BSLR Article: Competition law implications of generic drug price rises

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Innovative medicines are typically developed and brought to market with the protection of patents and various forms of market exclusivity, giving the innovators time to make a sufficient return on their investment to incentivise the costly research and development required. Once the patents and exclusivity expire, other companies can launch generic copies of the medicines, driving the price down by competition. How, though, does the system cope if competition in those generic drugs dries up? When will there be competition law implications?

Although this article focuses on a series of recent investigations, failures of competition in the generic market is not a new concern. In 2001, the Sackler-owned Napp was found to have engaged in abuse of a dominant position in the UK for its off-patent sustained-release morphine, both by targeted discounts to hospitals and by excessive pricing in the community segment of the market.[2] Then in 2002 there was an investigation by the UK Serious Fraud Office into suspected collusion to increase the prices of certain generic drugs, in particular warfarin and penicillin-based antibiotics.[3] However, attempts to bring a criminal prosecution for conspiracy to defraud were ultimately thrown out in 2008 by judgments of the House of Lords and Court of Appeal, on the basis that agreements in restraint of trade were not necessarily criminal offences unless they were accompanied by aggravating elements such as misrepresentation and deception.[4]

The more recent investigations can be dated back to July 2010, when an article in the English press highlighted that the price of some generic medicines had risen by 1000% over two years.[5] Various products were identified, including hydrocortisone tablets, which had risen from £5/packet in 2008 to £44.40/packet. The article noted that the main supplier of that drug to the NHS was a small pharmaceutical firm called Auden Mckenzie.[6] A week later, the same newspaper was pleased to report that the price had been cut back to £7.40/packet.[7]

Two years later, the price of an old epilepsy drug called phenytoin rose significantly following its transfer from Pfizer to Flynn Pharma, initially costing the NHS an additional £44m/year.[8] This was rapidly noted by some in the NHS and questions were asked in the UK Parliament, which led to an investigation by the Competition and Markets Authority (CMA).

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[2] Decision CA98/2/2001 *Napp* (30 March 2021), largely upheld in *Napp v DGFT* [2002] CAT 1 and [2002] EWCA Civ 796. See also the evaluation of that intervention at https://www.gov.uk/cma-cases/napp-pharmaceutical-holdings-ltd-alleged-abuse-of-a-dominant-position.

[3] *R (Kent Pharmaceuticals Ltd) v Director of the Serious Fraud Office* [2003] EWHC 3002 (Admin); [2004] EWCA Civ 1494.

[4] *R v GG plc* [2007] EWCA Crim 2659; [2008] UKHL 17 (following *Norris v Government of the United States* [2008] UKHL 16); *R v GG plc (No.2)* [2008] EWCA Crim 3061 (confirming the refusal of permission to amend the criminal indictment).

[5] Jason Lewis, "'NHS doesn't care about cost of medicine': Drugs firms accused of profiteering by raising prices by ONE THOUSAND per cent", Mail on Sunday, 18 July 2010.

[6] Then owned by Amit Patel, of whom more later. Auden Mckenzie was acquired by Allergan in 2015 and then, as part of Teva's acquisition of Allergan's generics business in 2016, the relevant business was divested to Intas/Accord in 2017. A claim was brought by Auden Mckenzie against Amit Patel in 2017, including issues relating to hydrocortisone, but this was settled on a confidential basis in 2020. See *Auden Mckenzie v Amit Patel* [2019] EWHC 1257 (Comm); [2019] EWCA Civ 2291.

[7] Jason Lewis, "Drug firm slashes prices after MoS investigation -saving taxpayer £500k", Mail on Sunday, 25 July 2010.

[8] HC Deb 8 November 2012 vol 552 c 680W.

Three years on, in 2015, the newspapers were again reporting on price rises, this time highlighting a 2000% price rise of generic drugs.[9] The article made reference to the CMA investigation in relation to phenytoin and price rises in the US of Daraprim (pyrimethamine) after its acquisition by Martin Shkreli, as well as price rises in the UK by Auden Mckenzie and AMCo.[10]

By 2016, there was a report that the price of hydrocortisone had now risen to £85/packet.[11] That article neatly summarised the strategy adopted by four generic pharmaceutical companies as follows:

> *The four companies identified by The Times have focussed on drugs that have been out of patent for many years and which are no longer profitable enough to interest large pharmaceutical companies. They typically buy the exclusive marketing rights to these medicines from big pharmaceutical companies. By then dropping the brand names and selling the medicines under their generic names instead, the companies are able to take advantage of a loophole in NHS pricing controls. The drugs move from Category C, where manufacturers face a profit cap, to Category A, for which the Department of Health sets a reimbursement price based on cost information from two wholesalers, AAH and Alliance Healthcare, and from two major manufacturers, Teva and Actavis, if they make the drug. Yet with the medicines examined by The Times, the companies are often the sole or dominant supplier for the two wholesalers, effectively leaving them free to set their own prices before the wholesalers add their profit margins. They can face no competition for years because of the limited market for their drugs and the lengthy process involved for rivals seeking a new marketing authorisation from the regulator. Even where there are a small number of competitors, the market is failing to prevent huge price rises in some cases.*

The four companies identified were Auden Mckenzie; Amdipharma and Mercury (by now merged into AMCo and acquired by Concordia); and Atnahs.[12]

Following a consultation in 2015,[13] legislation was proposed in 2016 to close this "loophole"[14] and in 2017 the NHS was given the power to limit the price of generic pharmaceuticals even where the same manufacturer has other branded products subject to the voluntary Pharmaceutical Price Regulation

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[9] Jo Ungoed-Thomas and Bénédicte Earl, "2,000% drug price rise 'milks' NHS", Sunday Times, 25 October 2015.

[10] AMCo was formed by the merger of Mercury Pharma (previously Goldshield, one of the companies investigated by the SFO) and Amdipharm in 2013; it was subsequently sold to Concordia in 2015, which then changed its name to Advanz in 2018.

[11] Billy Kenber, "'Extortionate' prices add £260m to NHS drug bill; Four firms exploit loophole to make fortunes at taxpayers' expense", The Times, 3 June 2016. See also Billy Kenber, *Sick Money* (Canongate, 2021).

[12] In contrast to the other companies, Atnahs does not appear to be involved in any of the investigations discussed in this article. However, there was nevertheless some press criticism when one of its founders, Vijay Patel (who was also involved in Amdipharm and Waymade, of which more below), was named in the 2019 New Year Honours List: see Martin Rosenbaum, "Official failings in vetting of businessman for OBE revealed", BBC News, 10 February 2021 following *Martin Rosenbaum v Information Commissioner* (Dismissed) [2021] UKFTT 2020_0050 (GRC).

[13] See https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/459219/stat_scheme_consultation_2015.pdf, para 3.39.

[14] See https://www.gov.uk/government/publications/health-service-medical-supplies-costs/health-service-medical-supplies-costs-bill-factsheet, see section 2.

Scheme (or PPRS).[15] It is unclear whether the legislation has been used since its introduction or whether the threat of its use has sufficed to change behaviour.[16] In any case, changing the legislation did not address past price increases for generic products.

The CMA has therefore sought to use competition law to challenge both the price rises themselves, under the prohibitions on abuse of a dominant position,[17] and any agreements seeking to restrict competitive entry by new suppliers, under the prohibitions on anti-competitive agreements.[18] It has used one or both approaches in a series of investigations, beginning in May 2013 (phenytoin[19]), then in March 2016 (hydrocortisone [20]), October 2016 (liothyronine [21]), October 2017 (fludrocortisone, [22] nortriptyline,[23] nitrofurantoin,[24] prochlorperazine[25] and an unnamed product[26]) and October 2020 (lithium carbonate[27]).

The first of these approaches is particularly challenging, as unilateral price increases will only exceptionally constitute an abuse of a dominant position. In *United Brands*,[28] the ECJ held that one way to establish that prices are abusive is to demonstrate two things: first, that the difference between the price charged and costs actually incurred is *excessive* and second, that the price imposed is *unfair*, either in itself or when compared to competing products. As Advocate General Wahl said more recently in *AKKA/LAA*,[29] "*there is simply no need to apply [a rule against excessive prices] in a free and*

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[15] Health Services Medical Supplies (Costs) Act 2017, s4, amending s262(2) of the National Health Service Act 2006, brought into force on 7 August 2017 by The Health Services Medical Supplies (Costs) Act 2017 (Commencement No. 1 and Saving Provision) Regulations 2017.

[16] Where prices are limited, these limits are enforced by The Health Service Medicines (Price Control Penalties and Price Control Appeals Amendment) Regulations 2018. Annual reviews have been published under Regulation 6, which suggest that no price limits had been imposed by July 2020: see the first review in 2019 at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/822073/health-service-products-and-medicines-regulations-2018-annual-review.pdf, para 10.4 and the second in 2020 at https://www.gov.uk/government/publications/health-service-products-and-medicines-regulations-2018-annual-review-2020/annual-review-of-the-health-service-products-provision-and-disclosure-of-information-regulations-2018-and-the-health-service-medicines-price-contro, para 3.3.

[17] Article 102 of the Treaty on the Functioning of the European Union (TFEU) / Chapter II of the UK Competition Act 1998 (CA98).

[18] Article 101 TFEU / Chapter I CA98.

[19] Cases C3/9742/13 & 50908 - https://www.gov.uk/cma-cases/investigation-into-the-supply-of-pharmaceutical-products.

[20] Case 50277 - https://www.gov.uk/cma-cases/pharmaceutical-sector-anti-competitive-practices; https://www.gov.uk/cma-cases/pharmaceutical-sector-anti-competitive-agreements; https://www.gov.uk/cma-cases/pharmaceuticals-suspected-anti-competitive-agreements-and-conduct; https://www.gov.uk/cma-cases/hydrocortisone-tablets-alleged-excessive-and-unfair-pricing-anti-competitive-agreements-and-abusive-conduct-50277.

[21] Case 50395 - https://www.gov.uk/cma-cases/pharmaceutical-sector-anti-competitive-conduct.

[22] Case 50455 - https://www.gov.uk/cma-cases/pharmaceutical-drugs-suspected-anti-competitive-agreements-and-conduct.

[23] Case 50507-2 - https://www.gov.uk/cma-cases/pharmaceutical-sector-suspected-anti-competitive-agreements-and-conduct-50507-2.

[24] Case 50511-1 - https://www.gov.uk/cma-cases/pharmaceutical-drugs-suspected-anti-competitive-agreements.

[25] Case 50511-2 - https://www.gov.uk/cma-cases/pharmaceuticals-suspected-anti-competitive-agreements.

[26] Case 50780 - https://www.gov.uk/cma-cases/pharmaceutical-sector-suspected-anti-competitive-agreements-and-conduct. In this case the CMA was again investigating both potential abuse of a dominant position and anti-competitive agreements. In 2019, the CMA decided to close this investigation on administrative priority grounds.

[27] Case 50951 - https://www.gov.uk/cma-cases/investigation-into-supply-of-lithium-based-medication-for-the-treatment-of-bipolar-disease.

[28] Case 27/76 *United Brands v Commission* EU:C:1978:22, para 249-250.

[29] Case C–177/16, *AKKA/LAA* EU:C:2017:286, in particular the Opinion of AG Wahl, para 3.

competitive market: with no barriers to entry, high prices should normally attract new entrants. The market would accordingly self-correct". This means there is a high bar for finding that high prices are abusive, which had led to relatively few cases and presumably explains the CMA's difficulties in using this approach.

Although our focus is on the UK cases, this has not simply been a UK (and US) phenomenon. In May 2017 the European Commission opened an investigation into price increases of five off-patent cancer medicines (chlorambucil, melphalan, mercaptopurine, tioguanine and busulfan).[30] In Denmark, the Competition and Consumer Authority found abuse in relation to oxytocin in a decision that has been upheld at both levels of appeal.[31] ~~Equally~~Finally, the Italian, Dutch and Spanish authorities have investigated price increases for chenodeoxycholic acid.[32]

All the cases discussed in this article relate to price increases for generic drugs (or drugs that have otherwise been known for many years). They do not appear to involve so-called "pay for delay" prior to patent expiry.

1. Phenytoin

This was the first of the recent cases and the CMA ran into trouble trying to use its first approach (excessive pricing as an abuse of a dominant position). We have previously discussed the CMA's original decision and the successful appeal before the Competition Appeal Tribunal (CAT) in this Review and do not repeat that detailed discussion here.[33]

In brief, the CMA found that both Pfizer and Flynn Pharma held dominant positions and had abused them by charging excessive and unfair prices, where the price to the NHS for their anti-epilepsy phenytoin sodium capsules had risen by more than 2000%. The CMA imposed fines of £84.2 million on Pfizer and £5.2 million on Flynn.

Although the CAT upheld the findings of dominance, it overturned the findings of abuse and remitted these to the CMA, while requiring the CMA to pay a significant proportion of Flynn and Pfizer's costs of the appeal. On abuse, it found that the CMA had relied too heavily on an idealised "Cost Plus" approach (cost plus a reasonable rate of return) rather than seeking to use all the available evidence to establish a benchmark price or range that would have pertained in real world competitive conditions. In particular, the CAT criticised the CMA's use of a 6% "Return On Sales" (based on the PPRS) as a reasonable rate of return and its failure to take into sufficient consideration the price of Teva's competing phenytoin tablets.

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[30] Case AT.40394 *Aspen* - https://ec.europa.eu/competition/elojade/isef/case_details.cfm?proc_code=1_40394.
[31] See discussion in Behrang Kianzad "Excessive Pharmaceutical Pricing as an Abuse of Dominant Position – the Case of *CD Pharma* (Denmark)" *GRUR International*, 70(12), 2021, 1188-1196.
[32] Italian Competition Authority (ICA), Case A524; Netherlands Authority for Consumers and Markets, Case ACM/20/041239; Spanish National Markets and Competition Commission, Case S/0028/20/LEADIANT.
[33] *Flynn and Pfizer v Competition and Markets Authority* [2018] CAT 12. Alison Jones and Christopher Stothers, "Establishing Unfairly High Prices: The Implications of the CAT's judgment in *Flynn and Pfizer v Competition and Markets Authority*" 17(1) BSLR 19-26 (2019).

Both sides appealed, and in due course the CAT's judgment was largely upheld by the Court of Appeal.[34] The Court of Appeal did overturn the CAT's decision to require the CMA to pay costs,[35] but the Supreme Court reinstated that on further appeal in 2022.[36]

Meanwhile, following the decision of the Court of Appeal, the CMA has been considering the remittal on abuse and in August 2021 issued a further Statement of Objections, provisionally finding that "*the companies exploited a loophole by de-branding the drug…with the effect that the drug was not subject to price regulation in the way branded drugs are. As Pfizer and Flynn were the dominant suppliers of the drug in the UK, the NHS had no choice but to pay unfairly high prices for this vital medicine.*" ~~There is as yet no indication whether the parties have responded to that Statement of Objections, so the case may run for some time yet.~~That was followed in July 2022 by a second decision by the CMA, again finding abuse of a dominant position and this time fining Pfizer £63.3 million and Flynn £6.7 million. The decision has not yet been published and the press release does not explain how the failings of the original decision have been addressed.

2. Nortriptyline

In the next two cases, nortriptyline and fludrocortisone, the CMA focussed instead on whether agreements between undertakings were anti-competitive, with rather more success as most of the parties ultimately settled the cases.

Nortriptyline is an off-patent drug prescribed to relieve symptoms of depression, available in two strengths, 10mg and 25mg.

In 2014, King and Auden Mckenzie were the only two suppliers of nortriptyline with UK marketing authorisations. However, Lexon, a wholesaler, was taking steps to find alternative sources of the drug, either through parallel imports or by manufacturing itself in a joint venture with Medreich. In September 2014, both King and Auden began to supply Lexon with fixed volumes of the drug at a much lower price than previously (Auden supplying 10mg and King supplying 25mg). In May 2015, after Auden was acquired by Actavis, Actavis stopped supplying Lexon with 10mg tablets but King took over the supply on the same terms.

Nevertheless, Medreich obtained a third UK marketing authorisation and, in July 2015, Lexon and Medreich started supplying nortriptyline in the UK, both directly and to Teva (which marketed under Teva's own brand). The CMA found that, following the launch, King contacted Lexon to verify claims made by customers about its prices, and contacts between the two firms continued for some months. In March 2016, King learned that Alissa had also obtained its own nortriptyline licence, and also contacted Alissa to discuss its launch plans.

The CMA was concerned that this constituted market sharing by King and Auden[37] followed by information exchange by King, Alissa and Lexon.[38]

[34] [2020] EWCA Civ 339.
[35] [2020] EWCA Civ 617.
[36] [2022] UKSC 14.
[37] Case 50507.2, 4 March 2020 (Market sharing decision).
[38] Case 50507.2, 4 March 2020 (Information exchange decision).

On the first, following a settlement with King and Auden, the CMA found that they were party to an agreement from September 2014 until May 2015 that had the object of market sharing and fixing prices and quantities of nortriptyline.

On the second, following a settlement with King and Alissa (but not Lexon), the CMA found that King, Alissa and Lexon had shared commercially sensitive information relating to prices, volumes, timing of supplies and entry plans, with the aim of keeping nortriptyline prices high – or at least to slow their decline. The CMA fined each of the parties.[39] Lexon appealed the decision to the CAT, which upheld the CMA's decision on substance as well as in relation to the fines imposed. [40]

The investigation also led to director disqualifications for a director at each of the four parties.[41]

3. Fludrocortisone

Fludrocortisone is used to treat adrenal insufficiency and is an old drug, having been off patent since 1971.

Aspen acquired the UK marketing authorisation of fludrocortisone from BMS in 2014, and began taking steps to de-brand the drug. In parallel, the Dutch company Tiofarma had been developing its own manufacturing process, which by chance allowed the tablets to be stored at room temperature (rather than requiring that they be stored in a fridge like the Aspen product). A UK company, Amilco,[42] agreed that Tiofarma would obtain a UK marketing authorisation for this "ambient storage" fludrocortisone, which was granted in November 2015. Meanwhile, Amilco approached Aspen proposing that Aspen distribute the new Tiofarma product instead of the Aspen product, leading in due course to a supply and distribution agreement under which Amilco would receive 30% of the increased price. In due course the list price per tablet increased from £0.05 to £1 (or circa 1,800%). Following the article in The Times in June 2016,[43] Tiofarma raised concerns that the price rises for fludrocortisone could be seen in the same anticompetitive light. A few months later, Aspen acquired all rights from Tiofarma relating to "ambient storage" fludrocortisone.

The CMA considered that the distribution agreement entered into between the parties amounted to payment by Aspen to Amilco and Tiofarma to stay out of the market. The CMA was concerned that – prior to the acquisition - Tiofarma's fludrocortisone was the only source of competitive constraint on Aspen's fludrocortisone, and the distribution agreement and subsequent acquisition was therefore capable of preventing entry of emerging competition, and removing the only competitive threat existing in the market at the time.

In 2019, Aspen agreed to settle the case with the CMA in relation to the distribution agreement and offered binding commitments in relation to its later acquisition. The commitments included the divestment of UK rights over the "ambient storage" fludrocortisone, the reintroduction and

[39] King was fined £75,573 and Alissa £174,912 (with fines reduced because they admitted the infringement) and Lexon was fined £1.2million.
[40] Case 1344/1/12/20.
[41] For King, Dr Philip Hallwood (7 years, undertaking of 4 March 2020); for Auden Mckenzie, Mr Amit Patel (5 years, undertaking of 4 June 2020, almost 10 years after he was named in the article on hydrocortisone in the Mail on Sunday); for Alissa, Mr Robin Davies (2 years, undertaking of 2 September 2020) and for Lexon, Mr Pritesh Sonpal (4 years, undertaking of 11 January 2022).
[42] Another UK company owned by Amit Patel.
[43] Fn 118 above.

commercialisation of cold-storage fludrocortisone, and the payment of £8 million to the Department of Health and Social Care.[44]

Following this initial settlement with Aspen, both Tiofarma and Amilco agreed to settle with the CMA. The CMA handed down its decision in 2020, including fines totalling around £2.3 million for Aspen and Tiofarma (Amilco having no turnover in the previous year), with a director's disqualification for Amilco (the same director who was disqualified for Auden Mckenzie on nortryptyline).[45]

4. Hydrocortisone

The CMA then tried to use both approaches in relation to hydrocortisone (the drug about which concerns had first been raised in the press in 2010). Hydrocortisone is used for patients whose adrenal glands do not produce sufficient quantities of natural steroid hormones. The CMA noted that: "*Any patents granted to reward innovation by their originator expired at the latest during the 1970s. Being long off-patent, hydrocortisone tablets were in the third stage of the drug lifecycle,*[46] *when the price of even essential drugs is expected to be kept low by the potential for competitive entry and competition.*"[47]

The CMA was concerned in this case both by the initial price rises (like phenytoin) and subsequent agreements with potential market entrants (like nortriptyline and fludrocortisone). The CMA found that between 2008 and 2016 pack prices rose from under £1/pack to £72/pack (over 10,000%), with the result that NHS spending on hydrocortisone tablets rose from around £500,000 a year in 2007 to over £80 million a year in 2016. The CMA estimated that the process of competition took five to six years to return to pre-2008 prices.

On the price rise, the CMA decided that Auden Mckenzie had abused its dominant position by imposing excessive and unfair prices for hydrocortisone tablets from October 2008. In reaching its conclusions on abuse, the CMA relied on the test set out in *United Brands*, considering whether the prices where *excessive* relative to Auden's costs and whether they were *unfair* in themselves (including in light of the fact that these tablets were long off-patent and there had not been any innovations or improvements which justified the price hike). In light of the phenytoin judgments, although the CMA stuck with "Cost Plus", it unsurprisingly used a different measure of profitability (Return On Capital Employed), suggesting something in the range 5-15%, but also noted that in "Return On Sales" terms this was five times the size of the target ROS figure under the PPRS (which figure had been rejected by the CAT in phenytoin).[48] This gave the Cost Plus per pack in the range £2.17-£5.20, against sales prices £29.53-£65.31.[49] CMA also spent considerable time assessing whether the prices in question were both excessive and unfair when compared to competing products.[50]

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[44] Case 50455, 3 October 2019 - https://assets.publishing.service.gov.uk/media/5d94c607ed915d5540d5b093/Case_50455_-_Commitments_Decision.pdf .
[45] Case 50455, 30 September 2020 - https://assets.publishing.service.gov.uk/media/5f746219e90e0740c86c7611/50455_Non-confidential_Public_Decision_.pdf
[46] The CMA noted that "*The first stage of the drug lifecycle concerns the invention of new drugs while the second stage concerns patent protection and recovery of research and development associated with the invention of a new drug*".
[47] Case 50277, 15 July 2021.
[48] Paras 5.201-5.215.
[49] Para 5.220.
[50] Paras 5.233-5.237 and paras 5.376-5.429.

On the subsequent agreements, the CMA decided that Auden Mckenzie had entered into anti-competitive agreements with Waymade and AMCo in 2011 and 2012 under which it agreed to make substantial monthly payments in exchange for them not entering the market independently with their own hydrocortisone tablets. Those payments totalled almost £2 million to Waymade and £21 million to AMCo.

This led to the CMA deciding to fine the Auden Mckenzie-related entities a total of £221.2 million,[51] Waymade £2.5 million and the AMCo-related entities £42.8 million.[52]

Appeals to the CAT by the parties other than Waymade are due to be heard in November-December 2022.[53]

5. Liothyronine

Two weeks after its hydrocortisone decision, the CMA also issued its decision in relation to liothyronine tablets[54], which are primarily used to treat hypothyroidism. This time the conduct challenged was simply the price rise (like in phenytoin) and the supplier and its related entities were fined a total of £100 million.[55]

Liothyronine was developed in the mid-1950s and then marketed as Tertroxin. By 1992, Tertroxin, was long off-patent and it was acquired by Goldshield.[56] Goldshield continued to sell under the Tertroxin brand until 2007, when it de-branded the drug and relaunched it as a generic. Following the de-branding, Goldshield (and its successors in interest, ending with Advanz) applied a series of price increases amounting to an increase of over 6,000% over a ten-year period, until two new suppliers (Morningside Healthcare and Teva Pharmaceuticals) entered the market in 2017. The CMA found that these price increases were not driven by an increase in costs or meaningful improvements to the drug and were abusive.

In assessing whether the price charged by Advanz was both excessive and unfair (per *United Brands*), the CMA again used Return On Capital Employed for the reasonable rate of return.[57] The CMA also considered how Advanz's price compared to its competitors, although in this case it found that none of these possible benchmarks were valid or meaningful. In particular, the parties argued that the prices of liothyronine following entry by others in 2017 (referred to be the CMA as "Post-Entry Prices") should be considered as relevant comparators. However, the CMA considered that the prevailing Post-Entry Prices continued to be significantly inflated as a result of Advanz' excessive pricing.[58] The parties also put forward a number of alternative comparators including prices forecast by new and potential entrants

[51] A dispute between the vendors
[52] Interestingly, the CMA having started the case in March 2016, AMCo challenged a further search of its premises by the CMA in 2017, but this was unsuccessful: *CMA v Concordia* [2017] EWHC 2911 (Ch); [2018] EWCA Civ 1881; [2018] EWHC 3158 (Ch); [2018] EWHC 3448 (Ch); [2019] EWHC 47 (Ch). These judgments mention that the CMA's investigation extended to another drug, carbimazole, although no further details of that investigation appear to be public.
[53] Cases 1407 and 1411-1414/1/12/21.
[54]Case 50395, 29 July 2021.
[55] Advanz plus previous owners of the relevant business.
[56] The Goldshield Group was rebranded as Mercury Pharma in 2012, following a change in ownership. In 2012 Mercury merged with Amdipharm to create the Amdipharm Mercury or AMCo Group. In 2015, Concordia acquired the AMCo Group, and in 2018 Concordia changed its name to Advanz.
[57] Paras 5.126-5.162.
[58] Para 5.278

in the market, but in each case the CMA did not consider these comparators to be robust (for example, because forecast prices would also be artificially inflated as a result of the abusive conduct).[59]

The decision is again being appealed to the CAT and is due to be heard in September-October 2022.[60]

6. Nitrofurantoin

This is another agreements case, raising similar issues to nortriptyline, where nitrofurantoin is an antibiotic used to treat urinary tract infections.[61]

AMCo had been the sole supplier of nitrofurantoin until Morningside entered the market in mid-2014. In July 2019, the CMA issued a statement of objections to the undertakings involved (AMCo, Morningside and a wholesaler called Alliance Healthcare). The CMA alleged that (i) Alliance had agreed to acquire equal volumes of nitrofurantoin from AMCo and Morningside (from 2014 to 2017); and (ii) AMCo and Morningside had agreed to supply the drug exclusively to Alliance (in 2014 and 2015). The CMA also provisionally found that AMCo disclosed sensitive pricing information to Morningside in May 2014.

However, in October 2021, the CMA decided to close its investigation on administrative priority grounds, on the basis that the case would not be the best and most effective use of its resources at the present time.

7. Prochlorperazine

The CMA's final decision arising from the 2017 investigations is another agreements one, which relates to prochlorperazine, an anti-nausea medication which has been around since the 1950s.[62]

In this case, Alliance Pharmaceuticals (part of the same corporate group as Alliance Healthcare) had acquired prochlorperazine from Reckitt Benckiser in 2009. In 2013, it entered into a distribution agreement with Focus.[63] The CMA found that between 2013 and 2017 the prices paid by the NHS for prochloperazine rose from £6.49 to £51.68 per pack (a 700% increase).

The CMA found Lexon and Medreich had been taking steps to launch a jointly-developed prochlorperazine (like nortriptyline), but instead were paid a share of the profits that Focus earned by selling the Alliance product. The CMA found an overarching agreement between Alliance, Focus, Lexon and Medreich and fined them a total of £35 million.

A full non-confidential version of the CMA's decision is yet to be published, and all of the parties (except Medreich, who sought leniency) have brought appeals before the CAT.[64]

8. Lithium

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[59] Paras 5.327 – 5.359
[60] Cases 1419 and 1421-1422/1/12/21.
[61] Case 50511-1.
[62] Case 50511-2, 3 February 2022. See - https://www.gov.uk/government/news/cma-fines-firms-over-35m-for-illegal-arrangement-for-nhs-drug
[63] Focus was acquired by AMCo in 2014, and so is now part of Advanz.
[64] Cases 1432, 1434 and 1438-39/1/12/22.

The final UK case concerns lithium carbonate, which has been used to treat bipolar disease for many years, including Camcolit which was first authorised in 1977 and Priadel which was first authorised in 1985.

Essential Pharma acquired the rights to Camcolit from Norgine in 2014 and in 2015 increased the price significantly. Essential then acquired Priadel from Sanofi in 2018. UK clinical guidance suggests that prescription of lithium should be by brand and that patients should be maintained on a particular brand. According to the CMA, 86% of patients took Priadel while only 12% took Camcolit. However, in April 2020, Essential proposed to discontinue Priadel.

Following complaints from the Department of Health and Social Care, the CMA launched an investigation in October 2020 on grounds of potential abuse of a dominant position. However, soon after launching its investigation, the CMA announced that Essential Pharma had offered a number of binding commitments, including continuing to supply Priadel for the next five years, which were accepted by the CMA.[65]

9. Aspen's cancer drugs

2017 was a busy year for the CMA. It was also the year in which the European Commission opened an investigation into alleged excessive pricing by Aspen of several off-patent cancer drugs, principally used to treat leukaemia and other haematological cancers. The Commission found that Aspen had increased the price of these drugs by several hundred per cent, which provided Aspen with very high profits – both in absolute terms and also when compared with similar pharmaceutical companies. The Commission also considered that mostly there were no alternative drugs.

In 2020, Aspen offered a number of commitments to the Commission, which were accepted and made binding in 2021.[66] The commitments included: the reduction of prices by approximately 73% across Europe; the capping of prices at this reduced level for a 10-year period; and a guarantee that Aspen would not terminate supply of these drugs for at least 5 years (and for an additional 5-year period, it make its marketing authorisation available to other supplier if it decided to terminate supply).

Although the commitments were offered prior to the end of the Brexit transition period, they only became legally binding after the end of that period. In April 2022, the CMA announced that it had assisted the NHS to secure binding undertakings from Aspen in relation to the UK, thus enabling the NHS to monitor compliance by Aspen to its commitments following Brexit.[67]

10. Oxytocin

The Danish proceedings related to oxytocin, a drug from the 1950s used in connection with childbirth that once again went out of patent many years ago. Sigma-Tau had the only Danish marketing authorisation and between 2009 and 2014 had exclusively distributed it through the distributor Sobi at a price of DKK 44. In 2014 CD Pharma took over as exclusive distributor, but the Danish procurement entity (Amgros) decided to buy instead from Orifarm (a parallel importer and generic manufacturer). Orifarm was unable to source sufficient supplies, and in April 2014 CD Pharma agreed to meet the

[65] Case 50951, 18 December 2020.
[66] Case AT.40394 Aspen, 10 February 2021.
[67] See: https://www.gov.uk/government/news/cma-helps-nhs-secure-price-and-supply-commitment-for-cancer-drugs

shortfall, but initially at a price of DKK 945 (a 2000% price increase). In October 2014 this was reduced to DKK 225, and then down to DKK 78 for two years before increasing back to DKK 112.

Following an investigation, the Danish Competition and Consumer Authority in 2018 found that CD Pharma held a dominant position on the Danish market from 2014 until Orifarm finally obtained its own Danish marketing authorisation in 2017. It went on to hold that CD Pharma had abused its dominant position by excessive pricing between April and October 2014. The Authority applied the *United Brands* test, finding not only that the profit margin was excessive but that the price in those months was unfair not only in itself but as compared to the price over time, competitors' prices and the price in different countries. That decision was upheld by the Competition Appeal Board in late 2018 and by the Maritime and Commercial Court in 2020.[68]

101. Chenodeoxycholic acid

Finally, Italian pharmaceutical firm Leadiant Biosciences has found itself at the centre of scrutiny by competition authorities in Italy, the Netherlands and Spain in connection with price increases of chenodeoxycholic acid for the treatment of cerebrotendinous xanthomatosis (CTX), which arises from a rare genetic disorder.

Although the drug's off-label clinical use for CTX had been documented in the literature since at least the mid-1980s,[69] in 2017 Sigma-Tau obtained an authorisation and orphan designation for that use, giving 10 years of marketing exclusivity. It then transferred the product to Leadiant. This makes it a slightly different case to the generic drugs considered to date, given the newly approved indication and the protection of orphan marketing exclusivity.

In May 2022, the Italian Competition Authority (ICA) fined Leadiant €3.5 million after finding it had abused its dominant position. According to the ICA, Leadiant had engaged in a "multifaceted strategy" which was "carried out through a dilatory and obstructive behaviour" in the price negotiation procedures with the Italian Medicine Agency. [70] Amongst other things, the ICA considered that Leadiant's rate on capital was at least 250%, while its profits were also highly disproportionate to its costs. Leadiant has already been fined almost €20 million in 2021 by the Dutch Competition Authority in relation to abusive conduct relating to the same drug, and proceedings are also still ongoing in Spain, all of which signals continued focus by European competition regulators on this area of enforcement.

Conclusion

In 2017 regulatory law was changed in the UK to allow the NHS greater power to limit price increases of generic drugs. It is unclear whether that power has yet been exercised, but in the meantime we are seeing the outcome of several attempts by UK and other authorities to challenge such price rises under competition law. To date, the results have been mixed, particularly where the authorities have sought to challenge price increases in themselves (notwithstanding the frequent focus in press releases and coverage on very high percentage increases).

[68] There was some disagreement as to dominant position, but the judges all agreed as to abuse.
[69] Assessment Report for Chenodeoxycholic acid sigma-tau (15 September 2016), p43.
[70] Case A524, 17 May 2022.

Many of the investigations discussed in this article were started in 2017. Aside from the regulatory change, that timing was notably *after* the CMA's original phenytoin decision but *before* this was overturned in the judgments of the CAT and Court of Appeal, so was a time when the CMA may have been more confident in the scope of its powers. Despite the setback of those judgments, the CMA has progressed the investigations and is still seeking to use competition law to curb perceived excessive or unfair prices for generic pharmaceuticals, including now a second decision on phenytoin. It has particularly targeted high percentage price increases for old, off-patent generic drugs which have not obviously been the subject of additional innovation. However, other, more novel issues still arise, as can be seen in the lithium and chenodeoxycholic acid investigations.

The most challenging approach taken by the CMA has been to target excessive pricing itself, which following *United Brands* requires a nuanced assessment of whether a given price is excessive and unfair, including by reference to comparator products.[71] For many years the traditional approach to price increases has been to allow the market to self-correct, with competition authorities only stepping in as a last resort and typically in the presence of specific market features which suggest that such a correction might not occur, such as high, non-transitory, barriers to entry.[72] Nevertheless, the CMA has been using everything in its antitrust toolkit as creatively as possible to broaden its enforcement powers in these cases, and is still attacking price increases per se in phenytoin (again), hydrocortisone and liothyronine. However, phenytoin has ~~not yet reached~~ only just been the subject of a second decision while the other two will be challenged before the CAT later this year. When those judgments are handed down we will see whether the CMA's attempts to fix the problems with the first phenytoin decision have been successful (in circumstances where the Supreme Court has confirmed that the CMA may need to bear the parties' legal costs of appeal if the CMA gets it wrong).

The CMA is clearly in more comfortable territory where it is challenging agreements between pharmaceutical companies which appear to ward off potential competitive entry. Attacking simpler antitrust abuses such as market sharing or information exchange may provide the CMA with a more robust legal basis for its interventions, and that approach can be seen on nortriptyline, fludrocortisone, hydrocortisone, nitrofurantoin and prochlorperazine.[73] However, such an approach is highly fact-dependent and will not be possible in all cases of price rises of generic drugs.

The most recent investigation opened by the CMA in October 2020 (lithium) suggest that 2017 may not have been the high-water mark for antitrust enforcement relating to high prices of generic drugs. The new case related to old but *branded* drugs (rather than a debranding strategy), and did not ultimately lead to a full decision, given that commitments were offered by Essential immediately after the CMA launched its a formal investigation.[74] At the very least, this still shows the continuing impact of a CMA investigation.

Parties operating in the sector may well note that the CMA's enforcement in this arena still appears to be responsive to reports by investigative journalists suggesting the NHS is overpaying certain generic manufacturers. Potential buyers of generic businesses in particular would be wise to include a press review as part of any due diligence exercise, particularly if a large proportion of the enterprise value relies on past or anticipated price rises for particular generic drugs within the portfolio. That is all the

[71] See note 26 above.
[72] See Case C–177/16, *AKKA/LAA* EU:C:2017:286, Opinion of AG Wahl, para 3, note 24 above.
[73] Although the last of these has been the subject of several appeals.
[74] Case 50951, 18 December 2020, para 2.5.

more so where the revenues of a larger buyer can give them much greater exposure to fines than the (typically) smaller generic companies which have been the subject of the CMA's investigations to date.