THE GUIDE TO LIFE SCIENCES

Editors
Ingrid Vandenborre and Caroline Janssens

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This article was first published in October 2022
For further information please contact insight@globalcompetitionreview.com

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Published in the United Kingdom by Law Business Research Ltd
Holborn Gate, 330 High Holborn, London, WC1V 7QT, UK

www.globalcompetitionreview.com

ISBN 978-1-83862-882-6

Printed in Great Britain by
Encompass Print Solutions, Derbyshire
Tel: 0844 2480 112

Acknowledgements

The publisher acknowledges and thanks the following for their learned assistance throughout the preparation of this book:

Arnold & Porter Kaye Scholer LLP

Compass Lexecon

Eversheds Sutherland

Gilbert + Tobin

Goodwin Procter LLP

King & Spalding LLP

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Publisher's Note

One of the unexpected side-effects of the covid-19 pandemic is how the hunt for both vaccines and treatments has pushed the life sciences industry centre stage, with debates over price controls and IP waivers making headlines around the world. While many of these concerns are global, the same is not always true of the solutions adopted by national regulators. As Ingrid Vandenborre and Caroline Janssens point out in their introduction, there has been growing regulatory attention paid to mergers in this innovative space and increasing intervention by antitrust agencies in a range of practices particular to the biopharma sector. Practical and timely guidance for both practitioners and enforcers trying to navigate this fast-moving environment is thus critical.

The first edition of *The Guide to Life Sciences* – published by Global Competition Review – provides exactly this detailed analysis. It examines both the current state of law and the direction of travel for those jurisdictions with the most impactful life sciences industries. The Guide draws on the expertise and experience of distinguished practitioners globally, and brings together unparalleled proficiency in the field to provide essential guidance on subjects as diverse as biosimilar competition and product denigration, as well as a forensic examination of the most significant and far-reaching regulations and decisions from around the world.

Contents

Introduction

Ingrid Vandenborre and Caroline Janssens[1]

Antitrust agencies around the world have been highly active in recent years, examining a range of practices, including alleged denigration of rivals' products, price increases, biosimilar entry, delayed entry of generic medicines, collaboration agreements and local regulatory/procurement practices. There is also growing attention to mergers, especially in dynamic, innovation-driven areas. While many of the concerns are similar in most jurisdictions, enforcers have addressed those specific to the functioning of their local markets and antitrust principles. This first edition of Global Competition Review's *Guide to Life Sciences* explores how enforcers have approached these practices and where key jurisdictions diverge or converge in their analysis.

Spending on pharmaceuticals constitutes a significant share of government spending on healthcare. This has driven increased regulatory focus on pharmaceutical pricing, including from competition authorities. While competition authorities in the European Union and the United Kingdom have historically been reluctant to intervene, the pharmaceutical sector has seen mounting regulatory interest in alleged excessive pricing practices in recent years. Even with economists highlighting the complexities and shortcomings around the enforcement of exploitative abuses of companies in a dominant position through excessive pricing, antitrust scrutiny of pharmaceutical pricing is expected to continue. By contrast, while we have seen a recent push from academics in the United States to recognise high (excessive) prices of pharmaceuticals as an antitrust violation, US courts have not yet recognised these claims.

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1 Ingrid Vandenborre is a partner and Caroline Janssens is a senior professional support lawyer at Skadden, Arps, Slate, Meagher & Flom LLP.

Biosimilars, and more generally biological medicines, have received growing attention from competition authorities across Europe. Recent antitrust investigations in the EU and the UK have examined how commercial practices adopted by incumbent suppliers may hinder biosimilar competition. However, the inherent features of biologicals, such as high costs and longer approval times, raise fundamental challenges in increasing biosimilar competition.

Product denigration cases in life sciences have been rare in the EU and around the world, and in most of them the denigration behaviour was combined with other infringements such as abuse of patent procedures or product hopping. There has since been an abundance of similar investigations at national level, with France leading the way, where cases have expanded the scope of the conduct to include product denigration and the provision of unsubstantiated, but not necessarily incorrect, information to consumers and other parties concerning either the company's own products or competing products.

Cooperative agreements have always played an important role in the pharmaceutical industry with companies partnering from early stage research and development through to late-stage commercialisation. The covid-19 pandemic has been an opportunity for the industry to demonstrate the benefits that expeditious and flexible cooperation can bring, and competition authorities have also recognised this. Beyond the pandemic, the pharmaceutical industry is facing increasing pressure to enhance affordable access to new medicines. In that context, cooperation agreements will remain of central importance to pharmaceutical companies, perhaps increasingly so.

With regard to merger control, clearance processes for some pharmaceutical transactions are expected to become more uncertain. This is due to several procedural developments in many countries designed to broaden jurisdiction over acquisitions by incumbents of nascent competitors that could play a significant competitive role in the market in the future ('killer acquisitions'), coupled with flexible and creative notification requirements and new theories of harm. The Multilateral Pharmaceutical Merger Task Force (a working group comprised of the US Federal Trade Commission (FTC), the Canadian Competition Bureau, the European Commission (EC) Directorate General for Competition, the UK's Competition and Markets Authority (CMA), the US Department of Justice Antitrust Division and offices of state attorneys general) can play an important role in brokering alignment in analysis between key jurisdictions.

Competition authorities in Europe, and in particular the EC, have historically been very active in antitrust enforcement and merger control review in the pharmaceutical sector. Consistent with its focus on innovation, the EC has significantly increased its scrutiny in recent years and is expected to continue

doing so, including, as we have seen, by way of expanding jurisdictional scope of review. At Member State level, France has been leading the way on enforcement of product denigration, while Germany and Austria have increased their scrutiny of innovation-driven markets with the introduction of alternative transaction value thresholds in 2017, designed to capture high-value/low-revenue deals.

Italy has been a pioneer in antitrust enforcement in life sciences, with landmark cases on excessive pricing and product denigration influencing the EC's decisional practice. The Italian Competition Authority is likely to continue its enforcement efforts in this area in the future. In contrast, the activity of the Authority in merger control in recent years has been limited.

In the Netherlands, the focus has been on price levels, with the Authority for Consumers and Markets making important contributions to the debate on excessive pricing both through case practice and working papers.

In the UK, the CMA is expected to continue to regard the life sciences sector as an enforcement priority. With regard to merger control, recent cases have illustrated the CMA's willingness to push the limits of jurisdictional rules and intervene in deals in dynamic, innovation-driven sectors where target companies have limited (or no) revenues or direct activity in the UK. In addition, Brexit has created heightened risks of parallel conduct investigations and merger reviews in the EU and UK.

To date, the life sciences sector has not raised major competition law issues in Switzerland, under neither the cartels, abuse of dominance nor merger control rules. It remains to be seen whether recent and ongoing regulatory changes, as well as mutual market access concerns with the EU, will lead to a different competitive environment in the near future.

In the US, recent merger enforcement in the pharmaceutical sector continues to follow traditional principles and reasoning. However, it is increasingly likely that the FTC's enforcement actions will reflect more aggressive theories of harm. Recent behavioural enforcement has largely consisted of pay-for-delay litigation and continuing prosecution of price-fixing charges against generic manufacturers. However, the FTC has given strong indications that it has competitive concerns with fees and rebates paid by pharmaceutical manufacturers to pharmacy benefit managers, which is likely to lead to new fronts of enforcement.

In Australia, the life sciences sector is not currently identified as a priority area for Australian Competition and Consumer Commission (ACCC) enforcement. However, there have been some important regulatory developments affecting the sector, such as the repeal of a safe harbour for intellectual property assignments or licensing arrangements, and the ACCC has also taken some significant cases

against companies in this sector in recent years. Lastly, in Brazil, the health sector is under close scrutiny from the Brazilian antitrust authorities, and this is not expected to change in the near future.

CHAPTER 2

Excessive Pricing

George Zacharodimos[1]

Introduction

This chapter provides an overview of recent decisions finding an excessive price infringement in the pharmaceuticals sector. Competition authorities in the European Union and the United Kingdom have historically been reluctant to intervene on the basis of excessive pricing, but the pharmaceutical sector has seen mounting regulatory interest in alleged excessive pricing practices in recent years. The recent decisions introduce a cost-plus approach to identify excessive pharmaceutical prices or require the existence of 'plus factors' in the conduct of companies. Antitrust scrutiny of pharmaceutical pricing, pricing negotiations with health authorities and supply practices is expected to continue.

The development of the applicable legal test in Europe

The European Commission (EC) first developed its theory of excessive pricing in 1975 in what became the *United Brands* case, in which the prices charged by United Brands were deemed 'excessive in relation to the economic value of the product supplied'.[2] The EC compared the prices of branded bananas to prices of unbranded bananas, which were up to 40 per cent lower, as well as the prices charged in Ireland to those in Germany, Denmark, the Netherlands, Belgium and Luxembourg, which were considerably higher.[3]

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1 George Zacharodimos is an associate at Skadden, Arps, Slate, Meagher & Flom LLP. The author wishes to thank Ingrid Vandenborre for her helpful comments.

2 Commission Decision of 17 December 1975 relating to a proceeding under Article 86 of the EEC Treaty (IV/26699, *Chiquita*) (76/353/EEC), 1976 O.J. (L 95) 1, 15.

3 id., at 15–16.

On appeal, the European Court of Justice (CJEU) developed a test (the *United Brands* (UB) test) to determine whether a price is excessive, which consists of two limbs:

- whether the difference between the costs actually incurred and the price actually charged is excessive (Limb 1); and
- if so, whether a price has been imposed that is either unfair in itself or when compared to competing products (Limb 2).[4]

The CJEU also emphasised that other methods may be valid to establish an excessive pricing abuse, such as comparator tests.[5]

In subsequent years, the EC and the CJEU developed the UB test further. Until the EC's investigation into Aspen Pharmaceuticals' pricing practices, the UB test had not been applied in the pharmaceutical sector by the EC (or the CJEU), and the EC had pursued just a handful of cases involving excessive pricing.

- In *Deutsche Post*, the EC found that Deutsche Post charged an excessive price for the delivery of international post. International post had the same price as the domestic postal service, despite the fact that the costs of forwarding cross-border mail were less than the domestic tariff (i.e., the price was 25 per cent higher than the company's estimated costs).[6]
- In 2004, it investigated but rejected two complaints against alleged excessive pricing. In *Scandlines Sverige AB v. Port of Helsingborg*, the EC found that there was insufficient evidence to conclude that the port charges in question would have 'no reasonable relation to the economic value' of the services and facilities provided to ferry operators, when all relevant (economic) factors for the determination of economic value are taken into account.[7] Although revenues derived from ferry operations exceeded the costs actually incurred, the EC affirmed that the UB test is cumulative (i.e., a price needs to be excessive

4 Case 27/76, *United Brands Co. v. Commission*, 1978 E.C.R. 209, 301, paragraph 252.

5 id., paragraph 253; see also Commission Decision of 10 February 2021 relating to a proceeding under Article 102 of the Treaty on the Functioning of the European Union (TFEU) and Article 54 of the EEA Agreement (Case AT.40394 (*Aspen*)), paragraph 83 and n. 55 (quoting Case 27/76, *United Brands Co. v. Commission*, 1978 E.C.R. 209, 302, paragraph 253).

6 Commission Decision of 25 July 2001 relating to a proceeding under Article 82 of the EC Treaty (COMP/C-1/36.915, *Deutsche Post AG – Interception of cross-border mail*) (2001/892/EC), 2001 O.J. (L 331) 40, 73, paragraph 166.

7 Case COMP/A.36.568/D3, *Scandlines Sverige AB v. Port of Helsingborg*, Commission Decision of 23 July 2004, paragraph 246, https://ec.europa.eu/competition/antitrust/cases/dec_docs/36568/36568_44_4.pdf.

and unfair) and that the economic value must be determined with regard to the particular circumstances, also taking into account non-cost-related factors such as the demand for the product or service.[8]

- In *IMAX*, the EC also rejected Euromax's claim that IMAX had abused its dominant position in the supply and maintenance of the 15/70mm format IMAX system, as Euromax failed to objectively prove that IMAX's price was unfair compared to others or in itself.[9]
- In *Rambus*, the EC accepted commitments for the company, for a period of five years, not to charge any royalties for DRAM chips based on JEDEC[10] standards, which were adopted when Rambus was a member of JEDEC, and to charge a maximum royalty rate of 1.5 per cent for the subsequent DRAM chips standards, which were adopted after Rambus was no longer a member of JEDEC (i.e., below the 3.5 per cent it had been previously charging).[11]

More recently, in *Gazprom*, the EC imposed a set of obligations on the company to enable the free flow of gas at competitive prices in Central and Eastern European gas markets.[12] The EC preliminarily considered that Gazprom's prices were excessive, as its weighted average mark-up above costs was 170 per cent, and unfair, as they were, on average, between 22 per cent and 40 per cent higher than Gazprom's long-term contract prices in Germany and Western European gas hubs, which were the selected benchmark prices. As regards the unfairness (Limb 2) assessment, the EC noted that the analysis of unfairness in itself is an option 'if no appropriate price benchmark exists'.[13]

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8 id., paragraphs 226–227.

9 Case COMP/C-2/37.761, *Euromax v. IMAX*, Commission Decision of 25 March 2004, https://ec.europa.eu/competition/antitrust/cases/dec_docs/37761/37761_12_3.pdf.

10 JEDEC is a US-based industry-wide standard-setting organisation.

11 Commitment Decision of 9 December 2009, relating to a proceeding under Article 102 of the Treaty on the Functioning of the European Union and Article 54 of the EEA Agreement (Case COMP/38.636, *Rambus*), https://ec.europa.eu/competition/antitrust/cases/dec_docs/38636/38636_1203_1.pdf.

12 Commission Decision of 24 May 2018 relating to a proceeding under Article 102 of the Treaty on the Functioning of the European Union (TFEU) and Article 54 of the EEA Agreement (Case AT.39816, *Upstream Gas Supplies in Central and Eastern Europe*), https://ec.europa.eu/competition/antitrust/cases/dec_docs/39816/39816_10148_3.pdf.

13 id., paragraph 65.

Over the years, the CJEU has delivered judgments relating to the excessiveness of:

- fees charged for the issuance of certificates in the motor vehicle sector (*British Leyland*);[14]
- prices for funeral services (*Pompes funèbres des régions libérées*);[15]
- royalties charged for music repertoire (*SACEM II and III*);[16]
- royalties on copyright-protected music for television broadcasts (*Kanal 5*);[17] and
- rates for licensing of musical works for performance in public places such as shops and service centres (*AKKA/LAA*).[18]

In *AKKA/LAA*, when assessing whether a copyright management organisation is charging unfairly high rates, the CJEU concluded that it is appropriate to compare its rates in Latvia with its rates in neighbouring countries, appropriately adjusted, so long as the countries are selected on objective, appropriate and verifiable criteria and comparisons are made consistently.[19] The CJEU added that 'a difference between rates may be qualified as "appreciable" if it is both significant and persistent on the facts, with respect, in particular, to the market in question', as well as that the difference can be explained by the company under investigation 'by relying on objective dissimilarities' between the various countries.[20] Advocate General Nils Wahl, in his opinion, also noted that 'a price cannot easily be set significantly above the competitive level where the market is not protected by high barriers to entry or expansion'.[21]

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14 Case C-226/84, *British Leyland v. Commission*, 1986 E.C.R. 3297.

15 Case 30/87, *Bodson v. SA Pompes funèbres des régions libérées*, 1988 E.C.R. 2507.

16 Joined Cases 110/88, 241/88 and 242/88, *Lucazeau v. Société des Auteurs, Compositeurs et Éditeurs de Musique (SACEM)*, 1989 E.C.R. 2823.

17 Case C-52/07, *Kanal 5 Ltd. v. Föreningen Svenska Tonsättares Internationella Musikbyrå (STIM) upa*, 2008 E.C.R. I-9311.

18 Case C-177/16, *Autortiesību un Komunicēšanās Konsultāciju Aģentūra/Latvijas Autoru Apvienība v. Konkurences Padome*, ECLI:EU:C:2017:689 (14 September 2017).

19 id., paragraphs 41, 44.

20 id., paragraphs 55, 57.

21 Opinion of Advocate General Wahl of 6 April 2017, paragraph 48, Case C-177/16, *Autortiesību un Komunicēšanās Konsultāciju Aģentūra/Latvijas Autoru Apvienība v. Konkurences Padome*, ECLI:EU:C:2017:286.

Excessive pricing cases in the pharmaceutical sector

As mentioned above, excessive pricing investigations in the pharmaceutical sector were rare until recently. In the past, only the German Federal Cartel Office (FCO), in 1974, and the UK Office of Fair Trading (OFT), in 2002, had brought excessive pricing cases against pharmaceutical companies. The FCO found that Roche charged excessive prices for Librium and Valium and ordered the company to lower the prices by 35 per cent and 40 per cent, respectively, but its decision was then overturned by the German Supreme Court.[22] The OFT found Napp to have charged excessive prices in the community segment of the market for sustained release morphine tablets and capsules in the UK, with its decision being upheld by the Competition Appeal Tribunal (CAT).[23]

However, during the past eight years, and after the EC's inquiry into the pharmaceutical sector, competition authorities in the EU and the UK have shown an increased interest in the sector and have devoted resources to pursuing more than a dozen (publicly announced) excessive pricing cases in the sector.

The first investigations focused on off-patent drugs whose prices were significantly increased:

- Aspen's Leukeran, Alkeran, Purinethol, busulfan and Lanvis (cancer medicines);
- Pfizer/Flynn's phenytoin (treatment of epilepsy);
- Advanz Pharma's liothyronine (treatment of thyroid hormone deficiency);
- Auden/Actavis's hydrocortisone (treatment of adrenal insufficiency); and
- CD Pharma's Syntocinon (oxytocin, given to pregnant women in connection with childbirth).

More recently, however, competition authorities have started investigating pricing practices relating to:

- medicines with exclusivity rights (Essential Pharma's Priadel, a treatment of bipolar disorder);
- orphan drugs (Leadiant Biosciences' chenodeoxycholic acid (CDCA), a treatment of cerebrotendinous xanthomatosis (CTX) metabolic abnormality); and
- innovative medications for the treatment of spinal muscular atrophy.

22 Federal Court of Justice, 12 February 1980, Az. KVR 3/79, 76 *Entscheidungen des Bundesgerichtshofes in Zivilsachen* [BGHZ] 142–153 (Germany) (*Valium II*).

23 *Napp Pharm. Holdings Ltd. v. Director Gen. of Fair Trading* [2002] CAT 1 (UK).

The first of these cases was initiated by the Italian Competition Authority (AGCM), which brought a case against Aspen regarding the prices of its oncology portfolio. In its 2016 decision, which was upheld by the Italian Supreme Administrative Court, the AGCM found that Aspen abused its dominant position by pressuring the Italian Medicines Agency (AIFA) into accepting excessively high prices, and imposed a fine of approximately €5.2 million on the company.[24] In 2017, the Spanish competition authority (CNMC) also announced an investigation into Aspen's price increases as well as supply practices, but the proceedings were archived when the EC opened a formal investigation into Aspen's practices relating to the same oncology portfolio in May 2017, covering the entire European Economic Area (EEA) except Italy.

The EC's *Aspen* case is the leading case on excessive pricing in the pharmaceutical sector in the EU and is particularly instructive on the application of the UB test. After the AGCM's infringement decision against Aspen, the EC accepted Aspen's pricing and supply commitments, without imposing a fine or concluding whether there was an infringement by Aspen. The commitments were made legally binding in February 2022 and obliged Aspen to:

- reduce the relevant drugs' prices by, on average, approximately 73 per cent;
- make one-off payments to national payors and patients, as appropriate, to give retroactive effect to the reduced prices as of the date that Aspen approached the EC with a concrete commitments proposal (October 2019);[25] and
- guarantee continued supply of these medicines for five years, and to either continue to supply or make the marketing authorisations available to other suppliers for an additional five-year period.

In 2016, in *Pfizer/Flynn*, the UK's Competition and Market's Authority (CMA) fined Pfizer and Flynn £84.2 million and £5.2 million, respectively, and ordered a reduction of prices after finding that the companies had charged excessive and unfair prices for phenytoin sodium capsules, following an increase of up to

24 See Case A-480, *Price Increase of Aspen's Drugs* (AGCM, 29 September 2016) (Italy) (English translation), https://en.agcm.it/dotcmsDOC/pressrelease/A480_eng.pdf (*Aspen Italy*).

25 *Aspen*, paragraphs 210–212, 227–234.

2,600 per cent after the drug was de-branded (and removed from the price regulation regime) in September 2012.[26]

- The CMA's decision was appealed and subsequently annulled by the CAT. The latter concluded that the CMA should have gone beyond a cost-plus calculation (i.e., a comparison between the price charged and a benchmark higher than cost) to determine excessiveness and that it had misapplied the UB test to determine the unfairness of prices.[27]
- On further appeal, the UK Court of Appeal held that the CAT was wrong to require the CMA to go beyond a cost-plus assessment to determine price excessiveness, but it upheld the CAT's judgment on the facts, including a remittal of the issues of abuse and penalties to the CMA.[28] In June 2020, the CMA opened a remittal investigation, and in July 2022, fined Pfizer and Flynn £63 million and £6.7 million, respectively.[29]

In Denmark, the Competition and Consumer Authority (DCC) found, in 2018, that CD Pharma, a distributor of pharmaceuticals, abused its dominance by charging excessive prices when it increased its price of Syntocinon by 2,000 per cent after learning that parallel trader Orifarm ran out of stock and failed to deliver the drug to the public hospitals' national buyer.[30] The Danish Maritime and Commercial Court upheld the DCC's finding.[31]

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26 Case CE/9742-13, *Unfair pricing in respect of the supply of phenytoin sodium capsules in the UK* (Competition and Markets Authority (CMA), 7 December 2016) (UK), https://assets.publishing.service.gov.uk/media/594240cfe5274a5e4e00024e/phenytoin-full-non-confidential-decision.pdf (*Pfizer/Flynn*).

27 *Flynn Pharma Ltd. v. CMA* [2018] CAT 11 (UK), www.catribunal.org.uk/sites/default/files/2018-08/1275-1276_Flynn_Judgment_CAT_11_070618.pdf (*Pfizer/Flynn CAT*).

28 *CMA v. Flynn Pharma Ltd.* [2020] EWCA Civ 617 (UK), www.judiciary.uk/wp-content/uploads/2020/05/Flynn-Pharma-v-CMA-Final.pdf (*Pfizer/Flynn Court of Appeals*).

29 Press Release, CMA, '£70 Million in Fines for Pharma Firms that Overcharged NHS' (21 July 2022), www.gov.uk/government/news/70-million-in-fines-for-pharma-firms-that-overcharged-nhs. The full text of the decision was not available at the time of writing.

30 Press Release, Danish Competition and Consumer Authority (DCC), 'CD Pharma has abused its dominant position by increasing their price by 2,000 percent' (31 January 2018), www.en.kfst.dk/nyheder/kfst/english/decisions/2018-cd-pharma-has-abused-its-dominant-position-by-increasing-their-price-by-2-000-percent/ (*CD Pharma*, press release).

31 *CD Pharma v. Competition Council*, Sag BS-3038/2019-SHR (Maritime and Commercial Court, 2 March 2020) (Denmark) (*CD Pharma*). The DCC also transferred the case to the Danish State Prosecutor for Serious Economic and International Crime.

Following complaints, the Dutch, Italian, Spanish and Belgian competition authorities launched investigations into Leadiant's pricing practices for the orphan drug CDCA.[32] CDCA was originally used for the treatment of gallstones but has also been used for the treatment of CTX, a rare genetic metabolic disorder, since the 1970s. The drug was originally sold under the name Chenofalk, and later under the name Xenbilox. In 2017, Leadiant was granted orphan designation and marketing authorisation for its CDCA-based drug for the treatment of CTX, following which it stopped selling Xenbilox and released CDCA under the trade name CDCA-Leadiant at significantly higher prices in several countries.

- In July 2021, the Dutch Consumer and Markets Authority (ACM) found that Leadiant had allegedly charged an 'exorbitantly high' and 'unfair' price for CDCA and imposed a €19.5 million fine.[33] Leadiant has appealed the decision and has also submitted a complaint with the ACM against Dutch health insurers, claiming that they colluded by refusing to negotiate a price reduction. The ACM has suspended the payment of the fine pending the assessment of Leadiant's complaint.[34]
- In May 2022, the Italian authority also imposed a fine of €3.5 million on Leadiant for abusing its dominant position by charging excessive prices for CDCA[35] as:
    - it allegedly managed, through a complex strategy, to delay and obstruct the price negotiations for the product (e.g., by delaying the supply of information requested by AIFA); and

32 In 2021, the Israel Competition Authority also opened excessive pricing proceedings enforcement proceedings against MBI Pharma, which markets Leadiant's CDCA drug in Israel, following a complaint from the Ministry of Health.

33 See Case ACM/20/041239, *ACM v. Essetifin S.p.A.* (1 July 2021) (Netherlands), www.acm.nl/sites/default/files/documents/summary-of-decision-on-abuse-of-dominant-position-by-leadiant.pdf (*Leadiant, Netherlands*) (summary of decision on abuse of dominant position by Leadiant). The full text of the decision was not available at the time of writing.

34 Matthew Newman, 'Leadiant wins suspension of Dutch "excessive pricing" fine as regulator probes insurers', MLex (23 December 2021), https://mlexmarketinsight.com/news/insight/leadiant-wins-suspension-of-dutch-excessive-pricing-fine-as-regulator-probes-insurers.

35 Italian Competition Authority (AGCM) decision of 17 May 2022, www.agcm.it/dotcmsdoc/allegati-news/A524%20chiusura.pdf (in Italian) (*Leadiant, Italy*).

    - CDCA's price was allegedly excessive, as it was disproportionate to the costs, and unfair, as its molecule had been on the market for a long time, it has no therapeutic added value compared to the previous medicines and Leadiant engaged in limited research and development (R&D) activities. Leadiant has appealed the decision.[36]
- In December 2020, the CNMC launched an investigation into Leadiant's prices. Leadiant submitted proposed commitments that were rejected by the Competition Directorate of the CNMC in March 2022. The decision was upheld by the CNMC in June 2022 and the probe against Leadiant is currently ongoing.[37]
- The Belgian Competition Authority (BCA) has also launched an investigation into Leadiant's pricing practices regarding CDCA, following a complaint by the Belgian consumer organisation Test-Achats/Test-Aankoop. In 2019, the Minister of Economic Affairs used his price regulation powers to reduce the maximum price of CDCA by 75 per cent and his injunctive powers to request the BCA to prioritise the claim.[38]

In the UK, the CMA recently concluded its investigations into the pricing practices of Advanz Pharma, Auden/Actavis and Essential Pharma.

- In *Advanz Pharma*, the CMA fined Advanz £40.9 million, and two private equity firms that were former owners of businesses that now form part of Advanz £60.5 million, for inflating the price of thyroid hormone replacement tablets between 2009 and 2017.
    - The CMA determined that, in 2007, Advanz developed a 'price optimisation' strategy by which it identified generic drugs with limited or no competition and high barriers to entry, and subsequently de-branded them to remove them from the price regulation regime. This allegedly allowed Advanz to increase the price of thyroid hormone replacement tablet packs by 6,021 per cent (between 2007 and 2017).

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36 Nicholas Hirst, 'Leadiant to Appeal Italian Antitrust Sanction that "Undermines" EU Policy on Orphan Drugs', MLex (2 June 2022), https://mlexmarketinsight.com/news/insight/leadiant-to-appeal-italian-antitrust-sanction-that-undermines-eu-policy-on-orphan-drugs.

37 CNMC Decision of 15 June 2022, R/AJ/012/22 LEADIANT 4, www.cnmc.es/sites/default/files/4169200.pdf (in Spanish) (*Leadiant, Spain*).

38 See 'Woekerwinsten maken op kap van patiënten is onaanvaardbaar', Christian Democratic and Flemish party (Belgium) (6 September 2019), www.cdenv.be/actua/wouter-beke-verbiedt-woekerprijs-voor-geneesmiddel-tegen-zeldzame-ziekte-ctx/.

- According to the CMA, the price increase was not driven by any meaningful innovation or investment, volumes remained broadly stable and the costs of production did not increase significantly.
- The price increase led to the placement of the drug on the NHS's 'drop list' in July 2015, meaning that patients were faced with the prospect of having their current treatment stopped or having to purchase the drug at their own expense.[39]
- The parties have appealed the CMA's decision before the CAT.[40]

- In *Auden/Actavis*, the CMA imposed fines on Auden/Actavis, and on Allergan plc, Accord Pharmaceuticals and Intas, for their ownership periods of Auden and Accord UK (formerly known as Actavis UK), respectively, for excessive pricing in relation to the supply of hydrocortisone tablets (used to treat inflammatory skin conditions as well as Addison's disease) in the UK, as well as for a market-sharing agreement with Waymade and AMCo.[41] Auden Mckenzie bought the licences for hydrocortisone and launched its own generic versions in 2008. Accord UK took over the business in 2015 and was held liable for Auden's conduct before that date.
  - The CMA found that Auden Mckenzie and Actavis increased the price of hydrocortisone tablets by over 10,000 per cent compared to the original branded version of the drug, which was sold by the drug's previous owner until April 2008.
  - According to the CMA, both companies exploited the fact that de-branded drugs are not subject to NHS price regulation, enabling them to increase their prices without constraint for over a decade (October 2008 to July 2018). Although prices fell gradually once competitors entered the market, Actavis continued to charge higher prices than its rivals.
  - Auden, Accord UK and Allergan have appealed the CMA's decision before the CAT.[42]

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39 Case 50395, *Excessive and Unfair Pricing with Respect to the Supply of Liothyronine Tablets in the UK* (CMA, 29 July 2021) (UK), https://assets.publishing.service.gov.uk/media/61b8755de90e07043f2b98ff/Case_50395_-_Decision_final___.pdf (*Advanz Pharma*).

40 See Case 1411/1/12/21, *Advanz Pharma Corp. v. CMA*, Competition Appeals Tribunal (CAT) (UK), www.catribunal.org.uk/cases/141111221-advanz-pharma-corp (last visited 28 July 2022).

41 Case 50277, *Hydrocortisone Tablets: Excessive and Unfair Pricing and Anti-competitive Agreements* (CMA, 15 July 2021) (UK), https://assets.publishing.service.gov.uk/media/624597bbe90e075f0b5a3da4/Case_50277_Decision.pdf (*Auden/Actavis*).

42 See Case 1413/1/12/21, *Auden Mckenzie (Pharma) Limited & Another v. CMA*, CAT (UK), www.catribunal.org.uk/cases/141311221-auden-mckenzie-pharma-limited-another

- The CMA also investigated Essential Pharma regarding its decision to withdraw the supply of Priadel (a lithium-based medication for the treatment of bipolar disease) in the UK, and directly or indirectly imposing unfair prices.[43]
  - The CMA had concerns that Essential Pharma may have abused its (suspected) dominance by adopting a strategy to withdraw Priadel from UK patients with a view to impose excessive prices, either by securing a price increase for Priadel or by causing patients to switch to the more expensive Camcolit (also commercialised by Essential Pharma).
  - Following the launch of the CMA's investigation, Essential Pharma reached an agreement with the UK Department of Health and Social Care (DHSC) to increase the price of Priadel.
  - Nevertheless, to remove the possibility of a withdrawal despite the price increase and the supply agreement with the DHSC, Essential Pharma committed to the CMA not to withdraw and to ensure appropriate and continued supplies of Priadel for five years.
  - Essential Pharma is further constrained in any decision to discontinue and divest or license the supply of the product during the commitment period.

In 2019, the Belgian and Italian consumer groups Test-Achats/Test-Aankoop and Altroconsumo filed complaints with their national competition authorities over the price of an innovative medication for treatment of spinal muscular atrophy,[44] which was under market exclusivity. The investigations are ongoing.

Application of the excessive pricing test in the pharmaceutical sector

In all the recent decisions discussed above, competition authorities applied the UB test. In the vast majority of cases, the finding of excessive pricing related to the implementation of a price increase, either following an acquisition, a re-branding agreement or the receipt of orphan drug status, all of which change the product's brand, profile or owner.

(last visited 28 July 2022) and Case 1407/1/12/21, *Allergan plc v. Competition and Markets Authority*, CAT (UK), www.catribunal.org.uk/cases/140711221-allergan-plc.

43 Case 50951, *Decision to Accept Commitments Offered by Essential Pharma in Relation to the Supply of Priadel* (CMA, 18 December 2020), https://assets.publishing.service.gov.uk/media/5fdb73c18fa8f5148deb3005/Commitments_decision.pdf (*Essential Pharma*).

44 See Press Release, Altroconsumo Organizzazione, 'Spinraza unfairly priced. Italian and Belgian antitrust authorities urged to investigate on drug' (24 July 2019), www.altroconsumo.it/organizzazione/international/press-releases/2019/spinraza-unfairly-priced-italian-and-belgian-antitrust-authorities-urged-to-investigate.

After defining the market and determining dominance, competition authorities:

- first, compare the prices charged or revenues earned with incurred costs and assess whether the resulting profits are excessive (Limb 1); and
- second, assess whether the price is unfair in itself or when compared to competing products (i.e., whether there are reasons underlying (or justifying) the profits identified as excessive, and in particular reasons not yet reflected in the price/cost analysis in Limb 1 (Limb 2)).

Market definition and dominance

The EC and EU/UK national competition authorities generally define markets narrowly in the context of excessive pricing allegations. In *Aspen*, the EC defined the markets at the molecular (ATC5) and galenic form level (active pharmaceutical ingredient and tablet/intravenous form),[45] excluding pharmaceuticals recommended for treatment of the same indications because of inelastic demand – younger and elderly patients cannot use certain alternatives – and different (higher) prices. The relevant geographic markets were considered to be national in scope.[46] In the *Leadiant* cases, the ACM and the AGCM concluded that the relevant product market was for the supply of CDCA-based drugs for the treatment of CTX.[47]

The CMA and UK courts have taken a similarly narrow approach. In *Pfizer/Flynn*, the markets were as narrow as the manufacture/distribution of Pfizer-manufactured phenytoin sodium capsules distributed in the UK (including parallel imports), as patients were not able to be switched to another, cheaper drug in light of guidance issued by the UK Medicines and Healthcare products Regulatory Agency.[48] In *Auden/Actavis* and *Advanz Pharma*, the relevant product markets were defined as the supply of 10mg and 20mg hydrocortisone tablets, and the supply of liothyronine tablets, respectively. In *Essential Pharma*, the CMA distinguished the different lithium carbonate medicines based on differences in dosage and release characteristics.[49]

45 *Aspen*, paragraphs 31–58.
46 id., paragraphs 59–61.
47 See *Leadiant, Italy*, paragraph 320; *Leadiant, Netherlands* (summary of the decision).
48 *Pfizer/Flynn*, paragraphs 4.9–4.13, 4.29–4.30.
49 *Essential Pharma*, paragraphs 3.5–3.10.

Once the relevant markets are defined, the assessment of dominance has generally been based on a number of market characteristics, high barriers to entry or a very large market share.

- In *Aspen*, the EC premised its preliminary findings on high market shares, limited entry, lack of countervailing bargaining power as generic alternatives were not available for almost the entire relevant period, and high barriers to entry due to regulatory requirements and limited and declining market size.[50] The EC also found that Aspen was capable of profitably increasing prices, generating very high profit margins and maintaining those prices and margins over a significant time period, which itself indicated a dominant position.[51]
- In *Pfizer/Flynn*, the CMA also relied on limited and declining volumes (drugs were obsolete for the treatment of most indications) and the ability to profitably sustain supra-competitive prices and very high market shares over time.[52]
- In *Advanz Pharma*, the CMA considered the generic drug to have limited or no competition and high barriers to entry.[53]
- In *Auden/Actavis*, the CMA based its dominance finding on the companies' high market shares and financial performance, as well as the windfall of regulatory benefits (barriers to entry/expansion) stemming from the orphan designation granted to a competing product (Plenadren).[54]

Limb 1: price excessiveness

To assess whether profits are excessive, the authorities' first task is to identify the prices charged and the costs incurred for the products in question.

To calculate relevant costs, authorities take into account the costs of production (i.e., direct costs (costs directly attributable to the production, supply and distribution of the relevant product)) plus a part of the indirect costs (common costs incurred in the supply of more than one product (i.e., not directly attributable to any specific product)).[55]

Competition authorities have taken different positions in relation to the costs to be taken into account, with the EC rejecting the inclusion of product acquisition costs and suggesting that only earnings before interest, taxes, depreciation and amortisation (EBITDA) could function as an appropriate measure in the

50 *Aspen*, paragraphs 66–72.
51 id., paragraph 71.
52 *Pfizer/Flynn*, paragraphs 4.210–4.225.
53 *Advanz Pharma*, paragraph 4.132–4.145.
54 *Auden/Actavis*, paragraph 4.288–4.298.
55 *Aspen*, paragraphs 108–109.

Aspen case, as earnings before interest and taxes (EBIT) may be subject to large one-off accounting charges (for example, one-off impairment costs).[56] On the other hand, the ACM also took into account costs and revenues that could be attributed to Leadiant's project to obtain orphan drug designation and marketing authorisation, including the risk that the project could fail.[57]

Furthermore, as regards the allocation of indirect costs, there are several methods that authorities may rely on, each with certain limitations. For example, a regulator may allocate costs in relation to products' relative cost of goods sold (COGS) or volumes. However, actual COGS may not be reported (e.g., standard costing accounting) or available, and comparability of relevant volume units across a business may be limited in the case of heterogeneity of products.

Indirect costs can also be allocated based on revenues. In *Aspen*, the EC considered that a revenue-based allocation is likely to increase the share of indirect costs attributed to the relevant products in the case of suspected excessive pricing and relied on COGS-based allocation supplemented with a volume-based allocation.[58] Similarly, in *Pfizer/Flynn*, *Advanz Pharma* and *Auden/Actavis*, the CMA rejected revenue as a basis and allocated indirect costs according to sales volumes of packs sold, and applied different approaches as part of its sensitivity analyses (e.g., based on sales volumes by capsule instead of packs, activity-based costing or equal allocation and equi-proportional mark-up methods).[59]

Assessment of profitability and excessiveness

Following the determination of relevant costs, the authorities analyse the profitability of the prices at stake to conclude whether they are excessive. The recent decisions reflect a variety of approaches, from strictly cost-based approaches to margin assessments, but converge around a cost-plus assessment, namely a comparison of prices to total costs increased by a mark-up (i.e., a reasonable rate of return or profit margin).

56 id., paragraph 122.

57 *Leadiant, Netherlands* (summary of the decision).

58 *Aspen*, paragraphs 112–115.

59 *Pfizer/Flynn*, paragraphs 5.44–5.47; *Advanz Pharma*, paragraphs 5.120–5.125; *Auden/Actavis*, paragraph 5.126.

In the Italian *Aspen* case, the AGCM applied:

- a gross margin test that was based on a comparison of gross margins (of pre-increase prices) to total indirect costs (both in percentage of sales) to support the determination that the prices before the increase granted a margin in line with Aspen's average gross margin;[60] and
- a cost-plus method, calculating the difference between prices and costs, including direct costs, a portion of indirect costs and a reasonable rate of return on sales (ROS). The AGCM chose a ROS profitability of 13 per cent based on Aspen's business activities (generic/branded drugs with limited investments in R&D).[61]

In *Aspen*, the EC applied a cost-plus approach, namely comparing prices to total costs, increased by a reasonable mark-up (EBITDA margin), which was, in this case, calculated at 23 per cent based on the median measure of EBITDA observations of comparator companies. Only a significant excess over this cost-plus level was deemed excessive.[62] Following the price reductions based on Aspen's commitments, Aspen's prices would, at a maximum, exceed the cost-plus level (i.e., 23 per cent EBITDA) 'by [10-20%] on average across the Relevant Markets' (the actual figure is confidential).[63]

The CMA also followed a cost-plus approach in *Pfizer/Flynn*, *Auden/Actavis* and *Advanz Pharma*.

- In *Pfizer/Flynn*, the CMA compared the price with a theoretical benchmark of costs plus 6 per cent ROS, which represented the standard ROS under the Pharmaceutical Price Regulation Scheme of which both Pfizer and Flynn are members (but that did not apply to the phenytoin sodium capsules sold by Flynn).[64]

60 *Aspen Italy*, paragraph 142. Return on sales (ROS) is given as the ratio between operating earnings and net profits (see id., paragraph 171, n. 134).

61 id., paragraph 171.

62 *Aspen*, paragraphs 132–138.

63 id., paragraph 239 (square brackets are used in the original and reproduced here).

64 *Pfizer/Flynn*, paragraphs 5.85–5.106.

- In *Auden/Actavis*, the CMA used return on capital employed (ROCE)[65] as a profitability metric. It calculated the capital employed by Auden/Actavis and determined that, for Auden/Actavis, the appropriate return on that capital was '[5%–15%]' (the actual figure is confidential), which was the rate used by Actavis when valuing Auden's business.[66]
- In *Advanz Pharma*, the CMA calculated the reasonable rate of return by multiplying capital employed (the amount Advanz had to deploy to operate in the relevant market) by its weighted average cost of capital (WACC) (i.e., the average percentage return that debt and equity investors expect in return for their investment). In this case, the CMA applied a 10 per cent WACC on capital employed for its cost-plus assessment.[67]

The DCC estimated CD Pharma's profit margin and mark-up, and held that a profit margin of around 80 per cent and a mark-up of at least 500 per cent supported a finding that the price was excessive.[68] In the *Leadiant* cases, the ACM compared Leadiant's internal rate of return against a reasonable return for investors of 15 per cent,[69] and the AGCM used a ROS of 21 per cent as its profitability benchmark (which is appreciably higher than the benchmark used in the Italian *Aspen* case).[70]

Limb 2 – price unfairness

In most pharmaceutical excessive pricing cases, the application of the second limb of the UB test has been limited, and several leave open the question of what conduct, other than the cost/price comparison factors already determinative for the Limb 1 assessment, contributed to the assessment that Limb 2 was met as well. The focus has largely been on the extent of the differential between the pre-increase price or the price level of competitors and the lack of explanation of that difference.

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65 Return on capital employed is measured by assessing profits against the level of capital employed.

66 *Auden/Actavis*, paragraphs 5.150–5.215 (square brackets are used in the original and reproduced here).

67 *Advanz Pharma*, paragraphs 5.126–5.159.

68 See DCC, 'Excessive pricing in pharmaceutical markets – the Danish CD Pharma-case', www.en.kfst.dk/media/54222/excessive-pricing.pdf.

69 *Leadiant, Netherlands* (summary of the decision).

70 *Leadiant, Italy*, paragraph 265.

Whereas the EC considered in *Aspen* that the two prongs of the second limb ('unfair in itself or when compared to others') apply alternatively and not cumulatively,[71] the UK Court of Appeal considered that they are not strict alternatives. According to the Court, if a company relies on evidence other than that put forward by the authority to establish that the price is not excessive or unfair, then the CMA has a legal obligation to fairly evaluate it. The CMA may decide to proceed with the 'unfairness in itself' prong, but it has to give some consideration to prima facie valid comparators advanced by the companies.[72]

In most cases, the authorities have focused on 'plus factors' relating to the companies' alleged behaviour (for example, alleged strategic sequencing of price increases, de-branding/removal from the price regulation regimes or threats to health authorities to delist or withdraw products). In the *Aspen* case, the EC preliminarily found that:

- the prices were unfair in themselves because:
    - Aspen undertook no particular activity in relation to the products (e.g., potential innovations, R&D or commercial risk-taking) and there was a disproportion between the (limited) increases in the costs of the products and the (very high) increases in prices; and
    - Aspen employed a conscious strategy when implementing the high price increases that were deemed harmful to patients and the national health budgets;[73]
- the price increases were not legitimised by the need to cross-subsidise certain markets of loss-making products, and high profitability due to the orphan nature of the products was not justified as the Orphan Drug Regulation was not applicable in this case;[74] and
- as it had preliminarily established that prices were unfair in themselves, there was no need to compare them to others. However, it commented that generics, innovator competitors or more expensive therapeutic substitutes were not suitable comparators for assessing unfairness. Most generic comparators' prices did not yet reflect levels of sufficiently effective generic competition, and innovative (exclusivity-protected) products could not provide meaningful insights into what competitive price levels of off-patent drugs would be.[75]

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71 *Aspen*, paragraph 82.

72 *CMA v. Flynn Pharma Ltd.* [2020] EWCA Civ 339, paragraphs 259–260.

73 *Aspen*, paragraphs 168–170.

74 id., paragraphs 171–175, 202–206.

75 id., paragraphs 196–200.

In the Italian *Aspen* case, the AGCM took into account similar circumstances in its 'unfairness in itself' analysis, and rejected the possibility of any comparison with other products sold for the same indications in Italy, as well as with generics sold in other Member States, on the basis that they did not belong to the same product or geographic markets.[76]

The AGCM also opted for an assessment of the unfairness in itself of the company's pricing policy in the *Leadiant* case, and based its analysis on the nature of the product, low R&D investments and the lack of added therapeutic value of the orphan drug compared to existing therapies.[77] Similarly, the ACM alleged that Leadiant obtained the orphan drug designation because of the very limited number of CTX patients, but did not introduce any innovation or therapeutic added value compared to the previous CDCA-based drug. The ACM also noted that the price was far higher than the prices of Leadiant's previous (molecularly identical) versions of the drug (Chenofalk and Xenbilox) a few years earlier.[78] In *CD Pharma*, the DCC noted that CD Pharma's behaviour could raise the price levels on a more permanent basis in the post-abuse period.[79]

In *Pfizer/Flynn*, the CMA found that the prices were also unfair 'in themselves' because they had no reasonable relation to the economic value of the capsules, which was not higher than their cost of production plus a 6 per cent ROS (i.e., the cost-plus benchmark). Like in *Aspen* and *CD Pharma*, the CMA focused on circumstances surrounding and leading up to the price increase, considering, for example, internal assessment and correspondence with distributors regarding the (reputational) impact of the strategy.[80] Similarly, in *Advanz Pharma* and *Auden/Actavis*, the CMA relied, among other things, on the significant increases in price, the impact on NHS and patients, the lack of innovation and improvements and the features of the relevant markets, such as lack of regulatory constraints, high demand inelasticity and high barriers to entry.[81]

Reasonable relation to the economic value of the product

To be abusive, prices should have no reasonable relation to the economic value of the product. Non-cost-related factors, such as demand for the product or service, value from the customers' or patients' perspective and additional benefits not

76 *Aspen Italy*, section IV.3.4 F.
77 *Leadiant, Italy*, paragraphs 245, 559–589.
78 *Leadiant, Netherlands* (summary of the decision).
79 *CD Pharma*, press release.
80 *Pfizer/Flynn*, paragraphs 5.336, 5.410–5.438.
81 *Advanz Pharma*, section 5.E.II; *Auden/Actavis*, section 5.D.II.

reflected in the costs of supply, should be considered.[82] This is particularly relevant for innovative pharmaceuticals or pharmaceuticals involving material improvements or developments. Where innovative products require (significant) up-front investment on the basis of a clear and significant patient demand, an assessment based only on development cost, formulated in hindsight once the product is fully developed, may be overly restrictive and may disincentivise product development. However, non-cost-related factors have not been taken into account in the authorities' decisions to date. In *Advanz Pharma* and *Auden/Actavis*, the CMA examined whether non-cost-related factors increased the economic value of the drugs, but concluded that their economic value was captured in the 'cost-plus'.[83]

Conclusion

The recent decisions introduce a cost-plus approach to identify excessive pharmaceutical prices, which makes the inclusion of the appropriate costs and identification of the correct profitability comparators of particular importance in the determination of price excessiveness. Moreover, given the authorities' reliance on the existence of 'plus factors' with regard to the unfairness limb, conduct during pricing negotiations or product launch decisions may come under scrutiny.

82 See, for example, Case COMP/A.36.568/D3, *Scandlines Sverige AB v. Port of Helsingborg*, Commission Decision of 23 July 2004, https://ec.europa.eu/competition/antitrust/cases/dec_docs/36568/36568_44_4.pdf, paragraphs 226–227; *Albion Water ltd, Albion Water Group Limited v. Water Services Regulatory Authority and Dwr Cymru Cyfyngedig, United Utilities Water Plc* [2008] CAT 31, paragraph 222.

83 *Advanz Pharma*, section 5.E.IV; *Auden/Actavis*, section 5.D.IV.

The covid-19 pandemic – and the amount of public money that governments are spending on healthcare – has thrust the life sciences industry into the international spotlight, with debates over price controls and IP waivers making headlines around the world. While many of these concerns are global, the same is not always true of the solutions adopted by national regulators. The first edition of *The Guide to Life Sciences* – edited by Ingrid Vandenborre and Caroline Janssens – provides practical and timely guidance for both practitioners and enforcers trying to navigate this high-stakes environment. The Guide draws on the wisdom and expertise of distinguished practitioners globally to provide essential guidance on subjects as diverse as biosimilar competition and product denigration, as well as a forensic examination of the most significant and far-reaching regulations and decisions from around the world.

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ISBN 978-1-83862-882-6