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**DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS
COMPETITION COMMITTEE****Summary of discussion of the Roundtable on Excessive Pricing in Pharmaceuticals****Annex to the Summary Record of the 130th Meeting of the Competition Committee held on
27-28 November 2018****28 November 2018**

This document prepared by the OECD Secretariat is a detailed summary of the discussion held during the 130th meeting of the Competition Committee on 27 November 2018.

More documentation related to this discussion can be found at
www.oecd.org/daf/competition/excessive-pricing-in-pharmaceuticals.htm

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Summary of the Roundtable on Excessive Pricing in Pharmaceuticals

1. Introduction

1. The **chair** began by mentioning that the increasing cost of providing healthcare is an important political concern. A related issue is the increasing price of pharmaceutical products. There are many ways in which to address this, including competition law, including, in some cases, excessive pricing cases. One of the main reasons for not using excessive pricing cases is the fear that, by tinkering with the price of pharmaceuticals, one could deter innovation. Excessive pricing provisions in most countries have been used for non-patented pharmaceutical products, in particular products that had a patent which expired. Nonetheless, there have been recent proposals to extend the scope of the use of excessive pricing provision to IP protected pharmaceutical products.

2. The chair then gave the word to **Pedro Caro de Sousa** from the **OECD Secretariat**, who described the background paper and the main questions that arise as regards this topic. He pointed out that this roundtable takes place at the intersection of two different areas of work that the OECD looked at in the past: pharmaceutical markets and exploitative excessive prices. He noted that earlier discussions on excessive prices focused on the difficulties of bringing such cases, and on the developments of screens to ensure that excessive pricing cases are only brought in truly exceptional circumstances where no other viable alternative exists. He then identified a number of questions that recent excessive pricing cases in the pharmaceutical sector give rise to, such as whether they meet these screens and whether the applicable legal and economic tests need to be adapted. A point of particular emphasis was that there has been a significant increase in the occurrence of price spiking in generic pharmaceuticals, and this raises the question of whether bringing individual excessive pricing cases is an appropriate response to a potentially systemic challenge.

2. What are the alternatives to bringing excessive pricing cases?

3. Following the Secretariat's presentation, the **Chair** then moved the discussion to how to address high prices in pharmaceuticals if a country does not decide to bring excessive pricing cases. To set the scene, he asked **Martin Wenzl**, from OECD ELS, to make a presentation on the pricing of pharmaceuticals, and on the relevance of market characteristics and market regulation to this pricing. Mr Wenzl began by identifying some widely accepted objectives of health policy: (i) to improve population health; (ii) to provide equitable access to health; (iii) to ensure the quality of health services and products; (iv) to provide value for money. These policy goals require a balance between paying enough to provide manufacturers of innovative medicines incentive to further invest in R&D and ensure that these products continue coming to market, while simultaneously maximising the value of current spending.

4. Mr Wenzl pointed out that a number of price regulation methods have been developed to achieve this, before touching on some recent pharmaceutical pricing trends. While pharmaceutical prices have not been increasing significantly, prices increases seem

nonetheless to exceed increases in product effectiveness. Health expenses with pharmaceuticals seem to have remained steady over the past few years, similarly to the level of profits from pharmaceutical research. Generics play an important role in lowering pharmaceutical prices and health expenses, but their market penetration vary significantly across countries. Ultimately, Mr Wenzl noted that there are large variations in the extent and impact of generic entry depending on the type of generic product and the applicable market.

5. Lastly, Mr. Wenzl described how generics markets seem to be facing increased concentration. Competition is usually more intense in large markets, but even in these markets concentration seems to be increasing: in the US, for instance, up to 40% of generics are only supplied by a single supplier, and there is an increasing number of anecdotes concerning price increases by manufacturers with market power.

6. The **chair** then passed the baton to **Professor Margaret Kyle**, a professor in Paris at the CERNA Centre Industriel des MINES, Paris Tech, where she holds a chair in market for technology and intellectual property. Professor Kyle started by noting that excessive pricing enforcement is widely perceived by economists as being a last resource mechanism, if at all appropriate. Some economist suggest that competition enforcement against excessive pricing may be justified when there are high and non-transitory barriers to entry, market power and no available sectoral regulator.

7. As regards whether these conditions are met in the pharmaceutical context, Professor Kyle distinguished between innovative and generic segments. In the innovative sector, there are significant barriers to entry created by IP rights. However, such barriers are temporary, and whatever market power may arise from IP rights will normally be the result of legitimate innovation. Furthermore, there is extensive market regulation in the innovative segment of pharmaceutical markets, which would seem to argue against bringing excessive pricing cases. Additionally, there are significant challenges regarding how to determine the value of a pharmaceutical product. These challenges are reflected in the onerous and extremely detailed methodologies adopted to price innovative products by health authorities. Professor Kyle concluded that it is not clear that a competition agency would be well suited for pursuing this type of value evaluation. If regulation / IP systems are not doing their work, we may want to look at them, but it would be suboptimal to try to address these systems' failings by bringing competition enforcement actions.

8. On the generic segment, Professor Kyle t explained that there might be non-IP barriers to generic entry, something which seems to be reflected in the data on generic entry, which is lower than anticipated. There are also usually no innovation arguments against intervention, and regulation is a lot less stringent. While this means that there is a stronger case for bringing excessive pricing cases in this sector, Prof Kyle argued that priority should be given to addressing the causes of high-prices, such as closing regulatory loopholes.

9. Lastly, Professor Kyle pointed out that there are risks with comparing international prices to determine excessive pricing. Such an approach may preclude differential pricing, which often reflects differences in demand, and could penalise poorer countries. On the other hand, assessing whether a price is excessive by engaging in before-and-after price comparisons may ultimately preclude price increases in the future, leading to higher prices from the moment a product is launched in the market, including for innovative pharmaceuticals.

10. The **Chair** thanked the speakers, and then asked a question about how to address very concentrated pharmaceutical markets, where generic entry is rare or generic exit is occurring. **Professor Margaret Kyle** agreed that absence of generic entry is an issue and that competition agencies should tackle. She expressed concern about the fact that we do not see more significant generic entry, and suggested that competition authorities should be thinking about what kind of merger activity has taken place among generics, and also about more traditional competition enforcement. However, she did not think excessive pricing cases are necessarily the most direct way to tackle that problem. Adequate price regulation could play a valuable role here, in ensuring that one rewards products that actually bring a lot of value to market and protecting the incentives for innovation.

11. The Chair called on the **United States**, which described how its law focuses on how a monopolist attains or maintains monopoly power in order to preserve incentives to innovate and ensure that market signals function properly. US antitrust law does not apply to so-called exploitative practices, including charging “too high a price”. This approach extends to pharmaceutical products.

12. The US emphasised the limitations of competition agencies in addressing and remedying high prices directly. Competition agencies lack competence to determine whether a price is “too high” or what a fair price might be. Related to that, the US pointed out that some humility was required with respect to the difficulty of crafting an appropriate remedy to address certain price levels, including if those prices are too high.

13. The US also described a number of causes for high prices for pharmaceuticals that are unrelated to competition law. A number of such causes are dealt with by the FDA, with which the competition agencies cooperate. These causes include manufacturing disruptions, raw material shortages and the like, quality control issues, product recall and non-collusive oligopoly pricing. Finally, the US identified and described a number of typical collusive and exclusionary practices that might lead to high prices which are the subject of antitrust enforcement. In those cases, US antitrust agencies do not hesitate to enforce antitrust law against such practices. These include instances of price-fixing, market allocation, reverse patent settlement, and abuses of government processes.

14. The **Chair** then asked whether the US considered its approach to be effective, particularly given that its prices are known to be higher than in Europe. The **United States** said that its approach has had direct results in terms of improving legislation. This led, in turn, to the entry of generic drugs into the market, which has been shown to dramatically lower the price of pharmaceuticals to consumers. These goals have been achieved while avoiding addressing whether individual prices are correct, which should be ultimately determined by the market rather than competition agencies.

15. **Canada** explained that it has the fifth highest expenditure on retail pharmaceuticals per capita in the OECD, so drug pricing is a very serious issue in the context of the Canadian national healthcare system. Canada approaches pharmaceutical prices in a number of ways, which can be broken down into three main approaches: regulation, enforcement and advocacy. From a regulatory standpoint, and with respect to patented medicines, Canada has a regulatory body at the federal level that has a mandate to ensure that prices of patented medicines sold in Canada are not excessive. Every new patented medicine that comes into the market is given a price ceiling based on international price comparisons with seven other like countries, and products cannot be sold above that ceiling, although the ceiling can move up over time.

16. The competition agencies pursue significant competition enforcement in the pharmaceutical sector. This includes examining instances of pharmaceutical competitor collaborations, including joint R&D, joint commercialization and joint production agreements, to ensure that they do not substantially lessen or prevent competition. The competition bureau also pays particular attention to pre and post generic entry practices, such as hard product switching, pay-for-delay and other prohibited agreements between competitors. Canada also engages in careful merger review, and tries to ensure that generic entry and pricing is not distorted by anticompetitive practices.

17. Canada's competition agencies also engage in advocacy to ensure that competitive processes are protected. For example, they conducted a study on the generic drug sector and provided some advice to various players in the marketplace on how they could keep those prices low. Canada concluded by saying that competition in the pharmaceutical industry in Canada is intertwined with the regulatory framework that governs the industry. Thereby, facilitating greater price competition between pharmaceutical manufacturers may require a mix of regulatory solutions to complement competition enforcement, in order to reduce regulatory barriers to entry for generics and ensure that manufacturers cannot manipulate the regulatory process to deter price competition.

18. **Spain** explained that medicines are subject to different regulatory systems. Pharmaceutical laboratories are free to set the price for pharmaceuticals that are not financed by the National Health System; by contrast, publicly financed pharmaceuticals are subject to strict regulation on prices. Spain described two main types of regulation. There is a fixed-price system for IP protected products, where the competition authority has a supervisory and monitoring role concerning pricing trends. However, the Spanish competition authority does not intervene in the price setting process: it plays a supervisory role only once the medicines are already being marketed or by issuing reports during public consultation phase new prices are approved. There is also a reference price mechanism, which applies to medicines that are subject to competition but which are reimbursed by the State.

19. Given the complexity of the pharmaceutical sector and the broad variety of medicines and use-cases, the Spanish competition authority does not have an automatic screening method to consider whether prices are excessive in the pharmaceutical sector. The assessment is made on a case-by-case basis, and takes into account an enormous variety of criteria. At the same time, the agency has a team devoted to identifying price trends. As a result of this screening process, the agency have identified prices increases, which did not necessarily correspond to anti-competitive behaviour. The Spanish competition agency also cooperates closely with health authorities to determine whether the reasons for these price increases are justified.

20. **Lithuania** described a market study it pursued which was triggered by an antitrust investigation. The investigation did not uncover any anticompetitive activity, but it found that high prices might be the consequence of flawed regulation, particularly as regards parallel pricing and public funding. This led the competition authority to launch a market study. This study found that there was a rule that drugs which were parallel imports could only be subsidised by national funds if they were four to ten percent cheaper than other drugs marketed in Lithuania. This rule was found to be unreasonable and a potential hurdle to market entry that led to higher consumer prices. The Health Ministry amended the rule, leading to increased entry by parallel traders.

21. A second market study focused on the rules for including and maintaining drugs in the list of drugs reimbursed from public funds. This market study identified another

unreasonable rule that excluded drugs that did not meet a certain percentage discount threshold. This prevented market entry of drugs that were cheaper than the ones in the market, but not cheap enough to be reimbursed because they did not meet based on the percentage hurdle that was set. As a result of this market study, the relevant rules were amended. However, over time new elements that give rise to competition concerns were established in the reimbursement system. Accordingly, the Lithuanian competition agency is still unable to determine what the effects of this reform were.

22. **Ukraine** explained that pharmaceutical markets are a permanent focus of the competition authority due to their social importance, market structure and complex regulation. Ukraine then described a number of market studies it had pursued in this area.

23. In 2016, a market study paid special attention to discounts provided by manufacturers to distributors, which did not lead to price reductions for final consumers. Instead, the result was that, for medicines acquired via public procurement procedures, the price was higher when drugs were sold by these distributors than the sale price of the same drugs in pharmacy chains. The competition agency determined that these discounting practices restricted market entry by parallel drugs, and made recommendations that aimed at improving the competitive environment in the pharmaceutical market. Another market study concerned the market for haemodialysis equipment and spare parts in Ukraine, which identified a number of problems preventing effective competition on the market. The agency made a number of recommendations towards more efficient kidney disease treatments and the development of competitive environment in the haemodialysis market. The adoption of prospective legislation to implement these recommendations is ongoing.

24. Lastly, research into public procurement procedures found that one of the reasons for high prices in pharma was that tenderers bid for bundles of patented and non-patented medicines. As a result, local and generic producers could not bid for these tenders at all. This led to tenders to be set up on the basis of international non-proprietary names of medicines, in order to allow smaller competitors to bid in public procurement tenders.

3. Is the fear that excessive price provisions will diminish the incentive to innovate, particularly if they apply to patented drugs, justified?

25. At this point, the **Chair** turned to a slightly more complex and controversial topic: bringing excessive pricing cases as regards IP-protected drugs. This is controversial because one of the main screens for bringing excessive pricing cases is that such cases should not diminish the incentives to innovate. As such, it is generally thought that excessive pricing cases should not be brought against IP-protected products.

26. The Chair then called on the **Netherlands** to make a presentation on their studies regarding whether excessive pricing cases could be brought as regards patented drugs. The Netherlands began by admitting that IP adds a level of complexity to excessive pricing cases. It is often argued that excessive pricing cases are undesirable in an IP context because they may harm incentives to innovate. Nonetheless, the Netherlands argues that it is actually possible to take incentives to innovate into account in excessive pricing cases and advanced some suggestions on how this can be done.

27. The Netherlands began by saying that there is no hierarchy between IP and competition law. Regulation is sometimes proposed as an alternative to the application of excessive pricing. From the Netherlands perspective, regulation and excessive pricing are complementary. Regulatory gaps that exist may be corrected through competition

intervention, particularly when timely regulatory intervention is not possible. Competition investigations may also reveal regulatory gaps.

28. IP rights provide incentives to innovate, but may also give rise to circumstances in which price pressure can be very low and lead high prices. This may be especially problematic in pharmaceutical markets, given the inelastic demand that one sees in this sector. Patients often have a very high willingness to pay, since their health is very important to them. At the same time, health systems are to a large extent collectively financed, which increases the ability to pay. Further, the buying power that ministries might have can be fairly constrained by societal expectations that all available drugs are actually covered, e.g. for rare diseases.

29. At the same time, incentives to innovate should be taken into account in any competition enforcement action. New drugs should clearly not be dealt with in the same way as out of patent drugs. Companies that are successful in designing a drug should not be punished for that, so that the *ex-ante* incentive to innovate is preserved. In this respect, competition agencies should bear in mind that capital costs are a significant part of the total research cost for drugs. Nonetheless, IP rights are granted to products which display varying levels of innovation. For example, innovation concerns are more limited in the case of IP rights protecting a variation on a drug which has been in the market for a long time. The question is how to distinguish between instances where high prices are a legitimate reward for risky innovation and those that are not.

30. The Netherlands then identified two main mechanisms to make such a distinction in the context of excessive pricing cases. One way is to rely on benchmark average costs of bringing a drug to the market. Another mechanism is to allow failures to be part of the cost basis even if those failures never took place, in order to adopt an *ex ante* perspective. This requires an assessment of the probability of a medicine's success *ex ante*. There are several ways this could be done. It would be ideal if the agency had information from the company itself on the probability of success at the moment of the investment. If this information is absent, as will often be the case, one could rely on the literature on the type and number of clinical studies necessary to bring a drug to the market. Quality of life considerations could also be used to complement assessments based on research costs.

31. To finish, the Netherlands emphasised that incentives to innovate must be taken into account and that excessive pricing cases are not an alternative to regulation. It would be more desirable if problems could be solved by regulation, but this does not, however, exclude the possibility of competition intervention.

32. **Professor Margaret Kyle** intervened to express her dislike for cost-plus approaches, and to ask why the competition agency should deal with this instead of health authorities. The **Netherlands** answered that they were not under the same amount of pressure as health authorities, so they were able to pursue these cases with more resources.

33. **South Africa** said that it does not generally support bringing excessive pricing cases, but that it did bring one in the Hazel Tao case in the early 2000's. However, this excessive pricing case was brought in the context of a crisis related to the HIV/AIDS epidemic that demanded extraordinary measures. South Africa expressed the view that the case was driven more by social than by legal elements.

34. Ultimately, the investigation led to a settlement agreement where the two multinational companies involved agreed to license the drugs to a generic manufacturer. As a result, prices dropped substantially, from averaging 8,000 Rand to less than 300 Rand. This settlement also led to the licensee becoming a leading generics company worldwide,

without adversely affecting the originating companies. This was likely because South Africa was a developing country with a small market. As such, and particularly given that most innovation occurs in developed countries, the intervention in this case did not significantly restrict drug manufacturers' incentives to engage in research and development.

35. **Russia** then spoke about FAS' legal duty to pursue international price reference comparisons regarding essential medicines. Since 2010, drug prices are set in Russia in accordance with the minimum price level for the same drugs in reference countries. However, this regime only became effective after rules on drug exchangeability and price comparison came into place, together with rules on the equivalence of different pharmaceutical forms and drug dosages.

36. Russia also described how this system was implemented to reduce the maximum selling prices of drugs manufactured in Russia in line with reference prices. As a result, the price of 1,043 essential medicines was subject to price reductions averaging 43 %. This led to significant budget savings and a clearer system of price comparison in the Russian market.

4. Country Experiences with Excessive Pricing in Pharmaceuticals

37. The **Chair** then moved the discussion to recent cases on excessive pricing cases, and called on Professor Margherita Collangelo, Professor of Law at University of Roma III, to provide an overview of these cases.

38. **Professor Collangelo** began by pointing out that there is an increasing focus on fairness and exploitative practices at EU level. European officials have made statements regarding how their task comprises protecting consumers from exploitation, including by reference to cases on the imposition of excess royalties in standard essential patents or high prices in the pharmaceutical sector. She then provided an overview of the main arguments for and against intervention against excessive pricing, and described the main screens that are commonly deployed for bringing excessive pricing cases in order to avoid type 1 errors (i.e. false positives). These screens usually require the identification of high entry barriers, that a dominant position is not the result of past investment or innovations, the absence of effective sectoral regulator, and the absence of negative impact on innovation.

39. Professor Collangelo's presentation also described the difficulties posed to competition law enforcement by the special characteristics of the pharmaceutical sector. There is extensive regulation in this sector, with different degrees of intensity and adopting different systems depending on the relevant jurisdiction. Further, incentives to innovate are typically safeguarded through patents, which leads to a cautious approach with regard to the antitrust intervention on prices when dealing with patented products. However, recent excessive pricing cases have nothing to do with patents or the need to preserve innovation, which makes their analysis simpler.

40. At this point, Professor Collangelo mentioned that, despite the absence of antitrust enforcement against exploitative abuses in the US, there has nonetheless been an academic debate there on whether such cases should be brought, particularly on the basis of section 5 of the FTC Act. There have also been many different initiatives to address high pharmaceutical price, including important regulatory measures, State rules on price transparency, and recent price dodging bills.

41. Professor Collangelo then quickly identified a number of recent excessive pricing cases, taking the Aspen and Flynn cases as her reference point. She identified the main characteristics of these cases, which include: (i) the relevant IP has long expired; (ii) the infringing companies adopt business strategies to increase prices; (iii) there is a regulatory inability to address these strategies; (iv) there is no market entry. Regarding IP, in both cases companies that typically do not invest in R&D activities acquired the rights to market a product from its former producers. Despite the differences between the drugs at issue, the facts of these cases are similar insofar the investments made for their development had been already recouped. As regards the business strategies, they allowed the companies to achieve price increase. For different reasons, neither of the drugs could be replaced by other medicines. From a regulatory standpoint, the companies' strategies took advantage of the regulatory frameworks in place, which ultimately allowed them to set prices outside the regulatory scheme.

42. Reverting to the enforcement screens, intervention in these cases seems to be in line with them. There were no R&D investments to be recovered; the market did not self-correct as a result of the price increases; both cases are instances of regulatory gaming, in which regulators found themselves dramatically exposed and without the proper means to react in accordance with the actual regulation itself. Professor Collangelo concluded that while excessive pricing enforcement is a second-best solution, it was justified in these cases in line with the screens proposed in the literature. While it is clear that sectoral regulation is preferable when addressing high prices in pharmaceuticals, in exceptional circumstances bringing excessive pricing cases can be justified – and that this was the case with these recent cases.

43. The chair then called on the **UK**, which had one of the main excessive pricing cases at stake. The UK said that it was going to make five points. The first is that excessive pricing cases are difficult to bring, but are sometimes unavoidable. Excessive pricing cases should be rare, mainly because one would expect high prices to be self-correcting, unlike with exclusionary abuses which restrict market entry. The second point is that there are necessary conditions before intervention against excessive prices takes place. These are that prices have to be substantially above cost; there must be a regulatory failure; there must be no prospect of entry in the short run, even if barriers to entry are not insurmountable; and, finally we must be sure that it is going to be no harm to dynamic competition or innovation incentives as a result of intervention. There has been some discussion about doing these cases where the medicine is still patented; it would be best, however, to keep these cases to generic products where there are no IP issues.

44. The third point concerns regulatory failure. All cases in the UK involve regulatory failure – e.g. firms were able to exploit regulation by debranding their drugs and their prices. The best solution in such cases is to close the regulatory loophole. However, if there is regulatory failure to close loopholes, competition authorities have to step in. It is correct to say that we want regulators to be dealing with this, not competition authorities; but it is also correct to say: when the regulator does not intervene, then the competition authority has to step in.

45. The fourth point concerns economic value. European case law identifies excessive prices as a price that has no relationship to economic value. To an economist, this is an extraordinarily unhelpful piece of case law, since nobody knows what economic value is. It is not an economic concept, and the case law only provides only superficial guidance on what it might mean. One potential meaning is that the price might reflect quality

considerations. However, this still does not change the fact that a generic company may have substantially raised its price by taking advantage of a regulatory loophole.

46. Lastly, the UK explained that, in excessive pricing cases, it is not really concerned with determining the competitive price correctly. Competition authorities do not want to become price regulators, and they do not have to become price regulators. Their job is to establish liability. After liability has been established, there is going to be a damages case in which it will be up to the courts to determine what the non-excessive price is.

47. At this point, the **Chair** invited Italy to give a presentation on its own excessive pricing case.

48. **Italy** started by noting that it has been cautious to intervene in exploitative abuses cases. The authority has so far identified the circumstances where intervention might be justified on a case-by-case, mainly focusing on markets that are unable to self-correct, characterised by the absence of effective regulation, and where the risk of distorting dynamic competition is very limited or non-existent. In this context, the authority has been particularly active in recent years in the pharmaceutical sector, in light of its importance in terms of access to health care and impact on public expenditures.

49. It then discussed its Aspen case, which concerned a number of behaviours by a generics company directed at changing the classification of cancer drugs with a view to increase their price while still being reimbursed by the Italian state. In Italy, there are two major classes of drugs relevant here. Class A consists of drugs that are deemed essential and are fully reimbursed by the national health system after a negotiation process where the regulator cannot itself impose prices. Class C comprises drugs that can be freely priced by companies, and that are paid for by patients.

50. Aspen acquired the rights over the drugs in 2009 by Aspen. At the end of 2013, Aspen submitted to the regulator requests for reclassification of its drugs from Class A to Class C. The regulator rejected that request, considering the drug essential due to the lack of therapeutic alternatives for certain categories of patients. Because of aggressive negotiations with the regulator, Aspen nonetheless obtained price increases from 300% to 1500% in 2014. From the authority's point of view, the outcome of the negotiation was influenced by the credible threat advanced by Aspen of leaving the Italian market if the regulator did not accept the price increases.

51. When pursuing its analysis of whether these negotiated price increases were an abusive conduct, the Italian competition authority began by defining the market at the molecular level, which was not controversial. Regarding dominance, it was based on: (i) the lack of effective competition, as Aspen was the only supplier in each relevant market; (ii) the lack of potential competition, since new generic manufacturers lacked the economic incentive to enter in view of the limited the volume of the market; (iii) the presence of an asymmetrical bilateral monopoly characterised by weaker buyer power on the part of the State.

52. As regards whether the conduct was abusive, the authority carried out the European two-step test to assess whether the price was excessive and unfair. To determine whether the price was excessive, the authority followed European case law which favours the application of more than a single methodology. The authority relied in particular on a gross margin test and on cost-plus method. Regarding unfairness, a variety of economic and legal considerations were taken into account. First, the authority conducted an intertemporal comparison of prices; second, there were no economic justifications for the price increases; third, the price increase could not be justified by reference to quality; fourth, there were no

IP rights or research and development expenditures that would justify such pricing practices.

53. The authority ultimately required Aspen to practice prices that were not excessive. Given non-compliance by Aspen, the Italian competition authority started non-compliance proceedings, which eventually led to an agreement with Aspen and to significant price decreases of up to 80%. The case is now pending before the Council of State, a second distance Court for judicial review. To finalise, the authority emphasised that the competition agency only intervenes when the stringent conditions identified to justify intervention against exploitative practices arise, ensuring that the potential for innovation is fully realised.

54. **Denmark** explained that while it brought an excessive pricing case, it was in line with the approaches described by Italy and the UK. Excessive pricing cases should be approached with caution, and, in the Danish excessive pricing case the Danish competition authority followed similar screens and methodologies to Italy and the UK. The Danish competition authority certainly does not see itself as a price regulator, which is why its case ended with a cease-and-desist provision instead of a fine, without indicating what should be the correct price.

55. The **EU** then made a presentation regarding excessive pricing. Article 102 of the Treaty on the Functioning of the European provides that an abuse of a dominant position may consist of imposing unfair prices. This prohibition applies to any product, including pharmaceuticals. This shows that the EU's competition law framework prohibits both exclusionary practices and exploitative conduct. The question is therefore not whether to bring exploitative pricing cases, but when. This is a matter that was covered in earlier interventions.

56. The EU then focused its presentation on the applicable test for excessive pricing. This test, first developed in *United Brands*, has two steps: whether the price is excessive and, if so, whether it is also unfair. In the recent European Court of Justice's judgment in *AKKA/LAA*, the court confirmed that a number of comparators could be used to establish whether price is excessive. These include comparisons over time or across markets, and by reference to the same company or its competitors. The *AKKA/LAA* decision also provided a number of important clarifications. As regards comparisons of prices across Member States, the court indicated that it is enough to pursue a single method of comparison and that there is no minimum number of Member States that have to be compared. The decision also clarified that a comparator has to be selected in accordance with objective, appropriate and verifiable criteria, and that the comparison has to be done on a consistent basis. When such a comparison reveals a significant and persistent difference in price, that difference will be considered appreciable, which may be indicative of abuse. In such circumstances, it falls on the dominant undertaking to justify its prices by reference to objective factors. In short, the European Court of Justice allows the examination of an excessive pricing case to be adapted to the particularities of a case, granting authorities a certain margin of manoeuvre.

57. The EU then described the recent spate of excessive pricing cases on pharmaceuticals in Europe as related to specific business strategies related to medicines with long-expired IP rights. When such strategies take place and entry does not occur despite high prices, this may give rise to competition intervention against excessive prices; however, whether this is the case needs to be assessed in a case-by-case basis.

58. At this point, the **Chair** asked the UK and Italy to explain what they understood by regulatory failure. The **UK** said that this occurred in its phenytoin case, where the regulatory framework allowed a company to debrand a drug that had been out of patent for decades and raise its price by several thousand percent. The regulator did nothing about it, even though one would expect them to have (i) buyer power and (ii) regulatory powers to intervene in prices. **Italy** said that this amounted to a credible threat to leave the Italian market as regards essential medicines. The threat, which the regulator had been powerless to counteract, was credible because there was proof of a shortage of medicines and no alternatives had entered the market.

59. The chair then asked **John Davies** to make a presentation. Mr Davies is senior vice president with Compass Lexecon, based in Paris. He was director of economic analysis and the chief economist of the UK Competition Commission many years ago, then the chief executive of the Mauritius Competition Commission, and, from 2011 to 2016, the head of the OECD competition division.

60. Mr. Davies began with a discussion of the EU test on excessive pricing, which looks into whether a price is excessive and unfair. He argued that cost-based approaches might be used in a circular fashion to define the market, establish dominance and that a price is excessive when the cost-based price is used as the benchmark to define the relevant market under a SNNIP test.

61. Starting with market definition and dominance, cost reflective pricing might not be the same as perfectly reasonably competitive market pricing. The oil industry was used as an example. On the supply side, one has a supply curve of oil sources with different costs, starting with cheap Saudi Arabia oil and going all the way to fracking oil sands. On the other side, one has a demand curve. The world price of oil is set by the intersection of demand and supply, which means that the world price of oil is set at essentially the cost of the highest cost oilfield. This price is far higher than the cost for Saudi Arabia of producing its oil. Under excessive pricing doctrines, a competition authority could theoretically say that Saudi Arabia was charging too high a price for its oil. To do this, of course, an agency would need to establish that Saudi Arabia oil is in its own market, which does not compete with other oil sources. It could do so by invoking the cellophane fallacy as regards world oil markets, and arguing that the market was a narrow one for Saudi oil.

62. Most would think this absurd, but in the pharmaceutical market this reasoning has been adopted when pharmaceutical manufacturers price their medicines in line with a marginally substitutable product which is much more expensive. However, this is a circular argument, where the market is found to be narrow and the medicine deemed dominant merely because the agency finds that the medicine is overpriced, which is the only reason it is substitutable to the putative competitor – i.e. the market comprises merely the dominant, and excessively priced drug. At this point, Mr Davies emphasised that he did not disagree with the CMA's conclusion on market definition in its case. However, elements other than the price need to be taken into account, because to do otherwise leads to circular reasoning around the SSNIP test. Market definition and dominance should be based upon external reasons that prevent substitution or entry, such as clinical or regulatory barriers to entry, or prior exclusionary conduct on the part of the dominant firm.

63. Following this, Mr Davies identified a number of challenges regarding identifying excessive pricing. A significant problem concerns multi-product costs. Businesses do not seek to allocate an even amount of their overhead common costs to every product that they have on the market, such as R&D costs in the pharmaceutical industry. Instead, they take into account their overall costs and then set prices by reference to demand and the

possibility to market different products separately. If authorities then come along and require an equal allocation of costs to each product, some products will likely be found to be excessively priced. A related problem concerns the identification of normal profit. While some would like to rely on the cost of capital, this concept may not be as helpful in practice as one might expect.

64. Another challenge concerns the identification of fair value, which depends on supply and demand factors unrelated to cost. The question of what is economic value makes no sense to most economists. One must look at demand and comparable products in order to determine whether a price is fair, and not so much at cost. Instead, competition agencies seem to be looking into whether there are justifications for certain price levels when assessing fairness.

65. Lastly, if excessive pricing is allowed by regulatory gaps, then such gaps should be closed and further instances of high prices prevented. This is surely a much more valuable outcome for a competition authority than the individual prosecution of an individual company, which does not seem to be the best approach to dealing with these problems.

66. The **chair** then gave the word to **BIAC**, which identified two key themes: the need for a clear and predictable regime of competition enforcement, and the need to protect investment in innovation.

67. As regards the predictability of competition enforcement, BIAC argued that the *United Brands* test is unclear and hard apply. Even if there are screens that limit the possibilities of enforcement in this area, that in itself does not bring about a predictable and rational antitrust enforcement regime. Secondly, one needs to be able to determine what a correct price is, and the agency needs to be able to identify it, which raises the question of how to integrate R&D cost and innovation into the antitrust assessment. This is extremely challenging and hard to do *ex post*, let alone anticipate *ex ante*. A third challenge concerns remedies. First, inasmuch as it concerns the setting of a correct price, the agency would have to consider the impact of that price remedy, and compare the welfare effects of a uniform and differential pricing. Secondly, there would be the challenge of monitoring the remedy.

68. BIAC also expressed its scepticism of attempts to bring excessive pricing cases against patented products, and of the assumptions underpinning the Netherlands' studies and presentation. Antitrust enforcement against excessive prices should be a last resort solution. BIAC, through a member of IFPMA – International Federation of Pharmaceutical Manufacturers Associations – expressed its support for a dialogue on coherent public policies to achieve sustainable financing models for medicines. That said, discussions on pricing, in particular in the realm of innovative pharmaceuticals, are often surrogates for addressing inadequate access to medicines. Pricing is a component of the discussion, but access can be ensured only through strengthening healthcare systems.

69. The pharmaceutical industry does not have free rein to set prices. Instead, it is subject to complex rules and regulations that determine prices. Furthermore, the value delivered by innovative therapies should be assessed in the context of overall healthcare spending. The industry supports the rigorous application of competition rules, but also urge authorities to enforce these rules so as to ensure legal certainty and avoid chilling investment and innovation. As such, competition law enforcement should not be used to address pricing matters in the area of pharmaceuticals, especially with regard to innovative patented products. This is particularly the case because competition authorities are not specialised price regulators and this type of intervention carries far more risks than benefits,

including the potential chilling effect on innovation. When we talk about the importance of creating a competitive marketplace for generics, we have to remember that the first in-class innovators of today are the low-cost generics of tomorrow, and that we need to create an environment that preserves this innovation ecosystem.

70. To close this session, the **Chair** asked Israel about its recent policy changes *vis-à-vis* excessive pricing. **Israel** went through an interesting process in this regard, which reflects a debate on the appropriateness of bringing excessive pricing cases. After announcing a policy for enforcement against excessive pricing in 2014, a very intensive public debate occurred. Given this debate, and the difficulties that the competition authority encountered in applying its new policy, the authority reevaluated its excessive pricing policy.

71. Following a very long public discussion, the authority published in early 2017 a new policy which identifies four major criteria that Israel takes into account when intervening against excessive prices. The first one is the absence of alternative competitive remedies. An antitrust authority's main purpose is to reduce barriers to entry and create a more competitive market, not to regulate prices. The second criterion is that prices must be significantly higher than expected. The third criterion is that the high prices are unfair. Unfairness is assessed by reference to two tests. The first is that there is a serious imbalance between the monopoly and the final consumer: a price is unfair only in cases where the monopoly is very powerful, and the consumer lacks bargaining power. The second test concerns the strength of the monopoly. The fourth and last criterion is that, if there is a regulator, there should be no excessive pricing intervention. As a result of these developments, there are currently no excessive pricing investigations pending by the Israeli competition authority.

72. At this point, the **Chair** closed. He identified widespread concern with high prices in pharmaceuticals. He also allowed that it is possible for competition law to act, particularly when regulators cannot. The discussion during this roundtable looked at regulation and regulatory bodies, and heard that they are not always up to the task of addressing high pricing practices. As regards competition law, it can do two things. One is to look at all the conditions that led to high prices, and in particular to focus on possible exclusionary practices that may have led to market power, and thus to high prices. However, not all high prices are related to anticompetitive / exclusionary practices. Therefore, competition agencies may decide to intervene against excessive prices directly.

73. The chair wondered whether recent excessive pricing cases were related to holdup issues and fairness, to protecting patients who were locked into specific treatments. In any event, none of the available instruments that could be applied to address such concerns seems to be intellectually coherent or easy to apply – so one is left with a political problem that we have to solve.