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Excessive Pricing in Pharmaceutical Markets – Note by Italy

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More documents related to this discussion can be found at

www.oecd.org/daf/competition/excessive-pricing-in-pharmaceuticals.htm

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Italy

1. Introduction

1. The OECD Roundtable on "*Excessive Pricing in Pharmaceuticals*" offers a valuable opportunity for the Italian Competition Authority (AGCM) to present its recent experience in relation to excessive pricing in the pharmaceutical sector.

2. The AGCM has generally been cautious to intervene against allegedly excessive prices practiced by dominant undertakings. In a competitive market, without barriers to entry, high prices would normally attract new entrants and the market would accordingly self-correct.

3. The Authority has so far identified case-by-case circumstances where intervention might be justified on the basis of an assessment of a combination of some key economic features, finding an appropriate balance between static and dynamic considerations. Among other factors, markets that may require antitrust enforcement are those (i) unable to self-correct on the supply and/or demand side, (ii) characterized by the absence of an effective regulation and (iii) where the risk of distorting dynamic competition, by antitrust intervention, is very limited if non-existent.

4. In this context, the Authority 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, taking into account in the prioritization of cases also - among other factors - fairness considerations. Enforcement has concerned exclusionary behaviors aimed at delaying generic drugs entry and a market partitioning conduct, as well as excessive prices practiced towards the National Health System (NHS), breathing new life to exploitative abuses.

5. The former cases were discussed in the contributions submitted for the OECD's roundtables on "*Generic Pharmaceuticals*" held in October 2009 and June 2014.[1] Therefore the present contribution focuses on the latter, where AGCM's intervention complemented the action of the Italian pharmaceutical regulator leading to a reduction of the prices of the drugs considered by as much as 80%.

2. Exploitative price abuses of dominant position in Italy: legal framework and precedent case-law

6. In Italy exploitative price abuses fall within the scope of article 3.1.a of Law 287/90 (the Competition Law) on abuses of dominant position or Article 102.a of the Treaty on the Functioning of the European Union (TFEU) if they may affect trade between Member States of the European Union.

[1] Generic pharmaceuticals, note by Italy, OECD, Competition Committee, October 2009; http://www.oecd.org/competition/sectors/46138891.pdf; Generic pharmaceuticals, note by Italy, OECD, Competition Committee, June 2014; http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DAF/COMP/WD(2014)50&docLanguage=En.

7. Exploitative pricing abuses constitute a niche area in the enforcement of competition law in Italy, the number of actual cases brought by AGCM being relatively limited. The few cases where formal investigations were pursued by the Authority relate to the transport sector and the cases in question shared two common features: the presence of a clear benchmark for prices and incomplete regulation.

8. More specifically, the first case dealt with alleged excessive prices in passengers' air transport and ended-up with a non-infringement decision. The case represents an illustration of the conservative policy adopted by the Authority when different methods to assess excessiveness do not converge to an unambiguous conclusion.

9. An infringement of competition was, instead, ascertained in two successive decisions concerning the handling services fees applied by the companies that managed the airports of Rome and Milan. Both airports' managing companies enjoyed a legal monopoly on the provision of the access to all airport infrastructures. The cases took place at the initial stage of the liberalization process of handling services at a time when regulation was still not fully implemented.

A306 Veraldi - Alitalia[2]

In November 2001, the Authority concluded an investigation into Alitalia to verify whether it had abused of its dominant position in connection with prices applied to passenger flights in 1999 and the first eight months of 2000 on the Milan-Lamezia Terme route, on which it had operated as a de facto monopolist. The investigation had been opened in response to a number of complaints alleging that the price conditions on this route were significantly more onerous than those applied on the Milan-Reggio Calabria route, similar in terms of distance but with a different competitive structure since it was also served by Air One.

Two methods of analysis were used to test whether the prices applied by Alitalia were unfair: i) comparison of the prices in the relevant market with those applied profitably in a benchmark market in which it faced greater competition; and ii) comparison of the sale price with the cost of the service.

In applying the first method, the Authority compared the prices charged by Alitalia on the Milan-Lamezia Terme route and the Milan-Reggio Calabria route. The analysis revealed that the prices charged for identical ticket types were systematically higher. The revenue per passenger was about 50% higher. However, since Alitalia operated at a loss on the latter route, it was not possible to draw a clear conclusion with regard to the unfairness of the prices.

In applying the second method, the Authority considered the cost per passenger that Alitalia incurred on a sample of routes having similar features on which it operated in competition with other carriers. The cost indicator obtained in this way was compared with the average revenue per passenger recorded by Alitalia in the relevant market. The latter was found to be around 30% higher. Although substantial, this margin did not appear clear evidence of a disproportionate difference between the price and the economic value of the service. It was thus not possible to interpret it unambiguously for the purpose of evaluating the unfairness of the price conditions applied by Alitalia in the relevant market.

[2] Decision no. 10115 of 14 November 2001, A306 VERALDI/ALITALIA, http://www.agcm.it/dotcmsCustom/getDominoAttach?urlStr=192.168.14.10:8080/4125629700387 4BD/0/E8D67179887D3E45C1256B1900358FB5/$File/p10115.pdf.

In conclusion, the investigation did not find sufficient evidence to demonstrate that the pricing policies adopted by Alitalia on the Milan-Lamezia Terme route constituted abuse of a dominant position.

A376 Airports of Rome - Handling fees[3]

In October 2008, the AGCM concluded an investigation into the management companies of the airports of Rome (Aeroporti di Roma – AdR S.p.A.), pursuant to article 82 of the EC Treaty (now article 102 TFEU), with regard to an abuse of a dominant position consisting of a) the application of excessive fees in the market of airport infrastructures for refueling services, b) the application of excessive fees in the market of airport infrastructures for cargo handling, c) the application of a tariff system resulting in the exclusion of competitors in the cargo handling market. AdR, as the exclusive management company of the Fiumicino and Ciampino airports, had a legal monopoly on the management and provision of all airport infrastructures and, therefore, on all the markets related to these services.

During the proceedings, the Authority ascertained that the airport fee applied by AdR for access to infrastructures had never been in line with the costs sustained for providing the services, but was instead calculated in a way that resulted in much higher prices. This practice, which took place between 2004 and 2005, was deemed as excessive pricing performed by a subject holding a dominant position.

Considering the seriousness and duration of these infractions, the Authority imposed to AdR a fine amounting to approximately 1,6 million Euros.

A377 SEA - Airport fees[4]

In October 2008, the Authority concluded an investigation into SEA Spa, pursuant to article 82 of the EC Treaty (now article 102 TFEU), with the ascertainment of an abuse of dominant position consisting of: a) the application of excessive fees on the market of infrastructures for refueling services; b) the application of excessive fees on the market of infrastructures for catering assistance; c) the application excessive fees on the market of infrastructures for cargo handling.

SEA, as the exclusive management company of the Linate and Malpensa airports, had a legal monopoly in the management and provision of all airport infrastructures and, therefore, in all the markets related to these infrastructures.

During the investigation, the Authority ascertained that SEA had applied unilaterally fixed fees that were not cost-oriented and that resulted in excessive gains in the light of the actual costs incurred in 1) the market for access to centralized infrastructures and related services, and 2) various markets for the provision of goods for the common and exclusive use of special categories (handler operators for refueling services, caterers, cargo handlers).

[3] Decision no. 19020 of 23 October 2008, A376 - AEROPORTI DI ROMA-TARIFFE AEROPORTUALI, http://www.agcm.it/dotcmsCustom/getDominoAttach?urlStr=192.168.14.10:8080/4125629700387 4BD/0/641723A8B58A87DBC12574F60053B4C2/$File/p19020.pdf;

[4] Decision No. 19189 of 26 November 2008, A377 - SEA/TARIFFE AEROPORTUALI, http://www.agcm.it/dotcmsCustom/getDominoAttach?urlStr=192.168.14.10:8080/4125629700387 4BD/0/5079A6D32F07B73BC1257520003FCB76/$File/P19189.pdf.

Upon consideration of the seriousness and duration of these infractions, the Authority imposed to SEA a fine amounting to approximately 1,5 million Euros.

3. Excessive pricing in the pharmaceutical sector in Italy

3.1. The regulatory framework

10. As the pharmaceutical sector is one of the most R&D intensive, intellectual property rights (IPR) may play a central role when assessing prices of drugs and the risk of distorting dynamic competition, by antitrust intervention, is higher. A well-functioning IPR system can promote competition by encouraging firms to invest in innovation granting an exclusive legal right for a limited period of time. In Italy, in 2017, investments in R&D in the pharmaceutical sector amounted to 1.5 billion Euros and to 7% of total R&D spending, ranking third among all sectors.[5]

11. From a supply perspective, the sector is deeply affected by regulation. Medicines are, indeed, subject to strict market access requirements related to public health considerations and to price regulation because of their impact on the NHS.[6]

12. The Italian NHS grants total reimbursement for "Class A" drugs that are deemed essential for the patients. The price of these drugs is defined through a negotiation process between the pharmaceutical companies and the sector regulator AIFA. More specifically, the mechanism that leads to the setting of prices does not impose on the company a given price level, but sets out the process whereby prices are determined through a negotiation with AIFA.

13. The revision of a price previously approved by the regulator in the "Class A" is admitted under condition of the companies proving a documented change in production costs. In the absence of an agreement with the pharmaceutical company, the drugs would be automatically moved in the "Class C", where the companies are free to set the price and drugs are not reimbursed anymore by the NHS but are on charge of the patients.

14. The regulator provides some trends in relation to the evolution of prices, for both "Class A" and "Class C" medicines. In the time frame from 2004 to 2017, the former show a decreasing trend, especially from 2005 and 2011-2012, while the latter a regular growth.[7]

15. On the demand side, Italy, like most national health systems, relies on a three edged demand structure consisting of patients, doctors and the NHS. For prescription medicines the ultimate consumer - the patient - is not the decision maker. Prescription doctors' choices

[5] Farmindustria, "*I numeri dell'industria farmaceutica in Italia*", July 2018; https://storage.googleapis.com/jb-wp-uploads2/farmindustria-staging-web/2018/07/i-numeri-dellindustria-farmaceutica-in-italia_luglio_2018.pdf.

[6] In Italy, in 2017, total public and private pharmaceutical spending amounted to 29,8 billion Euros of which 75% was reimbursed by the NHS (AIFA, "*L'uso dei farmaci in Italia, Rapporto Nazionale Anno 2017*", July 2018; http://www.agenziafarmaco.gov.it/content/rapporto-nazionale-sull%E2%80%99uso-dei-farmaci-italia-2017-0).

[7] AIFA, "*L'uso dei farmaci in Italia, Rapporto Nazionale Anno 2017*", July 2018; http://www.agenziafarmaco.gov.it/content/rapporto-nazionale-sull%E2%80%99uso-dei-farmaci-italia-2017-0.

on medicines to be used are not necessarily price sensitive and costs are, at least partially, reimbursed by the NHS.

3.2. The Aspen case

3.2.1. The conduct

16. In September 2016, the AGCM fined the Aspen pharmaceutical group for the infringement of Article 102, lett. a), TFEU for excessive prices concerning some essential off-patent drugs.

17. The AGCM began its investigation after a consumer association - as well as some media reports - had claimed that the NHS was experiencing shortages in the provision of Aspen's anti-cancer drugs.

18. The case involved a group of anti-cancer drugs, whose rights to market had been acquired in 2009 from GlaxoSmithKline by Aspen (the so-called "Cosmos package"), which, through aggressive negotiations with the Italian pharmaceutical regulator, obtained in 2014 sharp price increases ranging between 300% and 1500% (see *Table 1* below).

Table 1. Price increases of Aspen's drugs that triggered AGCM's intervention

Product name	Active ingredient	% increase in price
Alkeran tab.	Melphalan	+1540%
Alkeran inj.	Melphalan	+257%
Leukeran	Chlorambucile	+1166%
Purinethol	Mercaptopurine	+465%
Tioguanina	Tioguanina	+306%

Source: AGCM

19. In particular, at the end of 2013, Aspen had submitted to AIFA an initial request for reclassification of its drugs from the "Class A" to the "Class C". AIFA rejected the request for reclassification, considering the drugs essential because of the lack of therapeutic alternatives for certain categories of patients. In October 2013, Aspen and AIFA entered into a negotiation for new reimbursement prices for these drugs since the price applied in 2013 dated back to the time of the first marketing authorization. In March 2014, the negotiation ended with AIFA's approval of the new "Class A" prices for the Cosmos drugs, accepting the prices increase submitted by Aspen. In AGCM's view, the outcome of the negotiation was influenced by the threat, advanced by Aspen, of leaving the Italian market if the regulator did not accept the price increase. During the negotiations, a shortage of the drugs in question was observed in the Italian distribution system, despite the absence of any production problems, making the threat credible.

3.2.2. The analysis

20. The initial part of AGCM's analysis focused on the definition of the relevant markets. AGCM defined four relevant product markets at ATC5 - molecule - level. The assessment was based on the absence of therapeutic alternatives for specific groups of patients in determined phases of their illness.

21. As for Aspen's dominance, the AGCM ascertained both the lack of effective competition - Aspen was the only supplier in each of the relevant markets - and potential

competition. Despite the absence of patents' barriers to entry, new generic manufacturers lacked the economic incentive to enter in view of the scarce volume of the market.

22. In line with the criteria outlined in United Brands[8], the Authority carried out its assessment in two steps: first an assessment of the excessiveness of the new prices charged by Aspen with respect to costs, then an analysis of unfairness.

23. As for the economic tests, AGCM used different methodologies and assumptions in analyzing whether the prices could be deemed excessive in line with the criteria established by the European case law, which favors the application of more than one methodology. In particular, using a gross margin test, the Authority calculated the difference between prices - prior to the increases - and direct costs. The resulting gross margin - in percentage of sales - was compared to the total indirect costs - in percentage of sales - to conclude that prices before the increase already granted a margin in line with Aspen average gross margin. Therefore, percentage price increase ranging between 300% and 1,500% of initial prices led to an unreasonable excess of prices on the economic value. With the second method - cost plus method - the AGCM calculated the difference between prices and a comprehensive measure of costs including direct costs plus a portion of indirect costs plus a reasonable rate of Return On Sales (ROS).[9] The analysis allowed to conclude that new prices applied by Aspen generated an excess in percentage of cost plus, ranging from 100% to almost 400%.

24. The analysis then moved to the second prong of the United Brand's assessment of "*whether the price […] is either unfair in itself or when compared to competing products*".

25. In that regard, AGCM's decision is an example of the variety of economic and legal considerations relevant for the assessment of unfairness, in light of all the circumstances of the case including: (i) an inter-temporal comparison of prices, as previous prices already covered direct costs; (ii) the absence of any economic justifications for such an increase, as Aspen did not document any increase in production or distribution costs; (iii) the absence of any non-cost related factor leading to an improvement in quality or in the level of service to the NHS or patients; (iv) the nature of the drugs and characteristics of Aspen, as there was neither a patent coverage nor the need to recover R&D investments.

26. In view of these arguments the Authority considered the conduct adopted by Aspen as a very serious infringement because it concerned life-saving drugs - that were not substitutable for the most fragile categories of the population (elderly and children) - and

[8] A finding of excessiveness/unfairness in violation of Article 102 TFEU needs to be related to the situation in which the price does not *have "any reasonable relation to the economic value"* of the good or service in question following a two steps approach. In order to find *"whether the difference between the costs actually incurred and the price actually charged is excessive"*, an appropriate benchmark needs to be identified in a context where economic theory does not provide precise thresholds applicable to all circumstances. See, judgment of the Court of Justice of 14 February 1978; Case 27/76 United Brands Company and United Brands Continentaal BV v Commission of the European Communities; http://curia.europa.eu/juris/liste.jsf?language=en&jur=C,T,F&num=27/76&td=ALL.

[9] Different assumptions on the rate of return on sales were used in the calculation (13%, the average ROS of the sector, or [15-20]%, the specific Aspen group ROS) and the inclusion of the trademarks purchasing costs: (i) ROS 13%: excess between [100-150]% and [350-400]%; (ii) ROS 13%+trademarks: excess range between [100-150]% and [300-350]%; (iii) ROS [15-20]%: excess range between [100-150]% and [250-300]%; (iv) ROS [15-20]%+trademarks: excess range between [50-100]% and [200-250]%.

was implemented through the credible threat of interrupting their supply and imposed on Aspen a fine amounting to 5.2 million Euros.

27. One aspect which is often discussed in relation to excessive price cases concerns the remedies to be imposed if an infringement is found and, more specifically, whether a competition Authority should close its investigation suggesting the price to be implemented by the infringer. In that regard, the AGCM's decision imposed a cease and desist order - from conducts analogous to the ones sanctioned - leaving to the company to define how to comply with it. It was up to Aspen to charge prices which were compatible with competition law - displaying a reasonable relationship with the economic value of the drugs considered - and to inform the Authority of the actions adopted to comply.

28. As Aspen did not comply with the above described cease and desist order, the AGCM opened, in March 2017, a non-compliance proceedings. In March 2018, the Authority sent a Statement of Objections (SO) to Aspen, alleging a dilatory strategy by refusing to provide AIFA with relevant information in terms, among others, of the contracts signed with the actual drugs producers, so to justify the increase in production costs which Aspen declared to bear. It was only in April 2018, after having received the SO, that Aspen submitted all the relevant information and reached an agreement with the regulator, leading to substantial price reductions. More specifically, the prices towards the public have been reduced as much as by 80% (see *Table 2* below). The application of the new prices is retroactive, to the date of AGCM's infringement decision. In June 2018, the AGCM closed the non-compliance proceedings without sanctioning Aspen.[10]

Table 2. Comparison of Aspen's prices - towards the public - before and after AGCM's intervention

	2013 Prices	March 2014 (unfair) prices	April 2018 New Prices	Δ% 2014 - 2018
Alkeran tab.	5.8	95.1	19.24	-80
Alkeran inj.	69.21	247.35	116.68	-53
Leukeran	53.99	219.44	156.39	-29
Purinethol	16.82	95.1	33.62	-65
Tioguanina	7.5	95.95	17.34	-82

Source: AGCM

29. As emerges from the above description, the relationship between the AGCM and the sector regulator in charge of the pharmaceutical sector, AIFA, is one of complementarity.

30. This has also been recently confirmed by the judgment by the First Instance Administrative Court that upheld AGCM's decision in the Aspen case acknowledging that, because of the weak bargaining power of the regulator towards pharmaceutical companies, the mandates of the sector regulator and of the competition Authority are not antithetical

[10] Decision no. 27209 of 13 June 2018, A480B - Incremento prezzi farmaci Aspen - Inottemperanza; http://www.agcm.it/dotcmsCustom/getDominoAttach?urlStr=192.168.14.10:8080/4125629700387 4BD/0/4C18CC63482AFE14C12582C6004BBF4C/$File/p27209.pdf.

but rather complementary. Therefore, in all cases where regulation preserves room for maneuver by the companies that can affect competition, the applicability of competition law may not be excluded. Lastly, the Court highlighted that AIFA negotiates prices for pharmaceuticals with a view to balancing several interests, but it is not for AIFA to assess whether prices are not excessive and fair under competition rules.[11]

31. Lastly, since January 2017, AGCM and AIFA signed a memorandum of understanding in order to strengthen cooperation in areas of mutual interest, also in order to make AGCM duly informed about possible business conducts of antitrust relevance.

4. Conclusions

32. As illustrated by the handling services and drugs excessive prices cases, in markets characterized by an incomplete regulation, antitrust intervention may complement the regulator's action, especially when the latter displays a weaker bargaining power towards regulated companies. The pharmaceutical sector regulator and Aspen, for example, found an agreement only after the AGCM has issued a statement of objection in the context of a non-compliance proceedings.

33. 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.

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

35. 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, otherwise it could have an impact on firms' *ex ante* incentives to invest in welfare-enhancing activities such as innovation.

[11] Judgment n. 08945/2017 of the Tribunale Amministrativo Regionale per il Lazio of 26 July 2017; https://www.giustizia-amministrativa.it/cdsintra/cdsintra/AmministrazionePortale/DocumentViewer/index.html?ddocname=5E2RMFWDI3OQYIG55NPXXHKHMU&q=.