

**DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS  
COMPETITION COMMITTEE****Excessive Pricing in Pharmaceuticals - Summaries of Contributions****27 November 2018**

This document reproduces summaries of contributions submitted for Item 9 of the 130th meeting of the OECD Competition Committee on 27-28 November 2018.

More documents related to this discussion can be found at  
[www.oecd.org/daf/competition/excessive-pricing-in-pharmaceuticals.htm](http://www.oecd.org/daf/competition/excessive-pricing-in-pharmaceuticals.htm)

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## *Excessive Pricing in Pharmaceuticals - Summaries of Contributions*

This document contains summaries of the various written contributions received for the discussion on Excessive Pricing in Pharmaceuticals (130<sup>th</sup> meeting of the Competition Committee meeting, 27-28 November 2018). When the authors did not submit their own summary, the OECD Competition Division Secretariat summarised the contribution. Summaries by the OECD Secretariat are indicated by an \*.

## *BEUC*

Consumer organisations have been monitoring the evolution of prices of medicines in several member states. This has allowed our member in Italy to identify price hikes in cancer drugs commercialised by the pharmaceutical company Aspen Pharma that resulted into to an investigation by the Italian competition authority. Similarly, price monitoring activities have been carried out in Belgium and Spain. The European Commission has opened a formal investigation into Aspen's pricing practices in all EEA member states with the exception of Italy. BEUC is a third-interested party in the case.

The enforcement of competition laws in the field of excessive pricing is a challenging task for competition authorities. However, it is important from a consumer perspective that authorities remain vigilant and investigate potential situations in which a pharmaceutical company in a dominant position takes advantage of its market power to negotiate a price which in absence an abusive conduct would not have been possible to obtain. This intervention is justified by twofold reasons: on one side, the European legal framework does not tolerate firms abusing their dominant position by imposing excessive prices as stipulated in Article 102 TFEU and, on the other side, such cases in the field of pharmaceuticals can involve life-saving drugs therefore jeopardising citizens' rights to affordable healthcare.

## BIAC

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

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 patients. 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 its 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.

*Business at OECD* notes that 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 that threaten static welfare losses and undermine investment incentives, potentially chilling innovation both by the dominant firm and potential market entrants. As the paper discusses in detail, these risks and undesirable effects are compounded by a number of key features that set the pharmaceutical industry apart from other sectors.

*Business at OECD* respectfully submits that intervention against excessive prices may be justified, if at all, only in truly exceptional, narrowly defined cases.

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. 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. 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.

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.

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.

## Canada

In Canada, constraining the cost of pharmaceuticals is an ongoing concern. Currently, Canada relies primarily on two avenues to constrain excessive pharmaceutical pricing: (1) federal and provincial government policies directed at controlling pharmaceutical prices; and (2) the Competition Bureau's advocacy and enforcement work aimed at encouraging price competition in pharmaceutical markets. Key government policies include the Patented Medicine Prices Review Board, which establishes price caps on patented pharmaceuticals, and the pan-Canadian Pharmaceutical Alliance, which negotiates prices with pharmaceutical manufacturers on behalf of participating federal and provincial drug plans. The *Competition Act* does not contain a prohibition against excessive pricing so the Bureau's advocacy and enforcement work focuses on protecting the competitive process rather than enforcing a particular market outcome. The Bureau's enforcement can intervene at various stages of the pharmaceutical life cycle: research and development, commercialization, production, pre-generic entry and post-generic entry. Recent examples of the Bureau's enforcement and advocacy work in the pharmaceutical industry include the investigation of Alcon for alleged product hopping, the review of the merger between Teva and Allergan and the market study of the Canadian drug sector. Because competition issues in the pharmaceutical industry are intertwined with the regulatory framework that governs the industry, regulatory solutions may be required complement competition enforcement (e.g., reducing regulatory barriers to entry for generics and ensuring that manufacturers cannot manipulate the regulatory process to deter price competition).

## *Chinese Taipei*

For the pharmaceutical industry in Chinese Taipei, drug prices under the National Health Insurance (NHI) system are not decided by pharmaceutical firms themselves or the relevant product markets. When a pharmaceutical firm's drug is listed in the NHI system, its price will be regulated by the National Health Insurance Administration.

The pharmaceutical firm needs to consider the approved price when negotiating with every medical care institutions, which may lead to drug price gap in the NHI system. The price gap represents that approved prices the government is willing to pay to medical care institutions are often higher than the prices charged by pharmaceutical firms agreed through procurement processes. This may lead to a restriction of profitability of pharmaceutical firms, disadvantageous conditions for biopharmaceutical development and negative impacts on incentives for research and development. As a result of the NHI system, there are very few cases in relation to excessive pricing in Chinese Taipei.

## Denmark

According to section 11(3)(i) of the Danish Competition Act, exploitative pricing by a dominant firm may be considered abusive. However, the Danish Competition Council (“DCC”) and the Danish Competition and Consumer Authority (“DCCA”) have only adopted decisions related to excessive pricing in a limited number of cases.

The most recent case was adopted on 31 January 2018, case no.: 14/08469, *CD Pharma’s pricing of Syntocinon*. The DCC followed the test set out by the Court of Justice in *United Brands*<sup>1</sup>. CD Pharma, a pharmaceutical distributor, was found to have abused its dominant position by charging an excessive and unfair price for the drug Syntocinon from 28 April 2014 to 27 October 2014.

CD Pharma increased its price on Syntocinon from DKK 45 (approx. EUR 6) to DKK 945 (approx. EUR 127), corresponding to a price increase of approx. 2,000 pct. The DCC conducted 7 sensitivity analyses in order to estimate CD Pharma’s profit margin. 6 out of these 7 analyses resulted in a profit margin of 80-90 pct.

CD Pharma was unable to justify the price increase with, for instance, increased costs or special considerations related to research and development. All tests conducted by the DCC confirmed that CD Pharma’s price on Syntocinon was excessive and unfair.

Besides antitrust enforcement the DCC and the DCCA is working actively to promote competition in pharmaceutical markets. For instance, the DCCA participates in different kinds of inter-ministerial working groups. The DCC and the DCCA has no authority to change anticompetitive regulation, and this close collaboration with other ministries and regulators is therefore an important opportunity for the DCC and the DCCA to draw political attention to undesirable sector-specific regulation and to work for changes to the regulation leading to more competitive markets. Smaller publications are another advocacy tool commonly used by the DCCA. By drawing attention to different competitive issues, articles help create public debate and thereby serve as a platform for potential political action.

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<sup>1</sup> Case 27/76 *United Brands and United Brands Continental v Commission* (“United Brands”) [1978] ECR 207.

## EU

Article 102(a) of the Treaty on the Functioning of the European Union ('TFEU') prohibits imposing unfair prices. This prohibition of imposing unfair prices is generally understood to cover conduct such as charging excessive prices. It applies to any product or service, including pharmaceuticals.

The European Commission's competition enforcement practice has been focusing primarily on exclusionary practices, with the aim of restoring the competitive process in the affected market. However, the European Commission has always scrutinised markets also for exploitative conduct with a view to intervening where enforcement against unfair pricing or other exploitative practices was warranted.

From a policy perspective, an intervention against unfair prices may be warranted when market forces fail to bring prices back to normal levels within a reasonable time period.

Further, when considering whether to apply the prohibition of unfair prices in the context of innovative products, competition authorities have to factor investments, risk-taking and innovation into their assessment of unfairness and need to be mindful of the effect of an intervention on dynamic efficiency.

Also, a number of possible practical enforcement difficulties may arise. These may relate to determining when a price is excessive, what price is acceptable as a remedy and how to monitor the implementation of a remedy over time.

Pharmaceutical markets have a number of particularities resulting from the nature of pharmaceutical products, the pharmaceutical product life cycle and the role of regulation throughout the product life cycle. These particularities can result in highly inelastic demand that may make the pharmaceutical sector more prone to unfair pricing practices or concerns than other sectors.

The Court of Justice of the European Union has held that to determine whether a price is excessive and unfair, there is no single adequate method and that a competition authority has a certain margin of manoeuvre to define its framework.

Pricing practices of pharmaceutical companies that may raise concerns under Article 102(a) TFEU have in recent years increasingly attracted the attention of the European Commission and national competition authorities. In particular, practices of pharmaceutical companies imposing very high price increases for medicines after loss of exclusivity have led to the adoption of three infringement decisions in Europe since 2016 in Italy, the UK and Denmark, and the opening of further investigations.

The European Commission, competition authorities of Member States and courts in the EU are entrusted with ensuring the effective application of the unfair pricing prohibition in Article 102(a) TFEU. The Commission's antitrust enforcement will continue to promote open and competitive markets in the pharmaceutical sector and access to affordable medicines for European citizens, whilst safeguarding the incentives for innovation, research and development.

## India

The Indian Competition Act, 2002 (the “Act”) covers both exploitative as well as exclusionary abuses, which are set out in Section 4(2) of the Act. Imposition of unfair price has been explicitly stated as an abusive act under Section 4(2) (a) (ii) of the Act. Though ‘unfair price’ has not been specifically defined in the Act, CCI/Commission has laid down guiding principles through cases where such issue was under consideration. While dealing with all such cases, the Commission has ensured that the focus is not on controlling prices, but on preserving competitive conditions which would allow market forces to self-correct even if there is any irregularity. Interventions have been made sparingly in cases where markets were found incapable of self-correcting, necessitating the prescription of remedies. Even while devising remedies for rectifying unfair pricing, the Commission identified structural issues in the market, instead of pronouncing any pricing remedies<sup>2</sup>.

There are various challenges associated with intervening in excessive pricing cases, foremost being determining the benchmark price. This proliferates manifold when the case arises in pharmaceutical sector as the products/drugs/medicines are a result of years of research and development, generally preceded by series of failed attempts leading to high costs of failure. Thus, applying traditional standards (*e.g.* price-cost comparison) may wither dynamic efficiencies and disincentivise future research and development. Till date, the Commission has not found a contravention on account of excessive prices in pharmaceutical sector. One of the cases, which involves the issue of excessive pricing of medical syringes by super-specialty hospitals, is presently under investigation. The outcome of the said case is expected to disentangle many issues on excessive pricing in the pharmaceutical sector under the Indian competition regime.

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<sup>2</sup> Auto Parts case.

## *Indonesia*

Based on the Law No. 5 Year of 1999, the duties of Commission for the Supervision of Business Commission (KPPU) not only to enforce the law but also provide the policy recommendation to the government. Related to the issue of the high price of medicines in pharmaceutical sector in Indonesia, KPPU had conducted research to analyze this phenomenon. The results of the research took KPPU to provide some recommendations to be considerate by the related government, in which is The Ministry of Health.

Those recommendations consists (1) Strengthening the role of pharmacist to eliminate the significant role of doctors as “monopoly by agent” which have distorted the market (2) Eliminating the “Branded” Generic drugs (divided only to patent and generic) or Government also takes part to regulate the ceiling price of branded generic (3) Using TRIPs Flexibility (Compulsory license, Government Use and Paralel Impor) to reduce the price of patent drugs. One of KPPU’s recommendations to strengthening the role of pharmacist was accepted and realized by the Ministry of Health of the Republic of Indonesia with the stipulation and issuance of **Regulation of the Ministry of Health of the Republic of Indonesia No. 98 of 2015** on Providing Information of the Highest Retail Price for Drugs, which describes on Articles 8 and 9.

Furthermore, there was a case in pharmaceutical sector tackled by KPPU in order to enforce the Law Number 5 of 1999 (“Law 5/1999”). Based on the result of KPPU’s research, the market of the Pharmaceutical Industry of Amlodipine Therapy Class showed it had high concentration and excessive pricing. In dept investigation, it found that the business actors namely: PT. Pfizer Indonesia, PT. Dexa Medica, Pfizer Inc., Pfizer Overseas LLC (previously Pfizer Overseas Inc.), Pfizer Global Trading (co Pfizer) and Pfizer Corporation Panama allegedly violate the article Article 5 (Price Fixing) Article 11 (Cartels) Article 16 (Restrictive Agreement with a Foreign Party) and Article 25 (Abuse of Dominant Position). The data and evidences showed: (1) the price of products from PT. Pfizer Indonesia (Norvask) and PT. Dexa Medica (Tensivask) had the similar increasing price patern and parallel pricing from periode year 2004 to 2009; (2) Excessive pricing pattern for Norvask and Tensivask which each more expensive reached till 53.26 times and 45.85 time than the international reference price also each 65% and 23% more expensive than the same brand drugs for NHI. Those comparison analysis using the method of Yardstick; (3) all forms of communication (about price, total production and production plan) between PT. Dexa Medica and Pfizer Overseas LLC must be copied to PT. Pfizer Indonesia and purchasing order by PT. Dexa Medica to Pfizer Pfizer Overseas LLC must be email copied to PT Pfizer Indonesia; (4) Sharing information about the sales between Pfizer Indonesia and Dexa Medica through their distributor. Thus, they found quilty violate Law 5/1999 and ordered to pay certain fines.

## Israel

The Israel Antitrust Authority's (hereinafter: the "**IAA**") stated position concerning the question of a monopolist charging an unfair high price, has undergone recent developments.

In April 2014 the IAA issued a Public Statement regarding the Prohibition on Charging an Unfair Excessive Price by a Monopolist (hereinafter: "**Public Statement 1/14**"). Until this publication, the IAA *rarely* dealt with the subject, and its enforcement actions against monopolists were concentrated mainly on exclusionary practices aimed at forcing competitors out of the market. Public Statement 1/14 set forth that the IAA would enforce the prohibition on charging an unfair excessive price by a Monopolist. It sought to put forth parameters for determining what is an "unfair high price", while specifying various methods for calculating the "fair price" that a monopolist may charge. It also prescribed a "safe harbor" rule whereby monopolists whose prices are no more than 20% above the costs recognized in the Statement, will not be subject to enforcement of the prohibition by the IAA.

In February 2017, after examining the statement in cooperation with the public, the Director General of the IAA (hereinafter: the "**Director General**") issued Public Statement 1/17 concerning the IAA's Considerations in Enforcing the Prohibition against Unfairly High Prices (hereinafter: "**Public Statement 1/17**") – which replaces Public Statement 1/14.

The current Statement 1/17, sets forth the IAA's updated policy: The main considerations guiding the Director General in taking enforcement measures in cases where a concern arises that an unfairly high price has been charged. It also revokes the safe harbor presented in Public Statement 1/14.

This contribution will elaborate upon the principles and criteria set forth in Statement 1/17. In short, the IAA firstly examines whether there are other relevant alternative competitive remedies; *Inter alia*, if no such competitive remedy is found, the IAA will examine whether the price charged is *significantly* and *clearly* higher than the price that would have been set under competitive conditions. Secondly, the IAA examines whether the high price charged is also unfair. The question of unfairness is determined *inter alia* in consideration of the power balance between the monopolist and the consumer and weighed in light of the relevant circumstances, such as the product characteristics and the demand, the monopolist's market share and market position, the structure of the sector in which the firm operates, the level of risk entailed in the production of the goods in this sector. The existence or absence of a sectoral regulator and the actions which it may have taken in the market.

## *Italy*

The Italian Competition Authority (AGCM) has been particularly active, in recent years, in the pharmaceutical sector in light of its importance, not only economically but also in terms of access to healthcare and medicines and impact on public expenditure. Enforcement has concerned exclusionary behaviors aimed at delaying generic drugs entry, a market partitioning conduct and an exploitative practice towards the National Health System.

In relation to the latter, AGCM's intervention complemented the action of the Italian pharmaceutical regulator - that displayed, because of incomplete regulation, a weaker bargaining power towards regulated companies - leading to a reduction of the prices of the drugs considered by as much as 80%.

Indeed, according to the Authority, the specific facts of the Aspen case warranted an antitrust intervention: the market was not likely to self-correct, the regulator did not have the ability to curb the significant and unjustified price increases as well as the need to remunerate R&D did not arise.

As the drugs under examination had been developed in a distant past and were since a long time off-patent, there was no risk of distorting dynamic competition. The need to remunerate R&D expenditures was, consequently, not relevant as the risk to distort innovation.

If cases are well screened, agencies intervene only when the stringent conditions identified to justify intervention arise, ensuring that the potential of innovation is fully realized. Intervention should, indeed, be limited to cases where the risk of distorting dynamic competition is very limited, if non-existent.

The AGCM has been, in general, very cautious in identifying circumstances where intervention against alleged excessive prices might be necessary following a case-by-case approach aimed at finding an appropriate balance between static and dynamic considerations based on the specific circumstances of each intervention.

## *Kazakhstan*

The article is divided into 3 sections.

The first one describes the existing provisions of the Competition Law of the Republic of Kazakhstan against excessive prices as a result of dominance abuse and concerted actions and powers of Competition authority to prevent, reveal and eliminate violation.

Also, this part describes the penalties for the Competition Law of the Republic of Kazakhstan infringements in terms of abuse of dominance and concerted actions.

The second part describes the system of state regulation and control of pharmaceuticals sector in the Republic of Kazakhstan, as well as price regulation in pharmaceuticals market issues.

The third part considers the case of violation of the Competition Law of the Republic of Kazakhstan in pharmaceutical market and the decision of Competition authority.

## *Lithuania*

In Lithuania, the pharmaceuticals sector is subject to regulation. Even though the Lithuanian Competition Council has not investigated excessive pricing cases in this sector so far, the competition authority has been rather active in conducting market studies and making recommendations with the aim to promote competition in this sector. In particular, the focus of the market studies of the Competition Council was on the impact of parallel imports of pharmaceuticals as well as the reimbursable pharmaceuticals' market in Lithuania.

## *Netherlands*

Taking a policy perspective on possibly excessive pharmaceutical pricing inevitably involves not just looking at prices as such but addressing the tension between innovation and cost control. Evidently the unmet need for new treatments requires incentives to innovate, not least to finance such innovation. In that context we look at the balance between innovation and cost control in the context of excessive pricing policy. First we consider the relationship between IP and competition law more generally. Then we consider the role of innovation within the excessive pricing test.

It has sometimes been charged that the existence of intellectual property (IP) rights and related rights effectively excludes the application of the competition rules. In EU competition law this is not so: the two types of law are not alternatives or mutually exclusive but apply in parallel..

- There is no necessary tension between the objectives of IP law –and excessive pricing. This does presuppose that the enforcement of the prohibition on excessive pricing takes the incentives for innovation into account. Vice versa the existence of patent protection does not bar enforcement of the excessive pricing prohibition.
- IP rights do not automatically create a dominant position because the scope of the IP right does not necessarily coincide with the definition of the relevant markets at hand. Orphan drugs usually excepted, there may well be competing therapeutic substitutes. Hence a relevant market must be defined, and dominance established there by looking inter alia at the existence of effective competitors, not just at the existence of IP rights.
- Finally in the context of excessive pricing for pharmaceuticals, more emphasis may be placed on a fair distribution between producers and consumers. In the context of such a distribution, it is possible and justified to take innovation into account. A stricter cost based test should be applied to drugs that involve limited innovation than to those where a significant investment in developing new cures is involved.

Hence from a legal perspective we submit that IP and competition law are not mutually exclusive but instead apply in parallel. The existence of IP rights are however relevant in the analysis of excessiveness and require a certain degree of caution, although not the kind of general caution that would lead us to regard such cases as off-limits. Rather we propose that in such cases the effects on the incentives to innovate should be taken into account. The two most important issues from an economic perspective and for cost research in this respect are (i) accounting for the costs of R&D efforts that do not lead to market introduction or survival bias and (ii) calculating the cost of capital. In the paper we make practical suggestion to this end.

In conclusion, because apparently self-correction of pharmaceutical prices fails frequently it appears that effective competition law remedies – including enforcing the prohibition on excessive prices – are necessary. In this context we believe that balancing cost control and innovation within the application of the excessive pricing instrument does not always involve a strict contradiction. There is not so much a correlation between high levels of innovation and high costs as between high margins and a lack of outside options. Hence we think that if the relevant social value can be determined with some confidence, prices can be safely capped, including by means of competition law in individual cases, with minimal loss to innovation.

## *Russian Federation*

The state regulation of prices for medicines included in the list of vital and essential medicines has been carried out since 2010, the basic requirements and principles of which are established by the Federal Law “On Circulation of Medicines”.

One of the main requirements that has been in force since 2010 is setting prices in Russia in accordance with the minimum price level for the same drugs being set in reference countries for Russia.

Moreover, the list of countries in accordance with which information is provided by drug manufacturers has been established by the Government of the Russian Federation and has been in effect since 2010.

The FAS Russia in pursuance of the instructions of the President of the Russian Federation V. Putin conducted an international comparative analysis of prices and found a significant excess of prices for a part of drugs in Russia compared to the minimum selling prices in many countries around the world, including those that are reference for Russia.

According to the results of the set of measures undertaken by the FAS Russia to reduce the maximum selling prices of drug manufacturers registered in Russia to the minimum prices in reference countries for Russia, as of October 15, 2018, prices of 1043 previously registered expensive vital and essential medicines were reduced. The average price reduction was 43%, and the largest decline in monetary terms was 240 000 rubles (\$3 650) for one consumer package, which led to significant budget savings (according to calculations, only for the federal budget, savings were more than 5 billion rubles (\$76 080 340) per year).

In addition, as a result of the research conducted by the FAS Russia, countries were identified with persistently high or consistently low prices for medicines.

In this regard, as well as in order to reduce the time and increase the effectiveness of the work carried out by the FAS Russia concerning the reduction of prices for medicines, the Russian Ministry of Health, together with interested federal executive bodies, have developed a draft Decree of the Government of the Russian Federation “On the state registration and re-registration of maximum sale prices for medicines included in the list of vital and essential medicines "(hereinafter - the draft Decree), which establishes obligation to owners or holders of medicines registration certificates to revise registered prices of medicines in the event of their reduction in the reference countries.

## *South Africa*

This paper has been prepared to highlight South Africa's experience in the investigation of excessive pricing within the pharmaceutical sector. The discussion in the paper revolves around the following:

- the economic and legal theories to support competition intervention in the pharmaceuticals markets;
- experiences in competition cases involving excessive pricing in pharmaceuticals
- enforcement challenges that competition authorities face in pharmaceutical cases particularly those assessing excessive pricing; and
- price regulation and the extent to which there exists cooperation between sectoral regulators and competition authorities in pharmaceutical markets.

The Competition Commission of South Africa ("the CCSA") has previously intervened in the pharmaceutical market through the investigation of the case relating to the supply of Anti-RetroViral ("ARV") treatment ("Hazel Tau Case"). This case remains the landmark excessive pricing case in the pharmaceutical industry in South Africa. Through this case, the CCSA dismantled the barriers to entry into the production of ARV treatment. Since 2004, the number of people receiving ARV treatment increased from 47500 to 3 407 336 in 2016. The ultimate results of the CCSA intervention enabled patients to have access to ARV treatment at lower prices.

The paper highlights some of the recent work conducted by the CCSA in this market. The work include the ongoing investigation of against the suppliers of breast cancer in South Africa and the scoping study underway aimed at identifying pharmaceutical drugs that may be excessively priced.

The paper also discusses some of the challenges encountered in antitrust enforcement in pharmaceutical market. The paper concludes by highlighting cooperation between the CCSA and sector-specific regulators in the pharmaceutical sector.

## *Spain\**

The National Commission on Markets and Competition (CNMC) takes into account the particularities of the pharmaceutical sector, as a way to understand and investigate the affected market, independently on how it is defined. Spanish pharmaceuticals pricing systems are different depending on whether pharmaceuticals are publicly financed by the National Health System (SNS) or not. In general, pharmaceutical laboratories are free to set the price for pharmaceuticals that are not financed by the SNS. By contrast, publicly financed pharmaceuticals by the SNS are subject to strict regulation of prices.

In the last five years, although the CNMC has not received any complaint against excessive prices situations in pharmaceutical products, it has pursued several antitrust investigations in the pharmaceutical market regarding exclusionary conduct; focused on medicines and medical devices. It has also started an investigation into excessive prices, but this case was transferred to the European Commission.

Given the complexity of the sector and the broad variety of cases, the CNMC does not have an automatic or specific protocol or screening method to consider whether a price is excessive in the pharmaceutical sector. The assessment is done case by case, taking into account the enormous variety of criteria that should be applied.

In cases of price abuse, the National Commission on Markets and Competition (CNMC) shall act as consultative body on matters related to competition. In particular, the CNMC may be consulted by the Legislative Chambers, the Government, Ministerial Departments, Autonomous Communities, Local Corporations, Professional Bodies, Chambers of Commerce and the business or consumer organisations. The CNMC can also set additional ways of communication with other public authorities, either through formal or informal contacts in the context of its collaboration and information duties.

## *Ukraine*

The basic principles of the Antimonopoly Committee of Ukraine (hereinafter AMCU) according to the law are legitimacy, publicity and the protection of rights of economic entities on the basis of both the equality of economic entities in terms of law and the priority of consumer rights. Therefore consumers' welfare is in the focus of the AMCU and historically most of cases were started based on consumers' applications. From time to time such cases are brought as a result of market study or initiated *ex officio*.

Ukrainian legislation on protection of economic competition contains provisions that address excessive price abuses as an element of unilateral conduct and anticompetitive concerted actions.

In some cases the AMCU tackles concerted practices on regulated markets which are aimed at avoiding specific price regulation thereby leading to an anticompetitive effect and detriment to consumers.

The question whether the price is fair or unfair in practice appears rather challenging. In order to determine the exploitative pricing, the AMCU uses the following methods:

- a price comparison with the similar product or geographic market with competitive conditions;
- an analysis of price dynamics within the past time period, especially if the company did not have dominant position in previous periods;
- if the similar market or price data are not available, a price-cost comparison or profitability analysis is used;
- a simulation of *but-for* prices and further comparison with actual prices.

Earlier cases involving allegations of excessive pricing for domestic customers employed comparison of prices set by the dominant company on the internal market with its export prices.

The AMCU underlines that competition authority is not a price regulator as itself. An investigation of high prices and further intervention of the AMCU is appropriate in the markets with limited competition, structural signs of monopolization or signs of collusive behaviour. Regarding regulated markets and natural monopolies, the role of AMCU is to ensure that the regulatory acts do not distort competition (in a way of competition assessment of draft laws and secondary legislations) rather than control if the price is fair or not.

### ***Pharmaceuticals***

Pharmaceutical markets are in permanent focus of the AMCU due to its social importance, specific market structure and sophisticated regulation as well as ongoing medical reform. In 2016-2018 the AMCU presented results of two comprehensive market studies, issued a number of recommendations to regulators, proposals to the government, passed decisions in four cases on anticompetitive conduct of pharmaceutical manufacturers and distributors, one case on abuse of dominance by a pharmaceutical manufacturer and a number of cases on unfair competition. The primary role in addressing high prices in pharmaceutical products belongs to the regulator, though.

AMCU actively advocates generic medicines' entry and consumption. One of the recent cases was related to softening the competition between original and generic drugs.

The enforcement in pharmaceutical markets is illustrated by unilateral conduct (refusal to supply, excessive pricing. However, there were no predatory pricing cases in this sphere) and anticompetitive concerted actions (market sharing agreement as well as concerted actions which led to excessive pricing in public procurement procedures).

Thus, the competition advocacy and enforcement on the pharmaceutical market is one of the AMCU's top priorities.

## *United Kingdom*

The Background Note by the Secretariat already sets out a number of reasons in favour and against intervention<sup>3</sup> and, therefore, these will not be repeated here.

In the United Kingdom, there is a clear legal basis to intervene against excessive prices. Chapter II of the Competition Act 1998 (mirroring Article 102 of the Treaty on the Functioning of the European Union ('TFEU')) specifically prohibits the imposition of unfair purchase or selling prices or other unfair trading conditions as an abuse of a dominant position.

The CMA also considers that in certain circumstances it is important as a matter of policy to intervene directly against excessive prices.<sup>4</sup> Ensuring consumers are not exploited by unfairly high prices is at the heart of antitrust enforcement and much enforcement activity is focused on preventing companies being able to achieve the level of sustained market power that is necessary to impose excessive prices.

Although many of the industries that are most likely to give rise to the risk of excessive pricing (particularly the traditional utility sectors) are subject to *ex ante* regulation, this coverage is not complete. For example, as set out below, there is no *ex ante* regulation in respect of generic medicines in the United Kingdom ('UK') with the prices paid by the National Health Service ('NHS') determined by competition. However, as is set out in the following section, certain generic drug markets are characterised by high barriers to entry and expansion and inelastic demand – thereby creating the conditions where prices could potentially be increased to abusively high levels.

Where such gaps in the regulatory system exist there are strong public policy reasons for the CMA to intervene using its enforcement powers.

It is often suggested that the introduction of new specific regulatory regimes would be a preferable means of dealing with excessive prices instead of antitrust enforcement. However, this approach would often require legislative change and therefore would take time to implement. Further, this approach would only partially address the harm caused because it would be forward looking and would not address historic harm. For example, it is unlikely to mean that private actions could be taken by exploited customers to recover excesses they have may have paid as would be possible following an antitrust intervention. Also, competition law enforcement is often the trigger that leads to regulatory intervention,<sup>5</sup> such that the two approaches do not have to be mutually exclusive.

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<sup>3</sup> OECD (2018), Excessive Prices in Pharmaceutical Markets DAF/COMP(2018)12, Background Note by the Secretariat, Section 2.2.

<sup>4</sup> This is consistent with academic research on the preparatory works associated with the initial drafting of Article 102 of the TFEU (then Article 86) which reveal that this provision was originally intended to apply only to 'exploitative' abuses and not 'exclusionary' abuses (Pinar Akman, "Searching for the Long-Lost Soul of Article 82EC", Vol. 29, No. 2 (2009) Oxford Journal of Legal Studies, page 271).

<sup>5</sup> This is for instance what happened in the UK where the Government, following the CMA's investigations, introduced new legislation – Health Service Medical Supplies (Costs) Act 2017 – to extend the powers of the Department of Health in relation to the pricing of generic drugs.

We are obviously alert to concerns that competition authorities may become quasi price regulators when intervening against excessive prices. We consider any intervention very carefully and would generally only intervene where there is an absence of effective regulation and where the price in question is unlikely to be competed down in a reasonable timeframe.

Finally, the difficulty and complexity of the analysis and the risks of false positives can also be overstated, as this is not exclusive to excessive pricing. There are several areas of competition law that are complex and difficult but where competition law intervention is less controversial.

## *United States*

U.S. antitrust law does not recognize excessive pricing as an antitrust violation in and of itself,

thus allowing legitimate market participants acting independently to set their prices as high as they choose. This policy choice stems from the legislature's determination that ultimately competition will produce not only lower prices, but also better goods and services. Additionally, the policy reflects the difficulty in identifying what prices are excessive and concerns that antitrust enforcement against excessive pricing may chill incentives to compete and innovate in the first place and interfere with the proper functioning of markets.

Market participants who violate the antitrust laws, however, may be subject to remedies that affect their ability to charge supra-competitive prices. In addition, high or rapidly increasing prices often play an important role in the Agencies' antitrust investigations because they may constitute evidence of anticompetitive effects of potential antitrust violations.

There are many tools available to U.S. antitrust agencies today to address high drug prices, including law enforcement; competition advocacy before the legislature and the courts; reports, studies, hearings, and workshops; and working with other governmental entities and sector regulators to promote consumer access to affordable medicines.