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GENERIC PHARMACEUTICALS

-- Note by Spain --

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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

1. The Spanish Pharmaceutical market is characterised by the concentration of the demand (the main buyer is the National Health System -NHS) and it´s highly regulated. In particular, both prices and margins are fixed by Law in the case of reimbursable under prescription drugs.

2. The Spanish pharmaceutical market was traditionally dominated by brand medicines with little presence of generics. Compared with other Member States, the entry of generics in Spain has been late. However**,** competition between brand and generic medicines is increasing, mainly due to a regulation that favours the prescription of generics.

3. The first purpose of this paper is to stress and explain some of the most recent developments in this sector regarding generic pharmaceuticals. Second, it aims at drawing the attention to the scarce number of complaints received by the Spanish Competition Authority regarding such an important and strategic market as that of generics. Finally, this contribution tries to give some ideas on what can be done in order to encourage complaints regarding anticompetitive practices and improve the efficiency of *ex-officio* actions in this sector.

2. Overview of the Spanish generic pharmaceutical sector

4. The Spanish Pharmaceutical sector is regulated under the Act 29/2006 of Guarantees and the Rational Use of Medicines and Health Products. This act has been modified several times in the last years.

5. In particular, since the last OECD roundtable on generics in 2009, the Spanish Administration has adopted several measures in order to restrain pharmaceutical expenditure. Many of these measures are referred to the regulation of generic drugs.

6. In 2010[1] the prices of generics were lowered in some cases even by 30%[2]. Furthermore, the Government launched a campaign in the media to promote the consumption of generics[3]. As a result, in 2010 and for the first time, the pharmaceutical expenditure decreased. Successive reforms have strengthened this trend.

7. Moreover, discounts (in terms of volume or early payment) on reimbursable drugs offered by the industry and wholesalers to pharmacies were limited up to 5% in branded drugs and up to 10% in generics are accepted[4]). The reason is that these discounts were not passed on to final prices. As a consequence, competition between distributors only benefited pharmacies that obtained higher margins, but neither consumers nor the NHS.

8. Since 2011[5] prescription by active ingredient is imposed (except when there are medical reasons that justify the prescription by brand) and pharmacies are obliged to sell the medicine with the lowest

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1 Royal-Decree Law (RDL) 4/2010, March 26th.

2 The system to calculate the reference price of homogeneous groups was changed: before 2010 it was calculated as the average of the 3 cheapest medicines. Since the new Act came in force, it is based on the cheapest one (lowest cost/treatment/day).

3 http://www.medicamentosgenericosefg.es/index.html

4 Recently, all discounts have been limited to 10%, regardless of the brand.

5 RDL 9/2011, August 19th.

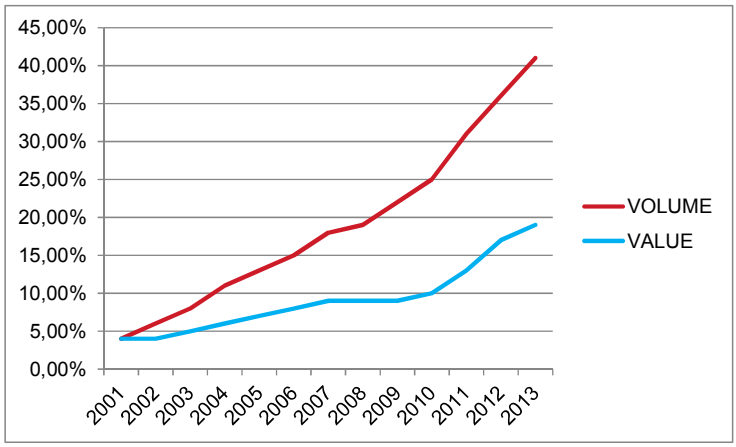
price. In case that brand and equivalent generic drugs have the same price, the obligation to sell the generic was no longer in force[6].

9. But in 2012[7] the obligation of selling the generic drug instead of the branded one when they have the same price is established again. In addition, the new regulation imposes the co-payment and reduces the number of drugs funded by the NHS, including some generic specialties. As a result, the consumption of medicines, including generics, dropped, and the growth of the generics market was restrained[8] (though generics improved its position compared to branded drugs).

10. Following the new regulations, several autonomous communities (CCAA) have created purchasing groups to provide medicines and medical devices to public hospitals, strengthening the bargaining power of demand, and the NHS has launched some public tenders which can be joined by CCAA, in order to achieve better prices.

11. All of these reforms have resulted in savings for the NHS and in a relevant growth of the generics market share. Moreover, the expiry of some important patents (most recently: desloratadin, candesartan and montelukast[9]), have also contributed to this result: in 2013 in Spain generics amounted 41% in volume and 19% in value[10] (the potential market for generics in Spain could reach 73% in volume).

Evolution of the share of generics in Spain (%volume and value)



Source: IMS Health

12. The total value of generics in Spain in 2012 added to 1406 Million €. The main companies active in this market are Cinfa (21.5%), Teva (19.2%), Stada (10.1%), Normon (9.6%), Kern Pharma (7.9%), Novartis (7.2%) and Mylan (4.9%)[11].

6 The Act 29/2006 established that if prescription was done by active ingredient and branded drug and the equivalent generic drug had the same price, the pharmacy was obliged to sell the generic drug.

7 RDL 16/2012, April 20th.

8 Source: IMS Health.

9 In 04/2012, 06/2012 and 01/2013 respectively.

10 Source: IMS Health

11 Source: Press, Correo Farmacéutico.

3. Recent competition enforcement in the generics sector in spain. possible reasons regarding levels of enforcement

13. The growing concentration of demand is likely to encourage concentration or incentives for coordination on the supply side, in order to countervail the increasing buying power.

14. Given this context, the growing importance of the generics market and its direct link with public interest, it could be expected an intensive activity by competition authorities in this sector preventing and/or sanctioning bid rigging and cartel cases as well as "pay for delay" practices. However, the fact is, at least in Spain, that the number of complaints received is far from expected.

15. In the last 5 years, the Spanish Competition Authority has investigated 4 cases: 2 cases of boycott to generic laboratories and 2 cases of anticompetitive litigation. But only one of the cases resulted in the imposition of fines (one of the boycotts investigated).

16. In the case S/649/08 PRODUCTOS FARMACÉUTICOS GENÉRICOS the Council of the former competition authority (the CNC) imposed a fine on 4 organizations of pharmacists for an attempt of limiting purchases from a generic laboratory (DAVUR) that had reduced its prices. The anticompetitive practice was carried out through letters sent to pharmacies warning that DAVUR's lower prices could significantly affect the annual price revision made by the Health Ministry, leading to lower reference prices of generic medicines on the following year and, therefore, a decrease in their future revenues.

17. In the case S/0437/12 ESPECIALIDADES FARMACÉUTICAS GENÉRICAS another generic laboratory (SUMOL) complained that the President of the Association of Producers of Generics (AESEG) had encouraged a boycott via twitter against some generic laboratories that had reduced their prices. The Council of the former CNC found that the alleged message didn´t meet the conditions to affect competition. In the frame of the same complaint the CNC investigated the existence of alleged illegal discounts to pharmacies made by some generic laboratories, but there were no grounds for infringement since there was no proof of such discounts. Therefore, proceedings were concluded and the case was filed away.

18. In the case S/0441/12 PFIZER, the former CNC investigated a possible abuse by PFIZER consisting in delaying the entry of generic competitors of its specialty Xalatan (latanoprost). This behavior had been previously investigated and sanctioned in Italy. In Spain, however, proceedings were concluded with no grounds for infringement as no proof of such an abuse was found (unlike the Italian case, there was no evidence of letters or threats by Pfizer regarding generics of its specialty Xalatan) and the European Patent Office, in fact, confirmed the validity of the patent.

19. In the case S/0228/10 NOVARTIS the CNC investigated a possible case of anticompetitive litigation by Novartis, but the proceedings were also concluded without a declaration of infringement since there was no evidence of abuse of the right to effective judicial protection.

20. As for mergers, there have been no cases filed in the generics sector in particular[12].

21. Regarding *ex-officio* actions, these face the difficulties in accessing information that could reveal the existence of problems in the functioning of the generics markets. However, the Spanish Competition Authority has recently engaged in several actions aimed at strengthening cooperation with other Health

[12] Note that our law establishes two thresholds for notification, one based on market shares and other on volume of sales.

Authorities in order to improve exchanges of information. It has also addressed several information requests *ex officio* in the sector of generics.

22. Taking into consideration the above, it seems to be necessary to find out the reasons that could explain the reduced number of complaints received by the competition authority in this sector. One possible reason could be that laboratories assume that the natural jurisdiction for patent litigation is Commercial and Civil Courts.

23. Though it is true that patent litigation often involves particular interests that are confronted, there is also a public interest linked to them (in fact, the same public interest that justifies the concession of patent protection). This public interest is especially relevant in the case of medicines, not only because of its impact on public health but also because of its economic importance, notably in a country like Spain, with a generous public health system and compelling budgetary restrictions. Therefore, distortions in the competitive functioning of the generics markets caused by the wrong use (or abuse) of patent protection are likely to affect public interest and, thus, the competition authority would be entitled to investigate them. Likewise, any collusion aimed at avoiding lower prices by generic companies limits consumer benefits and should be sanctioned by the antitrust body.

24. Therefore it is necessary to increase efforts to promote the activity of antitrust authorities in this sector, emphasizing the role that the competition watchdogs can play as the natural guarantor of the above-mentioned public interest. It is crucial that competitors, consumers and other Administrations are aware of the scope of this surveillance, which goes far beyond private interests. It is important to emphasize that antitrust regulation should not be overshadowed by the revealed preference for private actions shown to date by the generic producers. Cooperation with other Authorities is a key element for the success of this strategy.

4. Actions to foster competition enforcement in the market for generic pharmaceuticals

4.1 Encouraging complaints before the Competition Authorities.

25. Advocacy actions among players in the generics market can contribute to make generic pharmaceuticals aware that several behaviours carried out by their competitors, suppliers and clients can harm competition and, thus, public interest and therefore they can report such practices to competition authorities. Procedures in this jurisdiction are often timely and economically more attractive than civil trials, interim measures can be adopted at an early stage and if the authority finds that there has been an infringement, affected complainants are still entitled to ask for private compensation before civil courts in terms of damage actions.

26. It could also be interesting to develop some advocacy actions among civil judges, to make them aware when they receive a case involving patent disputes, that the behaviours they are asked to examine could imply competition infringements, and, in due cases, transfer the information to the antitrust watchdog so that it may intervene in litigation and act as *amicus curiae*.

27. Finally, advocacy actions could also be carried out among other administrations, in particular, public hospitals and other health departments that play a key role in public procurement. Given that these institutions can call for auctions and public tenders to buy medicines and sanitary products, it is important that they are aware that they can report to competition authorities any competition disruption they may detect.

4.2 Enhancing the efficiency of ex-officio actions

28. In order to detect irregular behaviours by competitors in the generics markets, and given the difficulties to accede to detailed, updated and disaggregated information that could reveal the existence of infringements, competition authorities could cooperate with other administrations, including other regional or national antitrust bodies, in order to focus on the companies, products and tenders that could pose a major risk to public interest in case competitive market functioning was distorted.

29. Competition watchdogs can screen public auctions to buy medicines and vaccines, analysing if the resulting price is above normal price, comparing bids offered by the participants to identify evidence of collusive behaviour, etc. It could be interesting to design a theoretical test to be applied in auctions to reveal early signs (or even evidence) of irregularities.

30. Competition authorities could also screen the expiry of patents of blockbusters. Given that these medicines constitute a tempting business for competitors, it could be expected that they take positions in the market when that expiry gets close, to prepare their entry (for example, applying for authorisation to market their products, registering brands, etc). Given increasing countervailing power of demand, competition enforcers could cooperate with the Ministry of Health, the regional authorities and the Drugs Agency to make a list of medicines that deserve special attention (because of their share on public expenditure, their patent situation, etc…) to be carefully monitored.

31. The authority could also screen patent litigation proceedings before Civil and Commercial Courts. This screening could help detecting some infringements such as "pay for delay" cases. For example, if a complaint against a patent is unilaterally withdrawn and there is a suspicion of a transactional agreement between the parties, the authority could investigate if there is an anticompetitive behaviour behind such an agreement.

32. Finally, cooperation with other competition authorities to exchange ideas and experiences can be another way to improve *ex-officio* actions.

5. Final remarks

33. The importance of this sector and its impact on public interest justifies an especial attention by the competition authorities. However, the number of complaints referred to the antitrust bodies is sometimes abnormally reduced, partly due to the preference for judicial jurisdictions.

34. Advocacy actions, cooperation with other administrations and deep screening of market and jurisdictional activity could help increasing acknowledge on the role and benefits of competition enforcement and, thus, encouraging complaints before the competition authorities by particulars or enhancing *ex-officio* investigations.