# The 2025 Prognosis: Global Regulators' Continued Scrutiny of Life Sciences

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#### I. Introduction

In 2025, global antitrust enforcers continue their focus on the life sciences sector. In the United States, the U.S. Department of Justice, Antitrust Division (DOJ) and the Federal Trade Commission (FTC) have challenged several life sciences transactions, and they have intensified scrutiny of pharmaceutical pricing and conduct practices. Across the Atlantic, on the merger side, the UK Competition and Markets Authority (CMA) is poised to take a more pragmatic approach in light of policy developments focused on investment but remains active in antitrust enforcement where transactions may impact the National Health Service (NHS) or otherwise worsen outcomes for UK patients in terms of choice, pricing or innovation. The European Commission (EC) and EU national competition authorities (NCAs) continue their efforts to expand their jurisdiction over transactions in light of perceived under-enforcement of "killer acquisitions" of pipeline assets and other deals which fall below traditional merger review thresholds. Outside of the transactional space, the EC has been focusing on non-pricing conduct such as gaming the IP system and disparagement of competitors, while the US agencies and the CMA remain focused on pricing.

This article summarizes key developments in each jurisdiction.

# II. Life Sciences Merger Control in 2025

## A. UNITED STATES

The FTC has challenged two life sciences transactions in 2025—GTCR's proposed acquisition of Surmodics and Edwards Lifesciences' proposed acquisition of JenaValve. These cases underscore the FTC's continued focus on life sciences transactions and shed light on the agency's use of the 2023 Merger Guidelines and their approach to remedies in the current administration.

In re GTCR BC Holdings, LLC and Surmodics, Inc.

In March, the FTC sued to block GTCR's acquisition of Surmodics, Inc. GTCR is a private equity firm that, in 2022, acquired a majority stake in Biocoat, Inc., which is the second-largest provider of outsourced hydrophilic coatings in the United States. Surmodics, which GTCR now proposes to acquire, is a provider of medical device technologies and the largest manufacturer of outsourced hydrophilic coatings in the United States. Surmodics' and Biocoat's hydrophilic coatings are essential for the safe and effective use of catheters, guidewires, and other medical devices. The FTC claims the merger would unlawfully combine the two largest providers of outsourced hydrophilic coatings for medical devices, giving GTCR a dominant market share and harming competition. The states of Illinois and Minnesota joined the FTC's lawsuit as co-plaintiffs in April.

The FTC's complaint alleges the deal violates Section 7 of the Clayton Act in two ways. First, the FTC claims the transaction "is presumptively illegal because it would significantly increase concentration in the already highly concentrated hydrophilic coatings market." According to the FTC, the combined company's share would exceed 50% of the outsourced hydrophilic coatings market, a combined share that exceeds the shared-based presumption of harm (30%) in the 2023 Merger Guidelines.

Second, the FTC alleges the merger would remove significant head-to-head competition between Surmodics and Biocoat, leading to losses in innovation, price competition, and product quality. The FTC describes how "Surmodics and Biocoat consistently identify each other as key competitors," as evidenced by internal documents, and that "headto-head competition between Surmodics and Biocoat accelerated after GTCR acquired Biocoat." In addition, the complaint notes that significant time and cost are required for new companies to develop, test, and receive FDA approval for new coatings, making new market entry unlikely to counteract the alleged anticompetitive effects of the merger. Altogether, the FTC claims the transaction may result "in lower quality and service levels, diminished innovation, and higher prices for hydrophilic coatings sold to U.S. medical device customers."

In its defense, GTCR has argued that the FTC's market definition is flawed and that the merger would not harm competition. GTCR also raised constitutional challenges against the FTC's administrative process, arguing it violates separation of powers principles. GTCR has also proposed divesting certain Biocoat assets to Integer Holdings to resolve the FTC's concerns. The FTC rejected this offer, claiming the divestiture was inadequate and that Integer lacked the necessary assets to compete effectively.

The FTC's evidentiary hearing in administrative court is scheduled for February 2, 2026, and the parties are waiting for a decision from the Federal District Court in Illinois regarding a preliminary injunction prohibiting the transaction pending a decision by the administrative court.

In re Edwards Lifesciences Corp. and JenaValve Technology, Inc.

In August 2025, the FTC sued to block medical device supplier Edwards Lifesciences from acquiring

JenaValve Technology. The FTC alleges that Edwards's acquisitions of JenaValve and JC Medical, another developer of transcatheter aortic valve replacement (TAVR) devices, would give Edwards a monopoly in the developing market for TAVR devices for the treatment of aortic regurgitation (AR), a severe heart condition affecting millions of Americans over 50, which can lead to heart failure if left untreated.

The FTC alleges that Edwards is attempting to monopolize the emerging TAVR-AR device market. The only current FDA-approved treatment for AR requires open-heart surgery, which is often not recommended for high-risk patients. The TAVR-AR devices being developed by Edwards—through JC Medical—and JenaValve would provide a less invasive alternative, giving high-risk patients a new treatment option that represents a critical innovation for an underserved market.

The FTC claims Edwards' acquisition of both JC Medical and JenaValve would combine the only two companies with active U.S. clinical trials for a TAVR-AR device and that eliminating head-to-head competition between JenaValve and Edwards will reduce incentives for innovation and could increase prices. According to the FTC, Edwards was offered a chance to resolve antitrust concerns by divesting JC Medical but "repeatedly rejected" the proposal.

Edwards argues that the merger would benefit patients by accelerating the availability of new treatments. Edwards has also argued that the FTC underestimates the possibility of other companies entering the market, including those using the less rigorous 510(k) approval process once a device receives initial FDA approval.

The FTC filed a motion for a preliminary injunction on August 6, 2025, in the Federal District Court in D.C. The same day, the FTC filed an in-house administrative complaint to stop the deal. The Federal District Court in D.C. granted the FTC's request for a temporary restraining order on the acquisition through January 9, 2026. As of October 2025, the court is still considering the FTC's preliminary injunction request.

# Key takeaways:

 The FTC continues to pursue cases in the life sciences sector, with a particular focus on medical device transactions in 2025.

- The FTC is leveraging the 2023 Merger Guidelines to push for a structural presumption for transactions that "significantly increase concentration in a highly concentrated market."
- The FTC's renewed openness to remedies is a double-edged sword. The agency will not accept inadequate remedies, as in GTCR, but also will highlight in advocacy where parties have been unwilling to engage in remedy negotiations, as in Edwards.

## **B. UNITED KINGDOM**

The CMA's policy and jurisdictional approach to merger review has evolved significantly over the past year

While the CMA remains a major player on the global enforcement stage, its approach to life sciences mergers has changed materially since the days of Roche/Spark and Illumina/PacBio.

In the initial years post-Brexit, the UK CMA positioned itself as an aggressive global competition enforcer, creating a regulatory environment which was at times seen as both burdensome and unpredictable for businesses. However, the election of the Labour government last year marked a clear shift in direction, with the CMA seeking to play a more proportionate and pragmatic role aligned with the Government's focus on economic growth and investment. Soon after his election, Prime Minister Keir Starmer pledged to "rip up" bureaucracy and urged competition regulators to support the agenda as later outlined in the Government's "Strategic Steer." The Steer emphasized that the CMA's work should "support growth and investment," and that its actions should be "swift, predictable, independent and proportionate."

The most visible sign of change came in January 2025, when Doug Gurr, former UK head of Amazon, became the CMA Chair. His appointment has widely been seen as a signal of change. Since then, the CMA has taken further steps to deliver against the Government's agenda and announced a package of reforms focused on delivering more predictable, proportionate, and business-friendly outcomes.

The CMA's Mergers Charter, published in March 2025, sets out a non-binding statement of intent for merger reviews. It promotes "constructive and direct

engagement" and supports "well-informed, evidence-based, and timely decisions," reflecting the Government's call for a more proportionate and predictable approach. These principles are embedded in the CMA's evolving "4Ps" framework, which aims to focus on improving pace, predictability, proportionality, and process.

To boost investor and business confidence, the 4Ps guidance seeks to clarify the more controversial aspects of the CMA's jurisdictional tests - the "material influence" test and "share of supply" threshold. In particular, the CMA has committed to predictable use of the share of supply test on jurisdiction by limiting itself to predefined metrics (value, cost, price, quantity, capacity and number of employees) – rather than the more creative metrics it explored the past. This will be welcome news for life sciences companies in particular given the historic use of the share of supply test to review pharma deals which, on their face, appeared to have limited UK nexus (e.g. in *Roche/Spark*).

Our experience this year suggests the CMA's shift is more than rhetoric: we are seeing a considered approach in the deals that receive proactive questions from the CMA's merger intelligence committee and a pragmatic approach to cases where there is a limited UK nexus, particularly in cross-border transactions which are also subject to scrutiny by other regulators. That said, the CMA has not yet been faced with a truly substantively challenging life sciences transaction since the change in policy was announced, and so the jury remains out on how these concepts will be applied to challenging deals that clearly impact (albeit not uniquely so) the UK market.

Life sciences was highlighted as a priority sector in the UK Government's June 2025 Industrial Strategy, which set out ambitions for the UK to become a leading life sciences economy in Europe and the third most important life sciences economy globally (after the US and China). Against this backdrop, we expect the CMA to be inclined to show that its new 4Ps framework—emphasizing pace, predictability, proportionality and process—is meaningfully impacting its approach to reviewing life sciences transactions in the years ahead.

CMA merger review signals return to mainstream theories of harm and willingness to engage on remedies

The CMA has opened one life sciences merger investigation in 2025 to date—the proposed acquisition by Rhône Capital L.L.C. and Archimed SAS of DHG Holdco S.à r.l., which remains ongoing. Since 2020, the CMA has reviewed a large number of mergers in the sector, with no prohibitions and only two in-depth investigations.

A review of CMA merger decisions in recent years suggests that the authority remains vigilant yet pragmatic—clearing deals that present no *prima facie* competition concerns or where an appropriate and proportionate remedy is available. Notably, the theories of harm considered in recent years largely fall into more mainstream categories, such as horizontal overlap concerns (e.g., *Theramex/Viatris, Cochlear/Oticon, Roche/LumiraDx* and *Thermo Fisher/Olink*) and vertical foreclosure (e.g., *United Health/EMIS*).

A central theme running through most of these cases, and which dealmakers will want to consider proactively, is the likely impact of the transaction on the UK National Health Service (NHS), including any risk of the deal exacerbating NHS budget pressures. For example, a key focus area in Theramex/Viatris was the concern that any price increases resulting from the transaction would ultimately be borne by the NHS. The deal took place amid rising home replacement therapy (HRT) demand following the 2023 introduction of the HRT Prepayment Certificate, which capped annual costs for patients, along with greater awareness of the possible benefits of HRT. Similarly, the NHS featured prominently in United Health/EMIS. While concerns were raised about potential foreclosure of rivals' access to EMIS's patient record systems, the CMA ultimately cleared the deal in Phase 2 without remedies, citing limited evidence of anticompetitive intent and the NHS's ability to intervene if necessary.

Several recent cases have involved undertakings, indicating openness to engage on remedies after a period of significant skepticism on both sides of the Atlantic. We expect that upfront buyer requirements will remain an important factor in pharma remedies cases as buyer expertise is critical to remedy viability—as illustrated most recently in *Theramex/Viatris*.

Looking ahead, the UK regulatory landscape looks more predictable and manageable for the industry that it has done for some time. While the CMA remains rigorous in its scrutiny of deals with a clear UK nexus, it seems less inclined to assert jurisdiction over cases with limited domestic impact or to act as a global policeman on novel issues, which is an encouraging shift for life sciences investment and M&A.

Finally, we note that prior to the Strategic Steer the CMA assessed several AI-related partnerships and acqui-hires, most of which (four out of five) were found not to qualify for merger review. While the CMA's future approach regarding non-M&A deal structures remains uncertain, the current pro-growth climate (and the desire to provide greater certainty around the material influence threshold) indicates that, insofar as non-M&A deal structures in the life sciences space are to be scrutinized at all, the EC may take the lead in this area in view of the recent Lear Report findings (see below). Indeed, to date, the only decision on record in relation to pharma licensing and collaboration agreements is the CMA's CSL Behring/UniQuer 'found not to qualify' decision.

# Key takeaways:

- Expect a pragmatic CMA which is keen not to be seen as the roadblock to life sciences investment in the UK. We can expect—and are seeing—a lower appetite for marginal cases and novel theories of harm.
- However, the CMA will remain an important enforcer where there are prima facie competition issues. In particular, be prepared for scrutiny where the NHS or UK patients may be particularly impacted by the transaction.
- There is increased willingness to engage on remedies – including at Phase 1 – but early engagement to allow the CMA enough time to test the suitability of those remedies is key.

## C. EC AND EUROPEAN NCAs

In 2025, the EC completed its review of eight transactions in the life sciences space. Nearly all of those (seven) were reviewed and approved under the simplified or super-simplified procedure—meaning they were considered non-problematic. The one case which was not reviewed under the (super-)simplified procedure—Roquette Frères' acquisition of the Pharma Solutions business from International

Flavors and Fragrances—was cleared unconditionally in Phase I.

None of these cases resulted from an Article 22 referral from EU Member States or involved remedies. Despite this uncontroversial 2025 track record, it is clear that the EC remains committed to scrutinizing concentrations in the life sciences space closely—including in respect of perceived underenforcement of "killer M&A" deals involving early-stage pipeline assets and other potentially problematic deals that fall below review thresholds.

These continued areas of focus are illustrated, among other things, by the Lear study, published by the EC in November 2024, which focuses on the topic of "killer acquisitions" in the pharma sector. The report concludes that, while the EC's assessment of notified mergers is "overall effective", there remain potential gaps in detecting killer acquisitions that are not subject to mandatory merger control, including certain non-M&A deal structures. The report also suggests that the EC's wider antitrust toolkit-Article 101 and 102-could offer a tool to address killer acquisitions that fall outside of the purview of merger control (alongside contemplating legislative reform). Before publication of the Lear report, active steps had already been taken to close this perceived enforcement gap.

First, the EC has been encouraging EU Member States to enable their national agencies to review below-threshold transactions, such as deals involving pre-revenue pipeline assets. This has resulted in a proliferation of "call-in" powers at the national level - much to the frustration of dealmakers grappling with even more ambiguity around required approvals and timelines. While the level of discretion to "call in" transactions varies, this trend empowers NCAs to "pick and choose" to some extent the deals (and sectors) they want to review more closely. Rather than systematically applying turnover-based thresholds, national enforcers can increasingly find ways to review deals based on, for example, the presence of an active complainant, the perceived importance of a target, its technologies, and/or critical local research facilities, or back door encouragement from the EC to ask probing questions around jurisdiction.

The German and Austrian merger control regimes offer another gateway for pipeline deals to be scrutinized. These regimes can capture pre-revenue

deals in instances where the deal value threshold is met (€400 million in Germany and €200 million in Austria) and there is sufficient local nexus – e.g., as a result of local research or marketing activities. If those conditions are satisfied, these NCAs can either review the transaction themselves or consider a referral to the EC.

The Austrian Federal Competition Authority has been willing to make extensive use of its power but suffered a setback in March 2025 when the Supreme Court confirmed it did not have jurisdiction to review Edwards Lifesciences' acquisition of JenaValve Technology as there was insufficient nexus to Austria. Although the value of the transaction exceeded the relevant threshold, the target's local turnover was very limited (less than €100k annually), with only one local customer (an Austrian hospital) and no Austrian subsidiaries, branches or R&D activities. This shows that while jurisdiction continues to expand, it is not unlimited.

The German Federal Cartel Office's willingness to scrutinize life sciences mergers by relying on the value-based threshold can similarly be illustrated through recent cases. Notably, its 2024 clearance decision of Thermo Fisher's acquisition of Olink following an in-depth review—despite the fact that turnover thresholds were not met. Similarly, the authority cleared BioNTech's acquisition of CureVac in October 2025 following a review based on the transaction value threshold without the turnover threshold being met.

Second, the EC had also already started making use of the antitrust toolkit to scrutinize below-threshold pharma deals with its ongoing investigation into animal health company Zoetis. The EC is considering whether Zoetis' termination of a pipeline asset, which it acquired as part of its non-notifiable acquisition of Nextvet in 2017, amounted to an abuse of dominance. Prior to the unilateral termination by Zoetis, this pipeline asset was out-licensed to a third party and—if successful—could have been launched for the same indication as Zoetis' marketed product.

While the EC has stated that it is not investigating the legality of the initial acquisition by Zoetis and is only scrutinizing the subsequent termination of the pipeline asset, it may be difficult to disentangle the two in practice. In essence, the EC's investigation will need to determine the difference between a unilateral decision to terminate a pipeline product

that is scientifically or commercially flawed (a decision made by pharma companies every day) and an anticompetitive strategy whose main or sole purpose was exclude a potential rival. This will likely largely depend on what internal documents suggest was Zoetis' "intent" behind termination of the pipeline project.

Third, the EC is still considering—off the back of the Lear Report—whether further policy or legislative changes are required, such as the establishment of a transaction registry covering therapeutic indication and mechanism of action overlaps and periodic status updates on development and discontinuances. To date, there are no indications that the EC has picked up on this recommendation.

# Key takeaways

The bottom line is that enforcers in Europe have an increasingly broad toolbox at their disposal to review life sciences deals. Across the toolbox, factors increasing the risk of scrutiny include:

- The presence of one or more active complainants, such as competitors, customers, payers, KOLs or a consumer or patient organization;
- The existence of pipeline overlaps given European agencies' focus on protecting innovation and the perception (rightly or wrongly) that there is underenforcement in respect of alleged "killer M&A" deals; and
- As more broadly the case in merger control and antitrust reviews in Europe, internal documents will remain key in determining the outcome of any reviews.

# III. Life Sciences Conduct in 2025

## **A. UNITED STATES**

The Trump Administration has made lowering prescription drug prices a central policy priority, pursuing that goal through multiple channels, including the potential use of antitrust enforcement.

PBMs remain under fire in the United States.

Current FTC leadership continues to scrutinize Pharmacy Benefit Manager (**PBM**) conduct, echoing concerns raised under the prior administration that exclusionary rebate arrangements (e.g., conditioning higher rebates on limiting access to lower-cost generic or biosimilar competitors) and formulary steering (i.e., influencing which prescription drugs patients take by manipulating their placement on the insurance plan's formulary) may constitute unfair methods of competition.

PBMs are intermediaries in the US healthcare system that manage prescription drug transactions for plan sponsors (e.g., insurers and employers) and negotiate discounts with drug manufacturers on behalf of those customers. The FTC has observed that PBMs have gained control over multiple levels of the prescription drug supply chain allowing them to control the administration of approximately 80% of all prescriptions in the United States. In September 2024, the FTC brought an <u>action</u> against the three largest PBMs "for engaging in anticompetitive and unfair rebating practices that have artificially inflated the list price of insulin drugs."

This theme continued in January when the FTC released its Second Interim Staff Report on PBMs, finding that the "Big 3" PBMs-Caremark Rx, Express Scripts, and OptumRx-"hiked costs for a wide range of lifesaving drugs" and imposed significant markups on specialty generics (Freshfields' assessment of the Report here). In a subsequent listening session this June, panelists criticized the role PBMs play in generic drug pricing and availability, claiming PBM's "anticompetitive practices [. . .] have had significant, significant negative impact on the biosimilars industry," including by PBMs favoring "their own biosimilars, [and] delaying adoption of other biosimilars." Panelists also pointed to private labeling and pricing opacity, in addition to rebate walls (i.e., a drug manufacturer's use of rebate strategies in contracts with third party payors to give its products preferred status in drug formularies or to prevent sales of competing products), as practices that may increase costs and reduce patient access.

Exclusionary tactics remain a focal point.

The FTC continues to treat pay-for-delay (i.e., reverse-payment) arrangements as a key enforcement priority. Staff commentary and recent reports flag that quantity restrictions and other non-cash settlement structures may qualify as "possible compensation" that could constitute an unlawful reverse payment.

Product-hopping (i.e., slight reformulations or "new" presentations timed around patent cliffs) and

exclusive-dealing or distribution restrictions (including exclusive supply/authorized-generic deals that can foreclose rivals) are similarly an enforcement priority. The agencies' June <u>listening session</u> on Anticompetitive Conduct by Pharmaceutical Companies Impeding Generic or Biosimilar Competition identified these tactics among the chief practices it believes can harm competition and raise consumer prices.

The <u>FTC</u> also continues to scrutinize "the misuse of the FDA's Orange Book and drug safety programs and government regulations." In May, the Trump FTC announced its renewal of challenges against "improperly listed device patents" in the Orange Book. The <u>FTC</u> sent additional "warning letters" to a select group of pharmaceutical companies relating to 17 brand-name products (spanning 200+ patent listings). The patent listings being challenged were all previously disputed by the FTC under the Biden Administration, but these pharmaceutical companies opted to maintain these previously disputed listings in the Orange Book. Based on the FTC's recent listening sessions, it is clear these "misuses" will remain a focal point.

Legislation and executive orders apply further pricing pressure

In May, the Trump administration issued an executive order (EO) titled Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients. This EO directed various US government agencies to take actions, including the antitrust enforcement agencies (FTC and DOJ), to compel drug manufacturers to reduce drug prices to be "in line with comparably developed nations." Following the EO, the White House sent letters to 17 drug manufacturers outlining the steps required to implement most favored nation pricing and threatening aggressive action-i.e., the federal government "will deploy every tool in [its] arsenal to protect American families from continued abusive drug pricing practices" -if the drug manufacturers failed to take those steps. This EO followed the Inflation Reduction Act (IRA), which also included provisions aiming to lower the prices that Medicare and its beneficiaries pay for certain prescription drugs.

# Looking ahead

Given the bipartisan focus on drug pricing, we expect the FTC to maintain pressure on PBMs and continue to scrutinize any form of exclusionary tactics in drug approval and distribution throughout the current administration. The EO and IRA further clarify that the US government is willing to mobilize various agencies, including the antitrust agencies, to achieve lower prescription drug prices. This increases the priority profile for bringing antitrust enforcement actions against the pharmaceutical industry, and companies should expect this pressure to continue in the coming years.

#### **B. UNITED KINGDOM**

Although we expect the UK to take a more proportionate approach to merger review, there is no indication that the CMA plans to change its stance on antitrust conduct investigations and enforcement.

The CMA has historically had a strong enforcement focus on excessive pricing and hardcore cartel conduct in the pharma industry (again given the direct impact on the budget and proper functioning of the NHS), with substantial fines imposed in, e.g., the *Pfizer/Flynn (Phenytoin)* and *Hydrocortisone* cases.

More recently, the CMA has also investigated novel conduct issues such as Vifor Pharma's alleged disparagement of a rival product, which concluded in May this year. In this case the CMA piggy-backed off commitments Vifor agreed with the EC in the second half of 2024 to extend their application to the UK. Given the CMA's concerns that Vifor's disparaging claims may have led to financial harm to the NHS, Vifor agreed to compensate the NHS with the  $\mathfrak{L}23$  million settlement. This case signals a broader trend: the CMA is actively monitoring international investigations and settlements, with a view to extending relevant commitments to the UK market.

Also this year, ongoing negotiations under the Voluntary Scheme for Branded Medicines Pricing, Access and Growth (VPAG) have underscored the UK's challenge in balancing predictable NHS reimbursement with continued investment in pharmaceutical innovation and pressures from other jurisdictions. Introduced in January 2024 to replace the 2019 framework agreement, VPAG imposes

annual caps on branded medicine spending and requires manufacturers to pay rebates when NHS expenditure exceeds agreed thresholds. While intended to offer stability and collaboration, debate over high rebate percentages has exposed friction between the Government's focus on cost containment and the industry's warning that excessive rebates discourage R&D and reduce UK competitiveness.

These tensions came to a head in September of this year when a senior UK government official publicly questioned whether pharma companies had been coordinating announcements of scrapped investments to put pressure on the government in the context of the ongoing VPAG negotiations. The CMA has since confirmed that it has not seen any direct evidence of coordination of public announcements, and that it will not investigate. However, we expect antitrust agencies to continue to pay close attention to ongoing pricing, rebate and investment decisions as geopolitical tensions around drug pricing (and, in particular, perceived discrepancies between US prices and other countries) continue.

#### C. EU

Much like the US and the CMA, the EC historically treated pay-for-delay (i.e., reverse-payment) and excessive pricing as key antitrust enforcement priorities. However, more recently, the EC's enforcement efforts appear to have shifted away from traditional theories of harm to novel non-pricing conduct issues.

Most recently, the EC's has focused on pharma companies allegedly "gaming" the IP system to create legal uncertainty with the aim of preventing generics from entering the market, as well as on conduct aimed at disparaging competitors. In the second half of 2024, the Commission fined Teva for both types of conduct, accepted commitments from Vifor in relation to disparagement (as discussed above with respect to the UK), and closed an investigation into Novartis in relation to IP-related practices (without finding an infringement).

These conduct issues remained top of mind in the second half of 2025 with the EC conducting dawn raids in the vaccine sector based on suspicions of anti-competitive disparagement, while NCAs also continue to pursue novel theories of harm, with a

degree of cross-pollination between the two enforcement levels in Europe (i.e., EC and NCAs). For example, disparagement was traditionally enforced at the national level (in particular by the French NCA) and is now the key focus of the EC.

We expect both the EC and NCAs to continue to be active enforcers in Europe, with NCAs often considering themselves to be particularly well-placed to pursue behavioral investigations given that conduct and 'gaming' can at times be closely interlinked with the intricacies of national regulatory, access and reimbursement regimes.

## IV. Conclusion

Antitrust scrutiny of the life sciences sector remains robust on both sides of the Atlantic, with the antitrust agencies sharpening their focus on M&A theories of harm, innovation impact, pricing decisions, and exclusionary conduct. Life sciences companies should design compliance strategies that account for potentially divergent but increasingly intertwined regulatory priorities.

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