as Class I, regardless of the body part with which they come into contact. Furthermore, the classification rule for software would be amended, which could lead to significantly more software being classified as Class I.

- **PRRC**: Requirements regarding the person responsible for regulatory compliance (PRRC) would be alleviated. In particular, the detailed qualification requirements for the PRRC would be removed and micro and small enterprises (less than 50 employees and less than EUR10 million in turnover or balance sheet) would not be required to have their external PRRC "permanently and continuously" available.

- **Post-market surveillance**: The frequency with which the PSUR has to be updated would be decreased (for example for Class III or IIb devices from at least annually at present to once in the first year after certification and every two years thereafter). The reporting timeline for serious incidents that are not related to public health threats, death or serious deterioration of health would be expanded from 15 days to 30 days.

- **Well-established technology devices**: The proposal suggests more proportionate requirements for "well-established technology devices" (defined based on certain criteria such as having a simple, common and stable design and not being associated with safety issues in the past). Such devices would, *inter alia*, be exempted from the requirements to draw up a summary of safety and clinical performance, as well as to have the periodic safety update report (PSUR) reviewed by a notified body.



Measures to support innovation

- **In-house devices**: The proposal suggests providing more flexible conditions for in-house devices (devices manufactured or modified by a health institution and used exclusively within that same facility). In particular, in-house IVDs would no longer be subject to the condition that no equivalent device is available on the market, certain documentation requirements would be removed and the transfer of in-house devices to another health institution would be possible in duly justified cases. Furthermore, the proposal intends to expand the scope of in-house devices to cover laboratory-developed tests of central laboratories exclusively used for clinical trials.

- **Breakthrough and orphan devices to be prioritized**: The proposal introduces criteria for breakthrough devices (devices with a high degree of novelty and a significant clinical impact for a life-threatening or irreversibly debilitating disease) and orphan medical devices (intended for the treatment, diagnosis, or prevention of a disease or condition that affects not more than 12,000 individuals in the Union per year and for which either (i) insufficient alternatives are available or (ii) the device provides a significant clinical benefit). Once designated by an expert panel, breakthrough devices and orphan devices could benefit from prioritized conformity assessment procedures and the option of a rolling review. Orphan devices CE marked under the previous Directives would benefit from additional grandfathering provisions.

- **Derogations from conformity assessment procedures**: In addition to the current possibility for national competent authorities to authorize the placing on the market of non-CE-marked devices in the interest of public health or patient safety or health, the proposal would entitle the EU Commission to authorize the placing on the market in the event of a public health emergency at Union level and the national competent authorities to authorize deviations from the requirements related to changes to manufacturing, design or intended purpose in the event of serious cross-border health threats, disasters or crises.

- **Regulatory sandboxes**: The proposal suggests the introduction of regulatory sandboxes (controlled environments for the development, testing, validation and use of innovative products or technologies under regulatory supervision). These sandboxes can be established by the EU Commission or the Member States to address the needs of innovative and emerging health technologies.

Measures to ensure availability of devices

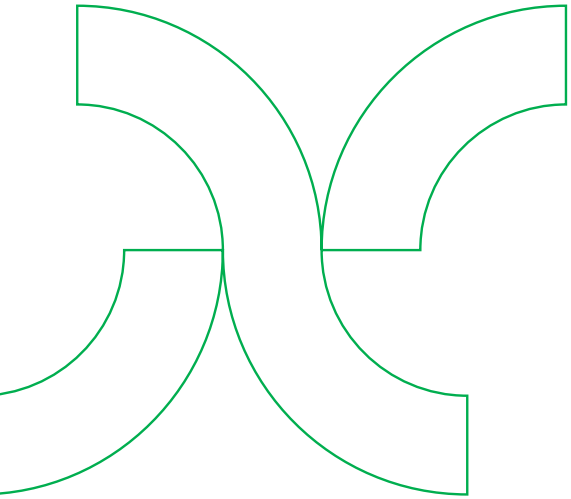
- **Critical devices**: The proposal suggests establishing an IT tool for information exchange regarding the interruption or discontinuation of supply of critical devices. The European Medicines Agency (EMA) would create a list of critical devices which are subject to such an information obligation.

- **International cooperation**: The proposal provides for increased international cooperation, for example through the EU Commission participating in international programs such as the Medical Device Single Audit Program (MDSAP) and in bilateral or multilateral reliance mechanisms or reliance programs, potentially providing significant benefits for medical device manufacturers.

Measures to increase predictability and cost-efficiency

- **Notified body timelines and fees**: The proposal suggests Notified Body fee reductions for micro and small enterprises as well as for orphan devices. In addition, the EU Commission has recently published another draft Implementing Regulation (see here) to create uniform requirements for conformity assessment procedures, including cost transparency and maximum timelines.

- **Notified body involvement**: Overall, the proposal intends to reduce notified body involvement in the conformity assessment procedures for medium-risk devices (e.g., by reducing the assessment of the technical documentation to one representative device of a category of devices/generic device group for Class IIa/IIb medical devices and Class B/C IVDs). Notified Bodies would be entitled to carry out remote audits instead of on-site audits.



Measures to improve interplay with other EU legislation

- **AI Act**: Under the proposal, most requirements for high-risk AI systems under Regulation (EU) 2024/1689 (AI Act) would become inapplicable for AI medical devices to avoid overlaps. The EU Commission would, however, be entitled to lay down specific requirements for AI-based devices via implementing or delegated acts, leaving some uncertainties.

- **Combined studies**: The proposal provides for a single application and coordinated assessment for clinical studies involving medicinal products, medical devices and/or IVDs.

- **Cybersecurity**: The proposal clarifies the interplay with Regulation (EU) 2024/2847 (Cyber Resilience Act). Currently, cybersecurity-related incidents that do not concern public health or patient safety are not reported, as medical devices are exempted from the scope of the Cyber Resilience Act. According to the proposal, cybersecurity vulnerabilities and severe incidents would have to be reported to the computer security incident response teams (CSIRTs) and to the European Union Agency for Cybersecurity (ENISA). Cybersecurity requirements would become part of the general safety and performance requirements.

CONCLUSION

The long-awaited proposal by the EU Commission constitutes a crucial step towards a future-proof regulatory framework for medical devices in the EU which maintains the high level of public health protection introduced by MDR/IVDR but avoids an unnecessary regulatory burden for the medical device industry, which largely consists of small and medium-sized enterprises.

The proposal will have to pass the EU Parliament and the Council of the EU before it can enter into force. The forthcoming negotiations between the European Parliament and the Council might refine several aspects of the proposal, particularly those relating to classification rules or the interactions with the AI Act. However, since the EU Parliament had already asked the EU Commission to propose “a systematic revision” of MDR/IVDR in a resolution in October 2024, it can be expected that the proposed amendments to the regulatory framework will be generally aligned with the legislators’ expectations.

Manufacturers, Notified Bodies, and health institutions should begin assessing how the proposed amendments may affect their regulatory strategies, including device classification, pathways and timelines for conformity assessment as well as post-market surveillance systems. Currently, stakeholders have the opportunity to submit their feedback during the next eight weeks, which will contribute to the further legislative process.

The EU Commission currently expects the new regulatory framework to be adopted and to become applicable by Q2 2027.

Two years on from its launch, how has the UPC impacted European Patent Litigation in the *life sciences sector?*

The UPC has been reshaping European patent litigation since its launch in June 2023. More than 480 patents have now been litigated in the court, and the number of actions is steadily increasing[1]. Initially, major pharmaceutical players were reluctant to risk the revocation of key patents in an untested pan-EU system. More recently, life sciences and medtech companies have been trialing UPC proceedings, no doubt encouraged by their efficient case management and well-reasoned and often patentee-friendly decisions. We expect this trend to continue as the Court of Appeal issues further harmonizing guidance on key substantive patent issues. In this overview we explore some of the key aspects and decisions of the UPC, and how they affect the life sciences industry.

AUTHORS

Frits Gerritzen
Partner

Stephan Neuhaus
Partner

Teresa Limberg
Associate

Beverley Potts
Senior *Knowledge Lawyer*

Marie Barani
Knowledge Lawyer

[1] The UPC local divisions have had more than 690 infringement actions, 350 counterclaims for revocation, and 125 actions for provisional measures; the central division has had 120 standalone revocation actions and the Court of Appeal 300 appeals (UPC Docket Navigator, February 2, 2026).

STATE OF PLAY ON PATENT VALIDITY?

The UPC has developed its own approach to patent validity, in particular claim interpretation, inventive step, added matter, sufficiency, and plausibility.

Claim interpretation

In NanoString Technologies v 10x Genomics[2], the UPC Court of Appeal held that, although the claims are the starting point for patent interpretation, their meaning must always be determined in light of the description and drawings. This isn't restricted to cases of ambiguity—claim construction is a holistic exercise carried out through the eyes of the skilled person. In G 1/24[3], the Enlarged Board of Appeal (EBA) of the European Patent Office (EPO) endorsed this principle, resolving diverging EPO case law and emphasizing the need for consistency with UPC and national court practice. This contributes to greater legal certainty and harmonization across Europe.

The Court of Appeal has also reaffirmed[4] that claim interpretation is a matter of law to be assessed by the Court, not by party-appointed experts. The Court emphasized that the "person skilled in the art" is a notional legal construct, representing the general specialist knowledge, experience, and abilities customary in the relevant technical field, rather than the knowledge of any particular individual or expert. While expert opinions may be considered, the Court must independently construe the claims, taking into account the understanding of a notional "person skilled in the art". Please see our more detailed article on this issue.

Inventive step

Two coordinated decisions issued by the (at that time) two different panels of the UPC Court of Appeal have clarified the court's holistic approach to inventive step[5].

First, the objective technical problem (or inventive concept) is defined by assessing the claim as a whole and not its individual features, in light of the description and drawings. To avoid hindsight, this should not include pointers to the claimed solution such as naming the already-patented medicine[6].

An invention will be considered obvious if the person skilled in the art without inventive skill or imagination would have arrived at the claimed solution as a next step, either prompted by a pointer or motivation from a realistic starting point in the prior art, or as a matter of routine. There can be more than one realistic starting point, and the invention should be inventive in view of each of them. It is a "would not could" approach. There must be a reasonable expectation of success or predictable results—the mere feasibility of an option or the fact that other teams were working on the same project are not sufficient for an invention to be obvious. For claims in "medical use" format, the expectation needs to be of an effective treatment that has a meaningful therapeutic effect, not just some degree of biological effect.

Overall, the approach seems to be in line with EPO and national (such as German or Dutch) practice. It requires the party seeking to revoke the patent to establish that any next steps required from the prior art would be predictable or carried out with a reasonable expectation of success.

Patentees can defend the inventiveness of patents by demonstrating that the research required to undertake the next step from the prior art was unattractive or uncertain at the priority date, or that it would be costly, involve practical or technical difficulties, or have a reasonable failure rate.

The UPC's view on whether or not the fact that a clinical trial is being conducted is a sufficient indicator of an expectation of success is still evolving. Contrary to the EPO Board of Appeals[7], the LD Munich has ruled that a phase III clinical trial near completion, with no interruption or discontinuation, may constitute a reasonable expectation of success[8].

You can read more on the UPC's approach to inventive step in our previous article.

[2] UPC_CoA_335/2023.
[3] G 0001/24.
[4] Insulet v EOFlow UPC_CoA_768/2024.
[5] Meril/Edwards Lifesciences, UPC_CoA_464/2024, UPC_CoA_530/2024, UPC_CoA_21/2025, UPC_CoA_457/2024, UPC_CoA_532/2024, UPC_CoA_27/2025, UPC_CoA_458/2024, UPC_CoA_533/2024; Amgen/Sanofi, UPC_CoA_528/2024, UPC_CoA_529/2024.
[6] Sanofi /Stadapharma, Reddy Pharma, Zentiva, UPC_CFI_146/2024, UPC_CFI_496/2024, UPC_CFI_147/2024, UPC_CFI_374/2024, UPC_CFI_148/2024, UPC_CFI_503/2024.
[7] T 136/24.
[8] Sanofi/Stadapharma, Reddy Pharma, Zentiva, UPC_CFI_146/2024, UPC_CFI_496/2024, UPC_CFI_147/2024, UPC_CFI_374/2024, UPC_CFI_148/2024, UPC_CFI_503/2024.

Added matter

The UPC Court of Appeal, in another life sciences case[9], confirmed that each patent claim must be directly and unambiguously derivable from the original application as filed. Implicit disclosure and clear and unambiguous consequences of explicit disclosure may be relied upon, but the wording must not convey additional technical information beyond the teaching or original filing. The UPC accepts implicit technical features where the person skilled in the art would recognize them from the technical context and language of the application (e.g., the Court of Appeal has checked how a sensor must be positioned based on the language of the claim and the description[10]). Hence, patentees should only rely on the original language and the technical disclosures in the original patent description. Whether the UPC will take a strict approach to added matter, as the EPO does, or will be more lenient, for example the German courts, is still to be seen.

Sufficiency

The UPC Court of Appeal[11] has advocated a holistic assessment to sufficient disclosure and determined that the decisive factor is whether or not the patent, read as a whole and considering general technical knowledge, enables a person skilled in the art to reproduce the invention without undue burden, even if this requires a reasonable amount of trial and error. Laborious, time-consuming, and/or demanding methods do not automatically constitute an unreasonable burden, because occasional failures must be accepted as part of scientific work, especially in life sciences. The disclosure does not have to cover "each and every" embodiment of functional claims—the non-availability of some variants is immaterial if suitable embodiments can be obtained by the skilled person. Fair protection extends to equally effective variants of the disclosed embodiments, even if those variants would not have been envisaged without the invention.

[9] Amgen/Sanofi, UPC_CoA_528/2024, UPC_CoA_529/2024.
[10] Abbott Diabetes Care/Sibio, UPC_CoA_382/2024.
[11] UPC_CoA_528/2024.

WHAT DO UPC RULINGS MEAN FOR PROVISIONAL MEASURES CONCERNING THREATENED INFRINGEMENT?

Imminent infringement

The UPC has clarified the requirement for an imminent infringement for PIs, both for medicines and medical devices.

The Court of Appeal considers that completion of administrative procedures for a generic medicine, such as pricing and reimbursement procedure or health technology assessment, can evidence a risk of imminent infringement before launch, provided that the patent-holder demonstrates that this enables commercialization without the need for further steps, and the only reason for taking such steps is to offer the generic medicine[12]. Click here for further details.

Obtaining and announcing a CE mark for a medical device is insufficient in itself, but when paired with marketing steps, such as providing ordering information and demonstrating products at a trade fair, it may establish a risk of imminent infringement justifying a PI. You can read more on imminent infringement[13] in our previous article.

Inspection and preservation of evidence

The UPC has shown a readiness to grant ex parte provisional measures for inspection and preservation of evidence, months in advance of the launch of a potentially infringing product, and before trade fairs. The patent-holder needs to demonstrate:

- a high likelihood of validity (for example, maintenance of the patent in an EPO procedure)[14] and infringement (for example by acquiring an identical product commercialized outside of UPC territories[15] or a biosimilar referring to the reference medicine[16]). The LD Brussels considers that the threshold is lower in these applications than in a case on the merits or a request for preliminary injunction[17]; and

- that evidence is likely to disappear or otherwise cease to be available (for example, because the information might cease to be available at the defendant's premises after starting proceedings on the merits, and it is at least not common to seize the dossier held by the European Medicines Agency (EMA) at the EMA administrative office)[18].

According to the LD Brussels, urgency is not a compulsory condition but left to the court's discretion. If there is a risk of evidence being destroyed, an ex *parte* measure should be ordered, even without urgency. On the other hand, urgency may be of paramount importance for an order being made ex *parte*, e.g., when products are presented at trade fairs or when the marketing authorization for a biosimilar has been granted and the company makes various declarations referring to an imminent product launch[19]. The LD Brussels also considered the proportionality of the measures: access to evidence may be limited to parties' representatives and access to non-UPC territory materials (e.g., FDA submissions) is refused. Security may be required for measures to preserve evidence.

[12] Boehringer v. Zentiva, UPC_CoA_446/2025, UPC_CoA_520/2025.
[13] Occlutech/Lepu Medical, UPC_CFI_553/2025.
[14] Genentech, F. Hoffmann-Laroche/Organon, UPC_CFI_407/2025, UPC_CFI_408/2025.
[15] LiNAMedical AG/Shutz Medical, UPC_CFI_1598/2025.
[16] Genentech, F. Hoffmann-Laroche/Organon, UPC_CFI_407/2025, UPC_CFI_408/2025.
[17] Ibidem.
[18] Genentech, F. Hoffmann-Laroche/Organon, UPC_CFI_407/2025, UPC_CFI_408/2025.
[19] Genentech, F. Hoffmann-Laroche/Organon, UPC_CFI_407/2025, UPC_CFI_408/2025.

WHAT HAS THE UPC HELD ON MEDICAL DEVICES AND INFRINGEMENT?

The UPC has held that there can still be an infringement even if customers do not normally use the patented infringing element of a medical device and the device manufacturer specifies a different use of its device. It suffices that the use of the patented feature remains possible, provided that such use is in line with professional practices and recognized rules of medical sciences, such as correctly applying the device and performing a medical procedure[20].

While the UPC recognizes that injunctions are normally granted when infringement is established, it has carved out an exception for a life-saving medical device which is the only available treatment for particular patients[21]. Patentees should therefore consider the proportionality of the injunction they are seeking and whether there are any alternative treatments.

WHAT ABOUT SECOND MEDICAL USE CLAIMS?

The LD Dusseldorf[22] decided the UPC's first case on second medical use claims, confirming that a substance for any specific use in a method of treatment can be patentable, provided that the specific therapeutic use is novel. The key question is whether or not the therapeutic use as claimed is directly and unambiguously disclosed in the application.

The Court also set a two-step test to determine infringement of these types of claims:

i. the alleged infringer must offer or place the medical product on the market in such a way that it leads or may lead to the claimed therapeutic use; and

ii. the alleged infringer must know or reasonably should have known that it does.

This cannot be considered in the abstract but requires an analysis of all the facts and circumstances of the alleged infringing use, including the relevant market and the share of claimed use compared to others, what is customary on the market, and actions taken by the alleged infringer, either to encourage or dissuade the patented use. What is said in the package insert or summary of product characteristics (SmPC) of a pharmaceutical product can be important but is not decisive in relation to any "skinny labeling"[23].

[20] Emboline/Aortic, UPC_CFI_628/2024, UPC_CFI_125/2025.
[21] Meril v Edwards, Ibid.
[22] Sanofi/ Regeneron v Amgen, UPC_CFI_505/2024.
[23] i.e., carving out protected indications in the (SmPC) to avoid infringements.

WHAT IMPACT WILL THE UPC'S 'LONG-ARM' JURISDICTION HAVE ON FUTURE CROSS-BORDER DISPUTES?

One key aspect of the UPC's decisions over the last 18 months has been the court's growing willingness to extend its jurisdiction beyond its member states (long-arm jurisdiction). This makes it increasingly likely that more international life sciences disputes will be decided in the UPC than originally anticipated.

UPC-domiciled (e.g., manufacture or distributor)

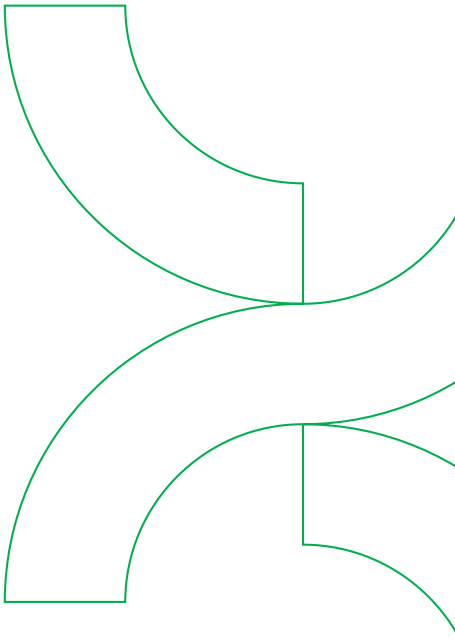
The suitability of long-arm jurisdiction in patent litigation was only recently put on the table of strategic litigation possibilities by the CJEU[24], when it ruled that, despite a validity challenge, an EU national court can adjudicate on infringement of a foreign EP, including in territories outside the EU, if the defendant is domiciled in its home territory[25]. The UPC has readily adopted this possibility in cases of UPC-domiciled defendants for all countries where an EP is validated, regardless of whether the states concerned are members of the UPC, EU, or Lugano Convention[26]. Those wishing to stop the manufacture and distribution of infringing products can therefore bring one UPC action covering not only manufacturing and distribution in UPC member states but also infringements in the UK, Spain, Poland, Switzerland, and Turkey.

Anchor defendants

A UPC-domiciled defendant can "anchor" other (non-UPC domiciled) defendants to disputes for "closely connected" acts infringing an EP counterpart in other EU states[27], Lugano states[28], and third states such as the UK[29]. This has allowed the UPC[30] to take jurisdiction over non-UPC group entities based on sales of the same pharmaceutical product[31] in connection with a UPC entity. For example, jurisdiction was adopted concerning Spanish and Norwegian local group entities infringing in their respective home countries, "anchored" by a Dutch group company, which was central to sales across Europe[32].

This could also lead to potential exposure for non-EU manufacturers and their EU-based intermediaries, such as marketing authorization holders of medicinal products and authorized representatives for medical devices imported into the EU. At first instance, a German authorized representative for a Hong Kong manufacturer was subject to an injunction preventing infringement of an EP in UPC Member States and Spain[33]. This was due to its critical role in EU distribution, even though it didn't manufacture or import the products. Furthermore, the German authorized representative was held to "anchor" jurisdiction against the non-UPC co-defendant, the Hong Kong manufacturer, for infringements in Spain (a non-UPC territory) because the claims were closely connected[34], as both defendants infringed there[35].

This decision has been appealed and the Court of Appeal has made a reference to the CJEU asking it to clarify whether the UPC's jurisdiction over a non-EU defendant insofar as it extends beyond the UPC, may be derived from a connection to the acts of the EU authorized representative, over which it did have jurisdiction by virtue of its domicile in a UPC Member State. Alternatively, if the UPC nevertheless has the power to grant provisional measures in respect of such acts. The CJEU will also answer whether the EU authorized representative is an intermediary whose services are being used to infringe, and therefore capable of being subject to a preliminary injunction.



[24] BSH Hausgeräte v Electrolux (C-339/2022).
[25] Art 4 Brussels Regulation (recast).
[26] Fujifilm v Kodak, UPC_CFI_365/2023, Dainese v Alpinestars, UPC_CFI_792/2024, Mul-T-Lock v IMC Creation, UPC_CFI_702/2024, Black Sheep v HL, UPC_CFI_386/2024, Dyson v Dreame, UPC_CFI_387/2025.
[27] Dyson v Dreame, UPC_CFI_387/2025. This decision is currently on appeal.
[28] Mul-T-Lock v IMC Creation, UPC_CFI_702/2024.
[29] Dyson v Dreame UPC_CFI_387/2025. There needs to be a plausible allegation of infringement of the relevant part of the EP in each jurisdiction.
[30] Moderna v Genevant Sciences and Arbutus Biopharma, UPC_CFI_191/2025.
[31] a Covid vaccine.
[32] Moderna v Genevant Sciences and Arbutus Biopharma, UPC_CFI_191/2025.
[33] Provided there is a plausible allegation of infringement in each country.
[34] Dyson v Dreame, UPC_CFI_387/2025. This decision is on appeal.
[35] The Hong Kong based company infringed by offering via its website (also) in Spain, which would not have been possible without the authorized representative, a company domiciled in Germany in that case, which was thus considered a necessary intermediary (which is liable under Art. 63(1) UPCA) for the infringement by the court. Given jurisdiction of the UPC under Art. 4(1) Brussels-Ia for the intermediary due to its seat in Germany, the Hong Kong defendant could be "anchored", according to Art. 8(1), 71b(2) Brussels-Ia; Dyson v Dreame, UPC_CFI_387/2025, Order of 08.14.2025, margin no. 56-65.

Place where the harm occurred

Of course, the UPC can also hear infringement claims against non-EU defendants if the harmful event occurs (or may occur) within its territory[36]. This includes cases where the damage occurs (or may occur) within the UPC territory, such as infringing a UPC patent by direct supply into the UPC. A Chinese medical device manufacturer and its Dutch subsidiary were subject to a PI for alleged infringement of an EP for implantable occlusion devices because they had obtained a CE marking for their product and participated in a device parade in Frankfurt[37]. As such, the harm would arise in Germany[38]. For a more detailed analysis of this case you can read our previous article.

A number of UPC first instance decisions implied that this can also include cases where the event giving rise to the damage occurs in the UPC territory. A Korean manufacturer was therefore subject to the UPC's jurisdiction because it shipped products to Poland, Spain, and the UK via its distributors in the UPC territory[39], the place of the events giving rise to the damage[40]. Furthermore, the LD Paris held that foreign companies with a website via which infringing products are offered can infringe if the website is accessible in UPC Member States[41], and that the UPC's jurisdiction extends to damage occurring outside the UPC territory (i.e., Switzerland, Spain, UK, Ireland, Norway, and Poland).

However, this decision was appealed and the UPC Court of Appeal has now confirmed[42] that, where the UPC has jurisdiction based on it being the court of the place where the damage occurred or is threatened to occur, there is no jurisdiction for infringement in territories that are not member states of the UPC. Claimants cannot therefore rely on infringing products being available on a website accessible in the UPC and the global nature of internet-based damage to expand the UPC's territorial reach.

FURTHER READING

For further expert analysis of other UPC cases concerning the life sciences sector, please refer to our dedicated UPC Insights page:

- Strict approach to correcting patent errors by interpretation
- UPC revocation actions: what is a reasonable number of auxiliary requests?
- UPC Security for Costs

[36] Art, 7(2) and Art, 71b Brussels Regulation (recast), Aylo v Dish, UPC_CoA_188/2024.
[37] Occlutech v Lepu Medical, UPC_CFI_630/2025.
[38] The injunction also covered Ireland, which is in line with Electrolux long-arm decisions. Jurisdiction to do this was not challenged.
[39] Hurum v NUC Electronics, UPC_CFI_162/2024.
[40] The action was ultimately dismissed because the infringing acts could not be attributed to the Korean defendant.
[41] Keeex v Adobe and Open AI, UPC_CFI_530/2025.
[42] Keeex SAS v Adobe and Open AI, UPC_CoA_922-925/2025, 03.13.2026

Europe's increased focus on the environment and corporate sustainability: *an expensive game changer for the pharma industry*

AUTHOR

Marie Barani
Knowledge Lawyer

Over the past decade, the European Union has enacted a host of new legislation to protect the environment, promote sustainability, and tackle climate change, including the European Green Deal to new reporting and due diligence obligations such as the Corporate Sustainability Due Diligence Directive (CS3D) and the Corporate Sustainability Reporting Directive (CSRD). Both are now covered by the provisional agreement on the Omnibus I Simplification Package, reached by the European Parliament and the Council mid December 2025, or by more specific, targeted actions, such as the revision of the Industrial Emissions Directive or the Urban Wastewater Treatment Directive (UWD). Here we explore what these frameworks mean for the life sciences and healthcare sector.

NEW GENERAL PHARMACEUTICAL LEGISLATION

In April 2023, the European Commission announced a complete review of the pharmaceutical acquis and released a proposal for a revised Directive on the Union Code relating to medicinal products for human use, as well as for a regulation laying down Union procedures for the authorization and supervision of medicinal products for human use and rules governing the European Medicines Agency, amending and repealing Directive 2001/83 and Regulation 726/2004, both now under a provisional agreement.

The provisional agreement introduces new requirements for environmental risk assessments (ERAs), which need to be added to every marketing authorization application. The goal of an ERA is to evaluate the risks to the environment arising from the use and disposal of medicinal products, and, in the case of potential risks, to propose adequate mitigation measures. This may, for example, include steps to minimize the quantity of products released into the environment, specific risk-minimization activities for patients, or appropriate labeling to facilitate the correct disposal of the product by patients and healthcare professionals.

The European Commission considered the existing ERA requirements insufficient to address environmental concerns because there are currently no hard consequences associated with a defective ERA or non-compliance with the identified risk mitigation measures. However, the new rules contain several far-reaching measures that will be available to the competent authorities to address these shortcomings. One of them makes ERAs a substantial part of the marketing authorization application process, to the point where a marketing authorization shall be refused and may be revoked, suspended or modified, and medicinal products may be prohibited or withdrawn from the market, if an ERA is insufficient, incomplete or if there are serious environmental risks that are not adequately addressed by the applicant.

In addition to the ERA becoming a substantive part of the marketing application process, national penalties could also be imposed for lack of compliance with the legislation if the ERA is not updated or required post-authorization ERA studies are not performed.

While ERAs have historically been considered a voluntary measure with no stringent consequences attached for non-compliance, the European legislator now appears to have addressed this shortcoming. Substantial criticism has been expressed over the new rules, including that, while significant consequences are proposed for non-compliance, there are no clear criteria introduced for regulators to assess ERAs.

The new system may therefore leave substantial room for discretionary assessments by the authorities on what is considered “insufficient”, leading to uncertainty for companies over the fate of their marketing authorization and product launch.

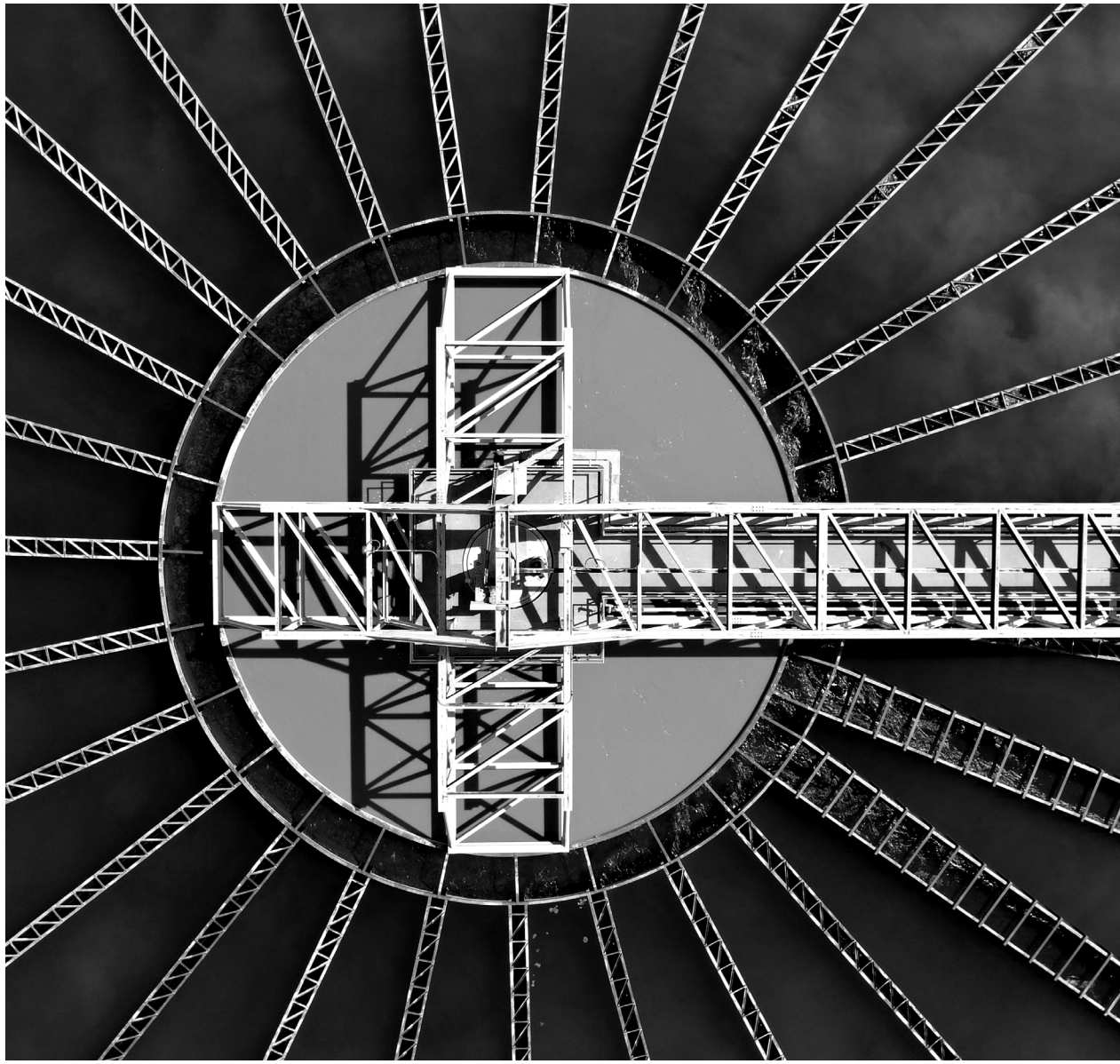
URBAN WASTEWATER TREATMENT DIRECTIVE (UWD)

While the UWD is a first substantial step in addressing pollution in wastewater, and the aim of the UWD is to be applauded, it is questionable to what extent the pharma and cosmetics industries alone should be held accountable for quaternary wastewater treatment. As a result, the innovative pharmaceutical industry organization, the European Federation of Pharmaceutical Industries Association (EFPIA), has challenged the UWD under various principles of European law, such as the "polluter-pays" principle, proportionality, legal certainty, and, most importantly, non-discrimination. However, the European General Court dismissed it as inadmissible on February 18, 2026.

Another action for annulment brought by Poland is still pending before the European General Court. As a mere annulment action does not have suspensive effects, companies should prepare to comply with the requirements under the UWD as from December 31, 2028.

FURTHER DEVELOPMENTS

Additional requirements stemming from non-pharma-specific legislation on corporate sustainability due diligence and corporate sustainability reporting directives, which aim to foster sustainable and responsible corporate behavior across companies' entire global value chains, are also expected after the Omnibus I Simplification Package is formally adopted, published, and applicable.



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