

Unclassified

DAF/COMP/GF/WD(2014)47

Organisation de Coopération et de Développement Économiques  
Organisation for Economic Co-operation and Development

10-Feb-2014

English - Or. English

DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS  
COMPETITION COMMITTEE

## Global Forum on Competition

### COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

#### Contribution from Spain

-- Session III --

*This contribution is submitted by Spain under Session III of the Global Forum on Competition to be held on 27-28 February 2014.*

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JT03352232

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## COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

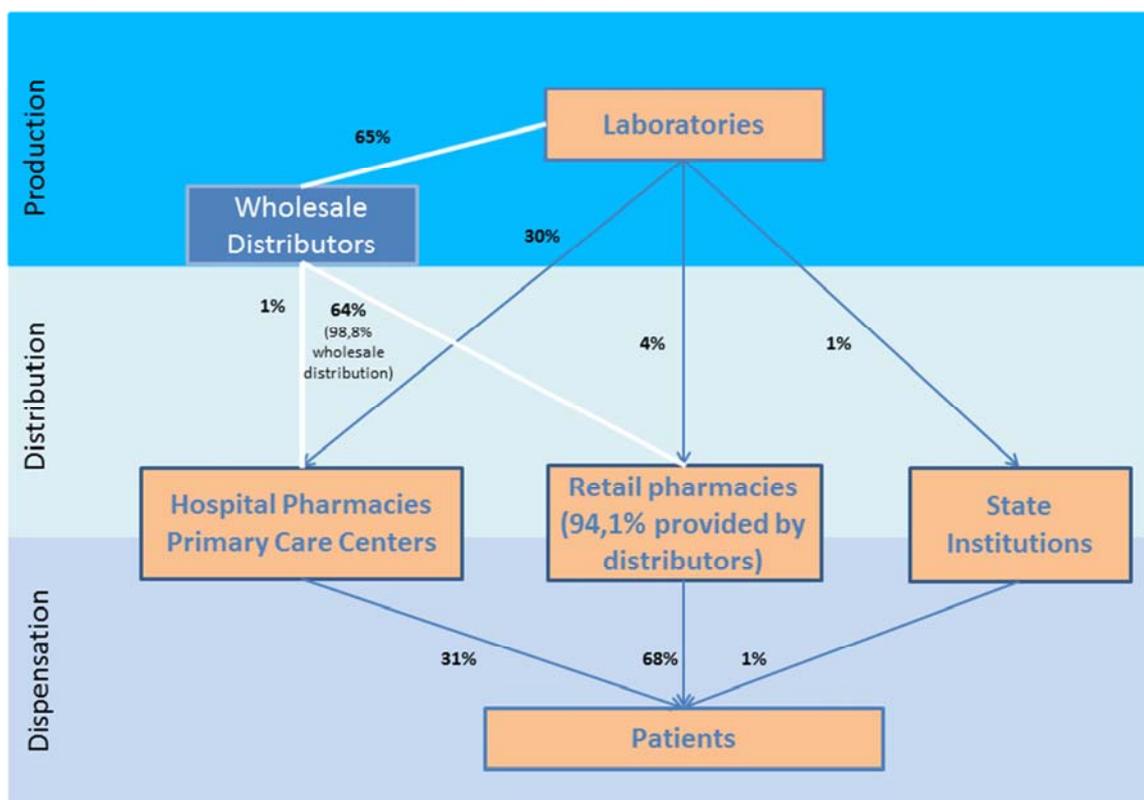
-- Spain --

### 1. Introduction

1. The main players in the Spanish pharmaceuticals distribution system are full line wholesalers (who distribute roughly 65% of all medicines). In a great extent, they are cooperatives of pharmacy retailers that account for 68% of total sales. Altogether, the sector includes more than 52 companies which are mostly grouped so that the major six cooperatives represent more than 75% of the wholesale market.

2. Retailers distribute 68% of total drugs dispensed to patients; the remaining 31% corresponds, essentially, to drugs distributed within the hospitals (that are directly supplied by laboratories).

Figure 1. Distribution chain for pharmaceuticals in Spain: 2012 market shares



3. Most of the pharmaceutical wholesalers (97%) are members of the National Association of Wholesalers and Distributors Pharmaceuticals (*Federación de Distribuidores Farmacéuticos –FEDIFAR-*). They work according to a multi-channel system, covering prescription products, non-prescription products, cosmetics and other products.

4. Prescription pharmaceutical products in Spain are only available through retail pharmacies and/or hospital pharmacies. Nonetheless, non-prescription products are now allowed to be distributed via the Internet by pharmacies, under a pharmacist's professional advice.

5. Regarding the dispensing method, the Spanish market for pharmaceuticals is 95% prescription products, against 5% non-prescription pharmaceuticals. The channels through which pharmaceutical products are dispensed to patients are divided into two main categories: general access retail pharmacies and hospital pharmacies. Other retail channels exist - only for non-prescription pharmaceutical products – but they account for a very small share out of the total pharmaceutical products dispensed.

6. General access retail pharmacies consist of a retail storefront, which has a dispensary where pharmaceutical products are stored and dispensed. The dispensary is subject to the pharmaceutical legislation, which has specific requirements for storage conditions, handling equipment, warnings, etc. In the Spanish pharmaceutical market, pharmacies remain the largest channel for the distribution of pharmaceutical products.

7. In short, pharmacy retailers in Spain are independent authorized agents – although some are forming purchasing groups such as MASFARMA- and, unlike in other European countries, enjoy a markedly protective regulation that eliminates competition at the retail distribution level. Traditionally, Spanish regulation has not only restricted to pharmacists the dispensation of prescription drugs, but also included provisions in order to prevent geographic concentration of pharmacies, to regulate opening hours and, especially, to set the need for a five-year university degree –not only to dispense but also to own a pharmacy–, and to require compulsory enrolment in the College of Pharmacists.

8. Hospital pharmacies usually handle more complex pharmaceutical products, with specific indications which require stricter safety regulations and patient compliance. Most of the products in these pharmacies are single-dose or unit dose. Hospital pharmacies are usually located in the premises of hospitals, with trained personnel, quality assurance and adequate facilities. Hospital pharmacies are used only for inpatient services.

9. The Spanish Competition Authority<sup>1</sup> (CA) has had the chance to point out such regulatory restrictions while informing the drafts of the different pieces of legislation that set up the regulatory framework for the distribution of pharmaceuticals in Spain. In parallel, within the past years, the CA has decided on some horizontal mergers affecting pharmaceutical wholesalers and distributors and has dealt with competition enforcement cases related to alleged dual pricing, to cancellation of distribution agreements with wholesalers, and to collective boycotts by Pharmacy associations to generic pharmaceutical producers.

## 2. Regulatory framework of the Spanish pharmaceutical sector

10. In 1986, the General Health Act established a National Health System (NHS) in Spain. It is a highly decentralised system, with universal coverage and financed through general taxation. There are 17 Autonomous Communities which have full powers regarding public health services provision and healthcare services planning. The health system financing remains centralized funded and it is then allocated between the Autonomous Communities according to a capitalisation scheme. Under the NHS, healthcare is provided free of charge except for pharmaceuticals where different co-payment schemes are

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<sup>1</sup> Originally, the *Tribunal de Defensa de la Competencia* –TDC-; later on, the recently extinguished *Comisión Nacional de la Competencia* –CNC-; and presently, the *Comisión Nacional de los Mercados y la Competencia* –CNMC- (the newborn single body that has integrated the CNC and the six regulators formerly in charge of supervising energy, telecoms, audio-visual, postal, rail and airport services).

in practice. Co-payment is proportional to the level of income, and the percentage to be paid by the patient generally ranges between 60% and 10%.

11. The main stakeholders in the pharmaceutical regulatory process include a number of highly specialized bodies spread over three different ministries and different levels of the administration<sup>2</sup>.

12. The key piece of Spanish legislation governing pharmaceutical products is Act 29/2006 on Guarantees and the Rational Use of Medicines and Health Products (the “Guarantees Act”).

13. Within the past few years, the need to transpose EU legislation into national law has led to amendments in the Spanish regulatory framework; the most recent being<sup>3</sup>:

- Changes relating to pharmacovigilance. The draft legislation that led to such changes, raised comments<sup>4</sup> by the Spanish Competition Authority on the provisions related to the infringement by distributors of their obligation to supply to pharmacy retailers<sup>5</sup>; on the provisions related to unfair competition infringements; on the provisions related to the requirements to become technical director of a pharmaceutical distribution entities; and on the provisions related to pharmaceuticals price setting.
- New post-authorisation obligations and more transparency and publicity requirements regarding the medicines themselves.
- Reinforcement of verification requirements with regard to the manufacture and import of medicines in order to avoid introduction of falsified active ingredients to the market.
- Regulation of two new parties in the distribution of medicinal products for human use:
  - persons brokering medicinal products (through the creation of a register and the imposition of new obligations); and
  - wholesale distributors in free trade zones or free warehouses, which must comply with the provisions applicable to wholesale distributors in general (ie, authorisations, obligations, requirements).
- Pharmaceutical companies and distribution entities are required to guarantee that pharmacies are supplied “*to ensure that patient needs are covered*”. Furthermore, the new legislation defines the

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<sup>2</sup> Namely : (i) The Directorate General of Pharmacy and Health Products of the Ministry of Health, which controls the pricing and reimbursement process. (ii) The Inter-ministerial Commission on Pharmaceutical Prices which imposes the price of reimbursable prescription-only pharmaceuticals dispensed in Spain and decides on final pricing and (iii)The Spanish Agency of Medicines and Health Care Products (Ministry of Health), which is responsible for the evaluation, authorisation, inspection, surveillance and control of pharmaceuticals.

<sup>3</sup> Act 10/2013, Royal Decree 557/2013, Royal Decree 686/2013, Royal Decree 782/2013 and Royal Decree 870/2013.

<sup>4</sup> CNC Legislative Proposal Report (IPN) 81/12.

<sup>5</sup> According to the CNC, the draft confused the legal requirement to have the market fully supplied with the weight that national supply should have on a distributor’s total sales (i.e. it seemed that exports were to be a marginal activity and, in fact -provided that the national market was sufficiently supplied-, this might not be the case).

situations in which measures may be adopted in order to resolve shortage situations, including limiting exports of medicines outside of Spain. Such measures may be applied to medicines that, due to their active ingredient, dosage or route of administration, are the only ones registered in Spain for certain pathology, or to those for which there is no alternative available to pharmacists.

- Wholesalers and pharmaceutical companies are only able to accept returns from pharmacies and pharmaceutical services directly supplied with the medicines being returned. The aim of this measure is to bring to an end a system that created opportunities for medicine trafficking.
- Each distributor must now have a certificate stating compliance with the Good Distribution Practices (GDPs) - in line with the European Commission Policy-
- New developments on the sale at a distance to the public of non-prescription medicinal products for human use (also known as over-the-counter (OTC) medicines). The new regulation requires full identification of the pharmacy retailer and the customer and establishes strict standards to ensure that customers are fully informed regarding the medicines that they buy. Besides, in order to avoid misuse or abuse of medicines, the pharmacy retailer is required to evaluate the appropriateness of dispensing the medicines requested, especially when the required amount exceeds standard treatments, or the requests are frequent or repeated.

14. Further changes on the Spanish pharmaceutical legal framework are expected. The Ministry of Health is drafting new regulation and, specifically, new changes will soon affect the benchmark pricing system and the homogeneous groupings of medicinal products in the National Health System. The draft has also been informed<sup>6</sup> by the Spanish Competition Authority focusing observations on three areas:

- As regards the calculation of the benchmark prices, the CNMC queries some of the exceptions (minimum threshold and benchmark price under consideration) to the general rules on calculation. Specifically, it questions the existence of a minimum threshold on the price to apply generally to all medicinal products and requests specific details on the reasons underpinning the application of the benchmark price<sup>7</sup>.
- With respect to applications for voluntary price discounts by laboratories for the purpose of receiving funds from the National Health Service, the sponsoring Ministry is asked to consider reducing or eliminating the required minimum percentage discount established in the draft regulation and in the Guarantees Act, in order to encourage competition between laboratories.
- In relation to the computerized system for managing supplies and setting prices of medicinal products, the sponsoring Ministry is reminded of the need to establish the necessary safeguards and precautions to prevent other operators from accessing commercially sensitive information.

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<sup>6</sup> CNMC Legislative Proposal Report (IPN) 105/13.

<sup>7</sup> Under the benchmark pricing system, regulated by the Guarantees Act, pharmaceuticals are divided into groups sharing the same active substances and forms of administration. The benchmark price for each group is the maximum price that the National Health Service will pay for the medicinal products in that group. The new regulation will implement that rule by secondary legislation and, besides benchmark prices, it will also regulate the lower and lowest pricing system as mechanisms for determining the National Health System's financing of each specific medicinal product and achieving savings in pharmaceutical spending.

### 3. Competition enforcement in the distribution of pharmaceuticals in Spain

15. From a competition point of view, the pharmaceutical market, due to its nature, is a highly regulated market in Spain where even many margins, discounts and prices are fixed by the Public Administration. As far as distribution is concerned, within the past years, the CA has decided on some horizontal mergers affecting pharmaceutical laboratories, wholesalers and distributors and has dealt with competition enforcement cases related to alleged dual pricing, to cancellation of distribution agreements with wholesalers, and to collective boycotts by Pharmacy associations to generic pharmaceutical producers.

#### 3.1 Mergers<sup>8</sup>

16. Horizontal mergers involving pharmaceutical laboratories and distributors have been frequent in recent years. As long as laboratories were authorised to directly supply pharmaceuticals, some of them cancelled supply agreements with distributors, leading to mergers between distributors under financial struggle. This trend goes on since the regulation keeps on setting lower prices for pharmaceuticals each year (and therefore, the corresponding distributor's margins keep on decreasing). However, none of the mergers proposed threatened effective competition and, thus, were approved in first phase without remedies.

#### 3.2 Enforcement<sup>9</sup>

##### 3.2.1 "Dual pricing" and cancellation of distribution agreements with wholesalers

17. Most of the cases evaluated by the Spanish Competition Authority in the pharmacy sector within the past few years have somehow been related to distribution of pharmaceuticals. Specifically, triggered by allegations posed by pharmaceutical distributors (in some cases also exporting companies) against measures adopted by some laboratories such as the termination of distribution agreements with some wholesale distributors or the imposition of the so called "dual pricing" clauses within their new contracts (which, according to the complainants, could hinder parallel trade).

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<sup>8</sup> Cases : C/0529/13: RECORDATI-LABORATORIOS CASSEN FLEET, C/0525/13: FSI-SILFURBERG-BURDARAS/INVENT FARMA, C/0516/13: NOVO A/S-XELLIA GROUP AS, C/0505/13: ZAMBON/PROFILE, C/0503/13: INDAS/ALBASA, C/0497/13: BIOGEN/TYSABRI, C/0485/12: CHEPLAPHARM/ NEGOCIO VESANOID, C/0440/12: JAZZ PHARMACEUTICALS/EUSA PHARMA, C/0427/12: SK CAPITAL III/IBA, C/0411/11: ROVI/FERRER/ALENTIA, C/0345/11: KHK/PRO STRAKAN, C/0324/11: LABORATOIRES THEA SAS/ACTIVOS NOVARTIS, C/0302/10: TEVA/NEGOCIO PRODUCTOS SALUD MUJER DE MERCK. C/0291/10: FRESENIUS /GAMBRO, C/0288/10: RECKITT/ACTIVOS DE COMBE, C/0275/10: GRIFOLS/TALECRIS, C/0210/10: DFE/DOMO PHARMA, C/0155/09: BIOVAIL/CAMBRIDGE LABORATORIES, C/0146/09: MERCK/MEDICULT, C/0145/09: JUSTE/JUSTESA IMAGEN, C/0126/08: THERMO FISHER/BONSAI, C/0121/08: CSL/TALECRIS, C/0016/07: RECORDATI/OE HOLDING, C/0332/11: ARAGOFAR/VASCOFAR, C/0204/09: COFARES/GRUPO EUROSERV, C/0161/09: COFARES/VICENTE FERRER, N/07076: GRANVILLE BAIRD / NEUE FALKEN.

<sup>9</sup> Cases : S/0479/13 CITICOLINA (still pending), S/0441/12: PFIZER (still pending), S/0437/12 ESPECIALIDADES FARMACÉUTICAS GENÉRICAS (still pending), S/0228/10: NOVARTIS, S/0038/08: FEFE VS LABORATORIOS Y ALMACENISTAS FARMACEUTICOS, 628/07: PREPARADOS FARMACEUTICOS, S/0030/07: LABORATORIOS FARMACEUTICOS, S/0023/07: BIOVET, S/0437/12: ESPECIALIDADES FARMACÉUTICAS GENÉRICAS, S/0323/11: INDUSTRIAL FARMACEUTICA CANTABRIA, S.A., S/0176/09: SEDIFA/GRUFARMA, 649/08: PRODUCTOS FARMACÉUTICOS GENÉRICOS, S/0017/07: EAEP VS LABORATORIOS FARMACEUTICOS, 2623/05 SPAIN PHARMA.

18. Such behaviors have been analyzed either as possible agreements between laboratories aimed at reducing the number of distributors (Article 1 of the Spanish Competition Act), as a possible abuse of dominant position (Article 2), or as alleged refusal to supply to certain distributors.

19. In none of the cases the alleged conduct was considered to be anticompetitive and the Competition Authority filed the proceedings. As regards to the “dual pricing” clauses, there is a double price actually, but it is due to the fact that Article 90 of the Guarantees Act only requires laboratories to apply to the regulated price to pharmaceuticals being reimbursed by the national Health System (prescription-only pharmaceuticals) provided they are dispensed in national territory. Laboratories may apply their free prices on the rest of their medicines, especially those sales made abroad. Therefore, technically, it does not amount to a “dual pricing” scheme because, as a matter of fact, the laboratory sets a single (free) price that is replaced by the state controlled price only in those cases where the distributor shows that the pharmaceutical product has been dispensed within the national territory and, thus, it does not infringe Article 1 of the Spanish Competition Act. However, the Revision Court (*Audiencia Nacional – AN-*) has partially estimated appeals on two of these cases, still pending to be resolved by the Supreme Court.

### 3.2.2 *Boycotts to generic pharmaceutical producers.*

20. Competition concerns have been raised in Spain between distributors and pharmaceutical producers of generic pharmaceuticals on the one hand and between the pharmacies and pharmaceutical producers on the other.

21. In 2007, a relevant case was originated by a complaint from *Laboratorios DAVUR* (a Spanish company which produces and commercializes generic pharmaceuticals) against four Pharmacy Associations claiming restrictive practices allegedly consisting on a collective boycott against DAVUR products through a collective recommendation of these associations to their associates (pharmacies).

22. In March 2007, *Laboratorios DAVUR* decided to decrease the price of twelve of its generic pharmaceuticals below the reference prices set by the Health Ministry. The following were, among others, the main marketed pharmaceuticals of the company: Omeprazole, Simvastatin, Paroxetine and Fluoxetine.

23. After this decision, several Pharmacy Associations made recommendations to almost all the pharmacies in Spain (22.360 e-mails were sent) in order to stop the commercialisation of DAVUR medicines on the basis that, from their point of view, pharmacists were not obliged to dispense the cheapest medicine but the medicine that is included in the Ministry Order imposing reference prices of generic medicines. The e-mails and letters sent also recognised the fear that DAVUR 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.

24. As a result, many Spanish pharmacists decided not to deal with *Laboratorios DAVUR* impeding the entry of its products in their pharmacies.

25. During the investigation proceedings, *Laboratorios DAVUR* came to an agreement with the main claimed associations and withdrew its complaint. Nevertheless, the investigation continued ex-officio. Finally, on the 24th March 2009, the Spanish Competition Authority resolved to declare the existence of infringement of article 1 of the Spanish Competition Act, qualified as a collective recommendation to homogenize the pharmacies behavior against *Laboratorios DAVUR* in the market for generic medicines subject to medical prescription. A total fine of EUR 1 million was imposed to these associations.

#### 4. Final Remarks

26. In Spain the pharmaceutical sector has some unique characteristics that generate specific problems: both prices and margins are fixed by Law throughout the value chain in many cases, in particular, in reimbursable prescription-only pharmaceuticals<sup>10</sup>. The current situation of the Spanish economy and the pressure of the aging population on the National Health System create a favorable environment to adopt reforms.

27. In the last few years, and mainly due to an increase in sanitary expenditure, new legislative initiatives have been adopted in order to reduce drug prices and to reduce the number of pharmaceuticals being financed by the NHS within this sector, but the existing regulation does not leave much room to competition on prices among pharmacy retailers and strictly regulates the distribution of pharmaceuticals.

28. It may be worth exploring alternatives to introduce competition in the distribution of pharmaceuticals as a way to reduce sanitary expenditure. There is, particularly, some work to be done as regards to the existing requirements for new pharmacies to entry the market, to the distribution remuneration schemes (fixed margins), and to the restrictions to the distribution of non-prescription pharmaceuticals by retailers other than pharmacies.

29. An initiative that might foster competition is the centralized purchasing of pharmaceuticals by the government on behalf of the regional governments in order to supply hospitals and primary care centers. This initiative - planned within the recent legal reforms but still not developed by regulation- is clearly pro-competitive because it reinforces the countervailing buyer power and prevents from bid-rigging and from excessive prices.

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<sup>10</sup> Fixed margins do not affect health care products. In this regard, the Spanish Competition Authority has recently conducted inspections at several firms, associations and federations active in the production and distribution of absorbent products for the adult incontinence sector on grounds of possible anti-competitive practices, including the fixing of prices and terms of trade as well as sharing the market.