CPI's Europe Column Presents:

Excessive Pricing in Pharmaceutical Markets

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January 2019

CPI COMPETITION POLICY INTERNATIONAL

Introduction

This piece summarises the contents of a background note written for an OECD roundtable on excessive pricing in pharmaceuticals which took place in Paris on 28 November 2018.[2]

There are strong arguments for not intervening against exploitative excessive pricing, which have led to the development of stringent enforcement screens that build on the assumption that such cases should only be brought in exceptional circumstances. However, recent years have seen significant calls for intervention against high prices for pharmaceutical products, and there have been a number of competition enforcement cases regarding exploitative excessive pricing in this sector. These cases meet the criteria set out in enforcement screens developed as regards excessive pricing.

At the same time, the conditions that justify bringing such cases in the first place seem to have become relatively common in the pharmaceutical sector. Given the cost and challenges of bringing excessive pricing cases, these developments raise questions regarding what is the best response to high prices in this sector and whether there are alternatives to bringing exploitative excessive pricing cases. The application of competition law against high prices in the pharmaceutical sector requires a deep understanding of market dynamics and sectoral regulation, and of the various regulatory responses that may be deployed to address high prices. As such, it may be appropriate for competition authorities to explore various avenues for intervention, if possible in cooperation with the applicable sector regulators.

In this note, Section 2 reviews the framework for competition enforcement against 'pure' excessive prices. Section 3 looks at the main features of pharmaceutical markets and their regulation. Section 4 looks at recent examples of excessive pricing cases in pharmaceutical markets, and evaluates how these cases fit within the general competition law and policy framework for enforcement against excessively high prices. Section 5 seeks to understand what types of competition intervention may be appropriate to address high prices in pharmaceutical markets. Section 6 concludes.

Excessive Pricing

Various factors explain the level at which prices are set. If the market is competitive, it is expected that the price will be set close to cost. Prices will tend to be higher the further a market deviates from perfect competition. In situations of legal or *de facto* monopoly, economic theory predicts that a *monopoly price* will be imposed. For any price higher than the monopoly price, the monopolist would lose sales in excess of what he would gain by the price increase. As a result, economic theory predicts that prices will not be raised above the monopoly price.

Given this, a prohibition against excessive prices seems superfluous from a purely economic standpoint. Prices above the monopoly price are not possible, or are at the very least irrational. If a prohibition against excessive pricing amounted to a prohibition against monopoly pricing – i.e. the highest possible price –. this would mean that competition law prices would penalise the mere fact that a company holds a dominant position; however, competition law does not prohibit dominant positions *per se*, but only their abuse. If, on the other hand, prices between the competitive and monopoly levels were prohibited, this would lead to a paradox – because monopoly prices would be allowed, while lower prices would be prohibited as excessive.

Given these challenges, it is unsurprising that excessive pricing is an area of limited competition enforcement around the world. Excessive pricing in the absence of exclusionary conduct or collusion is usually perceived either as a temporary and self-correcting market failure, or as a problem to be addressed through sector-specific regulation.[3] While many competition laws around the world contain provisions against excessive prices, competition agencies have only exceptionally brought such cases. Some jurisdictions even preclude competition enforcers from calling into question the high prices

charged by a "pristine monopolist" absent collusive or exclusionary practices.[4] Where exploitative excessive pricing is prohibited, it has remained for a long time conceptually underdeveloped and underused in practice.[5]

Nonetheless, legal provisions prohibiting excessive prices have been the subject of continuous enforcement over the years.[6] Therefore, a longstanding debate has taken place as regards the circumstances in which it might be appropriate to bring excessive pricing cases, if at all. There is broad agreement that enforcement against excessive pricing presents *high risks* of type I error (i.e. mistaken intervention) with potentially *high costs* (because the market may self-correct in the absence of intervention, and an error will lead to dynamic inefficiency related to low investments and innovation). On the other hand, type II errors (i.e. mistaken failures to intervene) have relatively lower costs mainly related to allocative inefficiency, which are widely thought to be significantly smaller than the costs caused by dynamic inefficiencies.[7] This points towards a presumption against competition enforcement as regards excessive pricing.

It is nonetheless arguable that, in certain market and institutional circumstances, it is appropriate to bring excessive pricing cases. Reflecting this, a number of stringent screens for bringing such cases can be found in the literature.[8] While differing as to the details, these screens have in common that they require: (i) the offending firm to have significant market power, close to a pure monopoly position in the market. The closer the market structure is to an oligopoly, the less likely it will be that a dominant firm will have sufficient market power to generate excessive prices. In addition, the higher the degree of market power, the less likely it is that the market will self-correct within a relevant timeframe.[9] Some authors also require that market power must be the consequence of current or past exclusive or special rights, or of un-condemned past exclusionary anticompetitive practices; (ii) there must be high and durable barriers to entry which make the market unlikely to self-correct. As long as markets can self-correct, high prices and profit margins will be transitory phenomena which do not justify a competition intervention; (iii) intervention should not occur when it may adversely impact research and innovation, where the risks and costs of enforcement errors are highest; (iv) alternative regulatory intervention must be impossible, extremely unlikely, inappropriate or absent.

Pharmaceutical Markets

Pharmaceutical markets have important features that significantly depart from the standard models for competitive markets. These features go a long way towards explaining why pharmaceutical markets are deeply affected by regulation. As a result, a proper understanding of how competition law works in this area – including as regards excessive pricing – requires a solid knowledge of the structure of the market and its regulation.

From a demand-side perspective, many consumers do not select or pay for a number of medicines, whose cost is supported by third parties such as insurers or the State. Furthermore, pharmaceuticals can be indispensable to patients – even critical to preserving life – which leads to inelastic demand for treatment. At the same time, prescribing doctors select, but do not consume or pay for medicines. Lastly, insurance companies and national health services are liable for the payment of a large number of medicines, but have limited tools to control their consumption and selection.[10] Taken together, these market characteristics create the potential for extremely high prices in some cases, particularly where demand is extremely inelastic and the ability to pay faces only limited constraints. From a supply-side perspective, safety and efficacy concerns, together with the IP protection of numerous medicines, mean that the pharmaceutical industry is highly regulated.

Different pharmaceutical markets are subject to different levels of regulation, in particular price regulation. The regulatory framework is less comprehensive as regards off-patent drugs, where inter-brand competition is relied on to contain prices. Once medicines are not patent protected and

exclusivity periods have expired, they can become subject to inter-brand competition from generics or biosmilars. When a generic enters the market, it tends to be priced more closely to the marginal cost of production than the original product. This will put pressure on the company that manufactures the originator drug to lower its prices in order to remain competitive.[11]

In most jurisdictions, the competitive effect of generic entry on drug prices is significant. For example, studies of pharmaceutical markets in the United States and EU indicate that the first generic competitor typically enters the market at a price that is 20% to 30% lower than that of the originator medicine, and gains substantial market share from the originator product in a short period. Subsequent generic entrants may enter at even lower prices – discounted as much as 80% or more off the price of the originator drug – and prompt earlier generic entrants to reduce their prices.[12] Mechanisms to promote generic entry and use are thus common around the world.

Recent Excessive Pricing Cases in Pharmaceutical Markets

EU law on excessive pricing influences most jurisdictions that sanction excessive pricing. Article 102 (a) of the Treaty for the Functioning of the European Union ('TFEU') prohibits conduct by a dominant company, which consists in '*directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions*'. This has been interpreted as prohibiting not only those prices that are unfairly low – such as predatory pricing – but also prices that are unfairly high. In *United Brands*, the ECJ explained that a price is abusive if '*it has no reasonable relation to the economic value of the product*', and that an abuse can be identified through a twofold test that considers whether: (i) the price cost margin is excessive and (ii) the price imposed '*is either unfair in itself or when compared to competing products*'.[13]

This decision sets out a two-stage test which is still deployed in excessive pricing cases. In recent years, a number of excessive pricing cases were brought against pharmaceuticals. Short overviews of the main cases in this area are provided below.[14]

UK – Pfizer / Flynn

In 2017, the UK's CMA adopted an excessive pricing decision regarding an out-of-patent anti-epileptic drug, Epatunin, whose cost is reimbursed by the UK's National Health Service. This drug is subject to a principle of continuity of supply, which meant that patients who were stabilised on Epatunin were advised by the relevant UK health regulator to remain on this specific formulation. Up until 2012, Pfizer sold Epatunin as a branded drug under an applicable price regulation scheme. In 2012, Pfizer sold Epanutin's UK marketing authorisation (i.e. the right to sell this product) to Flynn Pharma. As a result, Pfizer became an upstream manufacturer of the drug under an exclusive supply agreement, but granted distribution rights to Flynn Pharma. Flynn Pharma then obtained approval in the UK to sell the product as a generic, rebranded it, and started marketing it under a new name. As a consequence of a regulatory gap,[15] this meant that the rebranded generic version of Epatunin was not subject to any price regulation. Pfizer increased the price it sold the drug to Flynn Pharma, which also increased the retail price significantly – the retail price of a pack of 84 capsules of 100 mg increased from GBP 2.83 to GBP 67.50.

The CMA concluded that Flynn and Pfizer explored a regulatory loophole which allowed: (i) Pfizer to sell Epatunin to Flynn at prices 8 to 17 times higher than previous NHS prices; (ii) Flynn to then re-sell the drug at prices 25 to 27 times higher than previous retail prices. Applying the framework for excessive pricing developed by the EU courts, the CMA found that the prices applied by Pfizer and Flynn were both excessive and unfair. On appeal, the Competition Appeal Tribunal found that the CMA did not correctly apply the legal test for excessive pricing, *inter alia* by incorrectly relying on a cost

plus approach and by failing properly to assess the possible impact of meaningful comparators when determining whether Pfizer and Flynn's prices were unfair.

Italy – Aspen

Generics company Aspen bought Cosmos drugs' trademark and marketing rights from GlaxoSmithKline. Cosmos drugs are out-of-patent cancer medicines for the treatment of specific categories of patients (namely old people and children) that are essential and non-substitutable. These drugs are reimbursed by the Italian health service and their price is subject to negotiations with the Italian regulator ('AIFA').

In 2013, Aspen started negotiations with AIFA and insisted that the Cosmos drugs should be categorised as non-reimbursable, which would mean the drugs would no longer be subject to price regulation. Aspen also threatened to withdraw the Cosmos drugs from the market, and deliberately caused a shortage of Cosmo drugs in the Italian market during price negotiations. This aggressive conduct by Aspen – in a situation where the Cosmos portfolio comprised lifesaving and irreplaceable drugs – led AIFA to agree to price increases of up to 1,500%. In 2016, the Italian competition authority condemned this price increase as excessive pricing, a decision since confirmed by the Italian First Grade Administrative Court.[16]

Denmark – CD Pharma

Syntocinon is an out-of-patent drug containing oxytocin, an active substance given to pregnant women in connection with childbirth in Danish hospitals. CD Pharma had an exclusive distribution agreement with the producer of Syntocinon, which ensured its ability to supply the market. During 2007-2014, the price of drug Syntocinon was stable around DKK 44 (EUR 5.9).

The wholesale buyer for hospitals, Amgros, put out a tender on Syntocinon which was won by a parallel importer. However, this company was unable to provide Amgros with the full amount of required Syntocinon. Since CD Pharma was the only alternative supplier in the Danish market, Amgros had to buy a residual quantity of Syntocinon from CD Pharma, which on this occasion increased the price of the drug by 2,000%. The Danish Competition Authority ruled that CD Pharma's price increase amounted to an abuse of a dominant position and ordered it to refrain from similar behaviour in the future.

Observations

These cases share a number of similarities. First, they relate to medicines that have long been off-patent, so there are no R&D and investment recoupment justifications for high prices, nor concerns with excessive pricing cases interfering with innovation. Second, the claims of excessive pricing all relate to sudden and significant price increases of products that have long been in the market. Third, the medicines in question are essential to patients, and there was no reasonable prospect of the entity responsible for providing those medicines – usually entities linked to the State and national health services, which bear the cost of those medicines – not purchasing them. Fourth, the authorities consistently found that there was no prospect of timely market entry of alternative products, because of either supply constraints, the regulatory framework, or the limited size of the market. Fifth, regulatory intervention was perceived to be unable to provide an appropriate, or at least timely, response to the price increase.

In other words, these cases fulfil the requirements set out in the stringent screens for bringing excessive pricing cases reviewed above. This reflects the competition authorities' efforts to ensure

that competition intervention against excessive prices was necessary and limited to those situations where such competition law enforcement is the best available alternative.[17]

How Best to Deal With High Prices in Pharmaceuticals

An important question in this context is why there has been a spate of excessive pricing cases in the pharma sector, particularly when such cases were virtually unheard of until recently. A particularly remarkable characteristic of these cases is that they did not address IP protected drugs – meaning that, theoretically, entry by generics and inter-brand competition would have been possible. It is commonly assumed that competition among generic and originator products results in lower prices and increased access to safe and effective treatments. This argues against extensive regulation. Instead, market forces should be allowed to play themselves out, leading to lower prices through competition.

A potential issue with this view is that it builds on assumptions – that multiple generics will enter and remain in the market; that market entry and competition will occur upon the expiry of IP rights; that prices will come down – which may be becoming less prevalent than previously thought. It has been found that the median and the mean number of generics suppliers has declined in recent years, due both to increased exit and reduced entry of generics manufacturers, and that the share of generics supplied by only one or two manufacturers has increased over time. In effect, it seems that in the US approximately 40% of generics' markets are supplied by a single manufacturer.[18]

The lack of therapeutically equivalent drugs in the market limits competition and may contribute to extraordinary price increases, which have recently become a matter of widespread concern regarding generic drugs.[19] The US Government Accountability Office has found that, between 2010 and 2015, the overall price of medicines had fallen as a result of, among other things, significant price decreases for generics. However, examining the price histories of 1,411 generic drugs during this period, it also found that over 20% of generic drugs had seen their price double or more,[20] and that 3% had seen their price quintuple or more.[21] Furthermore, the number of generic drugs that saw their prices raised has been increasing in recent years.[22]

There are a number of potential explanations for these developments, including market exit by generics manufacturers,[23] medicines shortages,[24] and increased collusion.[25] These structural developments seem to have occurred in tandem with the development of business strategies that identify market segments where prices can be successfully increased. For example, companies may identify niche essential drugs that are not under patent and whose market is so small that no competitors will enter the market, or where supply is limited for regulatory or contractual reasons. This strategy may be coupled with attempts to game the regulatory system in order to evade price controls.[26]

Given the seeming pervasiveness of high prices and price increases in pharmaceutical markets where inter-brand competition would be expected to operate, it can be questioned whether bringing excessive pricing cases is the right answer for the problem. Excessive pricing cases are unavoidably fact-specific, operate *ex post*, are subject to high error risks and costs, and rarely set out bright-line guidance on how to set accurate prices in the future. It is widely thought that they should only be brought in extraordinary circumstances, but the conditions giving rise to excessive prices seem to be relatively common in the pharmaceutical sector, which would seem to call for less blunt forms of intervention with wider sectoral impact.

Conclusion

Competition authorities have a variety of tools at their disposal to deal with high prices in pharmaceutical markets. One of the ways through which competition authorities can deal with concerns regarding high prices in pharmaceutical markets is by studying markets in order to determine the source of market failures, and either advocate or adopt remedies (if they have the power to do so) to address such failures. A better understanding of the market may provide support to competition enforcement actions, including, potentially, the bringing of excessive pricing cases. Where the market investigation finds that the absence of competition cannot be addressed other than by regulation, the competition authority may choose to either defer to established regulators or publicly call for the establishment of such a regulator. Lastly, political processes may also have a role to play in addressing this issue.

[1] Expert, Directorate for Financial and Enterprise Affairs at OECD.

[2] OECD (2018), "Excessive Pricing in Pharmaceuticals" DAF/COMP(2018)12, available at https://one.oecd.org/document/DAF/COMP(2018)12/en/pdf.

[3] OECD (2011), 'Excessive Prices' DAF/COMP(2011)18, p. 8-11.

[4] In the US, see *Berkey photo, Inc. v. Eastman Kodak Co*., 603 F.2d 263, 297 (2d Cir. 1979); *United States v. Trans-Missouri Freight Ass*, 166 U.S. 290 (1897); *United States v. Trenton Potteries Co*, 273 U.S. 392 (1927); *United States v. Aluminium Co. of America*, 148 F.2d 416 (2d Cir. 1945); *Verizon Communications Inc. v Law Offices of Curtis v Trinko LLP* 540 US 398, 407, 124 S Ct 872 (2004). In Mexico, under Article 10 of the Federal Law of Economic Competition only those conducts by dominant firms that have the aim or effect of impeding or preventing a firm entering into, or expanding within, a market will be competition offences. Canada, however, takes a different, and original approach: section 32 of the Canada Competition Act, R.S.C. 1985, c C-34 (Can.)) provides a number of possible remedies to the unreasonable enhancement of prices of any article or commodity that benefits from exclusive rights arising from IP rights. In addition, the Canadian Patented Medicines Price Review addresses excessive pricing and has the power to order price reductions. Excessive pricing is also not an infringement of competition law in Australia.

[5] P. Akman, P. and L. Garrod, "When are excessive prices unfair?" (2011) Journal of Competition Law and Economics 7(2) 403, p. 404-405; F. Jenny, F., "Abuse of Dominance by Firms Charging Excessive or Unfair Prices: An Assessment",

in Jenny, F. and Y. Katsoulacos (eds.), *Excessive Pricing and Competition Law Enforcement* (2018, Springer), Springer, http://www.msm.nl (accessed on 09 August 2018), p. 4.

[6] For a thorough overview of enforcement against excessive prices, see id., p. 2-20.

[7] Id., p. 25.

[8] D. Evans and J. Padilla, "Excessive Prices: Using Economics to Define Administrable Legal Rules", (2005) Journal of Competition Law and Economics 1(1) 97; M. Motta and A. De Streel, "Exploitative and Exclusionary Excessive Prices in EU Law", in Ehlermann, C. and I. Atanasiu (eds.), European Competition Law Annual 2003, What Is an Abuse of a Dominant Position?, (2006, Hart); M. Motta and A. De Streel "Excessive Pricing in Competition Law: Never say Never?", in The Pros and Cons of High Prices, (2017, Swedish Competition Authority); R.Nazzini, "Abuse Beyond Exclusion: Exploitation and Discrimination Under Article 102 TFEU", in Hawk, B. (ed.), International Antitrust Law & Policy: Fordham Competition Law 2012, Juris Publishing, New York; L. Röller "Exploitative Abuses", in Ehlermann, Claus-Dieter Marquis, M. (ed.), European Competition Law Annual 2007: A Reformed Approach to Article 82 EC (2008, Hart); and the Opinion of AG Wahl in Case C-177/16 *Latvijas Autoru apvienība*' ECLI:EU:C:2017:286, paras. 48-51, 106-112.

These screens are helpfully summarised in Motta and A. De Streel "Excessive Pricing in Competition Law: Never say Never?", p. 21-22, and Jenny, F., "Abuse of Dominance by Firms Charging Excessive or Unfair Prices: An Assessment", p. 37-39.

[9] OECD (2011), 'Excessive Prices' DAF/COMP(2011)18, p. 50.

[10] OECD (2014), 'Competition Issues in the Distribution of Pharmaceuticals' DAF/COMP/GF(2014)3, p. 5; National Academies of Sciences, Engineering, and Medicine 'Making Medicines Affordable: A National Imperative' (2018, NAP), p. xix-xx.

[11] Id., p. 76-75.

[12] OECD (2009), Generic Pharmaceuticals DAF/COMP(2009)39, p. 18.

[13] Case 27/76 *United Brands Company and United Brands Continental BV v EC Commission* ECLI:EU:C:1978:22, paras 250-252.

[14] Additional cases have been brought elsewhere – e.g. there have been excessive pricing cases regarding pharmaceuticals in China, and there is an ongoing investigation in South Africa at the time of writing.

[15] Which has been closed in the meantime by the Health Service Medical Supplies (Costs) Act 2017, s. 4.

[16] Tribunale Amministrativo Regionale del Lazio, s. I, Judgment No. 8945 of 26 July 2017.

[17] F. Jenny, "Abuse of Dominance by Firms Charging Excessive or Unfair Prices: An Assessment", p. 40.

[18] E. Berndt, R. Conti and S. Murphy, "The Landscape of US Generic Prescription Drug Markets, 2004-2016", (2017) National Bureau of Economic Research; National Academies of Sciences, Engineering, and Medicine 'Making Medicines Affordable: A National Imperative' (2018, NAP), p. 76-75; E. Berndt, R. Conti and S. Murphy, "The generic drug user fee amendments: an economic perspective" (2018) Journal of law and the biosciences 5(1) 103.

[19] National Academies of Sciences, Engineering, and Medicine 'Making Medicines Affordable: A National Imperative' (2018, NAP), p. 80.

[20] There were 315 such instances since 2010.

[21] A price increase of 500% or more was observed in 48 cases.

[22] GAO (2016), Generic Drugs under Medicare, US GAO, https://www.gao.gov/assets/680/679022.pdf

[23] F. Abbott, "Excessive pharmaceutical prices and competition law: doctrinal development to protect public health" (2016) UC Irvine Law Review 6(3) 281, p. 301.

[24] WHO "Medicines shortages" (2016) *WHO Drug Information* 30(2).

[25] In 2017, over forty state attorneys general brought a claim against a large number of generics manufacturers concerning allegations that the manufacturers collectively agreed to raise prices for a large number of generic drugs. See *In Re: Generic Pharmaceuticals Pricing Antitrust Litigation / In Re: State Attorneys General Cases* (2:17-cv-03768-CMR), Eastern Dist. of Penn, complaint available at http://ag.nv.gov/uploadedFiles/agnvgov/Content/News/PR/PR_Docs/2017/2017-10-31_State.AGs_Proposed_AmendedComplaint.PV.pdf.

[26] M. Colangelo and C. Desogus, "Antitrust Scrutiny of Excessive Prices in the Pharmaceutical Sector: A Comparative Study of the Italian and UK Experiences" (2018) *World Competition* 41(2) 225, p. 240-241.