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Excessive Pricing in Pharmaceutical Markets - Note by the European Union

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More documents related to this discussion can be found at

www.oecd.org/daf/competition/excessive-pricing-in-pharmaceuticals.htm

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1. Introduction

1. European law provides in Article 102(a) of the Treaty on the Functioning of the European Union ("TFEU") that an abuse of a dominant position may, in particular, consist in "directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions".

2. This prohibition of imposing unfair prices is generally understood to cover conduct such as charging excessive prices. Unfair pricing conduct concerns in essence the extraction of excessive profits by imposing high, unfair prices to customers. The prohibition of Article 102(a) TFEU applies to any product or service, including pharmaceutical products.

3. The European Commission, competition authorities of Member States and courts in the EU are entrusted with ensuring that EU competition rules are applied effectively, including the unfair pricing prohibition of Article 102(a) TFEU. As market forces in functioning markets usually restrain the ability of dominant companies to exploit consumers, the focus of the European Commission's enforcement practice lies in the first place on exclusionary abusive practices with the aim of restoring the competitive process in the affected market. However, the European Commission has always scrutinized markets also for exploitative conduct with a view to intervening where enforcement against unfair pricing[1] or other exploitative practices[2] was warranted.

4. Recently, practices of pharmaceutical companies imposing very high price increases leading to unfair prices have attracted the scrutiny by competition authorities, leading to the adoption of three infringement decisions in Europe since 2016 in Italy, the UK and Denmark, and the opening of further investigations.

2. Why intervene against unfair pricing?

5. Some parts of the legal and economic community have occasionally raised the question whether competition authorities in the EU should at all be concerned with unfair

[1] Since 2000, the European Commission has adopted two infringement decisions and three decisions accepting commitments in unfair pricing cases: Commission decision of 25 July 2001 in Case No COMP/36.915 Deutsche Post AG, OJ L 331, 15.12.2001, p. 40–78; Commission decision of 20 April 2001 in Case No COMP/34.493 DSD, OJ L 166, 21.6.2001, p. 1–24; Commission decision of 9 December 2009 in Case No COMP/38.636 Rambus, OJ C 30, 6.2.2010, p. 17–18; Commission decision of 15 November 2011 in Case No COMP/39.592 Standard & Poor's, OJ C 31, 4.2.2012, p. 8–9; Commission decision of 24 May 2018 in Case No COMP/39.816 Upstream gas supplies in Central and Eastern Europe.

[2] For instance price discrimination, see Commission decision of 14 April 2010 in Case No COMP/39.351 Swedish Interconnectors, OJ C 142, 1.6.2010, p. 28–29; Commission decision of 2 June 2004 in Case No COMP/38.096 Clearstream (Clearing and Settlement), OJ C 165, 17.7.2009, p. 7–11.

pricing or whether it would not be better to limit enforcement activity to exclusionary conduct only.

6. The EU legislator has answered this question by entrusting European Commission, competition authorities of Member States and courts in the EU with the mandate to ensure effective enforcement where dominant undertakings are found to abuse their market power by imposing unfair prices (Article 102(a) TFEU).

7. Moreover, the central goal of EU competition policy is to protect consumer welfare. Considering that unfair prices harm consumers directly, it seems difficult to argue that authorities should protect consumers only indirectly, that is only by intervening against exclusionary conduct to protect the competitive process.[3]

3. When to intervene

8. From a competition policy perspective, authorities are likely to carefully consider several factors when deciding whether or not to allocate resources to enforcement against exploitative conduct.

9. First, prices and profits are generally regarded as useful indicators and necessary incentives for firms in a market economy to decide where to invest, enter or expand. Taking away profits may thus undermine the markets' own mechanism to restore competition.

10. In many markets, prices may be temporarily high due to a mismatch of demand and supply or the exercise of market power. But markets may actually correct themselves in a reasonably short period of time. In a scenario of potentially unfair prices, it should therefore be considered to give market forces some time to play out and entry and expansion to take place, and see if this brings prices back to more normal levels within a reasonable time period. The time horizon will depend on the specific features of the market. If it takes too long for the market to correct itself, then intervention against exploitative conduct may be justified, in particular where consumer harm is significant.

11. Second, high profits may be justified by risk taking or past investment, or the result of a firm's innovativeness and own excellence. The incentive for such efforts should not be undermined by *ex-post* competition law enforcement, because this could harm the dynamic competitive process and could reduce both innovation and consumer welfare. Where this is the case, pricing may not be unfair and enforcement not warranted. This does not mean, however, that Article 102(a) TFEU cannot be applied to abusive practices in the context of innovative products and risk-taking. The prohibition of unfair prices applies to all products and services. But it does mean that competition authorities have to factor investments and innovation into their assessment of unfairness and need to be mindful of the effect of an intervention on dynamic efficiency.

12. More generally, competition authorities will consider a number of possible practical difficulties that they may face when intervening against unfair prices: these are related to determining when a price is excessive, what price is acceptable as a remedy and how to monitor the implementation of the remedy over time. Also, in some cases regulation may be an alternative means to address persistently high prices (as was done in the case of

[3] See judgment of 22 February 1973 in *Europemballage Corporation and Continental Can Company Inc. v Commission*, 6/72, ECLI:EU:C:1973:22, paragraph 26.

roaming tariffs in the European Union).[4] Regulatory authorities may have the market knowledge and experience and may be particularly well placed to regulate prices. However, the fact that high, unfair prices may theoretically also be remedied by way of regulation does not in any way affect the applicability of Article 102(a) TFEU to unfair pricing practices.

13. While these reasons justify a prudent policy, competition authorities also have to be mindful of their obligation to effectively enforce Article 102 TFEU in its entirety, i.e. including the prohibition of unfair pricing.

4. Some particularities of pharmaceutical markets

14. Pharmaceutical markets have a number of particularities resulting from the nature of pharmaceutical products, the pharmaceutical product life cycle and the role of regulation throughout the product life cycle. These particularities have to be taken into account when assessing pricing practices by pharmaceutical companies.

15. As explained in the OECD Secretariat's Background Note, pharmaceutical products are often price-demand inelastic, in particular concerning essential medicines that are life prolonging, necessary for health or improving quality of life.[5] Patients may be dependent on such pharmaceutical products. A factor contributing to inelasticity of demand for essential medicines can be that patients consume medicines, but often do not directly pay for them (patients may have to contribute with some minor co-payments); doctors prescribe the medicines, but neither consume nor pay for them; and national health services and insurance companies may have limited influence on prescription or consumption, but have to pay for the medicines. Another factor is that there can be high pressure on health systems to pay for certain medicines even at high prices. Health service providers may have limited bargaining power and a reduced ability to influence medicine prices in the negotiations with manufacturers, when medicines are essential for health or life or when no appropriate substitute products are available in the country concerned. The result of all these factors can be a high inelasticity of demand that may make the pharmaceutical sector more prone to unfair pricing practices or concerns than other sectors.

16. The pharmaceutical product life cycle, which also has to be taken into account when assessing pricing practices, consists of three different phases. Different regulatory aspects come into play throughout the pharmaceutical product life cycle; also, pharmaceutical prices may change and vary.

17. The first phase of the pharmaceutical product life cycle is the phase of discovery and development until all relevant approvals for the launch of a medicine are obtained (including marketing authorisation and, where relevant, pricing and reimbursement status). The discovery and development of a new, innovative medicine is generally a lengthy and costly process, and very risky. It can take up to over ten years to develop a new medicine which includes carrying out clinical studies demonstrating the safety and efficacy of a

[4] Regulation (EU) No 531/2012 of the European Parliament and of the Council of 13 June 2012 on roaming on public mobile communications networks within the Union (OJ L 172, 30.06.2012, p. 1-26).

[5] See OECD Background Note, "Excessive Prices in Pharmaceutical Markets", 27-28 November 2018, Section 4.1. Demand-side Considerations.

medicine. During this long period with uncertain results, originators incur high costs, but earn no revenues. This matters for the assessment of (subsequent) medicine prices.

18. The second phase of the pharmaceutical product life cycle is the phase where a new medicine is launched and sold on the market, while benefitting from product exclusivity, owing notably to intellectual property protection. Legislation grants originator companies various intellectual property rights and exclusivity mechanisms as incentive to invest in new R&D projects and to develop new medicines. Intellectual property rights and exclusivity mechanisms designed to incentivise research and development in novel medicines may include patents and the pharma-specific exclusivities: supplementary protection certificate,[6] "data exclusivity" or "marketing exclusivity",[7] or an orphan designation.[8] A common feature of these exclusivities is however that they are limited in time, and thus allow the entry of generic medicines at the end of the exclusivity. During the phase of exclusivity, originators enjoy sometimes very high profits. Such high profits are generally the reward for risk-taking and the successful investment. An assessment of pricing practices under the unfair pricing prohibition of Article 102(a) TFEU has to take account of intellectual property rights and incentives to innovate created by the legislator.

19. During the exclusivity period, national authorities use a number of tools to influence prices of medicines or contain spending. Pricing and reimbursement rules may apply external reference pricing to take account of prices in other Member States. Also, national reimbursement schemes may incorporate in their evaluations of novel medicines "value-based" health technology assessments ("HTA"). HTAs assess the value-for-money a new product brings to society, mainly in comparison to the price and value of existing medicines and therapies. More generally, these rules and the reimbursement status of a medicine have a strong influence on its availability on the market and its pricing.

20. The third phase of the pharmaceutical product life cycle is the phase after loss of exclusivity. This is the phase when generic competition can kick in in the form of cheaper generic medicines. In some national markets and for some products, where a sufficient

[6] The supplementary protection certificate is a pharma-specific patent extension right compensating pharmaceutical companies for the significant time generally required to obtain a marketing authorisation. See Regulation (EC) 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, (OJ L 152, 16.06.2009, p. 1-10).

[7] These are pharma-specific intellectual property rights created by the legislator to protect data relating to pharmacological and toxicological tests as well as clinical studies, which originator companies submit to relevant authorities to demonstrate the safety and efficacy of novel medicines. See Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67-128); and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.04.2004, p. 1-33).

[8] Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ L 18, 22.1.2000, p. 1-5).

number of generic companies compete down the price, this may result in price drops up to 90%.[9]

21. The price of a generic product may be regulated, for instance, in relation to the price of its reference (originator) product. In certain countries generic prices may be capped as a percentage of the price of the originator product.

22. In some markets, effective generic competition does not take place after loss of legal exclusivity. This may be for a number of reasons, including the amount of the expected profits in the market that may be too small to attract (sufficient) entry, for instance when markets are very small, or special features of the market and/or regulatory particularities that may constitute barriers to entry.[10] In such circumstances, the market may not correct itself resulting in competitive price levels.

23. Article 102 TFEU applies without distinguishing between pharmaceutical products that are innovative and exclusivity protected and those that are not. High prices or price increases in relation to off-patent medicines are less likely to be justified and are thus more likely to be caught by Article 102 TFEU, because the inventor has already benefitted from legal exclusivity as a reward for innovation. Recent infringement decisions by NCAs and ongoing investigations by the European Commission and the NCAs mostly concern products no longer benefitting from exclusivity.

5. Legal tests in jurisprudence

24. The European Court of Justice has held that a price is excessive and unfair when it has "*no reasonable relation to the economic value of the product*".[11] To determine whether a price is excessive and unfair, the case law has accepted a number of methods.

5.1. Price-cost test of United Brands

25. In United Brands, the Court set out a method with an emphasis on prices and costs. The Court considered that a price is unfair when a "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" (paragraph 250). In such circumstances the price exceeds the economic value of the product that would prevail under "normal and sufficiently effective competitive conditions" (paragraph 250).

[9] As observed, for instance, in Commission decision of 19 June 2013 in Case No COMP/39.226 Lundbeck, OJ C 80, 7.3.2015, p. 13–16; and Commission decision of 9 July 2014 in Case No COMP/39.612 Perindopril (Servier), OJ C 393, 25.10.2016, p. 7–12.

[10] For some medicines, switching to other products or formulations may medically not be recommended. Also, obtaining regulatory approvals may entail high costs compared to the market size.

[11] See, for instance, judgment of 14 February 1978 in *United Brands Company and United Brands Continental v Commission*, 27/76, ECLI: EU:C:1978:22, paragraph 250. In this and other judgments, where relevant, the Court of Justice based the economic value of a product on its costs of production including a necessary profit margin.

26. As regards the methodology of establishing whether a price is above the economic value of the product, the Court held that this could be determined objectively by assessing the excessiveness of the "profit margin" (paragraph 251) and the unfairness of the price, and hence suggested a two-pronged test: "The questions therefore to be determined are whether the difference between the costs actually incurred and the price actually charged is excessive, and, if the answer to this question is in the affirmative, whether a price has been imposed which is either unfair in itself or when compared to competing products" (paragraph 252).

5.2. Comparator tests

27. In various judgments (including *United Brands*), the Court has accepted that a number of "*other ways*",[12] i.e. tests, exist to establish an unfair pricing abuse. These other ways, accepted by the Court, rely on various forms of comparisons.

28. One example is the recent *AKKA/LAA* case.[13] In *AKKA/LAA*, the Court recalled its *United Brands* jurisprudence that other methods can be applied than the price-cost test specified in *United Brands* for determining whether a price is excessive. Building on previous cases dealing with copyright management organisations, the Court confirmed the methodology of a comparison of the prices charged by the dominant undertaking with prices charged for similar products or services in one or several other Member States. While holding that there is no need to apply different methods in parallel, the Court clarified that the authority has to ensure that the comparison that is being carried out is based on comparators "*selected in accordance with objective, appropriate and verifiable criteria*" and that the comparison is "*made on a consistent basis*" (paragraphs 41 and 44).

29. When the price difference between the product in question and similar comparator products is "*appreciable*", it is "*indicative of an abuse of a dominant position*" (paragraph 52). The price difference is "*appreciable*", when it is "*both significant and persistent on the facts, with respect* […] *to the market in question*", without there being any minimum threshold (paragraphs 55). What therefore matters are the particular circumstances of each case.

30. Finally, regarding justifications, the Court held that where a difference "*must be regarded as appreciable*", "*it is for* [… the undertaking] *holding a dominant position to show that its prices are fair by reference to objective factors*…" (paragraph 61). Such "*justification*" may include objective factors that have an impact on the cost of the product in question, provided those costs are not higher "*precisely* [due to] *the lack of competition on the market in question*" (paragraph 58, see also paragraphs 57 and 60).

31. Overall, the Court of Justice emphasised that "[i]t falls to the competition authority […that is investigating the practice] to define its framework" of analysis, bearing "in mind that the authority has a certain margin of manoeuvre and that there is no single adequate method" (paragraph 49).

[12] Judgment of 14 February 1978 in *United Brands Company and United Brands Continental v Commission*, 27/76, ECLI: EU:C:1978:22, paragraph 253.

[13] Judgment of 14 September 2017 in *Autortiesību un komunicēšanās konsultāciju aģentūra / Latvijas Autoru apvienība v Konkurences padome*, C-177/16, ECLI:EU:C:2017:689.

6. Practices encountered in the enforcement of EU competition law in pharmaceutical markets

32. Pricing practices of pharmaceutical companies that may raise concerns under Article 102(a) TFEU have in recent years increasingly attracted the attention of the European Commission and national competition authorities (NCAs). NCAs have adopted four infringement decisions related to unfair pricing in the pharmaceutical sector since 2000, one in 2001 and three more recently in 2016 and 2018 (all under appeal). All cases decided so far in Europe concern medicines in the third phase of the product life cycle, i.e. after loss of exclusivity. Additional investigations by the European Commission and NCAs are ongoing.

33. *Napp*: In April 2001, the United Kingdom ("the UK") NCA found that Napp Pharmaceuticals (Napp) abused its dominant position in the market for the supply of sustained release morphine tablets and capsules in the UK by supplying patients in the community sector at excessively high prices. Napp's prices and margins in that sector were found to be, in some cases, much higher than those of a range of different comparators. Napp was also supplying hospitals at much lower (predatory) levels, with exclusionary effects.[14] The *Napp* decision was upheld by the Competition Commission Appeals Tribunal in January 2002.[15]

34. *Aspen* (Italy): In September 2016, the Italian NCA found that Aspen abused its dominant position in Italy by imposing unfair prices for four off-patent anti-cancer medicines (alkeran, leukeran, purinethol and tioguanine). Aspen's price increases ranged from 300% to 1500% without there being any economic justification for the price levels imposed. Aspen had also exercised in a "distorted and instrumental" way its right to negotiate prices with the Italian Medicines Agency. In particular, Aspen had made use of aggressive tactics to impose these increased prices.[16] The first instance court, the Tribunale Amministrativo Regionale per il Lazio, fully upheld the decision in June 2017; an appeal against that judgment is still pending before the Consiglio di Stato.

35. *Phenytoin*: In December 2016, the UK NCA found that Pfizer and the distributor Flynn had each abused their respective dominant positions in the UK by charging unfair prices for phenytoin sodium capsules, an anti-epilepsy medicine manufactured by Pfizer.[17] Prior to the price increases, Pfizer was the seller of the capsules in the UK. In 2012, Pfizer sold UK distribution rights to Flynn, while it continued to manufacture the medicine exclusively for Flynn. Subsequently, Flynn "genericised" the medicine, i.e. de-branded it and made it a generic product so that the product would no longer be subject to any form of price regulation in the UK. After this de-branding, both Pfizer and Flynn significantly increased the prices of the capsules, i.e. Pfizer increased the sales price to Flynn and Flynn increased the sales price to wholesalers and pharmacies. Following the price increases,

[14] Office of Fair Trading, Case CA98/2/2001 *Napp Pharmaceutical Holdings Ltd and subsidiaries (Napp)* (30 March 2001).

[15] Judgment of the Competition Appeal Tribunal of 15 January 2002, *Napp Pharmaceuticals Holdings Limited and Subsidiaries and Director General of Fair Trading*, Case No.1001/1/1/01.

[16] Decision A480 of the Autorità Garante della Concorrenza e del Mercato of 29 September 2016.

[17] Competition and Markets Authority, Case CE/9742-13 *Unfair pricing in respect of the supply of phenytoin sodium capsules in the UK* (7 December 2016).

Pfizer sold the medicine to Flynn at prices 780% and 1600% above Pfizer's historic prices, and Flynn sold the medicine to wholesalers and pharmacies at 2300% and 2600% higher prices than those historically charged by Pfizer. In June 2018, upon appeal at first instance, the Competition Appeal Tribunal (CAT) upheld the CMA's findings on market definition and dominance while overturning the abuse analysis.[18] The CAT's judgment is not yet final, as all parties applied for permission to appeal the ruling to the UK Court of Appeal.

36. *CD Pharma*: In January 2018, the Danish NCA found that CD Pharma (a pharmaceutical distributor) abused its dominant position in Denmark by charging Amgros (a wholesale buyer for public hospitals) unfair prices for Syntocinon (which contains oxytocin, an active substance given to pregnant women during childbirth) after a price increase of 2000%.[19] The NCA found the price unfair after, inter alia, a comparison with the historic prices of former exclusive distributors and with the prices charged by CD Pharma in other countries. The NCA held that the price increase could not be justified by increases in costs or special considerations for research and development. An appeal against the NCA decision is pending before the Danish Competition Appeal Tribunal.

37. Administrative proceedings are currently pending in the Hydrocortisone tablets case[20] and the Liothyronine tablets case[21] in the UK, as well as in the EU Aspen case in which the European Commission initiated proceedings for the EEA (except Italy).[22]

7. Conclusions

38. In the framework of the EU legal system, Article 102(a) TFEU prohibits an abuse of a dominant position in form of unfair pricing practices. This prohibition of unfair pricing applies to all pharmaceutical products, like it applies to any other product or service.

39. The European Commission, competition authorities of Member States and courts in the EU have the obligation to ensure effective enforcement of this prohibition. At the same time, the competition policy considerations set out above call for a prudent approach in applying Article 102(a) TFEU.

40. Since 2016, the Italian, UK and Danish NCAs have adopted three infringement decisions relating to practices of pharmaceutical companies relating to unfair pricing (all decisions are under appeal). Further investigations are pending.

41. The Commission's antitrust enforcement will continue to promote open and competitive markets in the pharmaceutical sector and, in particular, access to affordable

[18] Judgments of the Competition Appeal Tribunal of 7 June 2018, *Flynn Pharma Ltd and Flynn Pharma (Holdings) Ltd v Competition and Markets Authority, Pfizer Inc. and Pfizer Limited v Competition and Markets Authority*, Case Nos.1275-1276/1/12/17.

[19] Decision of the Konkurrence- og Forbrugerstyrelsen of 31 January 2018.

[20] See https://www.gov.uk/cma-cases/pharmaceutical-sector-anti-competitive-practices.

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

[22] In May 2017, the Commission opened a formal investigation into concerns that Aspen Pharma had engaged in unfair pricing concerning cancer medicines in the EEA except Italy. See http://europa.eu/rapid/press-release_IP-17-1323_en.htm.

medicines for European citizens, whilst safeguarding the incentives for innovation, research and development.