



Discussion Points

Presented by Business at OECD Competition Committee to the
OECD Competition Committee

Excessive Pricing in Pharmaceuticals

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I. Introduction and Summary

1. *Business at OECD* welcomes the opportunity to provide its views on pricing in the pharmaceutical sector, in particular on the question whether competition enforcement intervention against perceived high prices in the pharmaceutical sector may be appropriate, and, if so, in which circumstances such intervention may be justified and which principles and methodologies should govern competition enforcement agencies' analyses into pricing conduct.
2. *Business at OECD* fully supports a dialogue on coherent public policies on healthcare spending. Yet despite concerns associated with increased healthcare spending the fact is that the percentage of healthcare budgets spent on drugs (on average 19.6% in 2015) in OECD countries is remarkably stable and has not gone up.¹ In the 34 OECD countries, overall health spending per capita increased by only 1.4% each year in real terms between 2009 and 2015, compared to an annual growth rate of 3.6% between 2003 and 2009. Similarly, pharmaceutical expenditure per capita fell by 0.5% each year in real terms between 2009 and 2015, whilst it increased by 2.3% during the period 2003-2009.²
3. *Business at OECD* acknowledges the concerns raised in relation to high prices for some pharmaceutical products. It is important however to clearly distinguish between perceived high prices for innovative products and the recent — and relatively limited — enforcement activities by competition agencies, particularly in Europe, in relation to high prices for products that have long been off patent and where the size of the market opportunity is

¹ *In the Balance: The Price of Pills*, BBC (Sept. 22, 2018), available at www.bbc.co.uk/sounds/play/w3cswk0k (Interview with Thomas Cueni, Director General of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)).

² OECD, HEALTH AT A GLANCE 2017: OECD INDICATORS 133, 141 (Nov. 2017), available at www.oecd-ilibrary.org/deliver/health_glance-2017-en.pdf?itemId=/content/book/health_glance-2017-en&mimeType=application/pdf.

assertedly too small to attract generic market entry and multiple suppliers to ensure a competitive marketplace.

4. Suggestions that excessive pricing for pharmaceutical products is “breaking down the system” and that, as a consequence, a comprehensive re-calibration of competition law enforcement in the area of pharmaceutical pricing is required, are misguided. The pricing of highly innovative products, while sometimes high, must be carefully balanced to ensure that they are delivering value to society at the relative price point. New medicines are valued first and foremost for their contribution to curing life threatening diseases, but also for treating the symptoms to restore quality of life and productivity for patient. The value delivered by medicines should also be assessed in the context of overall healthcare spending, where one therapy option may curtail the need for costlier and more invasive procedures, sometimes with significant side effects that bring additional costs and health consequences. Furthermore, the cost of medicines must be considered as part of the dynamic competitive process that incentivizes innovation. As further discussed in this submission, *Business at OECD* believes that competition law intervention in instances of alleged “excessive” pharmaceutical prices should be avoided and, in any case, reserved, if applied at all, to truly exceptional circumstances where, consistent with the enforcement trend to date, there has been exclusionary anti-competitive behavior above and beyond mere alleged excessive pricing.
5. Competition agencies appropriately do not wish to take on the role of price regulators. There is no consensus on the appropriate framework of analysis with regard to excessive prices. Thus, there is a very significant risk of Type I over-enforcement errors (i.e. false findings of antitrust violations) that threaten static welfare losses and undermine investment incentives, potentially chilling innovation both by the dominant firm and potential market entrants.
6. These risks and undesirable effects are compounded by at least two key features that set the pharmaceutical industry apart from other sectors. First, the research-based pharmaceutical industry is one of the leading global high technology industries, and invests more in research and development (R&D) than any other industry.³ It is a strategically vital sector in terms of public health, economic growth and employment. In Europe alone, the industry employs about 750,000 people, of which 115,000 are employed in R&D. Direct employment in the US is over 800,000 with an estimated 4,7 million jobs indirectly related to the sector.⁴ The cost of developing and launching new pharmaceutical products are extraordinarily high and are

³ *The 2017 EU Industrial R&D Investment Scoreboard*, EUR. COMM’N, available at <http://iri.jrc.ec.europa.eu/scoreboard17.html>. The scoreboard comprises the 2500 companies investing the largest sums in R&D in the world in 2016/17. These companies, based in 43 countries, each invested over €24 million in R&D for a total of €741.6bn which is approximately 90% of the world’s business-funded R&D. They include 567 EU companies accounting for 26% of the total, 822 US companies for 39%, 365 Japanese companies for 14%, 376 Chinese for 8% and 370 from the rest-of-the-world (RoW) for 13%. In 2016, the EU health industries spent about 14% of sales on R&D. An earlier 2006 Congressional Budget Report similarly found that the U.S. biopharmaceutical industry leads the nation in terms of R&D spend. U.S. CONG. BUDGET OFF., A CBO STUDY: RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY, (Oct. 2006), available at www.cbo.gov/sites/default/files/109th-congress-2005-2006/reports/10-02-drug-r-d.pdf.

⁴ TECONOMY PARTNERS & PHRMA, THE ECONOMIC IMPACT OF THE U.S. BIOPHARMACEUTICAL INDUSTRY (July 2017).

estimated to have increased almost fifteen-fold between 1970 (USD 179mm) and 2013 (USD 2.558bn).⁵ In light of the R&D-intensive nature of the industry, it is widely recognized that strong intellectual property protection is the cornerstone of pharmaceutical innovation.⁶ Intellectual property rewards innovation with time-limited market exclusivity in order to enable a return on the investment in costly R&D, comprised of failed and successful attempts at introducing novel technologies for the benefit of society. Competition law enforcement against “excessive” prices in relation to a patented product would be nothing short of misguided and would overlook the interplay of the regulatory frameworks and market forces that apply to innovative products. Conflating perceived high prices with so-called “excessive” prices makes industries with high R&D expenditures particularly prone to risks of over enforcement.

7. Second, competition and companies’ pricing conduct in the pharmaceutical sector must be assessed against the backdrop of a dense and comprehensive regulatory framework operating on both the supply side (to manage prices or volumes) and demand side (based on physicians prescribing budgets or patients’ co-payment incentives).⁷ Since 2009, many countries are seeing the virtues of taking a more holistic approach to pricing and have introduced measures such as health technology assessments designed to reflect the value delivered by a medicine rather than apply a crude “cost plus” based approach to pricing medicines.⁸
8. *Business at OECD* submits that any sector-specific regulation should be left to sectoral experts, rather than competition agencies. In particular, (i) special regulators enforcing the regulation may generally have a deeper insight in the sector at hand and may be able to address special types of market failures (giving rise to “excessive” pricing), perhaps even before they arise and (ii) *ex ante* regulation may be more conducive to legal certainty and a stable, predictable investment climate. Accordingly, *Business at OECD* submits that in some

⁵ Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20-33 (2016).

⁶ OECD COMPETITION, PATENTS AND INNOVATION II 155 (2009) (“for certain sectors like the pharmaceutical sector, patents are recognised as being very important for the appropriation of the revenues from innovation”). The European Commission’s pharmaceutical sector inquiry final report of 2009 notes that the window of exclusivity increased by 3.5 years from an average of 10.5 years to 14 years in 2007. EUR. COMM’N, PHARMACEUTICAL SECTOR INQUIRY FINAL REPORT 59 (July 8, 2009), *available at* http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf. Even if this period of exclusivity is maintained, which is open to doubt, it is still shorter than the period intended by the legislature of 15 years of effective protection.

⁷ ÖSTERREICHISCHES BUNDESINSTITUT FÜR GESUNDHEITSWESEN & EUR. COMM’N, DG COMPETITION: SURVEYING, ASSESSING AND ANALYSING THE PHARMACEUTICAL SECTOR IN THE 25 EU MEMBER STATES (July 2006), *available at* http://ec.europa.eu/competition/mergers/studies_reports/oebig.pdf; JAIME ESPÍN & JOAN ROVIRA, ANALYSIS OF DIFFERENCES AND COMMONALITIES IN PRICING AND REIMBURSEMENT SYSTEMS IN EUROPE: A STUDY FUNDED BY DG ENTERPRISE AND INDUSTRY OF THE EUROPEAN COMMISSION (June 2007), *available at* <http://ec.europa.eu/DocsRoom/documents/7605/attachments/1/translations/en/renditions/pdf>.

⁸ For instance, in Australia the Pharmaceutical Benefits Scheme seek to proactively address many of the competitive issues raised in the *OECD 2018 Background Note*.

instances regulators other than competition enforcement agencies are better positioned to implement measures that promote competition in the off-patent sector.

II. Demand-Side Measures Constraining Pharmaceutical Prices

9. In most countries around the world, there are many administrative and often overlapping measures in place to promote competition and ensure cost-effective consumption when it comes to innovative patented pharmaceutical markets.
10. Box 3 of the OECD Background Paper clearly sets out that there are many other common schemes including international reference pricing where the price is set on the basis of the prices charged in a basket of other countries for the same product. More complex methodologies seek to arrive at a measure of value-based pricing, including comparative effectiveness. For new medicines, Health Technology Assessments take account of a wide variety of medical, social, economic and ethical considerations in assessing health outcomes.⁹
11. In addition, there are additional measures listed in Table 1 of the OECD Background Paper targeted at patients, prescribers, the supply chain (wholesalers and pharmacists) as well as insurers to further control the quality and quantum of drug expenditure.¹⁰
12. Against this background, *Business at OECD* considers that there are no *prima facie* circumstances that would necessitate intervention by competition agencies in relation to the relative pricing of patented pharmaceutical products.

III. Complexities Associated with Measuring Whether a Price is “Excessive”

13. There is broad consensus in the competition legal and economic community that, in practice, it is virtually impossible to determine with any acceptable degree of certainty what constitutes a “competitive” market price, and how market prices measure up against that benchmark. Therefore, the risk of both Type I and II errors in this field are significant. *Business at OECD* is most concerned about situations where prices perceived as high are erroneously equated with being excessive while in reality they are competitive. Intervention by antitrust agencies in those instances risks artificially constraining the competitive market and the ability of firms to reinvest profits toward new innovation. In addition, undue intervention in and of itself diminishes the incentives to invest and innovate, to the detriment of consumers who are end-users and ultimate beneficiaries of those innovations.
14. Recognizing these points, US antitrust law does not provide for a cause of action against “excessive” pricing allowing for self-correction in the market when prices increase. Similarly, while EU competition authorities have considered “unfair prices” in a handful of cases, they typically have done so as part of a broader inquiry into alleged anti-competitive conduct. This

⁹ OECD, *Excessive Prices in Pharmaceutical Markets: Background Note by the Secretariat* 24 (Oct. 2, 2018), [hereinafter *OECD 2018 Background Note*] available at [https://one.oecd.org/document/DAF/COMP\(2018\)12/en/pdf](https://one.oecd.org/document/DAF/COMP(2018)12/en/pdf).

¹⁰ *Id.* at 20.

was recently confirmed by the UK Competition Appeal Tribunal (CAT) which found that excessive pricing was typically considered in combination with other conduct, usually exclusionary behavior or tying.¹¹ As a result, the concept of “unfair pricing,” especially in the pharmaceutical sector, is not well-developed and there remains a large degree of ambiguity regarding the determination of the context in which a price may be deemed “excessive” and therefore “unfair.” Moreover, the impact of such actions on innovation have scarcely been considered, let alone measured.

15. In the leading EU case, *United Brands*, the Court established that a price is unfair if it bears no reasonable relationship to the “economic value” of the product.¹² According to the *United Brands* judgment, this can be determined in two ways; (i) either the price-cost margin is excessive, or (ii) the price imposed is either unfair in itself or in relation to competing products.¹³ It requires a detailed analysis of the specific circumstances of each case. There is widespread consensus that the test is difficult to apply in practice.
16. The fact that a price generates a higher margin is not conclusive of abuse. Measuring cost plus a reasonable profit margin may be a baseline below which a price will not be considered excessive. But a price above that baseline cannot be assumed to be abusive. Moreover, identifying the relevant baseline is likely to be particularly difficult. Thus, in *Pfizer and Flynn Pharma*, the CAT condemned the CMA’s heavy reliance on the 6% rate of return provided by the UK Pharmaceutical Price Regulation Scheme (PPRS), which regulates the profits of branded products in the UK.¹⁴
17. A price-cost analysis is particularly complex and, indeed, of questionable relevance in relation to patented medicines, not least due to the question of how R&D risks involved in developing products before they reach the market are to be accounted for. The OECD 2011 Background Paper on excessive prices elaborates in detail on the difficulties of applying price-cost comparisons in practice, in part due to the fact that “*the profit maximizing pricing decisions ... involve setting prices such that the overall cost of production including all common or joint costs are covered*” and accounting for the limited period of market exclusivity for a new treatment before follow-on innovators, and ultimately, generics enter the market.¹⁵
18. These problems are compounded in sectors involving high risk R&D, epitomized by the innovative pharmaceutical sector. Few new products succeed and the winners have limited periods of intellectual property protection over which they need to recoup not only the costs of developing a successful new medicine (mindful of the numerous “failures” that will

¹¹ Flynn and Pfizer v CMA [2018] CAT 11 (Competition Appeal Tribunal), ¶ 282.

¹² Case 27/76, *United Brands Company v Comm’n*, 1978 E.C.R. 207. The CJEU recently recognized in Case C-177/16 that the excess price should also be appreciable in order to be abusive, i.e. significantly and persistently above the relevant price benchmark. Case C-177/16, *Autortiesību un komunikāciju konsultāciju aģentūra / Latvijas Autoru apvienība v Konkurences padome* ¶ 61 (Sept. 14, 2017), available at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:62016CJ0177>.

¹³ *United Brands*, ¶¶ 250-252.

¹⁴ Flynn and Pfizer v CMA [2018] CAT 11 (Competition Appeal Tribunal), ¶ 339.

¹⁵ OECD, *EXCESSIVE PRICES* 68 (2011), available at www.oecd.org/daf/competition/abuse/49604207.pdf.

inevitably have occurred along that path to success) as well as generate the revenue that can be invested in researching and developing tomorrow's treatments and cures. That is the trade-off between dynamic and static competition. Drug development in Europe has a cumulative failure rate of close to 90 percent. In the latest study from DiMasi, Grabowski, and Hansen (2016), the overall probability of clinical success (probability that a drug entering clinical testing will be eventually approved) was evaluated at 11.83%. The transition probability between the phases were the following: 59.2% between Phase I and phase II, 35.2% between phase II and phase III, 61.95% between phase III and new drug / biologic license applications.¹⁶ Even if the product is approved, relatively few medicines are a "commercial success," i.e. able to recoup the average cost of developing the new medicine.¹⁷

19. In this respect, the European Commission has recognised that "[w]hen calculating the profit margin proper consideration should be given ... to the investment risks involved in the industry concerned [I]n many industries there are substantial risks involved in developing products before they reach the market. Indeed, there may be several unsuccessful products developed for each product that is successfully brought to market. These risks should be taken into account when assessing the cost and profit margin."¹⁸
20. From an economic perspective, it is well established that the intensity of demand is relevant to the assessment because customers are generally willing to pay more for features they consider valuable. Those specific features do not necessarily imply higher production costs, but they increase the economic value of the product. As such, when this theory is applied to innovative medicines, the intrinsic economic value of a new treatment cannot be measured by any reliable cost-price formula.¹⁹
21. The launch of Gilead's Sovaldi is a good illustration of these principles in operation. At the time, Sovaldi was a breakthrough cure for hepatitis C. Its launch attracted negative press for its initial \$84,000 per patient price tag. However, no one questioned its clinical value — the UK National Institute for Clinical Excellence (NICE), for example, acknowledged that probably all Hep C patients could benefit from it, even if the response rate (and quality of evidence) varies across genotypes. Its list price of \$1,000 per pill (\$84,000 for a 12-week course, or \$168,000 for 24 weeks which is necessary for some patients) in the U.S. caught the attention of many: payers, media commentators, NGOs and other stakeholders. The price was seen as

¹⁶ DiMasi, Grabowski & Hansen., *supra* note 5, at 23 (The authors estimate that "The distribution of clinical period failures for the study were 45.9% for phase I, 43.5% for phase II, and 10.6% for phase III/regulatory review."). Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, Tufts Center for the Study of Drug Development, Briefing: Cost of Developing a New Drug, *available at* https://static1.squarespace.com/static/5a9eb0c8e2ccd1158288d8dc/t/5ac66afc6d2a732e83aae6bf/1522952963800/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18%2C_2014.pdf.

¹⁷ Ernst R. Berndt, Deanna Nass, Michael Kleinrock & Murray Aitken, *Decline In Economic Returns From New Drugs Raises Questions About Sustaining Innovations*, 34(2) HEALTH AFF. 245-252 (2015).

¹⁸ OECD, EXCESSIVE PRICES, *supra* note 15, at 318.

¹⁹ For illustrations outside of the pharmaceutical sector, *see* Case COMP/A.36568—Scandlines Sverige AB v Port of Helsingborg, Comm'n Decision, *available at* http://ec.europa.eu/competition/antitrust/cases/dec_docs/36568/36568_44_4.pdf; *Attheraces Ltd & Anor v The British Horseracing Board Ltd & Anor* Rev 2 [2007] EWCA Civ 38 (UK Ct. of Appeal).

a particular problem because potential volumes for the medicine are very high compared with other high cost medicines, e.g. orphan drugs, cancer drugs, etc., that are the traditional focal point for discussion on high prices. But in 2014, and again in 2015, the European Commission declined to investigate complaints of excessive pricing. In its view, EU Member States were using their economic bargaining power and their regulatory powers to contain the prices of Sovaldi, and market forces would do the rest. Several new antiviral products were at the time in advanced stages of development. Commissioner Vestager recognized the need for caution: “when we do take action against excessive prices, we need to make sure we’re not taking away the rewards that encourage businesses to innovate.”²⁰ Experience demonstrates that this caution was well-founded. Within a year of Sovaldi being launched on the market, several other companies began to launch rival products, driving prices for Sovaldi in the U.S. down by almost 70 percent.²¹

22. The question then arises, following the *United Brands* test, as to whether prices are intrinsically unfair or unfair in relation to “competing products.” Economists Evans and Padilla (amongst others) concur that the only unambiguous conclusion that emerges from the economic literature and the case law is that distinguishing between competitive and supra-competitive prices is daunting.
23. *Business at OECD* submits that the “intrinsically unfair” standard is unfit for purpose except in the wholly unrealistic case of pure and perfect static competition.
24. In the pharmaceutical sector, comparisons between prices charged in different Member States may be complex, if not impossible, as a result of different price and reimbursement regimes. *Business at OECD* agrees with the observation of the CAT that price increases over time are not in and of themselves sufficient for a finding that prices are excessive.²² Similarly, profitability ratios should, in *Business at OECD*’s view, not be indicative of excessive prices.²³
25. The CAT ruling in *Pfizer and Flynn Pharma* confirms that the bar for enforcement must be high, even in the off-patent sector and instructs the authorities not to make assumptions based on conditions of perfect competition. The CAT found that the UK Competition and Markets Authority (CMA) was wrong to have limited its assessment to a cost plus analysis, and to have adopted a model that would have been relevant to “circumstances of perfect or, more accurately (for the purpose of the present case), idealized competition, rather than the

²⁰ Margrethe Vestager, Protecting Consumers from Exploitation, Address Before the Chillin’ Competition Conference (Nov. 21, 2016), available at https://ec.europa.eu/commission/commissioners/2014-2019/vestager/announcements/protecting-consumers-exploitation_en.

²¹ *PhRMA Analysis of SSR Health Data*, SSR HEALTH (May 2018), available at www.ssrhealth.com/research-archive.

²² *Flynn and Pfizer v CMA* [2018] CAT 11 (Competition Appeal Tribunal), ¶¶ 354, 439. In contrast, in *Aspen Pharma*, the Italian competition agency based its finding of unfairness of the prices applied to certain cancer drugs inter alia on the unjustified price increase over time. Case A480—Price Increase of Aspen’s Drugs, available at http://en.agcm.it/mwg-internal/de5fs23hu73ds/progress?id=0_DylYqTtSohffXsnFAEne09gu-WDfkBPttYdwUG8oA,&dl, ¶¶ 329-343.

²³ *OECD 2018 Background Note*, supra note 9, at 33 n.15 (referring to the “insuperable difficulties the Commission ha[s] in establishing valid benchmarks”).

‘real world.’”²⁴ The CAT made clear that competition authorities “cannot simply choose [a] method of calculating the excess that was most favourable to establishing an infringement, to the exclusion of other methods.”²⁵

IV. Difficulties in Remediating the Issue Once a Price is Deemed “Excessive”

26. While the proper test for establishing excessive prices is unclear and the proposed methodologies give rise to a number of problems, intervention by competition agencies in the field of excessive prices gives rise to yet another complication: should it be established that a given price is abusive, what remedy should be imposed to resolve the competitive problem. Because there is no structural failure of the market, the remedy is likely to be of a behavioral nature. These remedies are therefore akin to price regulation, which is not the domain of competition authorities.
27. In the past, competition agencies have been sufficiently daring to hazard a guess at an appropriate level with diverging outcomes. In *United Brands*, the European Court found that a difference of 7% with competitors’ prices could not be regarded as automatically excessive.²⁶ In *Deutsche Post*, the European Commission found that charging 25% more than the economic value of a service was excessive, and in *Albian Water II* the CAT held that charging 47% above the costs reasonable attributable to the supply of a service was material and excessive.²⁷ However, these crude assumptions do not have, in and of themselves, any relevance to providing guidance in today’s pharmaceutical markets. For example, in *Napp*, the OFT found that Napp earned profit margins in excess of 80% in the community segment where its competitors earned less than 70%. It found that Napp’s prices were 33-67% higher than those of its competitors in 2000 and had not changed for 10 years after the expiry of its patent. Napp’s prices in the community pharmacy market were more than 10 times higher than its prices in the hospital segment, and between 4 and 7 times higher than export prices. It is not clear whether any of these differences are of themselves problematic. Critically, however, the theory of harm in *Napp* targeted an exclusionary strategy (rather than an exploitative strategy) by Napp to sell cheaply or at a loss in the hospital segment in order to foreclose market entry, enabling it to charge high prices in the retail market, a strategy going beyond “competition on the merits.”
28. More recent cases suggest that authorities and courts are — rightly in *Business at OECD’s* view — becoming more wary of determining what the appropriate pricing level should be.²⁸

²⁴ *Pfizer and Flynn*, ¶ 310.

²⁵ *Id.*, ¶ 314.

²⁶ *United Brands*, ¶ 266.

²⁷ Case COMP/C-1/36.915, *Deutsche Post AG*, 25 July 2001, ¶¶166-167; *Albian Water Limited v Water Services Regulation Authority* [2008] CAT 31 (Competition Appeal Tribunal), ¶1200.

²⁸ E.g. the CAT in *Pfizer and Flynn Pharma*.

V. Comments on Recent Investigations

29. The limited excessive pricing cases in the pharmaceutical sector are predominantly a European phenomenon.²⁹ The European Commission has not brought an excessive pricing case since 2001.
30. The OECD's Background Note observes that the excessive pricing cases discussed in the note share a number of similarities.³⁰ First, the products have (long) been off-patent, so there are no R&D and investment recoupments justifications, nor concerns with interfering with instant innovation related to that particular product. Second, the cases involve sudden and significant price increases. Third, the medicines at issue are essential to patients and purchasing organizations have little or no bargaining power. Fourth, there was no prospect of timely entry of a competitor. And fifth, regulatory intervention was perceived to be unable to provide adequate responses to the price increases.
31. *Business at OECD* does not dispute that the factors listed above have been relevant in each of the cases discussed in the Background Note. However, it submits that these factors should not be elevated to a checklist used for antitrust enforcement action. Each case requires a thorough, case-specific and rigorous analysis.
32. Further, competition authorities should refrain from intervening unless there is a sound basis in the law to do so. In such cases, the appropriate remedy is to fix the underlying anti-competitive behavior and/or regulatory loophole. Thus, for instance, following the UK CMA's findings in *Pfizer and Flynn Pharma*, the UK adopted new legislation granting the UK government the power to control generic drug pricing.³¹

VI. Conclusions and Recommendations

33. *Business at OECD* supports the application of competition rules prohibiting restrictive agreements and exclusionary unilateral conduct amounting to an abuse of market power. These rules should be rigorously enforced in relation to conduct that can be identified as causing material competitive harm. It is paramount that these rules are enforced in such a way as to ensure a level of legal certainty, particularly as regards rules dealing with unilateral conduct, that avoids chilling effects on pro-competitive conduct.
34. In particular, *Business at OECD* supports the application of the competition rules against unilateral exclusionary conduct, for example aimed at deterring entry or otherwise foreclosing rivals. These enforcement actions should however invariably be based on robust theories of harm and persuasive evidence.

²⁹ *OECD 2018 Background Note*, *supra* note 9, ¶ 39.

³⁰ *Id.*, ¶ 69.

³¹ The Health Service Medical Supplies (Costs) Act 2017, s.4 (U.K.).

35. Competition agencies should however be particularly reluctant to intervene in cases of alleged excessive prices. This is not only because there is no consensus on the necessary and sufficient conditions that must be met to confidently prosecute these types of cases, but also because these cases present formidable methodological complexities. These factors contribute to inconsistencies and legal uncertainties within and outside OECD countries.
36. As a result, there is a dangerous risk that intervention in these cases undermines the self-correcting nature of markets and distorts firms' investment and innovation incentives. Intervention aimed at exclusionary conduct preventing entry to the market may potentially be more successful in ensuring competition in the market than intervention against what may merely be the "results" of such exclusionary conduct, i.e. elevated prices.
37. *Ex-ante* price regulation (and enforcement by special sector regulators), while still objectionable, may in specific cases be preferable over ex-post antitrust intervention, especially because special regulators enforcing the regulation may generally have a deeper insight in the specific pharmaceutical markets at hand and because ex ante regulation may be more conducive to legal certainty and a stable, predictable investment climate. As a consequence, *Business at OECD* submits that there should be no room for antitrust intervention against excessive prices if there is a sectoral regulator with adequate power to address the perceived competitive problem. The OECD Background Note provides an example of a situation where changes to the sector regulation seem to have addressed a perceived excessive pricing problem.³²
38. In light of the above, *Business at OECD* respectfully submits that intervention against excessive prices may be justified, if at all, only in truly exceptional, narrowly defined cases.
39. First, at minimum, the market at hand should be characterized by exceedingly high and non-transitory barriers to entry which protects the dominant company from competition by new entrants, with no prospect of market entry.
40. Second, intervention against excessive pricing should not occur in the field of intellectual property rights. Allowing excessive pricing action would undermine the very object of those intellectual property rights and the incentive scheme created by these laws. Innovation is critical for creating competition.
41. Third, demand for the products should be highly inelastic, i.e. there should be persuasive evidence that purchasing organizations do not have meaningful buying power.
42. Only very extreme, sudden price increases without any obvious economic justification may warrant antitrust investigation, but sudden price increases should not in and of themselves be indicative of a potential competition problem.

³² OECD 2018 Background Note, *supra* note 9, ¶ 49 and n.33. Business at OECD notes however that specific laws with respect to pharmaceutical pricing may also discourage innovation and prejudice efficient firms.

43. If competition agencies decide to intervene against excessive prices in the pharmaceutical sector, they should only do so on the basis of a robust theory of harm and convincing evidence. In all instances, agencies should establish that the conditions under competition law, e.g. in Europe the *United Brands* test, are met. *Business at OECD* also supports the notion that agencies should apply a number of alternative methodologies to validate the outcome of their investigations.