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English - Or. English

14 May 2019

**DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS  
COMPETITION COMMITTEE**

**Executive Summary of the Roundtable on Excessive Prices in Pharmaceutical Markets**

**Annex to the Summary Record of the 130th Meeting of the Competition Committee held on 27-28 November 2018**

**28 November 2018**

This Executive Summary by the OECD Secretariat contains the key findings from the discussion held during the 130th Meeting of the Competition Committee on 28 November 2018. More documents related to this discussion can be found at <http://www.oecd.org/daf/competition/excessive-pricing-in-pharmaceuticals.htm>

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**JT03447435**

## Executive Summary

By the Secretariat\*

Considering the discussion at the roundtable held by the Competition Committee on 28 November 2018, the delegates' submissions, the panellists' presentations and the Secretariat's background paper, several points are noted:

**1. There are strong arguments for not intervening against exploitative excessive pricing conducts, which have led to the development of stringent enforcement screens for the bringing of such cases.**

Excessive pricing in the absence of exclusionary conduct or collusion is usually perceived either as a temporary and self-correcting market failure, or as a problem to be addressed through sector-specific regulation. Excessive pricing is an area of limited competition enforcement around the world, with some countries not even prohibiting such practices. Where prohibited, excessive pricing remained for a long time underdeveloped conceptually and underused in practice. Nonetheless, legal provisions prohibiting excessive prices have been the subject of continuous enforcement over the years.

Enforcement against excessive pricing presents *high risks* of type I error, i.e. mistaken intervention, with potentially *high costs* because the market may self-correct in the absence of intervention, and mistaken intervention will lead to dynamic inefficiency related to low investments and innovation. On the other hand, type II errors (i.e. mistaken failure to intervene) have a relatively *low cost*, mainly related to allocative inefficiency. This points towards a presumption against competition enforcement against excessive pricing.

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

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\* This Executive Summary does not necessarily represent the consensus view of the Competition Committee. It does, however, encapsulate key points from the discussion at the session, the delegates' written submissions, the panellists' presentations and the Secretariat's issues paper.

**2. The application of competition law against high prices in the pharmaceutical sector requires a deep understanding of market dynamics and sectoral regulation, and of the various regulatory responses that may be deployed to address high prices.**

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

From a demand perspective, many consumers do not select or pay for a number of medicines, whose cost is often supported by third parties (the State or private insurance companies). Furthermore, pharmaceuticals can be indispensable to patients – even critical to preserving life – which leads to inelastic demand for treatment, in particular and for specific medicines for which there are no viable alternatives. At the same time, prescribing doctors select, but do not consume or pay for medicines. Lastly, insurance companies and national health services are liable for the payment of a large number of medicines, but have limited tools to control their consumption and selection. From a supply perspective, safety and efficacy concerns, and the IP protection of numerous medicines, mean that the pharmaceutical industry is highly regulated.

These elements make it even more difficult than usual to identify the reference ‘competitive price’ against which the excessive price should be assessed, and are an element of added complexity in these cases.

**3. Recent years have seen significant calls for intervention against high prices for pharmaceutical products, and there have been a number of competition enforcement cases regarding exploitative excessive pricing in this sector. These cases meet the criteria set out in enforcement screens regarding excessive pricing.**

A recent spate of excessive pricing cases have been brought in the pharmaceutical sector recently. Within the OECD, those cases have thus far been brought in Europe and share a number of similarities.

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

In other words, these cases reflect the stringent screens for bringing excessive pricing cases reviewed, which reflects the competition authorities efforts to ensure that competition intervention against excessive prices was necessary and limited to those situations where this is the least-bad available alternative.

**4. Proposals regarding excessive price enforcement against IP-protected pharmaceutical products recognised that bringing such cases raises challenges related**

**to the complexity of the market and its regulation, which add to the inherent difficulty of determining whether a price is excessive.**

Arguments opposing competition law enforcement against excessive prices apply with even more force whenever the relevant product has market power as a result of an IP right. Monopoly prices are a reward for risky investment. Special caution is warranted in sanctioning excessive pricing with respect to products covered by IP rights because the misapplication of competition law might undercut incentives to innovation. As such, there is broad agreement that should be no intervention against excessive prices for innovative products within a pharmaceutical product's patent life and, in effect, no such case has ever been brought within the OECD to this moment.

Despite this, it has recently been argued that it is mistaken to absolutely exclude the possibility of bringing excessive pricing cases as regards IP protected pharmaceutical products. To minimise the impact of excessive pricing cases against IP protected products on innovation and investments, it was argued that agencies should take incentives to innovate into account in any competition enforcement action. As regards excessive pricing, this can be achieved by considering the probability of a medicine's success during the research stage, or by comparing research costs or other relevant benchmarks for similar products.

These approaches borrow from regulatory approaches for the determination of prices of pharmaceutical products, which are intensive, often controversial and pose significant burdens on specialised bodies. Furthermore, IP-branded products are subject to sectoral price regulation in a way that generics are not. As such, there were doubts about whether competition agencies should pursue such cases, and what would be the implications of such approaches to the relative roles of competition agencies and sector regulators. To this moment, these proposals are yet to be tested in practice.

**5. It may be appropriate to explore various avenues for intervention, if possible in cooperation with the applicable sector regulator.**

Excessive pricing cases are unavoidably fact-specific, operate ex-post, are subject to high error risks and costs, and rarely set out bright-line guidance on how to set accurate prices. It is widely thought that excessive pricing cases should only be brought in extraordinary circumstances. However, there are indications that the conditions that gave rise to the pricing practices sanctioned in pharmaceutical markets over recent years may be systemic, and hence that alternative forms of intervention may be appropriate. Furthermore, a number of jurisdictions are unable to pursue exploitative high pricing practices, because their competition laws do not prohibit such conduct.

This raises the question of what actions competition authorities may adopt to address high prices in pharmaceutical markets, in alternative or in addition to bringing excessive pricing cases. Competition authorities have a variety of tools at their disposal in this respect. First, competition agencies combat high prices by engaging in enforcement against anticompetitive practices such as collusive and exclusionary conduct. Another way through which competition authorities can deal with concerns regarding high prices in pharmaceutical markets is by studying those markets in order to determine the source of market failures, and either advocate or adopt remedies (if they have the power to do so) to address such failures. A better understanding of the market can also underpin subsequent competition enforcement, including, potentially, excessive pricing cases. Where the market study finds that the absence of competition cannot be addressed other than by regulation, the competition authority may choose to either defer to established regulators or publicly

call for the establishment of such a regulator. Ultimately, high prices in pharmaceuticals may raise broader social and political questions, which may be better addressed by regulators and political processes.