GCR Global Competition Review

The Guide to Life Sciences - Third Edition

Introduction: life sciences antitrust enforcement remains robust worldwide

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The life sciences industry – and the inherent tension between protecting innovation and a healthy competition space – continues to command attention from regulators. Edited by Ingrid Vandenborre, Caroline Janssens and Michael J Frese, the third edition of the Guide to Life Sciences provides practical and timely guidance for both practitioners and enforcers trying to navigate this high-stakes, fast-moving environment. The Guide draws on the wisdom and expertise of distinguished practitioners from around the globe to provide essential guidance on subjects as diverse as biosimilar competition and product denigration, as well as a forensic examination of the world's most significant and far-reaching regulations and decisions.

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Introduction: life sciences antitrust enforcement remains robust worldwide

Ingrid Vandenborre and **Caroline Janssens**
Skadden Arps Slate Meagher & Flom LLP

Summary

We are pleased to welcome you to the third edition of Global Competition Review's *Guide to Life Sciences*. This edition comes at a time when enforcement actions by antitrust authorities worldwide within the life sciences sector remain robust. Price increases, denigration of rivals' products, and delayed entry of generic and biosimilar medical products are the main focus of antitrust enforcement. Also, antitrust authorities, in particular in Europe and the United States (US), have continued to scrutinise transactions in life sciences with a focus on pipeline products, and the impact of mergers on non-horizontal business relations. In Europe, the European Commission (the Commission) and other antitrust agencies are seeking to expand their jurisdiction to be able to review transactions that do not meet existing merger control thresholds.

ANTITRUST ENFORCEMENT TRENDS

The pricing of medicines remains an enforcement priority for antitrust authorities in the European Union (EU) and the United Kingdom (UK) and is likely to remain so in the years to come, despite economists continuing to highlight the complexities of assessing excessive pricing allegations. There have been several investigations at both the EU and Member State levels and in the UK into the pricing of certain off-patent medicines and rare disease drugs, and into practices relating to medicines with exclusivity rights, and innovative treatments. The number of stand-alone and follow-on civil lawsuits brought before national courts in the EU for alleged unfair and excessive pricing of off-patent medicines continues to increase, in particular in the UK.

Product denigration cases in the life sciences sector are attracting scrutiny at the EU level, with two investigations before the Commission. While one case targets a potential abuse of patent re-filing procedures, combined with a possible denigration campaign casting doubts about the safety and efficacy of a competitor's product, the second case targets denigration as a stand-alone practice. Denigration cases are also pursued by other authorities. The UK Competition and Markets Authority (CMA) recently opened a product denigration investigation following claims for damages in civil courts. In France, which has been the frontrunner in denigration cases, a Supreme Court ruling is anticipated in the *Roche Novartis* case. Upcoming developments in these cases will clarify the definition and criteria of denigration.

MERGER CONTROL DEVELOPMENTS

In recent years, review processes for transactions in the life sciences space have evolved and become more uncertain. This is due to many countries broadening their jurisdiction over acquisitions through flexible notification requirements and new theories of harm.

The Commission has taken steps to review transactions that fall outside the mandatory EU and national notification thresholds, despite recent criticism of that approach from Advocate General Nicholas Emiliou in *Illumina/GRAIL*. Member States have also seen similar developments. Eight countries – Denmark, Italy, Ireland, Germany, Sweden, Iceland, Norway and the UK – have empowered their respective National Competition Authorities (NCAs) to scrutinise mergers that fall below the established mandatory notification thresholds. Three others – the Czech Republic, Finland and the Netherlands – are currently in the process of proposing or enacting measures to provide their NCAs with similar capabilities. Also, Germany and Austria have provided more clarity on their 'size-of-transaction' tests, and Luxembourg is moving to establish its first merger control regime.

In the UK, the CMA remains vigilant with its share of supply test. The Digital Markets, Competition and Consumers Act (the Act), which received royal assent on 24 May 2024, significantly alters the merger control process by introducing new filing thresholds to address concerns about 'killer acquisitions' (i.e., acquisitions by incumbents of nascent competitors that could play a significant competitive role in the market in the future).

All of these trends and developments are reflected in the following regional chapters.

REGIONAL DEVELOPMENTS

Competition authorities in Europe, particularly the Commission, have historically been very active in enforcement in the life sciences sector and this trend is expected to continue with regard to both antitrust and merger control enforcement. Regarding antitrust enforcement, the Commission has increased its focus on practices that limit innovation, such as the misuse of the patent protection system, patent settlement agreements, disparaging practices, refusal to develop or transfer pipeline medicine and excessive pricing, while continuing its scrutiny of pharmaceutical cartels. New labour market considerations are emerging, including acqui-hires and non-compete obligations placed on key R&D personnel. Merger control also continues to focus on innovation, pipeline products and dynamic competition. This is also true for the national competition authorities of EU Member States and the EU Courts.

Italy has been a front runner in antitrust enforcement in life sciences, with landmark cases on excessive pricing and product denigration influencing the Commission's decisional practice. The Italian Competition Authority is likely to continue its enforcement efforts in this area in the future. Also, the activity of the Authority in merger control is expected to increase with the Authority's new powers to review mergers falling below the national merger control thresholds, intended to catch acquisitions of nascent, innovative, target companies.

In Switzerland, the life sciences sector has not raised major competition law issues to date. However, ongoing proposed reforms to merger control rules may have consequences for future mergers in the life sciences sector. If passed, the new rules would replace the current dominance test with the significant impediment to effective competition (SIEC) test, which is applied in the EU and lowers the bar for the competition authorities to intervene in mergers. The proposed reforms would also assign the exclusive competence for merger cases affecting markets within the EU and EEA to the Commission, even if the Swiss notification criteria are met.

In the US, antitrust and merger control enforcement in the life sciences sector have become more aggressive and expansive in 2023 and 2024, with the Federal Trade Commission (FTC) pursuing novel theories of harm based on potential competition, harm to innovation, and dominance, and scrutinising transactions involving early-stage assets, vertical integration and crowded therapeutic areas that previously would not have received close investigation. While the FTC has faced some scepticism from federal courts, it has nonetheless shown some pragmatism and flexibility in accepting remedies or allowing transactions to close without significant challenges. It is anticipated that the FTC will continue closely scrutinising large transactions in the life sciences space, including those involving early-stage assets. The Department of Justice has also signalled its interest in examining potential harm to competition in industries adjacent to life sciences.

Lastly, in Australia, key recent and upcoming developments affecting the life sciences sector include significant reforms to the merger control rules that will introduce a mandatory

notification regime, expanded merger assessment factors and limited appeal rights, and will apply from 1 January 2026. These reforms are likely to increase the scrutiny of both proposed and completed mergers in the life sciences sector. Also, the Australian Competition and Consumer Commission (ACCC) opened criminal and civil cases against companies and individuals for alleged cartel conduct in the sector, alleged misuse of market power through anticompetitive life cycle management strategies and gun jumping. The ACCC will likely continue to scrutinise any conduct that could harm Australian consumers' access to cost-effective treatments or contribute to price escalation pressures.

ENDNOTES

[1] Ingrid Vandenborre is a partner and Caroline Janssens is competition/antitrust knowledge strategy lead with Skadden, Arps, Slate, Meagher and Flom LLP.

Skadden
Skadden, Arps, Slate, Meagher & Flom LLP and Affiliates

Ingrid Vandenborre ingrid.vandenborre@skadden.com

https://www.skadden.com