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Unfair and Excessive Pricing in Europe – Pharma Focus

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Introduction

1. The pharmaceutical sector is the subject of considerable attention from antitrust regulators worldwide. This is nowhere more evident than in the UK, where the Competition and Markets Authority (the “CMA”) has made the investigation of competition infringements by pharmaceutical companies a priority in recent years, with 11 ongoing investigations at present.

2. Scrutiny of pharmaceutical companies by antitrust regulators has historically been focused on ‘reverse payment’ or ‘pay-for-delay’ cases, where Article 101 TFEU/Chapter I Competition Act 1998 (“CA98”) concerns are principally at stake. Issues surrounding anti-competitive collusion in the sector have not disappeared, but increasingly the modalities of pharmaceutical markets, where substitutability may be limited, and costs of production can lag well behind pricing, have led to it becoming a focus for a less utilised enforcement tool – namely the prohibition on unfair and excessive pricing by dominant firms under Article 102 TFEU/Chapter 2 CA98.

3. This article considers the evolution of the law of unfair and excessive pricing in Europe, and its application in the pharmaceutical sector. The outcome of two instant cases – Pfizer and Flynn Pharma and Aspen Pharmacare – are likely to provide guidelines for the future of the regulation of this category of abuse in the steady stream of further cases under consideration. At a time when the regulatory regimes in the UK and the EU appear potentially to be diverging, these two cases may even see the start of the law developing in different directions in the future.

Regulatory Activity

4. Since 2013, the CMA has conducted a series of investigations into alleged excessive pricing. A number of cases are ongoing, including a long-running investigation into Concordia’s hypothyroidism treatment, Liothyronine, and three separate investigations into the pricing of different Hydrocortisone treatments for adrenal dysfunction.2

5. One case, Pfizer and Flynn Pharma, has already been decided. In 2016, the CMA made a finding of unfair pricing against two companies, Pfizer and Flynn, in respect of the prices they charged the NHS for the capsule form of anti-epilepsy drug phenytoin sodium, which had previously been sold in the UK by Pfizer under the brand name Epanutin.3 The CMA found that each company had abused its dominant position, ordered them to lower their prices and imposed fines of nearly £90 million. That finding was set aside by the Competition Appeal Tribunal (the “Tribunal”) in a judgment handed down in 2018, on the basis that the CMA had misapplied the relevant test. The Tribunal’s decision is now before the Court of Appeal, and the conjoined appeals are due to be heard in November 2019. It is hoped that the outcome of those appeals will clarify the parameters for the enforcement of the prohibition on unfair and excessive pricing in the UK and will enable the CMA’s ongoing investigations to be brought to conclusion on a robust basis.

6. The law on unfair and excessive pricing has also recently been considered by the Court of Justice in the Latvian Copyright case.5 The judgment (given in response to a preliminary reference from the Latvian Supreme Court) sets out a detailed and authoritative consideration of the factors relevant to unfair and excessive pricing cases, which the Tribunal in Pfizer and Flynn Pharma described as “very persuasive and helpful”.6 That analysis will be instructive for the activity of the European Commission (the “Commission”) which is itself actively pursuing unfair and excessive pricing as a category of abuse in the pharmaceutical sector. Following an investigation and fine imposed by the Italian Competition Authority, the Commission is investigating Aspen Pharmacare for its pricing practices in relation to five cancer treatments: Chlorambucil; Melphalan; Mercaptopurine; Thioguanine; and Busulfan. That investigation commenced in 2017 and is ongoing.

Unfair and Excessive Pricing – the Abuse

7. Unfair and excessive pricing, as a form of anti-competitive conduct, arises in the context of both Article 102 TFEU and Chapter 2 CA98. In the relevant provisions, abuse of a dominant position within the relevant market may include “directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions”. Unfair pricing comprises a number of examples of abuses, including not only excessive, but also predatory and discriminatory, pricing. This chapter focuses on the unfair and excessive aspect of the abuse.

European case law

8. The leading European case in this area is United Brands v Commission.7 In that case, United Brands was held to be dominant in the market for supply of bananas in the single market. As part of its assessment of the alleged abuse, the Commission scrutinised the conditions imposed by United Brands on the sale of bananas within the internal market, including the notorious “green banana” clause, under which distributors were prohibited from reselling United Brands’ bananas when still green. United Brands involved an assessment of a suite of alleged abuses, amongst which the Court of Justice gave the first outline explanation of the abuse of unfair and excessive purchase or selling prices.
9. The Court of Justice explained that the first step in such an analysis is to ascertain whether the dominant undertaking has “made use of the opportunities arising out of its dominant position in such a way as to reap trading benefits which it would not have reaped if there had been normal and sufficiently effective competition”. An example of such an abuse was “charging a price which is excessive because it has no reasonable relation to the economic value of the product supplied”.

10. Assessing whether a price is “excessive” is the first step in the analysis. One methodology for assessing whether a price charged is “excessive” is to compare the costs of production with the selling price, to reach a conclusion on whether there is a reasonable relation between the price and the economic value of the product. If there is no such relation, the price may be “excessive”. Crucially, however, the test in United Brands is not expressed to be limited to the comparison of price and costs. When the Court of Justice introduced its proposed approach, it left the categories of methodologies open, expressly using the words “inter alia”. The Court therefore did not appear to intend for the price/cost comparison to provide the only mechanism by which a price could be assessed as excessive.

11. If the first step of the test is satisfied – namely that a price is “excessive” – then the second step in the analysis is to assess whether that excessive price is “unfair”. For this second step, there are two possible limbs under which an excessive price can be found to be “unfair”. It can either be unfair “in itself”, or it can be unfair when compared to competing products. Again, when the Court concluded its analysis in United Brands, it made clear that the categories of test for an unfair price were not closed: “other ways may be devised – and economic theorists have not failed to think up several – of selecting the rules for determining whether the price of a product is unfair”.

12. The Court in United Brands ultimately annulled the finding of unfair pricing in the Commission’s decision, and the approach set forth in that judgment has been used as a benchmark in subsequent cases by both the EU and UK regulators. Subsequent cases have, however, seen the Commission and the European courts develop parameters or standards which provide guidance as to how the test will be applied in practice.

13. Further consideration was given to this issue (alongside a raft of other competition complaints) in Deutsche Post AG. In that case Deutsche Post had been treating mail that contained any reference to Germany (such as the German reply address in the contents of the mail) as indicating that the mail had, in reality, a German sender, whether or not the mail was actually sent from Germany. Deutsche Post took it upon itself to intercept, surcharge and delay cross-border mail that fulfilled these criteria. The consequence of this policy was that any such mail was subject to the full domestic tariff for the mail, which was significantly higher than the tariff applicable to mail originating from a foreign country, whether or not the mail had in fact been sent from abroad.

14. Deutsche Post had a virtual monopoly over postal services within the jurisdiction, and thus was dominant in the relevant market. In those circumstances, Deutsche Post’s conduct was held by the Commission to be abusive on a suite of different grounds. It was found to be discriminatory by imposing different conditions on equivalent transactions, it constituted a refusal to supply, it limited production, markets and technical development, but, critically for these purposes, the Commission also found that Deutsche Post’s conduct constituted an abuse of its dominant position on the grounds that the domestic tariff applied was excessively high and unfair.

15. The Commission applied the test laid down in United Brands. The Commission looked at whether the price was unfair by reference to the costs of providing the service, and any relevant benchmarks. That exercise was challenging because Deutsche Post had only recently introduced a transparent cost accounting system, so no reliable data existed for the relevant time period. Further, given Deutsche Post’s wide-ranging monopoly, a price comparison with competitors was not possible.

16. To assess the relationship between the price charged and cost, the Commission compared the tariff imposed with the estimated average cost of providing postal services, which Deutsche Post had itself previously estimated. On that basis, the Commission found that the tariff charged exceeded the average economic value of the service by at least 25%. The Commission also looked at the average profit margin per item in the bulk mailing market, to assess whether the difference between cost and price was excessive. This average profit margin was low, at an average of 3% in 1997. Bearing in mind Deutsche Post’s status as a monopolist, and the particular features of the bulk mailing market, the difference between price and costs suggested an excessive price in this instance.

17. Even though direct price comparison with competitors was not possible, the Commission searched for benchmark pricing in comparable jurisdictions. For this purpose, the Commission reviewed the comparable Nordic tariffs and the agreement on comparable tariffs concluded by the Dutch and Swedish post offices. These agreements suggested that even lower costs were applicable to similar transactions, and on that basis Deutsche Post’s charges would represent a 43% profit margin. By reference to the cost of providing the service “in itself”, and by reference to relevant benchmark comparators, the Commission found that the price charged bore no reasonable relationship to real costs or to the real value of the service provided. It exploited customers excessively and should be regarded as an unfair selling price.

18. The most recent consideration of the issue at the European level has been in the Latvian Copyright case, a judgment of the Court of Justice handed down in 2017. The case related to the fairness of rates for licences for the public performance of musical works in commercial premises and service centres in the Latvian market. A number of questions were referred to the Court of Justice by the Latvian court. In his opinion (largely adopted and endorsed by the Court), Advocate General Wahl gave a detailed review of the considerations applicable to cases of unfair and excessive pricing.

19. Before addressing the substance, the Advocate General recalled the theoretical rationales of a German monopoly on unfair and excessive pricing abuse. When a dominant undertaking applies prices above competitive levels – unfairly – there is an inefficient allocation of resources and consumer welfare is reduced. Some of that inefficient allocation of resources is transferred to the dominant company, but some is simply lost.

20. The Advocate General went on to sound a note of caution – warning that competition authorities should exercise care in intervening in pricing disputes. First, the risk of false positives is high. Given the inherent uncertainty, and the far greater difficulty of correcting errors in rulings rather than errors in markets, a cautious approach should be taken. Second, given the difficulties above, it is hard for a dominant entity to assess exactly where a price might be held to be excessive. For reasons of legal certainty, the threshold cannot therefore be set too close to the benchmark price. Third, and importantly, competition authorities are not price regulators, and have limited resources.

21. For these reasons, for a price to be qualified as “excessive” it must fulfil two conditions: it must be both significantly and persistently above the benchmark price.

22. As to the first condition – that the price be significantly above the benchmark price – only “important deviations” should qualify, i.e., prices should be “appreciably higher” than those to which
they are compared. For the second requirement, the price must remain above the benchmark for a substantial period of time. The Advocate General made clear that it would not be easy to say exactly how significant or how persistent the difference must be in any given case, but must be assessed on a case-by-case basis. The Advocate General restricted himself to observing that the more significant the difference between the benchmark and the actual price, and the longer the period that high price is applied, the easier it will be for the authority to discharge the burden of proof.

23. The Advocate General made one further important clarification regarding the burden of proof. It is for the competition authority to demonstrate that a price is excessive and unfair – that is to say, that the price charged bears no relation to the economic value of the product or service supplied, either by reference to the costs of producing the product, service, or relevant benchmarks.18 However, once that point is established by the competition authority, the defendant entity may rebut that finding by demonstrating that the prices are fair; for example, on the grounds of higher production and marketing costs, or more generally on the basis of the higher economic value of the product or service supplied.19 Information such as the dominant entity’s costs structure, its pricing policies and the structure of demand in the relevant market might not be readily available to the competition authority and it is reasonable therefore that this burden rests on the defendant.

24. Ultimately, the Court of Justice followed the Advocate General’s approach, and found that a price was excessive if, on an acceptable methodology, the difference between the price charged and the comparator prices was significant and persistent. In this case, the methodology was not a price/cost comparison, but a comparison of the pricing in Latvia with rates applied by other comparable national collection agencies for performing rights licences. It was then for the defendant organisation to rebut that finding by reference to objective factors.

UK case law

25. As it currently stands, the European Court judgments in United Brands and the Latvian Copyright case, and the Commission’s decision in Deutsche Post are relevant to the jurisprudence in the UK by reason of section 60(1) of the Competition Act 1998, which provides that competition issues in the United Kingdom are to be determined, so far as possible and having regard to any relevant differences, consistently with EU law. It is no surprise then that the treatment of excessive pricing claims by the courts in the UK has paid close attention to this EU jurisprudence.20

26. Accordingly, the English courts have been careful to emphasise that a high price, even one which is excessive when compared with the costs attributable to the price, is not itself an abuse. This is consistent with the European case law that sets out that an “excessive” price is only a necessary, but not a sufficient, condition, for a finding of unfair pricing under Article 102.

27. This was exemplified in Attheraces Ltd v The British Horseracing Board Ltd21 (“Attheraces”), where Mummery LJ emphasised that the law of excessive pricing does not outlaw “excessive profits”. Nor is it a regime whereby the courts regulate prices by fixing an unfair price for a product.22

28. Attheraces concerned the provision of pre-race horseracing data to overseas bookmakers. The British Horseracing Board (“BHB”) controlled the data, and a broadcaster, Attheraces (“ATR”), wished to sell it on to overseas bookmakers, and complained about the price which BHB charged for the data. The price charged by BHB was well in excess of the costs of production. The Court of Appeal considered whether the economic value of a product might far exceed its cost of production yet still be “fair” and found that it was legitimate also to consider the value of the product to the purchaser. When setting a fair price, the monopoly supplier was entitled to take into account not only the costs of supply, but also the value of the product to the customer. The Court recognised that consideration of the value to the purchaser alone might verge on abuse in particular circumstances, as a monopoly supplier could push the price as high as the purchaser could bear – using the colourful analogy of “not quite killing the goose that lays the golden eggs, but coming close to throttling her”.23 That could be held to be abusive, but on the facts of the case, the Court held that ATR’s competitiveness did not appear to have been materially compromised by the terms of its arrangements with the supplier.24

29. The judgment in Attheraces emphasised the need to look at the particular circumstances of the market in question when making a determination of unfairness. A different outcome, based on the circumstances of the market in question, emerged in Albion Water and Another v Water Services Regulation Authority and Others (“Albion Water”).25 The case concerned the price imposed by the owner of water supply infrastructure – Dwr Cymru – for the supply of water to a third party – Albion Water – which would then be used to compete with Dwr Cymru for a contract for water supply to a steel mill. The Tribunal’s judgment followed the reasoning of the Court of Appeal in Attheraces, but given the modalities of the water market in Wales, a price cost analysis was held to be appropriate. The Tribunal found that a price for a monopoly supply of non-potable water for industrial use that exceeded actual costs by between 46.8% and 70.6% was excessive, and noted in passing that an even lower difference between costs and price in Deutsche Post – of 25% – had been held to be excessive in that case.

30. The Tribunal in Albion Water was careful to say that it would not be appropriate to specify a particular amount by which a price must exceed the economic value of a product or service in order to infringe the Chapter 2 prohibition. The test in United Brands is whether the price “bears no reasonable relation” to the economic value. The assessment must be conducted on a case-by-case basis, having regard to the individual circumstances of the case. However, in this instance the Tribunal found that there were no relevant non-cost factors to take into account, and the price charged by the defendant effectively insulated it from competitive pressure and/or enabled it to exploit its control over customers within its appointed area.

Pfizer and Flynn Pharma v CMA

31. As explained above, the test for excessive pricing in the context of pharmaceutical markets is currently being litigated in the UK courts in the Pfizer and Flynn Pharma case.

32. To recap: the case relates to the pricing of an anti-epilepsy medicine – Phenytoin. Pfizer had historically manufactured and sold Phenytoin in capsule form to the UK market. In 2012, Pfizer sold the distribution rights for Phenytoin to another pharmaceutical company specialising in the acquisition and rescue of “end-of-life” pharmaceutical products. Following the sale of the distribution rights, Pfizer continued to manufacture the capsule form of the medicine exclusively for Flynn. Flynn proceeded to de-brand the medicine so that it was no longer subject to price regulation. The prices for the medicine were then increased very substantially by both Pfizer and Flynn, in Pfizer’s case increasing prices to between 780% and 1,600% above historic
33. In 2016, following a three-year investigation, the CMA issued a decision finding that the prices charged by both Pfizer and Flynn for Phenytoin were unfairly high and imposed a fine of nearly £90 million. Both companies appealed to the Tribunal, and in 2018 the Tribunal set aside the finding of unfair pricing. This was not on the basis that the prices charged were fair, but on the narrower basis that the CMA had applied the wrong test in coming to its conclusions.

34. The Tribunal agreed with the CMA’s definition of the market for Phenytoin and agreed that both Pfizer and Flynn Pharma were dominant in their respective markets. The battle lines were drawn around the application of the test for unfair pricing. Of particular interest to the Tribunal was the fact that the tablet form of Phenytoin, while not being directly substitutable with the capsule form (and therefore not part of the same market) was nevertheless priced at a higher level to the capsule.

35. The CMA had approached the application of the test in United Brands in two stages. First, it had looked at whether the price charged was “excessive”. It did this by reference to a comparison between the costs and the price of a medicine, with particular reference to a measure known as ‘Return on Sales’ which had been employed in the PPRS® across a portfolio of products. This measure yielded a reasonable rate of return of costs plus 6%.

36. The Tribunal viewed this approach as overly restrictive, and criticised it as being based on an idealised notion of perfect competition. The Tribunal considered that the CMA was wrong to exclude other methodologies such as a comparison with the tablet price (even though, save for the comparison with the tablet price, the Tribunal did not find that any of the suggested other methodologies presented a clear evidential picture). Nevertheless, the Tribunal considered that the CMA’s approach was too binary, simply excluding alternatives that it did not find helpful, and the Tribunal found that the CMA should have sought to establish a benchmark price (or range) by reference to other methodologies that were likely to apply in “normal and sufficiently effective competition using the evidence more widely available”.

37. Importantly, the Tribunal did not determine that the price could not be excessive if the right methodology was used. It simply found that the method used to arrive at the finding of an excessive price was erroneous.

38. As the second stage in its analysis, the CMA had then considered whether the “excessive price” was unfair. Following the approach laid down in United Brands, the assessment of whether an excessive price was unfair depended on whether it was unfair either (i) “in itself”, or (ii) by reference to benchmarks. In its Decision, the CMA treated these two limbs as genuine alternatives. If a price was unfair “in itself”, there was no need for it also to be unfair by comparison to relevant benchmarks, and vice versa.

39. The Tribunal disagreed with this approach. It made clear that it is possible, as a matter of law, to establish a breach of Article 102/Chapter 2 by succeeding on the basis of either limb. The limbs are expressed in the alternative and either one will do, absent countervailing factors. However, in circumstances were there is prima facie evidence of fairness under one limb – for example, by the existence of comparators at similar prices – it is not acceptable to simply ignore that evidence and focus only on the first limb. In this sense, limb two acts as a ‘sanity check’ on limb one, and the Tribunal emphasised the importance of this in the context of applying “highly imprecise tests such as ‘unfairness’”.

40. The proper approach, as articulated by the Tribunal, was to consider both whether an excessive price was fair “in itself” and by reference to comparators. The authority would be free to rely on either limb for a finding of unfairness, but it had to take into account in its overall analysis any prima facie convincing argument that pricing is fair under the other limb.

41. The final step was then to consider the economic value of the product and determine whether the price charged bore any reasonable relation to that value. The Tribunal emphasised the holistic nature of this exercise, and the importance of taking account of the nature of the product or service, together with the surrounding circumstances. The Tribunal found that the CMA’s approach was too limited, being focused on whether the price was unfair “in itself”, whereas it should have been conducted as an overarching assessment.

42. Leave has been granted to appeal to the Court of Appeal, and the cases are listed to be heard in November 2019. It is therefore to be hoped that authoritative guidance will be available before long as to the test to be applied in unfair and excessive pricing cases in the pharmaceutical sector, and in particular the proper treatment of comparator products, even when those products are not on the market in question. That guidance will, it is hoped, enable the CMA to proceed with its other pricing probes in the sector, and may even assist those entities seeking damages claims for their (sometimes very substantial) losses caused by the infringing conduct.

Divergent Approaches Emerging?

43. As noted above, unfair pricing is also a focus of European competition authorities in the context of the pharmaceutical sector. Of particular interest is the pending decision of the Italian Council of State in Aspen Pharmare ("Aspen").

44. In September 2016, the Italian Competition Authority (the “AGCM”) issued a decision finding that Aspen had engaged in excessive and unfair pricing tactics in respect of four of its cancer treatment drugs, known as Cosmos drugs, when imposing price increases on the Italian Pharmaceutical Agency ("AIFA"). The AGCM’s decision was upheld on appeal to the Regional Administrative Tribunal of Lazio ("Administrative Tribunal").

45. The abusive behaviour included Aspen’s conduct in price negotiations for the medicine, which is critical to the treatment of leukemia. Aspen sought to have the Cosmos drugs re-classified by AIFA such that the price of the drug would no longer be regulated. During the negotiations, Aspen repeatedly threatened to withdraw the Cosmos drugs (to which there are no alternatives) from sale, unless AIFA agreed to an increase in price of some 1,500%. Aspen also caused a substantial shortage in the market. AIFA relented and agreed to the price increase. Both the AGCM and the Administrative Tribunal found that Aspen’s actions amounted to unfair and excessive pricing, on the basis that the increase in price of the drug did not reflect increases in the cost of manufacturing it.

46. Aspen argued that the sole reason for the increase in price was brought about by the need to bring Italian drug prices into alignment with prices Europe-wide. Both the AGCM and the Administrative Tribunal found that this reason was an insufficient basis upon which to justify an increase in price. Both the AGCM and the Administrative Tribunal found that increases in manufacturing costs, increases in distribution costs, and the costs of innovation, research and development efforts were the only bases upon which a price increase could be justified.

47. The circumstances which led the AGCM and the Administrative Tribunal to find that Aspen’s pricing was excessive included that: (i) the price of the drugs had not changed since they were first...
introduced to the market by GlaxoSmithKline; (ii) no generics had entered into the market; and (iii) even when taking into account Aspen's costs of acquiring the drugs from GlaxoSmithKline, Aspen still generated a significant profit of between 50% and 250%.38

48. Interestingly, in this case, when considering whether the price increase was excessive and unfair as per the United Brands criteria, the Administrative Tribunal found that the margin analysis and 'cost plus' analysis (carried out to determine the profits generated by Aspen as a result of the sale of the drug) were sufficient to determine that the price was excessive. This stands in contrast to the approach endorsed by the UK Tribunal in Pfizer and Flynn Pharma, where such an approach was held to be insufficient. On that basis, it appears that the test as applied in Aspen is a harder one for a pharmaceutical company to satisfy, and the regime would arguably be tougher on excessive pricing than the approach endorsed by the Tribunal in the UK.

49. The European Commission is now itself investigating Aspen's conduct in relation to unfair pricing of Aspen's Cosmos drugs in the EU more generally.39 There have also been recent complaints of unfair pricing in Belgium and Italy against Biogen in the market for the orphan drug Spinraza – the only medicine on the market to treat spinal muscular atrophy.40 Further consideration of the law of unfair and excessive pricing in forthcoming European cases therefore seems likely, and clarity on the proper approach as a matter of EU law will be helpful for regulators and market participants alike.

Conclusion

50. As the Tribunal noted in its Pfizer and Flynn Pharma judgment: "[c]ases of pure unfair pricing are rare in competition law. Authorities find them difficult to bring and are, rightly, wary of casting themselves in the role of price regulators. Generally, price control is better left to sectoral regulators, where they exist, and operated prospectively; ex post price regulation through the medium of competition law presents many problems. However, the law prohibits unfair pricing in certain circumstances and in such cases there is no reason in principle why competition law cannot be applied, provided this is done on the correct legal basis and the analysis of evidence is sound.41 Precisely how that is to be achieved by Europe's competition regulators remains to be tested, but what seems clear is that the focus on pricing in the pharmaceutical sector is unlikely to recede in the near future. A clear and unified approach to assessing when pricing is unfair and excessive in the particular dynamics of the pharmaceutical market will assist all market participants – whether that is companies seeking to comply with their competition law obligations, regulators in restraining abuses, or injured parties being able to claim compensation promptly and efficiently. We will watch this space with interest.

Endnotes


5. Biedriba Autortiesibu un komunicēšanas konsultaciju agentūra – Latvijas Autors apvienība vi Konkurences padome (Latvian Copyright Case) ECLI:EU:C:2017:689.


8. United Brands at [252].

9. Ibid, at [250].

10. Ibid, at [253].


15. Ibid, at [104].

16. Ibid, at [105].

17. Ibid, at [106].


19. See, inter alia, United Brands, at [251].

20. It will of course be interesting to track the extent to which European and English courts continue to take a similar approach following Brexit. Notably, Flynn Pharma is listed to be heard by the Court of Appeal in November 2019, after the current date for the UK exiting the European Union. It is therefore possible that Section 60(1) will no longer apply, and there will be scope for the law of unfair pricing to develop along divergent lines, albeit from a common origin.


22. Ibid, at [119].

23. Ibid, at [217].

24. Ibid, at [212–218].


27. [2018] CAT 11, [430].


30. The Pharmaceutical Price Regulation Scheme (“PPRS”) is a non-contractual voluntary scheme, agreed between the Department of Health and the Association of the British Pharmaceutical Industry. It controls the overall profit scheme members make on the sales of their portfolio of branded licensed medicines to the NHS, and limits the ability of scheme members to increase the prices of their branded medicines, but it does not apply to generic medicines.

31. supra n. 27 at [310].

32. The CMA modified its position before the Tribunal, and acknowledged that a good comparator should be taken into account at some point in the analysis, although this could be at the assessment of whether a price was excessive, or at the point that one assessed whether an excessive price was unfair [365].

33. Ibid, at [368].

34. “Price Increase of Aspen’s Drugs”, Autorita Garante Della Concorrenza, Measure No. 26185, dated 26 September 2016,
available at: https://en.agem.it/dotemsDOC/pressrelease/A480_eng.pdf.
36. Above n. 37 at [379].
37. In one case, since 1955. See ibid., at [50, 331].
38. Ibid., at [379].
41. Supra n. 32 at [462].

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