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### COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

#### Contribution from Peru

-- Session III --

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## COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

-- Peru --

### 1. The Pharmaceutical Industry in Peru: A General Overview from the Competition Authority<sup>†</sup>

1. According to the Minister of Health between 2002 and 2012, pharmaceutical consumption in the country has doubled in terms of volume.<sup>1</sup> The Peruvian pharmaceutical market includes a large number of relevant agents. To begin with, wholesalers can be either international laboratories, both manufacturing and importing pharmaceutical products, or national medicine developers and independent importers. Secondly, patients access prescription medicines through a variety of channels. Privately insured patients may access therapies directly from private hospitals and medical centers.<sup>2</sup>

2. Public hospitals, primary health centers and specialized institutions (e.g. National Institute of Cancer Diseases<sup>3</sup>) usually buy pharmaceutical stocks through public tenders organized by the National Social Security System (EsSalud) and the Integral Health System (SIS), providing primary and specialized coverage for health services. Patients covered by EsSalud and the SIS are typically public servants and low and medium skilled workers.

3. Finally, on a general basis, patients have access to prescription drugs at independent drugstores and retail drugstore chains. Privately insured consumers can request the insurer to cover ex-post a fraction of the bill depending on their coverage. According to national figures as of August 2013, 65,8% of the population has some type of insurance. The same information reports that 5,7% of the population has private insurance, including individuals with more than one insurer.<sup>4</sup>

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<sup>†</sup> Written contribution prepared for the 2014 Global Competition Forum organized by the Competition Division of the OECD, by Javier Coronado, Chief Economist at Indecopi and Jesús Espinoza Technical Secretariat of the Defense of Free Competition Commission at Indecopi. Comments are welcomed at: [jcoronado@indecopi.gob.pe](mailto:jcoronado@indecopi.gob.pe). The authors would like to acknowledge the collaboration of Ms. Maruja Crisante, official of the Director General for Medicine and Drugs of the Peruvian Minister of Health who kindly answered a short questionnaire on specific regulatory issues regarding the treatment of generic products in the country as well as on other institutional arrangements.

*Disclaimer: The views expressed in this contribution are those of the authors and not necessarily represent the institutional position on the diversity of matters under discussion.*

<sup>1</sup> Conference document by Dr. Maruja Crisante, (2012) *Mercado Farmacéutico y Acceso a Medicamentos en el Perú*, Director General for Medicine and Drugs.

<sup>2</sup> In its turn, private hospitals and medical centers can be associated through vertical relations with Private Health Providers (EPS) and Insurance Companies (See Section 2).

<sup>3</sup> Instituto Nacional de Enfermedades Neoplásicas (INEN) is an specialized public entity that provides treatments and research on oncologic diseases.

<sup>4</sup> Instituto Nacional de Estadísticas e Informática (2013) *Boletín de Condiciones de Vida en el Perú*, N° 4, December. The figure of 5,7% include special public insurance coverage for personnel from the Army. This information is available at: <http://www.inei.gob.pe/media/MenuRecursivo/boletines/condiciones-de-vida-jul-set-2013.pdf>

4. This paper aims to describe recent trends in the market in Peru emphasizing recent development that have particular interest in the views of the competition authority.

## 2. Brief description of recent developments

### 2.1 General Overview

5. According to information from the Minister of Health<sup>5</sup>, specifically from the The Director General for Medicines and Drugs (DIGEMID) — national authority that grants *Sanitary Registers* to commercialize pharmaceutical products— between 2002 and 2012, pharmaceutical consumption in the country has doubled in terms of volume. Although consumption through public health institutions accounted for almost 44% of the units consumed in 2012, in terms of monetary values it represented less than 30% of the demand. On the other hand, independent drugstores and retail chains distributed around 48% of the units consumed in 2012, whereas their weight in terms of monetary values was of 60,7%.

6. Long run figures indicate that private retail channels distributed 17% more units in 2012 with respect to 1995, whereas the distribution through public health institutions was 6,7 times larger in 2012 than in 1995.

7. The notorious grow in overall consumption of pharmaceutical product is therefore explained mainly by the actions of the public health providers, although the total costs of such consumption is more related to the specific consumption through the retail channel.

8. The retail sector has changed remarkably in the last decades. It is interesting to notice that in the 90s the number of drugstores was of about 3 335 around the country, whereas nowadays this number exceeds the 24 600. Today, in fact, drugstores are ubiquitous along the Peruvian geography. That said, in the mid 90's the share of the business of independent drugstores was of around 86%, whereas in 2011 almost 60% of the business was retained by retail chains. This means that both the scale of the wholesale market has increased and the downstream branch of the industry has concentrated in nationwide retail chains.

9. Both recent trends in the retail sector and the public financing of pharmaceutical consumption are part of Indecopi's research and market consultations. In particular in Section 3, albeit confidential issues, we informed on a recent enquiry opened by the Competition Commission at Indecopi to investigate the retail distribution of pharmaceutical products.

### 2.2 Private Health Services: Vertical relations

10. Around 7% of the volume of pharmaceutical products is distributed through private hospitals. A recent ex-officio analysis by the Competition Commission at Indecopi revealed a trend in the market of health services by which Private Health Providers (specialized private contributive funds financing private health services) and traditional Insurance Companies are vertically integrated with historically independent private hospitals.

11. In today's market, EPS services are concentrated in four main players, with two of them with a combined share of more than 80% of the business. Therefore, the role of new commercial relations are also an important worry for Indecopi, which is currently immerse in developing a Market Consultation to better grasp the potential consequences of the more sophisticated relations between insurers in the upstream and private hospitals in the downstream.

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<sup>5</sup> Dr. Maruja Crisante, op. cit.

12. Although the share of consumers affected by potential miss-conduct by private hospitals in the market for pharmaceutical products is currently relatively of low significance, it is expected that the number of privately insured consumers will continue to increase in the short run.

### 2.3 *Trends in Generic Consumption and Competition*

13. Generic pharmaceutical products, commercialized under the International Nonproprietary Name (INN), are a key element for improving competition and increasing consumers' access to effective pharmaceutical products. In fact, under the Health Act of 1997, General Practitioners and other medical specialists should always prescribe a generic product when possible. Moreover, drugstores should also inform the customer of the availability of a generic variety of the requested therapy.

14. Those regulations seem to be more effective in the case of public primary centers and to a lesser extent in public hospitals. Likewise, although there is no public information on the matter, it is speculated that private practitioners are less prone to follow the rule.

15. According to DIGEMID public information<sup>6</sup>, through 2011 the volumes of generic pharmaceutical products through the retail private channel have been always below those of brand-name pharmaceuticals. In some periods, brand-name units sold have doubled those of generic products.

16. Trends also confirm that the so called *similar* products, which have the same pharmacological effects as the original counterparts but are not commercialized under the INN, are by far the most consumed through retail channels under non-proprietary brands.

17. By 2011 the value of the retail distribution of pharmaceutical products was explained very closely by sales of brand-name products and *similar* products, whereas the value of generic products explained a very low fraction of total retail sales.

18. This raw evidence suggests that there exists room for more generic competition for off patent products in the retail sector and possibly some role for parallel imports and compulsory licensing.

19. Parallel imports and compulsory licensing are a potential source for competition and might apply for the Peruvian case based on the exceptions agreed in the Trade Related Aspects of Intellectual Property Rights (TRIPS) in the Uruguay Round-Tables.<sup>7</sup>

20. Although it seems more feasible to take advantage of parallel imports in Peru for promoting price competition in the market rather than compulsory licensing, there are no specific National regulations to implement such measures and no studies have been conducted to identify potential pitfalls. For example, there is no evidence that can be used to determine whether parallel imports will have clear short run allocative efficiencies with little dynamic distortions in terms of the profitability of potential entrants.

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<sup>6</sup> Dr. Maruja Crisante, op. cit.

<sup>7</sup> See more developments of the TRIPS in Correa, C. 2002, *Repercusiones de la declaración de Doha relativa al acuerdo sobre los ADPIC y la salud pública*, World Health Organization, Health Economics and Medicines EDM Series N° 12.

### 3. Current Actions by Indecopi

#### 3.1 Bureaucratic Barriers to Entry and Regulation

21. As part of the competition advocacy activities in which Indecopi is committed, in March 2013, the Office of the Chief Economist issued a comprehensive study<sup>8</sup> examining 11 bureaucratic procedures required by the Ministry of Health for the introduction and commercialization of pharmaceutical products.<sup>9</sup>

22. The main issue found in the analysis, based on the perceptions of the companies, is that currently the bureaucratic procedures are not consistent with recent changes in the legal framework (Law N° 29459, fo 2009, and the Supreme Decrees N° 014-2011-SA and N° 016-2011-SA, respectively), seemingly increasing the discretion on DIGEMID's procedures which may delay the launch of new varieties in the national market.

23. According to data provided by wholesalers and validated by the economic team at Indecopi, each procedure can cost up to USD 13 433 per product.<sup>10</sup> This cost does not include the opportunity cost of the time elapsed between the date at which a company initiated the procedure to obtain the sanitary register and the effective grant of such register. Although the monetary value might not seem sizeable, especially for large international laboratories, it might in fact become an important legal barrier for generic importers and producers in the country.

24. Pharmaceutical products are not subject to price regulation in Peru. However, the National Congress is currently discussing several bills which seek to create an independent regulator to impose price restrictions.<sup>11</sup> Indecopi has consistently deliver opinions against the introduction of price controls even for cases in which products are commercialized upon a monopolistic position due to patent protection.

25. It has been recognized in international research works that most of the designs of price regulations of pharmaceutical products aim at reducing the burden of financing medicine consumption over the public budgets.<sup>12</sup> Even recent developments such as Reference Price regulation, which requires the existence of a generic or close substitute therapy as pivotal, are not proven to be effective both in reducing the cost of medicine consumption and might, on the contrary, distort entry decisions having undesirable welfare impacts.<sup>13</sup>

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<sup>8</sup> This advocacy was conducted in coordination with the Chamber of Commerce at Lima (CCL), specifically with private representatives of its Health Committee. The results are public and can be consulted at: <http://www.indecopi.gob.pe/repositorioaps/0/0/jer/publicacionesqs/ObservatorioMercados-2013.pdf>

<sup>9</sup> Indecopi is in a unique position to promote the reduction of legal and bureaucratic barriers in the markets. The Commission for the Elimination of Bureaucratic Barriers (CEB) at Indecopi has the mandate to act through proactive actions to identify illegal and/or irrational bureaucratic barriers, sanction both public officials and institutions when it verifies the illegal bureaucratic procedures or procedures that not met some rationality standard.

<sup>10</sup> This is the equivalent to S/. 35 430 in local currency at an exchange rate of 2,638 USD/S/. which is the average banking monthly exchange rate published by the Peruvian Central Bank (BCRP) for 2012.

<sup>11</sup> Project Law 2102/2012-CR, which declares of public interest the creation of a national regulator to design, apply and supervise price controls for pharmaceutical products.

<sup>12</sup> For instance, Puig-Junoy, J. 2005, *Price regulation systems in the pharmaceutical market*, in J. Puig-Junoy (ed.), *The Public Financing of Pharmaceuticals*, Edgard Elward Publishing.

<sup>13</sup> See for instance Danzon, P. and Chao, L.: 2000, *Does regulation drive out competition in pharmaceutical markets?*, *Journal of Law and Economics*, 43, 311-357.

26. Along this line, Indecopi has formally advised the National Congress that the short run gains of price controls, in terms of increasing access for low income families, could have dynamic consequences in the long run, distorting entry decisions even for generic producers. The National Congress initiatives have not proven that the short run social benefits are expected to be large enough to compensate for potential distortions in, for example, reducing incentives for local developers or the launch of innovative drugs in the local market.

27. The competition authority has advocated to defend three lines of action in the market: i) Reductions of barriers to entry, especially those related to bureaucratic procedures (See previous paragraphs), ii) Increasing the efficiency of public procurement of essential pharmaceutical products (See Section 3.4) and iii) Promoting rules for increasing the penetration of generic products.<sup>14</sup>

### **3.2 Competition Commission's Current Investigations**

28. The Technical Secretariat of the Defense of Free Competition Commission at INDECOPI has initiated an administrative proceeding against seven pharmaceutical retailers for the alleged price fixing of seventy six pharmaceutical products (such as dietary supplements, analgesics and antibiotics) across the Peruvian territory.

29. It should be noticed that this conduct is prohibited under articles 1 and 11 of Legislative Decree 1034, the Repression of Anticompetitive Conducts Act.

30. Due to restrictions set forth in article 31 of the aforementioned Legislative Decree 1034, regarding access to the current status of a proceeding (which is granted only to the defendant, the complainant and third parties with legitimate interest), the Technical Secretariat cannot give any further information about this proceeding.

### **3.3 Impact Evaluation of a Public Policy Regarding Tax Waivers for Pharmaceutical Products**

31. In 2001 the Peruvian National Congress passed the Law N° 27450 by which oncologic drugs are not affected by the 18% rate of the Value Added Tax (IGV) and between 9% and 12% of the import tariffs. In 2011 the national government created a multi-sectorial team whose members are the Minister of Health, the National Tax Agency (Sunat), the Minister of Economics and Finance (MEF) and Indecopi, so as to evaluate the impact of such measure over wholesale prices for oncologic drugs. The Office of the Chief Economist at Indecopi is in charge of the analysis of the evolution of the cost of public procurement of oncologic products.

32. Based on information from EsSalud from 2000 to 2012, the office of the chief economist at Indecopi reported that these policies have reduced prices in the short run in a wide range between 15,12% and 24,33%. Notwithstanding, the analysis of prices also concluded that the figures for long run price reductions, spanning a period between 2002-2012, accounted for up to 40,34%. It was observed that such reduction was mainly due to the dynamics of public tenders in EsSalud's procurements of oncologic products. The main causal effect identified for the long term fall in the cost of oncologic products was the competitive bid of an entrant provider that won EsSalud's contract.

33. The role for competition in public procurement of pharmaceutical products is fundamental for the reduction of contributive and non-contributive public health insurance costs in the country. Indecopi follows very closely the developments of recent pooled public tenders as described in the next Section 3.4.

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<sup>14</sup> See the public report, *Informe 017-2013/ST-CLC-INDECOPI* in: [http://www.indecopi.gob.pe/0/modulos/JER/JER\\_Interna.aspx?ARE=0&PFL=0&JER=1466](http://www.indecopi.gob.pe/0/modulos/JER/JER_Interna.aspx?ARE=0&PFL=0&JER=1466)

### 3.4 *Pooling Public Tenders for Enhanced Competitive Bids*

34. Since 2003, the Minister of Health, EsSalud and other public health financing institutions have engaged in pooling public tenders for the procurement of pharmaceutical products to profit from better economic conditions based on larger volumes for a number of essential medicines.

35. In 2008 the National Government created a multi-sectorial commission to, among other sectorial issues, analyze the results of the recent pooled public tenders. According to the official information, in 2006 one of the biggest pooled public tender to buy essential medicines included the Minister of Health (including 6 850 medical centers at the national level), EsSalud and most of the health service providers from the Army. The pooled public tender involved 165 essential medicines resulting in cost reductions of about 21% with respect to previous individual procurement processes.

36. In 2008 for the first time the pooled public tender of essential pharmaceuticals included a whole set of essential products from all the public service providers. In that occasion it was possible to save costs in relative terms in almost 30% with respect to previous individual procurement processes for 163 essential medicines.

37. So far these pooled public tenders have been implemented through *reversed* auctions. The winner bid in 2008 was around 11% below the reference value required for the process.

38. Indecopi is aware of the importance of continuing the process and works to prevent distortions. To this aim, in 2014 the Competition Commission together with Office of the Chief Economist will deliver a manual to public procurement design so as to prevent anticompetitive conducts in auctions and bids.