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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

Contribution from Chile

-- Session III --

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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

-- Chile --

1. Introduction

1. In Chile, competition remains an important tool for improving the availability, affordability and quality of pharmaceuticals. Recent data has shown that actions directed towards reducing the cost of health care in general, and pharmaceuticals in particular, may have a substantial impact on decreasing overall household expenditures, considering Chile has one the highest out-of-pocket medical spending levels in the OECD when measured as a proportion of final household consumption[1]. Although there is no official data regarding how much of this spending is due to pharmaceutical costs, leading scholars have estimated, using data from 2007, that expenditures on pharmaceuticals are responsible for 55% of households' total health expenditures[2], which would also make Chile's one of the highest out-of-pocket expenditures in pharmaceuticals relative to total household expenditures[3]. There is no reason to believe this proportion has varied in any significant way in recent years.

2. Various distortions that may explain the high cost of pharmaceuticals to consumers can be identified among the several stages into which the Chilean distribution chain for pharmaceuticals is divided. One of the most notorious symptoms of these distortions is the important presence of branded-generics, i.e., drugs that have a laboratory or pharmacy brand associated with them and that cost substantially more than the non-branded generic version of the same drug. The other main issue in the Chilean pharmaceutical market is the high level of concentration in retail distribution, where three players control 95% of total pharmaceutical sales measured in value. Although there are important connections between these two problems, the distortions underlying them should be treated separately. As part of its advocacy efforts, the National Economic Prosecutor's Office (Fiscalía Nacional Económica, or FNE) has recently published a market study seeking to improve cooperation among health sector regulators in solving some of these issues[4].

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1 Together with Mexico and Korea. OECD (2013), *Health at a Glance 2013: OECD Indicators*, OECD Publishing, p. 141.

2 Cid Pedraza C, Prieto Toledo L. "El gasto de bolsillo en salud: el caso de Chile, 1997 y 2007", *Rev Panam. Salud Pública*, 2012; 31(4)310–16: "El componente principal del gasto de bolsillo de los hogares es el gasto en medicamentos con un 55% del gasto total de bolsillo en 2007, siendo proporcionalmente más importante en los quintiles más bajos" (*Ibíd*., pp. 312-313).

3 Considering the OECD average share of out-of-pocket medical spending in pharmaceuticals relative to total healthcare spending is 36,6% (OECD (2013), *Op. Cit.*, p. 141.)

4 FNE, "Estudio sobre los efectos de la bioequivalencia y la penetración de genéricos en el ámbito de la libre competencia", Available at: http://www.fne.gob.cl/wp-content/uploads/2013/09/estu_001_2013.pdf

2. Branded pharmaceuticals and distortions at the prescription stage

3. There are various ways in which pharmaceuticals may be classified based on the manner in which they are being developed and marketed. We find four different types of pharmaceuticals in the Chilean market:

- *Originators*: the laboratory that produces the pharmaceutical also owns the drug's patent(s).
- *Branded generics*: the laboratory that produces the pharmaceutical uses an expired patent owned by another laboratory. The producer markets the pharmaceutical under a commercial name different from the drug's international nonproprietary name (INN).
- *Pharmacy-branded generics or store (private) branded generics*: the pharmaceutical is produced by a third party and commercialized under a private label owned by the distributor. The third party is normally vertically integrated with the retailer through ownership, though there are cases of vertical integration by contract.
- *Generic drugs or non-branded generics*: the laboratory that produces the pharmaceutical uses an expired patent owned by another laboratory and markets the product under its INN.

4. In the last four years, the marketshare of non-branded generics has fallen steadily both in terms of volume as well as the quantity of the units sold (-14.6% between 2008 and 2012). At the same time, the number of units sold of originator pharmaceuticals, branded generics and pharmacy-branded drugs has increased, as has their market share in terms of volume. By 2012, branded generics had a 38.6% market share in terms of volume, and a 46.5% market share in terms of value, while non-branded generics accounted for 28.5% of the units sold and 5.3% of the pharmacies' income. Though pharmacy-branded generics still have a small market share (7% in terms of value and 12.3% in terms of volume), their sales volume has increased dramatically since 2008 (62.6% between 2008 and 2012) [5].

5. Changes in market share may be difficult to explain if differences in prices are considered. The Research Department of the Chilean Economics, Development and Tourism Ministry has estimated that while the average non-branded pharmaceutical costs about 562 Chilean pesos (approximately $1.1 USD), branded generics on average cost 6.5 times more, and pharmacy branded generics three times more[6]. This difference increases substantially for certain active ingredients, especially when considering pharmaceuticals used in the treatment of critical and chronic diseases[7]. Furthermore, there are no evident differences in quality that may explain these price differences or increases in market share. Unlike the regulatory standards that must be met in the United States and the EC, until very recently, Chilean generic pharmaceuticals did not have to prove bioequivalence to the originator in order to be sold, which means that Chilean generic products, whether branded or non-branded, could not assure interchangeability[8].

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5 Ministerio de Economía, División de Estudios (2013), *El mercado de medicamentos en Chile*, p. 9. Available at: http://www.economia.gob.cl/wp-content/uploads/2013/04/Boletin-Mercado-de-Medicamentos.pdf (This study considers only the retail market. All market shares may vary substantially if the public market –public hospitals– is considered, though there is no aggregated data currently available).

6 *Id.*

7 SERNAC (2013), Estudio comparativo de precios de Productos: Bioequivalentes v/s de Referencia, Área Metropolitana, Available at:: http://www.sernac.cl/comparacion-de-precios-de-productos-bioequivalentes-vs-de-referencia-area-metropolitana-marzo-2013/

8 In other words, Chilean generics must be classified as "multisource pharmaceutical products" according to the WHO: "*Multisource pharmaceutical products*: Pharmaceutically equivalent or pharmaceutically alternative products that may or may not be therapeutically equivalent. Multisource pharmaceutical

6. The lack of independently determined therapeutic equivalence between originators and generic drugs has given doctors a justification to oppose legislation or regulations compelling them to prescribe pharmaceuticals by their INN. Doctors in Chile tend to prescribe pharmaceuticals of a specific brand, which consumers cannot legally substitute at the point of sale. Although this practice may be motivated by reasonable doubts about the quality of generic pharmaceuticals, it also raises agency costs due to important economic incentives provided to doctors by laboratories, which distort the relationship between doctors and their patients. While giving economic incentives to doctors is illegal in Chile, this conduct has high detection costs and has been difficult to distinguish from legal promotional and informational activities realized by pharmaceutical producers. Nevertheless, even legal promotional efforts done by generic producers tend to influence doctors' brand sensibility and prescription patterns, artificially driving patients' consumption towards expensive branded pharmaceuticals with little or no quality justifications.

7. Recent legislative action in Congress and policies driven by the Chilean Ministry of Health are tending towards bioequivalence at the manufacturing level. Coupled with compulsory INN prescriptions, regulatory reform is seeking to guarantee full pharmaceutical interchangeability. This may substantially broaden consumer choice and channel competition towards prices instead of promotional efforts aimed at doctors.

8. As of December 19, 2013, 310 pharmaceutical products have been certified as bioequivalents in Chile. This broadens consumer choice since users can replace prescribed pharmaceuticals with bioequivalent products without the need to acquire a new prescription from their doctor. Also, a new Prescription Drugs Act (Ley de Fármacos) is being discussed in Congress, which aims to broaden competition by implementing a "must carry" list of bioequivalent products, among other improvements.

3. Branded pharmaceuticals and distortions at the retail stage

9. Although the practice is not lawful in Chile, substitution of the specific brand prescribed by the doctor at the point of sale is a common occurrence. Since the pharmacy has no obligation to keep a copy of the medical prescription except in certain cases, monitoring compliance with the prohibition is not feasible in practice. Though substitution may help consumers in gaining access to cheaper pharmaceuticals, this is not always the case, since pharmacy personnel are also subject to economic incentives by manufacturers for dispensing a higher number of units of particular brands.

10. Even in the absence of direct economic incentives by manufacturers, pharmacy personnel tend to prioritize dispensing store-branded generics that, while cheaper than regular branded generics, still cost considerably more than average non-branded generics. Notwithstanding legislative action aimed at controlling and prohibiting such economic incentives for pharmacy personnel, these regulations have been fraught with the usual limitations of "command and control" strategies (such as high monitoring costs and an increasing tendency to find ways to evade the prohibitions), due to the absence of any positive incentives encouraging the prescription of non-branded generics. Likewise, legislation authorizing supermarkets to sell pharmaceuticals has been discussed as a possible mechanism to reduce intermediation by pharmacy personnel and their influence on consumers' choice of OTC pharmaceuticals. Nevertheless, this proposal has not obtained sufficient support in Congress for it to be approved.

11. With respect to the high level of concentration in the retail distribution stage, three players (*Farmacias Ahumada S.A.* –FASA-, *Farmacias Cruz Verde S.A.* -Cruz Verde- and *Farmacias Salcobrand*

products that are therapeutically equivalent are interchangeable." OMS (2006), WHO Expert Committee on Specifications for Pharmaceutical Preparations, Fortieth Report, Annex 7: Multisource (generic) pharmaceutical products guidelines on registration requirements to establish interchangeability, WHO Technical Report Series N°937, Geneva, p. 351.

S.A. –Salcobrand-) control 95% of total pharmaceutical sales measured in value [9]. Due to vertical integration, market structure at the retail level partially mirrors the high level of concentration at the wholesale level of the market, where the same three players (according to the most recent public data (2006)) control 87% of the market[10]. While FASA and Salcobrand operate as closed wholesalers, meaning that they only sell pharmaceuticals to their vertically integrated counterparts, Cruz Verde's wholesaler SOCOFAR also sells pharmaceuticals to independent (non-integrated) pharmacies. If only the independent segment of the market is considered, SOCOFAR is by far the most important player at the wholesale level with a 70% market share[11].

12. Concentration at the wholesale level, coupled with the pervasiveness of bundled discounts established by manufacturers, gives the three main retail distributors an important competitive advantage *vis-à-vis* their non-integrated competitors and has therefore contributed in maintaining market concentration. Even taking into account that bundled discounts may mean lower prices for consumers, the existence of a relatively small number of players raises the risk of coordinated behavior in the market, an outcome that actually took place in 2008 (as discussed) in the following section.

4. Pharmacies cartel case

13. On December 9, 2008, the National Economic Prosecutor's Office filed a complaint with the Chilean Competition Tribunal (Tribunal de Defensa de la Libre Competencia, or TDLC) against FASA, Farmacias Cruz Verde and Farmacias Salcobrand for colluding on prices with the objective of ending a price war.

14. On March 23, 2009, one of the defendants, FASA, and the FNE reached a settlement agreement which was presented to the TDLC and approved on April 13, 2009. Under the terms of this settlement, FASA explicitly acknowledged certain conduct, and committed to provide relevant information that would establish the participation of the other pharmaceutical retail chains in the alleged collusion. FASA acknowledged its participation in the unlawful practices, and agreed to pay 1,350 Annual Tax Units (approximately US$1.2 million), in what was defined as the "*equivalent of a fine*". In exchange, the FNE agreed to exclude FASA from trial, and to continue its prosecution only against Salcobrand and Cruz Verde.

15. On January 31, 2012, the TDLC ruled unanimously against the defendants, imposing fines of 20,000 Annual Tax Units or UTA (approximately US$18.5 million) –the maximum applicable fine available under the law in force at the time of the events– on Farmacias Cruz Verde and on Farmacias Salcobrand for colluding in the market for distribution of pharmaceutical products. According to the decision, the existence of a collusive agreement between these drugstore chains and FASA to increase prices of at least 206 pharmaceutical drugs between December 2007 and March 2008 was proven beyond reasonable doubt, a higher standard of proof than the one needed in the TDLC. In each of the analyzed drug categories, the three drugstore chains had a combined market share between 70% and 99%.

16. The TDLC ruling established the existence of this illicit agreement on the basis of direct evidence, linking information contained in e-mails and statements from drugstore and pharmaceutical

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9 Ministerio de Economía, División de Estudios (2013), *Op. Cit.*, p. 4.

10 Resolución 16/2006 (TDLC), (*Consulta de la Fiscalía Nacional Económica sobre Contrato de Franquicia de Socofar S.A.*). This data underestimates concentration at the wholesale level since it does not include the merger between FASA and D&S (which at the time had a 3.8% market share at the wholesale level) nor does it consider the fact that the retail stage is slightly more concentrated now than it was in 2006 where the same three players had a 90% market share.

11 *Id.*

laboratory executives, with the information about final price movements for each of the drugs referenced in the complaint, and with information regarding the regular price quotes that each drugstore chain assesses in its competitors' stores, as part of their monitoring strategy.

17. The evidence established that Salcobrand communicated to the other chains, via the pharmaceutical laboratory executives, its willingness to be the first to increase prices for certain drugs, and the three drugstore chains coordinated the dates on which each would follow suit by means of increasing its prices. The prices were increased according to an established pattern, denominated "1-2-3", under which the first price increase was applied by one chain (almost always Salcobrand) on "day 1", followed by another chain on "day 2", and the third on "day 3".

18. It was proven that one of the chains would communicate the date of the price increase to the corresponding laboratory, so that it could be communicated in advance to the other two drugstore chains, and confirmation be given that they would follow the increase. Some e-mails from laboratory executives even confirmed that they would notify the chains whenever one of them had problems implementing the agreed upon price increase, and would inform them of new dates.

19. The TDLC also found evidence of unusual price monitoring by each pharmaceutical chain of its competitors that coincided with the price increases –the same day or the day before-, for several consecutive days, for almost all the drugs at issue. This pattern of conduct was much more intensive than the normal price monitoring the chains did before the price increases, in which they usually got price quotes from their competitors' stores every 7 or 15 days, and never for two days in a row. The TDLC concluded that these uncommon monitoring patterns could not be explained without the existence of a previous conspiracy, which allowed each chain to know what its competitors were going to do.

20. To determine the fine, the TDLC took into account: (i) the severity of the illicit conduct, with collusion being the most serious of those sanctioned by the Competition Act, (ii) the fact that, in this case, the agreement impacted pharmaceutical products, the majority of which were used to treat chronic diseases, and that the effects of the conduct were capable of extending to the complete range of pharmaceutical products distributed by the retail pharmacy chains, thereby harming those who require the products for treatment.

21. The extent of the damages caused by the conduct was particularly serious given (i) that it involved practically all the supply of the drugs, (ii) the significant number of consumers affected throughout the country, and (iii) the fact that the agreement would probably have been maintained for more time, and it would have extended to other drugs, had the FNE not initiated its investigation.

22. The TDLC also took into account the economic benefits obtained by the drugstore chains from this unlawful agreement. Even though they had engaged in a price war, the price coordination allowed them to increase prices earlier than they otherwise would have done and thus avoid the costs of having ended the price war independently.

23. The fact that Cruz Verde and Salcobrand's legal predecessors –Comercial Salco S.A. and Farmacias Brand S.A.– had been found guilty of similar conduct in 1995 by the Comisión Resolutiva (legal predecessor of the TDLC), was not taken into account for determining the fine, given the time that had passed since the decision and the fact that that had been the last decision against them in this venue[12].

[12] The other requests of the FNE were denied. They were related to the existence of a contract between Salcobrand and Socofar S.A. (related to Cruz Verde), other possible acts or contracts between drugstore chains, and to the alleged participation of executives of one chain in the ownership and administration of other chain. These requests were denied because neither the alleged facts or conduct, nor their link to the illicit conduct that was established and sanctioned, had been demonstrated.