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ARTICLE

# Excessive pricing in the pharmaceutical industry: adding another string to the bow of EU competition law

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**Abstract**

The paper addresses the issue of excessive price abuse under Article 102(a) of the Treaty on the Functioning of the European Union (TFEU), by drawing inspiration from a recent stream of cases (developed first at the national and then at the EU level) involving pharmaceutical companies marketing off-patent drugs. In particular, the two 'most advanced' cases are analysed: *Aspen* in Italy and *Pfizer/Flynn* in the United Kingdom. This new-found attention towards exploitative practices in the form of excessive and unfair pricing by dominant undertakings that have traditionally been subject to a cautious antitrust scrutiny seems worth exploring for a number of reasons, as illustrated in the paper. Ultimately, it is argued that this further 'interference' of competition law into the realms of regulation may be actually justified, albeit subject to precise conditions for enforcement, and may pursue policy objectives in the wider context of EU health law.

**Key words:** Abuse of dominance; EU competition law; excessive prices; pharmaceutical pricing regulation

## 1. Introduction: scope and methods of the analysis

This paper takes on a complex and debated issue in antitrust enforcement, namely, excessive price abuse under Article 102(a) of the Treaty on the Functioning of the European Union (TFEU). It draws inspiration from a recent stream of cases (developed first at the national and then at the EU level) involving pharmaceutical companies marketing off-patent drugs. Preliminarily, Section 2 sets out the relevant EU pharmaceutical policy context regarding pricing regulation, followed by the role played by competition law in this regard. Section 3 provides a more thorough analysis of the case law and practice emerging in the pharmaceutical industry, and compares the approaches taken in the two 'most advanced' cases (namely, *Aspen* in Italy and *Pfizer/Flynn* in the United Kingdom). Lastly, provisional conclusions are drawn as to the impact of this line of case law on the substantial assessment required to establish a 'fair' level of prices in the pharmaceutical industry. This needs to take into account, on the one hand, the costs connected to developing and marketing drugs and, on the other hand, the price negotiation procedures imposed by the sector-specific regulatory framework. From a broader perspective, these cases seem to call into question the policy implications for the statutory role of EU competition law itself.

The research question that this paper tries to address is, therefore, related to the appropriateness (and, in the positive, its extent) of price control using competition law as one tool within the broader context of EU pharmaceutical governance. For the purpose of this assessment, the data that were gathered comprise the legislation currently in force in the European Union (and its Member States) as regards both the sector-specific regulatory framework and competition law enforcement, as well as the literature that has dealt with the issue of excessive price abuse

under Article 102(a) TFEU, equally presenting arguments for and against intervention in this field. Specific account was also taken of the policy guidance provided by the OECD (Organisation for Economic Co-operation and Development) as to excessive pricing in pharmaceuticals,[1] due to its influence on the discussion at the EU level of the implications of competition law intervention in this area. This theoretical background was then tested through a case law analysis, focused in particular on the cases that recently occurred in Italy and in the United Kingdom. The employment of a comparative perspective between the practices of the two Member States appears particularly illustrative of the legal challenges that may be faced by enforcers and courts in cases in which antitrust scrutiny is indeed exercised in relation to excessive pricing conduct.

## 2. The broader framework: pharmaceutical pricing regulation in the European Union and the role of competition law in this context

Pharmaceuticals, along with medical equipment and medical devices, are, broadly speaking, 'goods' within the meaning of EU single market legislation, especially free movement and competition law. They are further subject to extensive policy governance at both EU and national levels, with the aim of ensuring access to affordable and innovative medicines while maintaining a competitive structure in the relevant industry. Indeed, the pharmaceutical market belongs to those industrial sectors where regulation plays an essential role in defining their features, of which drug pricing and reimbursement schemes constitute an integral part. In this policy area (which has been referred to as "commercial or market pathway"),[2] however, the competence of Member States is predominant in shaping the conditions under which drugs are purchased by national health systems (NHS), insurance companies and patients. In particular, national arrangements in this regard are required to strike a sensitive balance between principles of financial sustainability[3] and the demand for new medicines and wider health treatment choices. NHS make recourse to different policy tools for establishing pricing and reimbursement procedures for pharmaceutical products. Such tools comprise, for example, the application of external reference pricing to compare prices charged in other Member States in order to derive a benchmark for the purpose of setting the price or reimbursement rate in their own country;[4] or mechanisms of value-based pricing as determined through health technology assessments.[5] Most EU Member States directly control the price of reimbursed medicines, while others have implemented systems where pharmaceutical companies are allowed to freely set their initial price levels.[6] In this latter case, however, price control is still indirectly exercised to the extent that drugs will benefit from reimbursement only up to a certain amount or on condition that the price is considered acceptable.[7]

EU secondary legislation has been enacted for the purpose of providing a partial harmonisation of pharmaceutical pricing regulations across EU Member States.[8] In particular, Directive 89/105/EEC[9] (the so-called 'Transparency Directive') sets forth certain requirements of transparency,

[1]In particular, on 27–28 November 2018, the OECD Competition Committee held a Best Practice Roundtable specifically devoted to 'Excessive pricing in pharmaceuticals': see the background note in OECD (2018) and the summary of the discussion in OECD (2019).

[2]Hancher (2010: 635).

[3]In this regard, the magnitude of the 2008 economic crisis aggravated the challenges that health systems in Europe had to face: for a comprehensive analysis of its impact and the policy responses, see, e.g. Thomson *et al.* (2014); Stuckler *et al.* (2017).

[4]See the definition and the findings on this policy tool in WHO (2015, para. 5.4).

[5]This specific tool is an evidence-based process that independently and objectively assesses a new or existing technology by means of a comparison with other health technologies or other standards of care, thus providing the competent national authorities with a scientific base for the purposes of pricing and reimbursement decisions.

[6]For a thorough assessment, see, e.g. Belloni et al. (2016).

[7]The EU countries that have adopted such a system of indirect control are Denmark, Germany and the United Kingdom.

[8]For example, Hancher (2010); Hancher and Sauter (2012: 167); Hervey and McHale (2015: 269).

[9]Council Directive 89/105/EEC [1989] OJ L40/8. For an overview of the relevant case law concerning the Transparency Directive, see Hancher and Sauter (2012: 171–173).

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objectivity and verifiability for pricing and reimbursement procedures. The procedural obligations imposed by the Directive include that decisions on pricing and reimbursement comply with a specific timeframe, contain a statement of reasons and be subject to judicial review. This piece of legislation, however, has not proven to be particularly effective,[10] and the proposal for amendments submitted by the European Commission in 2012[11] was ultimately withdrawn with the adoption of the Commission's Work Programme 2015 on the grounds of the absence of a foreseeable agreement.[12]

Against this background, the paper focuses on certain pricing trends that have recently been observed in relation to the inter-brand competition that occurs when a brand pharmaceutical goes off-patent and generic companies are able to enter the market. Due to a decline in the number of generic manufacturers over the years, stemming from low profit margins that contribute to market exits and a general consolidation in the market,[13] generic pharmaceuticals may actually create market segments (or 'niches') where prices can be successfully increased and charged. This contributes to the establishment of "effective monopolies"[14] insofar as the generic producer remains the last of the remaining suppliers for the given drug. In these cases, competition law enforcement may represent an additional tool to be resorted to in the so-called 'market pathway' in order to challenge anticompetitive price hikes of off-patent drugs. Such an interference of antitrust law as a further 'presence' within the pharmaceutical industry,[15] nonetheless, seems to lead to more blurred boundaries between regulation, considered as the *ex ante* activity laying down the rules governing the markets, and competition, understood as the *ex post* enforcement of those rules.[16] The question thus becomes whether antitrust enforcers are properly equipped to carry out such further task, especially in regulated sectors where governments have established public agencies with the precise aim of providing an autonomous control on the market.

Furthermore, antitrust scrutiny over the aforementioned conduct is confronted with the traditionally limited enforcement towards unfair pricing practices, despite the express prohibition laid down in Article 102(a) TFEU.[17] The approach arguing that competition law should refrain from intervening in this field builds on the traditional entrustment of the markets' capability of self-correction. Particularly high prices may point to the profitability of a given market, thereby attracting the entry of new incumbents that will then reduce the market power of the dominant firm and, consequently, prices. Moreover, with specific regard to the extent of enforcement against excessive price abuse, some commentators highlight the practical difficulties in establishing the threshold of excessiveness, which may result in enforcement errors (especially type-I, i.e. over-enforcement), and the inherent inadequacy of competition authorities to act as price regulators due to the need for deep market knowledge and long-term monitoring.[18]

Other than the legislative prohibition set out in Article 102(a) TFEU, arguments in favour of antitrust intervention[19] generally find their background in the protection of consumer welfare as the main goal of EU competition policy. This would indeed call for a direct enforcement against

[10]Due, in particular, to the Directive's limited scope and the fact that Member States often exceed the time limits prescribed by it: Hervey and McHale (2015: 270–272).

[11]COM(2012) 84 final.

[12]COM(2014) 910 final, Annex 2: 10.

[13]OECD (2018: para. 109).

[14]Abbott (2016: 301).

[15]This paper focuses on excessive pricing practices, but various kinds of strategies devised by pharmaceutical undertakings have been investigated (and often sanctioned) under both Articles 101 and 102 TFEU (e.g. with regard to the former provision, reverse payment settlement agreements between originator companies and generic manufacturers; as to the latter, cases of 'evergreening' of patents and 'product-hopping', i.e. switching from first- to second-generation drugs).

[16]The literature has extensively commented on this relationship: e.g. Laguna de Paz (2012); Dunne (2014); Drexl and Di Porto (2015).

[17]For an overview of the provision, see Robles Martín-Laborda (2018).

[18]For example, Evans and Padilla (2005); Motta and de Streel (2007).

[19]For an overall framework of these reasons, see Peeperkorn (2009: 612–613); Jenny (2018).

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excessive or unfair prices, rather than a mere indirect engagement against exclusionary abuses to preserve the competitive process. In addition, one should consider the so-called 'gap' cases insofar as Article 102 does not apply to the conduct of abusive acquisition of dominance, and, therefore, intervening against the exploitative practice would amount to the only viable option under EU competition law.[20] As a result, especially whenever the market is not capable of self-correcting[21] or at least not within a reasonable timeframe, competition authorities may retain a regulatory role of last resort. To this end, a number of stringent conditions have been proposed for bringing an antitrust case against exploitative excessive pricing, which, taken together, justify the intervention on an exceptional basis. In particular, according to the OECD guidance, the common features of these "screens for enforcement"[22] are the following: significant market power of the undertaking imposing excessive prices; the existence of high and durable barriers to entry that prevent the market from self-correcting; the absence of adverse effects on research and development (R&D) and innovation; and the unfeasibility (or even impossibility) of an alternative regulatory intervention.

Given these circumstances, both the European Commission and the Court of Justice of the European Union (CJEU) have followed a cautious approach to cases of excessive prices, in general focussing on enforcement against exclusionary abuses. Only a handful of cases have thus elaborated on the test to assess this anticompetitive conduct,[23] the most comprehensive of which is the well-known CJEU judgment in *United Brands* that dates back to 1978.[24] The EU Court proposed a two-pronged test, according to which it must first be established "whether the difference between the costs actually incurred and the price actually charged is excessive". If the answer is in the affirmative, then it must be determined whether such a price "is either unfair in itself or when compared to competing products".[25] No further clarification was provided in that instance, but the Commission has subsequently specified, with regard to the first limb of the test, that the calculation of the profit margin should also take into account "the investment risks involved in the industry concerned", and, for the second limb, that an anticompetitive high profit margin originates from a lack of effective competition due to the exercise of market power.[26]

In light of these considerations, the following section delves into the main cases brought in Italy and in the United Kingdom in which competition law enforcement has recently addressed excessive pricing practices in relation to off-patent drugs.

[20]A recurring example is that of excessive royalties charged by an undertaking that has obtained its dominant position as a result of non-disclosure of its patent when it was involved in discussion on setting a standard for the industry: Peeperkorn (2009: 612–613).

[21]Other commentators have, however, maintained that excessive prices are not self-correcting *per se*, as potential entrants ground their decision to enter on the basis of the expected more profitable post-entry prices rather than the high pre-entry ones: Ezrachi and Gilo (2009: 255–262); Gilo (2018: 123).

[22]This wording is used in OECD (2018: paras. 35–37).

[23]Besides *United Brands* (*infra*), the CJEU has addressed this issue in: *General Motors Continental NV v Commission of the European Communities*, 26/75, EU:C:1975:150; *Corinne Bodson v SA Pompes funèbres des régions libérées*, 30/87, EU:C:1988:225; *François Lucazeau and others v Société des Auteurs, Compositeurs et Editeurs de Musique (SACEM) and others*, 110/88, 241/88 and 242/88, EU:C:1989:326; and, most recently, *Autortiesību un komunicēšanās konsultāciju aģentūra/Latvijas Autoru apvienība v Konkurences padome*, C-177/16, EU:C:2017:689 ('*Latvian Copyright*'). The EU Commission, on its part, has tackled cases of excessive prices in: *Deutsche Post AG – Interception of cross-border mail*, COMP/C-1/36.915; *Scandlines Sverige AB v Port of Helsingborg*, COMP/A.36.568/D3; and *Rambus*, COMP/C-3/38.636.

[24]*United Brands Company and United Brands Continentaal BV v Commission of the European Communities*, 27/76, EU:C:1978:22.

[25]*United Brands*, 27/76, para. 252. After illustrating the mentioned test, the CJEU recognised that other methodologies may also be devised to ascertain prices unfairness, but did not address them further.

[26]See OECD (2011), and in particular the contribution from the EU, *Article 102 and excessive prices* (at 318).

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## 3. Case law analysis

### 3.1 In Italy

In September 2016, the Italian Competition Authority (ICA) ruled that the South African generic pharmaceutical group Aspen had abused its dominant position within the meaning of Article 102(a) TFEU by imposing on the Italian Medicine Agency [*Agenzia Italiana del Farmaco* (AIFA)] price increases of up to 1500% for a number of anticancer drugs known as 'Cosmos',[27] and had imposed a fine of over 5 million euros against the company.[28] The factual background of the case revolves around the mentioned medicines, used especially for certain categories of patients (elderly people and children) for which they lack any therapeutic substitutes. Their development goes back to the 1950s and 1960s, and the related patent protection had long expired when Aspen acquired their trademark and marketing rights from the originator GlaxoSmithKline (in 2009). These peculiar circumstances made it possible for there to be full amortisation of R&D, marketing and promotion investments at the time of Aspen's acquisition. Consequently, a market niche had successfully been established for this life-saving treatment in relation to which the generic producer bore only distribution costs since the production was also contracted out to third-party companies. With specific regard to the relevant pricing and reimbursement framework, Cosmos drugs were reimbursed by the NHS (belonging to the A and H classes), due to their clinical relevance and lack of substitutes, and their price was subject to negotiations with AIFA. Starting in 2013, Aspen pursued an aggressive strategy towards the regulatory agency in the context of the price negotiation procedures in order to obtain a 'de-listing' of the Cosmos drugs to the C class; that is, non-reimbursable but directly sustained by patients at a price set by the pharmaceutical company itself. The ultimate aim was indeed to increase the prices and to align them with those charged in other EU Member States. This stance taken by Aspen, however, could not be accepted by AIFA in light of the life-saving and non-substitutable character of the medicines at issue. Nevertheless, the regulator had to agree to a substantial upward revision of the prices[29] as a result of Aspen's threat to withdraw the drugs from the Italian market and make them available only through parallel trade from other European markets. The ICA started its investigation into this conduct in 2014 and closed the proceedings with the mentioned infringement decision on 29 September 2016. The main legal content of the decision is summarised as follows.[30]

First, the ICA established that Aspen held a dominant position in the relevant market (defined at ATC5 level, i.e. with regard to the active ingredient) as the sole marketing authorisation holder for the Cosmos drugs and given the lack of substitutability of the drugs for specific categories of patients. Next, it assessed the strategy put in place by the generic-producing company according to the two-step legal test illustrated by the CJEU in its *United Brands* ruling. More precisely, the ICA compared the costs incurred in the production of the drugs at issue and the price actually charged by Aspen in order to determine the excessiveness of the price. This was measured by the percentage gross margin (GM%, which is gross margin/revenues per cent) and by another methodology based on the average percentage rate of return on sales (ROS) realised by the two major generic undertakings active at a global level (13%). Both showed a substantial disproportion in price based on the economic value, with an excess of 'cost plus' ranging from 150 to 400%. A further benchmark used was the weighted average cost of capital (WACC) for the pharmaceutical

[27]More precisely, this basket of medicines is made up of the following active pharmaceutical ingredients: chlorambucil, melphalan, mercaptopurine and thioguanine.

[28]AGCM, Autorità Garante della Concorrenza e del Mercato, A480 – *Incremento prezzi farmaci Aspen*, decision of 29 September 2016, no. 26185. In *Bollettino AGCM* no. 36 of 17 October 2016, 5–99, retrieved from http://www.agcm.it.

[29]The new prices to the public for stock keeping unit (SKU) ranged from 95.10 to 247.35 euros, as opposed to the original prices that comprised between 5.80 and 69.21 euros: see the details in AGCM, *Aspen*, para. 4, table 1.

[30]In the Italian literature, see, e.g. Arnaudo and Pardolesi (2016); Colangelo (2016); Lanza and Sfasciotti (2017); Actis Perinetto (2017), who underlines a number of questionable aspects in the ICA's assessment that could make it difficult to infer a precedential value from it (at 107–110).

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sector as a whole (8%): in this regard, the WACC of the Cosmos drugs was between two and four times higher, confirming Aspen's unfair profits. As to the second prong of the test (i.e. the unfairness), the ICA ascertained that there were no other reasonable justifications (in particular, possible non-cost-related factors) for the price increases imposed on the sector regulator. Indeed, the competition authority maintained that Aspen made an instrumental use of the negotiation procedures by means of an 'oncology allocation mechanism' aimed at increasing prices at an EU-wide level.

This decision was subsequently upheld by the competent Italian administrative court of first instance (T.A.R. Lazio),[31] thereby confirming the substantive assessment of the ICA. In this regard, the court expressly recalled its previous opinion according to which it is essential to find a further anticompetitive purpose ("*quid pluris*")[32] to ground a finding of infringement of a given conduct, which may even be found lawful under other branches of law. In the case at issue, Aspen was indeed found to have abused the right to price renegotiation through the aggressive exercise of its bargaining power towards the sector regulator.

For the sake of completeness, it is worth mentioning that on 18 April 2018, Aspen and AIFA reached an agreement under which the prices recognised as excessive by the ICA were no longer applicable with retroactive effect from the date of the infringement decision. Consequently, the ICA acknowledged that the pharmaceutical company had properly fulfilled its obligations to ensure the charging of fair prices, and did not impose the further administrative fine provided in the event of non-compliance.[33]

In any case, the competition law enforcement against Aspen group's excessive pricing practices may have further developments at the EU level. In fact, on 15 May 2017, the European Commission initiated antitrust proceedings covering the European Economic Area other than Italy,[34] and the case is currently ongoing. This marks the first investigation undertaken by the EU institution into this kind of anticompetitive conduct in the pharmaceutical industry.

### 3.2 In the United Kingdom

By decision of 7 December 2016, the Competition and Market Authority (CMA) found that the pharmaceutical companies Pfizer and Flynn Pharma had abused their respective dominant positions under Article 102 TFEU (and the Chapter II provision of the Competition Act 1998) by imposing unfair prices for phenytoin sodium capsules manufactured by Pfizer in the United Kingdom and, consequently, fined them for a total of over 89 million pounds.[35] The facts of the case refer to the brand drug Epatunin, an off-patent anti-epileptic relying on a well-established base of patients who were stabilised on this treatment and should not be switched to other versions of the same active ingredient phenytoin sodium. Epatunin's UK marketing authorisation – without the associated trademark – was sold by Pfizer to Flynn in 2012, with Pfizer continuing to manufacture the drug which it exclusively supplied to Flynn for distribution in the United Kingdom. Flynn then obtained approval to sell the drug as a generic and started

[31]T.A.R. Lazio, sez. I, judgment of 26 July 2017, no. 8945. Retrieved from https://www.giustizia-amministrativa.it/web/guest/dcsnprr?p_p_id=GaSearch_INSTANCE_2NDgCF3zWBwk&p_p_state=normal&p_p_mode=view&_GaSearch_INSTANCE_2NDgCF3zWBwk_javax.portlet.action=searchProvvedimenti&p_auth=GQtKXRv3&p_p_lifecycle=0 [30 December 2019]. In the literature, Angeli (2017).

[32]T.A.R. Lazio, 2017, para. 6.7.

[33]AGCM, A480B – *Incremento prezzi farmaci Aspen-Inottemperanza*, decision of 13 June 2018, no. 27209. In *Bollettino AGCM* no. 26 of 9 July 2018, 5–22, retrieved from http://www.agcm.it.

[34]See the press release IP/17/1323, retrieved from https://ec.europa.eu/commission/presscorner/detail/en/IP_17_1323 [30 December 2019].

[35]CMA, *Unfair pricing in respect of the supply of phenytoin sodium capsules in the UK*, CE/9742-13, retrieved from https://www.gov.uk/cma-cases/investigation-into-the-supply-of-pharmaceutical-products [30 December 2019]. For a critical reading of the decision, see Meershoek (2018).

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marketing it under a new name, Phenytoin Sodium Flynn Hard Capsules (PSFHC). This overall strategy was devised to withdraw the branded drug from price regulation under the NHS's Pharmaceutical Price Regulation Scheme (PPRS).[36] Because generics are freely priced, this allowed Pfizer, on the one hand, to increase the price at which it sold the drug to Flynn and, on the other hand, Flynn to dramatically increase the selling price of PSFHC. In May 2013, the CMA opened a formal investigation following a complaint by the Department of Health and issued the infringement decision in the terms set out above. For this case also, the legal content of the decision is briefly recapped.

The relevant market was very narrowly defined, due to the narrow therapeutic index of phenytoin sodium, with the consequence that competition between PSFHC and other anti-epilepsy drugs based on the same substance was hardly possible. Therefore, the CMA found that both Pfizer and Flynn held a dominant position in relation to the production and distribution, respectively, of phenytoin sodium capsules in the United Kingdom.

Similar to the aforementioned ICA's approach, and adopting the two-step *United Brands* test, the CMA also determined the excessiveness of the prices by reference to a 'cost plus' method. More precisely, it calculated the reasonable return rate on the basis of the ROS allowed under the PPRS (which was 6%), and then cross-checked that value with the calculation of the return on capital employed. This method led to establishing an excess over the cost plus ranging from 30 to 700% for Pfizer and from 30 to 130% for Flynn. In order to ascertain that the prices charged were also unfair, the CMA then considered various factual elements, among them the particular situation existing in the relevant markets; the lack of any R&D investment and commercial risk for the companies; the complex strategy deployed in order to avoid adverse reputational damages for Pfizer had it 'de-branded' Epanutin itself; and a cross-country comparison that showed how price increases were not introduced in other EU Member States where the drug was sold profitably.

Pfizer and Flynn separately appealed the CMA's decision before the UK Competition Appeal Tribunal (CAT), which handed down its judgment on 7 June 2018.[37] Despite upholding the market dominance as determined by the competition authority, the CAT reversed and remanded the decision with regard to the findings on price excessiveness and unfairness on the ground that the CMA did not employ a multiple-methodology approach nor the appropriate benchmark price as required by the relevant CJEU case law. In this regard, heavy reliance was placed upon the AG opinion in the *Latvian Copyright* case,[38] which, however, shared the view arguing against intervention towards excessive pricing abuses that was described in Section 2 of this paper, and was not further upheld in the final judgment of the CJEU. Quite surprisingly, no account was given to the substantiated evidence of Pfizer and Flynn's intention to exploit both the NHS and patients by means of the extreme price hikes, which seemed to support the merits of the CMA's decision and the antitrust assessment that the authority had performed.

The CMA is currently handling a further case of excessive and unfair prices in relation to the supply of hydrocortisone tablets in the United Kingdom, involving the pharmaceutical company Actavis UK that allegedly devised a de-branding scheme similar to that sanctioned

[36]More precisely, at the time the disputed conduct took place, the relevant PPRS provided the freedom to set the price of new substances, which could not be subsequently increased except in exceptional circumstances, and included a fixed profit cap at a 21% return on capital and a 6% ROS: see further CMA, *Phenytoin sodium capsules*, paras. 3.130–3.138.

[37]*Flynn Pharma Ltd and Flynn Pharma (Holdings) Ltd v Competition and Markets Authority*, *Pfizer Inc. and Pfizer Limited v. Competition and Markets Authority* [2018] CAT 11, retrieved from https://www.catribunal.org.uk/sites/default/files/2018-08/1275-1276_Flynn_Judgment_CAT_11_070618.pdf [30 December 2019]. For a comment, see Abbott (2018); Killick and Komninos (2018); Hoekstra and Sauter (2018). The decision is currently under appeal and the appeals of Flynn and CMA were heard by the Court of Appeals on 26–28 November 2019 (retrieved from http://casetracker.justice.gov.uk/getDetail.do?case_id=20181874 [30 December 2019]).

[38]Opinion of AG Wahl, *Autortiesību un komunicēšanās konsultāciju aģentūra/Latvijas Autoru apvienība v Konkurences padome*, C-177/16, EU:C:2017:286.

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in *Pfizer/Flynn*. The investigation was opened in March 2016 and statements of objections were issued in December 2016 and August 2017.[39]

### 3.3 A comparison between the two most developed approaches (so far): Aspen and Pfizer/Flynn

As mentioned above, the *Aspen* and *Pfizer/Flynn* cases shared similar factual circumstances; namely, they both concerned drugs (albeit a brand treatment and a generic, respectively) that had long been developed and had already gone off-patent, and, therefore, the substantial price increases could not find justification in the recoupment of R&D investments. In addition, the strategies put in place by the companies exploited the situation of almost a lack of competition in the respective markets, though for different reasons. The relevant market in the *Aspen* case was very narrow and did not attract potential competitors due to the prospect of limited profits; while in the *Pfizer/Flynn* case, the de-branded medicine had a narrow therapeutic index, which resulted in a very limited substitutability with other anti-epileptics. These situations led to a significant price-inelasticity in the demand for Cosmos drugs and PSFHC alike, with the consequence that the NHS had to accept the excessive prices charged by Aspen and Flynn.

The antitrust assessments performed by the ICA and the CMA are also comparable in their common reference to the two-pronged test proposed by the CJEU in *United Brands*, but with occasional points of divergence that should be mentioned.[40] Overall, both decisions preferred a comparative method based on a price-cost analysis ('cost plus') to determine the excessiveness of the prices in question, but made different choices as to the additional cross-country comparison (i.e. the consideration of the price to which the product is commercialised in other countries), which was employed only by the UK authority. This benchmark was actually deemed "irrelevant" by the ICA on the ground that significant differences existed between the respective health and pharmaceutical regulatory systems of other European countries, and that Aspen had pursued a strategy on an EU-wide level, thereby negotiating high prices in other Member States as well.[41]

With specific regard to the first leg of the *United Brands* test (the determination of the excess of price based on costs), in both decisions, the notion of reasonableness had been largely referred to when identifying the relevant costs to be included in the benchmark price, as well as in establishing a rate of return that could be considered appropriate for the calculation of cost plus. For example, for the purpose of defining the benchmark price, the ICA did not take into account the expenses incurred by Aspen that represented a potential source of inefficiency (therefore, not reasonable) and did not, as such, directly impact the production and distribution of the Cosmos drugs.[42] Similarly, the CMA exercised its own judgment and prioritised "the interests of the customer, the NHS"[43] over those of suppliers in allocating a reasonable return margin on the costs actually incurred by the undertakings.[44] The CMA further recalled the allowable ROS under the PPRS scheme[45] in the determination of the reasonable rate of return. It, therefore, set a proper link with the relevant regulation that should have applied in the context of an ordinary pricing negotiation, but did not do so in the case at hand due to the regulatory loopholes exploited by the dominant pharmaceutical companies.

[39]Case update retrieved from https://www.gov.uk/cma-cases/pharmaceutical-sector-anti-competitive-practices [30 December 2019].

[40]For a comprehensive analysis, see Colangelo and Desogus (2018: 239–252).

[41]AGCM, *Aspen*, para. 330. This choice has been questioned in that it appeared to overlook the specificity of the pharmaceutical regulatory framework: Actis Perinetto (2017: 110).

[42]AGCM, *Aspen*, para. 179.

[43]CMA, *Phenytoin sodium capsules*, para. 5.92 referring to *Genzyme Limited v Office of Fair Trading* [2005] CAT 32, para. 255.

[44]The fundamental rights consideration underlying this margin of appreciation retained by the competition authority in the assessment of the prices' excessiveness has been stressed also in relation to the *Aspen* case by Mastrorilli (2018: 147).

[45]This benchmark has indeed been described in the decision as "the closest the UK comes to an agreed industry standard for returns on pharmaceutical products": CMA, *Phenytoin sodium capsules*, para. 5.97.

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Moving to the assessment of the unfairness of the prices (the second step in the *United Brands* test), both national competition authorities verified that there were no non-cost-related factors that could have increased the economic value of the drugs in question beyond the value of the respective cost plus, and, therefore, concluded that the price hikes were unjustified. Among the factual elements considered in this respect were the specific characteristics of Cosmos drugs and PSFHC (old off-patent medicines not requiring promotional activity and whose R&D investments were already recovered); the lack of actual competition in the relevant markets;[46] and the concerns expressed by the NHS in Italy and the United Kingdom in relation to the level of the prices, which confirmed the lack of a countervailing bargaining power on the buyer side.[47] In addition, it should be mentioned that the ICA clearly stated the impossibility of taking into account, in this qualitative evaluation, patient willingness to pay for the Cosmos drugs.[48] This was due to the peculiar life-saving nature of the medicines, which would have made patients potentially willing to accept any price increase.

In light of the above, it appears that the comparison between prices and costs has been heavily relied upon in both cases, not only in the assessment of the excessiveness of the prices but also in the subsequent analysis of their unfairness. Indeed, the absence of non-cost-related factors confirmed the substantial disproportion between prices and costs already ascertained through the first prong of the test, and, consequently, no resort was made to comparative methods (such as the cross-country comparison or a comparison to other competing products).

As some commentators have pointed out, this *prima facie* appraisal of price unfairness, which is mainly based on the price-cost test alone, may bear a close resemblance to the analysis required to ground a finding of restriction of competition by object under Article 101 TFEU.[49] More precisely, according to well-known CJEU case law, the 'by object' category applies to collusive behaviours between undertakings "so likely to have negative effects, in particular on the price, quantity or quality of the goods and services, that it may be considered redundant (…) to prove that they have actual effects on the market",[50] practically amounting to a presumption of illegality of the agreements. In a similar vein, an exploitative pricing practice may infringe Article 102(a) TFEU whenever the price increase appears clearly unjustified "in light of the nature of the involved goods and of the conditions of functioning and structure of the market".[51] Such striking cases as *Aspen* and *Pfizer/Flynn* seem to meet these conditions, and, therefore, the antitrust assessment carried out in those instances may be grounded on the exceptionality of their factual circumstances.

## 4. Concluding remarks

After having reviewed the state of play and some of the most recent developments in case law and practice regarding excessive pricing abuses in the pharmaceutical industry, tentative conclusions are proposed as to the appropriate extent of competition law enforcement in these instances and,

[46]AGCM, *Aspen*, paras. 347–348; CMA, *Phenytoin sodium capsules*, paras. 5.386–5.393.

[47]AGCM, *Aspen*, paras. 352–377; CMA, *Phenytoin sodium capsules*, paras. 5.400–5.409.

[48]AGCM, *Aspen*, para. 137.

[49]Colangelo and Desogus (2018: 250–251). Other commentators, however, have expressed doubts as to the 'fairness' of this approach: Meershoek (2018: 172–174).

[50]*Groupement des cartes bancaires (CB) v European Commission*, C-67/13 P, EU:C:2014:2204, para. 51. This judgment falls in a line of CJEU case law already dating back to *Société Technique Minière v Maschinenbau Ulm GmbH*, 56/65, EU:C:1966:38, and consistently maintained in subsequent decisions more recently: *Competition Authority v Beef Industry Development Society Ltd and Barry Brothers (Carrigmore) Meats Ltd.*, C-209/07, EU:C:2008:643; *GlaxoSmithKline Services Unlimited and others v Commission of the European Communities*, C-501 P, C-513 P, C-515 P and C-519/06 P, EU:C:2009:610; *Expedia Inc. v. Autorité de la concurrence and others*, C-226/11, EU:C:2012:795; *Toshiba Corporation v European Commission*, C-373/14 P, EU:C:2016:26; and, with specific regard to the pharmaceutical sector, *H. Lundbeck A/S and Lundbeck Ltd v European Commission*, T-472/13, EU:T:2016:449.

[51]Again, Colangelo and Desogus (2018: 251).

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more broadly, its role as one of the price control mechanisms in the EU market for medicinal products.

As aforementioned, the scrutiny that is progressively intensifying over price increases charged by generic undertakings begs the question of whether antitrust enforcement is the proper policy tool to stifle this anticompetitive conduct. This argument relates to the existence of an extensive regulation of the pharmaceutical market enacted both at EU and national levels and particularly to the establishment of independent sector regulators with the aim of ensuring consistency in the application of those rules. Nevertheless, the cases examined in the previous sections have shown how situations of very low (or even absent) inter-brand competition, particularly in extremely narrow markets, may create the conditions for substantial price increases of niche off-patent drugs that bring about detrimental consequences for the NHS's expenditures and, ultimately, for the patients. Also, these price hikes are often favoured by certain strategies that pharmaceutical companies put in place to game the price regulation procedures, against which the competent sector regulators may not be tasked with proper countermeasures. On these grounds, and under the narrow 'screens for enforcement' that have been illustrated above, the competition law scrutiny seems not only reasonably justified, but also able to apply in a complementary manner[52] to the relevant regulatory framework.[53]

In addition to these safeguards in establishing whether the antitrust intervention may indeed be appropriate, the extent of the assessment in excessive pricing cases should also be subject to a robust standard of proof. As already noted, EU case law and practice offer only limited guidelines that are mainly confined to the *United Brands* test and the further clarification provided by the European Commission. Therefore, national competition authorities appear to be caught in a predicament between the desirability of a thorough analysis of the investigated practices and the practical difficulties in modelling proper tests and benchmarks to assess them. This could be overcome, in bolder cases, through a *prima facie* review of the price's unfairness carried out primarily on the basis of a price-cost test. In other instances, however, the outcomes of such a comparison should be cross-checked and combined with other methodologies. In particular, it has been underlined that the notion of fairness proves to be intrinsically "elusive", as it cannot be entirely explained "purely on competition-related grounds" and may, therefore, lean towards considerations that are necessarily evolutionary in their application.[54] The inherent 'dilemma' between these positions clearly emerges in the *Pfizer/Flynn* case, where the CMA and the CAT actually took opposite views as to the necessary application of more methodologies to establish excessiveness and unfairness of the prices, even under factual circumstances that appeared particularly extreme.

With a view to addressing the increasing frequency of excessive pricing cases brought both at national and EU levels, a further kind of action may be considered. OECD guidance has indeed suggested that other "avenues for intervention", possibly "in cooperation with the applicable sector regulator"[55] – such as market studies or advocacy – should be explored, thus restricting competition law enforcement only to exceptional circumstances. A possible example in this regard may again come from the Italian experience, as the ICA and AIFA have agreed on a memorandum of understanding with the precise aim to setting up formal methods of cooperation on matters of common interest, among which price negotiation is specifically listed.[56]

[52]This 'complementarity' between competition law and sector regulation has been expressly recalled in the judgment of the Italian administrative court of first instance upholding the ICA's *Aspen* decision: see T.A.R. Lazio (2017, para. 8.2).

[53]Conversely, it was also argued that a preferable approach to address the regulatory failures should reside in a direct intervention 'to fix those very frameworks', therefore 'improving the regulatory policy rather than competition law enforcement': Calcagno *et al.* (2019: 171).

[54]Osti (2019: 191–193).

[55]OECD (2018: para. 117).

[56]*Protocollo d'intesa tra l'Autorità Garante per la Concorrenza e il Mercato e l'Agenzia Italiana del Farmaco*, signed on 19 January 2017 and entered into force on the same date. Retrieved from http://www.agcm.it/dotcmsDOC/allegati-news/Protocollo_AGCM-AIFA.pdf [30 December 2019].

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From a broader perspective, this intervention of EU competition law might serve a further 'enabling' purpose in the context of EU health policy, in the sense of creating possible spillover effects between the market pathway and the pharmaceutical regulatory framework. Antitrust enforcement against excessive price practices may indeed provide certain parameters of reference for sector regulators and courts in order to bridge the existing differences between national pricing and reimbursement procedures. This would not, however, affect Member States' competence over these policies given the close correlation with national interests and specificities. As a result, even in the likely absence, at least in the near future, of new EU-wide legislation governing pharmaceutical pricing, other 'quasi-regulatory solutions' may be found for addressing the widespread concern over cases of high prices of drugs while trying to strike a balance between the respective scopes of intervention of regulation and competition.[57]

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[57]For example, a further driver pursuing a similar regulatory function in the market pathway may consist in the promotion, at the EU level, of HTA as a basis for value-based decisions on pricing and reimbursement. See, in this regard, the legislative initiative recently proposed by the European Commission (COM(2018) 51 final) with the specific aim of 'create synergies' between the (still separated but interconnected) regulatory process and the HTA process (the importance of which was already recognised in the HTA Network reflection paper on 'Synergies between regulatory and HTA issues on pharmaceuticals', adopted on 10 November 2016. Retrieved from https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/ev_20161110_co06_en.pdf [30 December 2019]).

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