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GENERIC PHARMACEUTICALS

-- Note by Italy --

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This document reproduces a written contribution from Italy submitted for Item VI of the 121st meeting of OECD Competition Committee on 18-19 June 2014.

More documents related to this discussion can be found at http://www.oecd.org/daf/competition/generic-pharmaceuticals-competition.htm.

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1. Introduction: generic pharmaceuticals in Italy[1]

1. In reaction to the current economic crisis, most countries are experiencing a severe spending review, which also affects pharmaceutical expenditure. Italy is no exception. In this framework, generic pharmaceuticals and well-designed tendering procedures for public procurement can play a key role to allow for substantial savings while maintaining high standards of health care. The spread of generics is also being favoured by an important patent cliff, i.e. the expiration of numerous patents for significant drugs all over the world, in 2014 and 2015 and through 2018[2].

2. Italy has ample room for improvement in terms of sales of generics. Notwithstanding a significant increase over the last few years, the market share of generic drugs is still lower than 25%[3], compared with about 75% in Germany and the United Kingdom[4]. This is due to several factors, including: the design of the patent regulation system, the regulation of retail pharmacies and lower prices of pharmaceuticals when compared to the US and other EU countries[5].

3. While acknowledging that innovation in the pharmaceutical sector should be sustained by allowing innovators to enforce intellectual property rights, the Italian Competition Authority endeavours to ensure a level playing field by preventing competitive restrictions in public procurement and tackling conducts aimed at unduly delaying the entry of generics.

4. In the last few years the Italian Competition Authority has conducted several cases among which two stand out:

a) the Pfizer case, in which the Italian Competition Authority was confronted with the question concerning the scope and limits of the use of patents by pharmaceutical companies to prevent competitors from entering the market. Patent protection is crucial to ensure firms' incentives to invest resources for the development of new medicines. However, the Italian Council of State provided clear indications to identify in what circumstances a dominant firm exceeds the legitimate protection of its rights and interests;

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1 Consistently with the suggested issues and questions for consideration proposed by OECD's Competition Committee, this submission integrates the contribution drafted on the occasion of the 2009 Roundtable on Generic Pharmaceuticals (see Italy's Country Contribution on http://www.oecd.org/daf/competition/abuse/46138891.pdf) and mainly focuses on recent developments in competition enforcement with regard to generic pharmaceuticals in Italy.

2 For more detailed information about the most significant patent expiries of 2014 and 2015 and their economic implications, see the article *Pharma Learns to Brave the Patent Cliff*, in The Life Sciences Report, 25 February 2014, http://www.thelifesciencesreport.com/pub/na/pharma-learns-to-brave-the-patent-cliff.

3 In Italy, generics represented 24% of the total value reimbursed by the National Health System for the purchase of medicines in 2013. Source: Assogenerics, the national association of the generic industry).

4 Health at a Glance 2013. OECD Indicators.

5 As explained in the cited 2009 Country Contribution, an important characteristic of the Italian off patent system is the contemporary presence of both generics and copies (copies are drugs of the same active substance marketed, with their own brand name, often by the originator itself). In addition, regulation of retail pharmacies has affected generic competition insofar as the margins that the pharmacists receive on reimbursable drugs are established by law and are a fixed percentage of the product price, thus creating an incentive for the pharmacists to dispense the drugs at higher prices. Finally, prices of pharmaceuticals in Italy are generally lower when compared to the US or other European countries, as a result of the many cost containment interventions in the health care sector.

b) the Roche-Novartis case, in which the Italian Competition Authority tackled a collusion that did not involve generic medicines, but mirrored conducts typically aimed at stifling generic competition. Namely, in the Authority's opinion, the two parties to the proceedings tried to steer sales from a cheaper off-label product to a new and more expensive on-label drug.

2. Pharmaceutical companies' practices under competition scrutiny

2.1 The Pfizer case: when does an abuse occur?

5. In 2012, the Italian Competition Authority fined the pharmaceutical group Pfizer for a practice aimed at delaying generic companies' entry in the Italian market for the production and provision of anti-glaucoma eye drops, in breach of Article 102 TFEU[6]. The investigation followed a complaint filed by a generic company.

6. Pfizer's Xalatan was the most prescribed eye-pressure lowering eye drop for glaucoma in the Italian market. Since 1989, Pfizer held a patent for the relevant active substance. In 2009 Pfizer obtained a divisional patent[7] by the European Patent Office, protecting an amended version of the same active substance. However, Pfizer did not launch any new product in the Italian market on the basis of the divisional patent. Pfizer used the divisional patent to ask for a supplementary protection certificate[8] in Italy and Spain, where the parent patent expired earlier than in the rest of Europe. As a result, the entry of the generic drug in Italy was delayed.

7. The evidence gathered by the Italian Competition Authority showed that Pfizer had adopted a complex strategy including the following conduct: i) an illegitimate extension of patent duration through the request for a divisional patent (eventually revoked by the European Patent Office) and then for a supplementary protection certificate only in Italy; ii) patent-related law suits before civil and administrative courts; iii) actions aimed at preventing the national regulatory body from granting generic companies marketing authorizations and the reimbursement price; iv) the provision of misleading information in order to get a marketing authorization for its own generic product; v) an application for the extension of the paediatric patent.

8. The Italian Competition Authority considered that Pfizer's strategy had an abusive nature since the group's behaviour had no reasonable justification and was intended to exclude generic companies from the market. Pfizer's behaviour had the effect of illegitimately extending the intellectual protection of Pfizer's speciality Xalatan in Italy, and delayed the entry of generic equivalents by seven months. The Italian Competition Authority set a fine of approximately € 11 million, taking into account the harmful effects caused to the National Health System.

9. The decision was subject to judicial review that eventually confirmed the Authority's assessment.

10. The Italian Council of State, confirming the decision, observed that the key issue at stake was to what extent a dominant firm may protect its legitimate rights and interests. It asserted that whether the divisional patent had been lawfully obtained or not was not relevant to a competition assessment, because the notion of abuse of dominant position implies the existence of a lawful right, which is strategically

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6 See press release http://www.agcm.it/en/newsroom/press-releases/1986-pfizer-sanctioned-with-106-million-euro-fine-for-abuse-of-dominant-position.html.

7 A divisional patent application is a patent application which has been divided out of an earlier filed patent application (known as the parent application).

8 A supplementary protection certificate (SPC) is an intellectual property right that extends the duration of the exclusive right. It enters into force after expiry of a patent upon which it is based.

"abused" to exclude competitors. The Council of State clarified that abuse is an unjustified disproportion between the benefit for the right holder and the detriment for the counterparty. In that specific case, Pfizer's conduct caused a delay of generics' entry without leading to an additional use of the active substance. The real objective exceeded the protection of legitimate rights and was to delay the sale of generics. The Council of State added that the commitments (which had been rejected by the Italian Competition Authority) were utterly unsuitable to eradicate the anti-competitive effects already produced by the conduct: instead of removing the abuse of dominant position, they would have reinforced its effects by implying Pfizer's capacity to grant licences on the active substances. The judgment of the Council of State seems in line with EU Courts' decisions concerning the Astra Zeneca case[9].

2.2 The Roche-Novartis case: creating an artificial distinction

11. In February 2014, the Italian Competition Authority found that Roche and Novartis infringed article 101 TFEU by participating in an anticompetitive agreement in the market for ophthalmic treatments used to cure some serious vascular eyesight conditions, including age-related macular degeneration (AMD), the main cause of blindness in developed countries. Although the collusion does not involve generic medicines, it has several similarities with the conducts aimed at stifling generic competition, insofar as the two companies tried to neutralize the price competition exerted by a much cheaper off-label product available on the market (which in that context played the same role as a generic).

12. The investigation started in February 2013, on the basis of complaints filed by an association of private hospitals and the Italian Ophthalmologic Association. The evidence gathered in the course of the proceedings shows, in the Authority's view, that since 2011 Roche and Novartis colluded to create an artificial product differentiation and purport Avastin as more dangerous than Lucentis, in order to influence prescriptions of doctors and health services.

13. Avastin is a biotech medicine approved to treat some forms of cancer: yet, since mid-two-thousands it has been used off-label to treat also common eyesight conditions, on the basis of independent clinical research. Lucentis contains an active substance similar to Avastin's, but it has been submitted for regulatory approval by Genentech in the US - and Novartis everywhere else - specifically for the eyesight conditions previously treated through Avastin. There is a significant difference in price: while an injection of Lucentis in Italy costs € 900 (down from an earlier price of € 1700), the price of an off-label injection of Avastin tops at €81.

14. The Italian Competition Authority concluded that Roche and Novartis raised and spread concerns on the safety of the ophthalmic uses of Avastin among the medical community and the drug's end-users. In the Italian Competition Authority's view, this was part of an artificial product differentiation plan developed in order to favour the commercial performance of Lucentis, from which both Roche and Novartis took advantage. In fact, Roche collected significant royalties from the sales of Lucentis, which had been developed by its subsidiary Genentech, while Novartis directly gained from the sales of Lucentis. The Italian Competition Authority also took into account the significant percentage of Roche's shares held by Novartis (around 33%) as further evidence of the intertwining interests existing among the two groups. The efforts of Roche and Novartis in raising safety concerns on Avastin intensified as a

[9] Cfr CJ, Case C-457/10 P *AstraZeneca AB and AstraZeneca plc v European Commission*, 6 December 2012 and GC, Case T-321/05, *AstraZeneca v Commission*, 1 July 2010. In particular, the Court of Justice acknowledged that a strategy of a company in a dominant position "*to minimize the erosion of its sales and to enable it to deal with competition from generic products is legitimate and is part of the normal competitive process, provided that the conduct envisaged does not depart from practices coming within the scope of competition on the merits, which is such as to benefit consumers*" (AstraZeneca, paragraph 129).

growing number of independent comparative studies supported the equivalence of the two drugs in ophthalmic uses.

15. According to the Italian Competition Authority, this illicit collusion might have hindered access to treatment for many patients and caused the National Health Service to sustain additional expenses estimated at € 45 million in 2012. The Authority estimated that the potential cost increase for the National Health Service (in case of full replacement of Avastin with Lucentis for Italian AMD patients) would have been of almost € 600 million in 2013 and € 700 million in 2014.

16. The quantification of harm might prove relevant for follow on private enforcement actions. The agreement identified by the Authority has primarily affected the twenty Italian Regions, which are the administrative bodies appointed by the Italian Constitution for managing and providing public health services. It may be expected that the Regions will claim for the damages on public finances caused by the infringement. In that case, the quantification of harm operated by the Italian Competition Authority might represent a reference point for judges.

17. The Italian Competition Authority, in light of the seriousness of the infringement, imposed on Roche and Novartis fines totalling respectively € 90,5 and € 92 million.

18. The decision has been appealed and the case before the Court of first instance (the Administrative Tribunal TAR Lazio) is on-going.

3. Looking forward

19. Generics have played a key role to enhance competition in the pharmaceutical sector, by offering more choice and by lowering prices for chemical medicines (so-called "small molecule medicines"). In the near future, biosimilar drugs will exert a similar competitive pressure with respect to biopharmaceuticals, which are typically very expensive products[10].

20. The pharmaceutical industry has increasingly focussed on biopharmaceuticals, which differ in many ways from traditional chemical medicines, including the manufacturing techniques, their molecular size and complexity, or their stability[11]. While generics need to prove their bioequivalence with the reference medicinal product, "biosimilars" are developed to be "similar" to an existing biological medicine and commonly require a more complex and expensive manufacturing process.

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10 See J. Rovira, J. Espín, L. García and A. Olry de Labry, The impact of biosimilars' entry in the EU market, January 2011, a document prepared in the framework of a service contract with the European Commission (Directorate-General for Enterprise and Industry), http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/biosimilars_market_012011_en.pdf. The study argues that: "Biopharmaceuticals ("biologicals") are a rapidly growing class of pharmaceuticals which have provided the best available therapies for several life-threatening diseases […]. But biologicals also have a negative side: high prices which restrict access and generate added stress on health systems' already costly pharmaceutical budgets. Biological products are usually very expensive; some annual treatment costs fall in the range of US$25,000 to $100,000 (35,000 to 140,000 euros), others can be as high as $200,000 (280,000 euros)".

11 Most biopharmaceuticals are made in living systems such as microorganisms or animal cells, so that their exact characteristics are subject to inherent variability. Moreover, biological medicines have the potential to be recognised by the body as "foreign" and induce unwanted immune reactions. See European Commission, *Consensus Information Paper 2013. What you need to know about Biosimilar Medicinal Products.*

21. The European Union is the first region in the world to have set up a legal framework and a regulatory pathway for biosimilars[12]. However, dispensing is not regulated at the EU level. Each Member States may define whether it is for the doctor ("interchangeably") or for the pharmacist ("substitutability") to decide, and how patients are involved in the decision-making process.

22. In Italy, where the principle of substitutability for generics has been recognised by the law in several circumstances, the legislator has not yet adopted any specific provision concerning biosimilars. In March 2011, the Italian Competition Authority issued an opinion regarding a draft law intended to exclude the principle of therapeutic equivalence (i.e. the basis for any substitutability) for biosimilars and to prevent the healthcare units from including biological medicines and their biosimilars in competition in the same tendering lot. The Authority observed that the marketing authorization process for biosimilars requires the demonstration of substantial equivalence to the reference biological product in terms of effectiveness, safety and quality. Therefore, the prohibition envisaged in the draft law appeared likely to result in an unjustified restriction of competition that was not proportional to the purpose of guaranteeing protection of public health.

23. This position was confirmed in an opinion sent to some public healthcare administrations in May 2013, where the Italian Competition Authority reiterated that therapeutic equivalence between original biotech products and biosimilars should be adopted as a general principle in public procurement.

12 In the European Union, biosimilar medicinal products follow the specific provisions of EU legislation (the so-called "biosimilar pathway") which include defined high standards of quality, safety and efficacy. The concept of a "similar biological medicinal product" was adopted in EU pharmaceutical legislation in 2004 (Directive 2001/83/EC, as amended by Directive 2003/63/EC and Directive 2004/27/EC) and came into effect in 2005.