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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

Contribution from Mexico

-- Session III --

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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

-- Mexico [*] --

1. Introduction

1. This paper describes and analyzes distribution of medicines in Mexico and identifies possible competition concerns derived from regulation, market structure or market participants' conduct.

2. Medicines distribution systems in Mexico in recent years reflect important changes in the wholesale and retail (through pharmacies) distribution.

3. In wholesale distribution, market shares of main distributors have declined from about 80 % in 2009 to about 60 % in 2012. The latter due to an increased participation of regional distributors. In retail distribution there has been growth in pharmacy chains, accompanied by access of new players, in particular from supermarkets developing off-site pharmacies or acquiring existing pharmacy chains.

2. Present situation of the pharmaceutical sector

2.1 Market value

4. Sales of the pharmaceutical sector remained stable in real terms between 2005 and 2006, and managed to grow 5% in 2007. However, between 2008 and 2011 the national production sector fell and had a slight recovery in 2012. In nominal terms, the value of sales grew from 2005 to 2009, and began falling until 2012, when sales reached 98 thousand 896 million pesos. (See Table 1).

[*] Contribution submitted by the Mexican Federal Economic Competition Commission.

Table 1. Market value per source, 2005-2013

Source	2005	2006	2007	2008	2009	2010	2011	2012	2013/p
Sales Value (Millions of pesos October 2013 prices)[/1 /2]									
Value	*127,521*	*125,861*	132,066	123,656	117,210	112,022	95,350	99,301	82,965
Annual Growth (%)		-1%	5%	-6%	-5%	-4%	-15%	4%	
Apparent domestic consumption (Millions of pesos October 2013 prices) [/3]									
Value	*157,587*	*166,757*	176,233	178,187	176,941	160,349	140,827	147,517	129,547
Annual Growth (%)		6%	6%	1.1%	-0.7%	-9%	-12%	5%	
Sales Value (Millions of pesos)									
Value	*84,786*	*88,707*	97,766	99,410	99,247	99,285	89,938	98,896	82,706
Annual Growth (%)		5%	10%	2%	-0.2%	0.0%	-9%	10%	
Apparent domestic consumption (Millions of pesos)									
Value	*104,774*	*117,552*	130,465	143,277	149,764	142,078	132,798	146,904	129,138
Annual Growth (%)		12%	11%	10%	4.5%	-5.1%	-7%	11%	

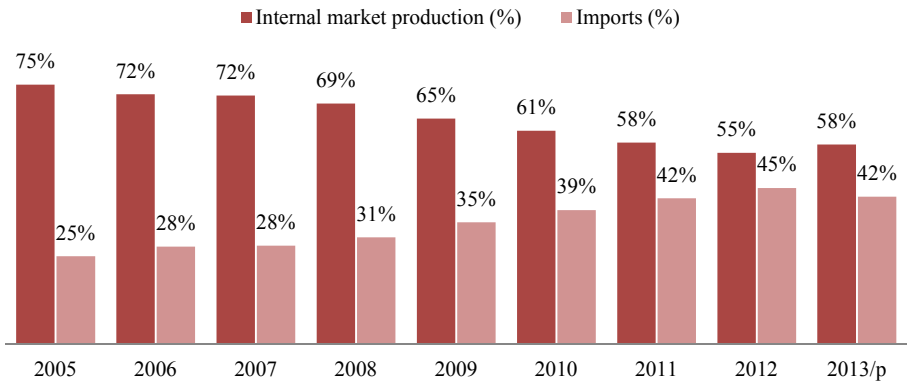
Notes: / p Figures as of October 2013.

1 / Price deflation was performed considering the National Producer Price Index, based on October 2013 prices.
2 / Sales value of products include activity types: 325411 "Manufacture of raw materials for the pharmaceutical industry" and 325412 "Manufacture of pharmaceutical preparations " excluding veterinary medicines, reported in the Monthly Industrial Extended Survey (EIMA) for the years 2005 to 2006 and the Monthly Survey of the Manufacturing Industry (EMIM) of INEGI for the years 2007-2013.
3 / Estimated as the value of production activity class 325412 "Manufacture of pharmaceutical preparations " (excluding veterinary products), plus imports and minus exports as reported in the Foreign Trade Statistics, Chapter 30 " Pharmaceuticals" of the National Institute of Statistics, Geography and Data Systems, INEGI (www.inegi.org.mx) according the Harmonized Commodity Description and Coding System..
Source: Own calculations based on INEGI and the "Proposal of policy for the pharmaceutical sector " by FUNSALUD AC 2011

2.2 Apparent domestic consumption

5. Moreover, apparent domestic consumption rose in real terms until 2008 reaching 178 million 187 thousand pesos. Since 2009, a significant decrease directly affected domestic production until 2012 when a recovery in growth is observed. However, domestic production continued to decline. It appears that production for domestic consumption has been losing share at a rapid pace, from 75% in 2006 to 55% in 2012, while imports have gained more participation going from 25% in 2005 to 45% in 2012. (See Figure 1)

Figure 1. Apparent domestic consumption[1] (Percentage)



Note: 1/ Apparent domestic consumption is the value of goods available in a country for consumption, and it is calculated as domestic production plus imports minus exports. It comprises the value of production by type of activity and product minus the value of exports of Chapter 30 "Pharmaceuticals Products" in the Harmonized Commodity Description and Coding System according to the trade statistics of INEGI. The latter as a proportion of the total value obtained from apparent domestic consumption in Table 1. Likewise, the percentage of imports corresponds to the value of imports of Chapter 30 "Pharmaceutical Products", as a proportion of the total value of Apparent Domestic Consumption. 2013 data are available until October 2013.
Source: Own calculations based on data from INEGI, 2014

2.3 Production

6. According to the Monthly Survey of the Manufacturing Industry (EMIM for its acronym in Spanish) production volume decreased by 31% between 2007 and 2012, from 3 thousand 505 million pieces in 2007 to 2 thousand 507 million in 2012. As a result of the international crisis that affected Mexico in 2009, there is an important decline in the volume of pieces produced and their sales in 2010 (-7 % and -6 %, respectively), as well as a decrease in employed personnel and the number of establishments (-3 % and -7 % respectively).

7. Also, as seen in Table 2, in 2012 the decline persisted in the volume of pieces produced in 2012 (-16%)[1] and sales volume (-14 %), which had a direct impact on the employment levels which fell to 47,905 people, as well as in the number of establishments, which went from 128 in 2007 to 116 in 2012.

8. Production is carried out jointly by laboratories that manufacture medicines and companies that are responsible for producing raw materials. The former, according to data from the National Chamber of the Pharmaceutical Industry (CANIFARMA for its acronym in Spanish), representing 93 % of the sector at the national level, while the second, representing only 7%.

Table 2[2]. Main characteristics of the market, 2007-2013

Source[1]	2007	2008	2009	2010	2011	2012	2013/p
Production volume							
Thousands of pieces	3,505,097	3,484,772	3,398,698	3,144,277	2,992,167	2,507,441	2,036,209
Annual Growth (%)		-1%	-2%	-7%	-5%	-16%	
Volume of Sales							
Thousands of pieces	3,429,822	3,313,522	3,168,171	2,968,321	2,780,499	2,385,694	1,887,014
Annual Growth (%)		-3%	-4%	-6%	-6%	-14%	
Occupied personnel							
People	51,603	52,452	51,128	49,454	48,922	47,905	44,733
Annual Growth (%)		2%	-3%	-3%	-1%	-2%	
Number of establishments							
Establishments	128	125	126	117	115	116	
Annual Growth (%)		-2%	1%	-7%	-2%	1%	

1 / In the case of volume of production and sales, the volume considered is the Monthly Survey of Manufacturing Industry and only includes details of the activity type 325412. For persons employed and Number of Establishments, it was not possible to exclude the number of establishments and related veterinary medicines within "325412 Manufacture of pharmaceutical preparations". Also, in the case of establishments, no data are available yet for 2013.

Source: Own calculations based on INEGI 2014 .

2.4 Foreign trade

9. As mentioned above, imports have increased in importance in apparent domestic consumption. This could have been a factor for a decrease of some domestic production in some pharmaceutical markets. Thus, in real terms, between 2005 and 2012 medicine imports grew 65.25%. In turn, exports only increased by 20% in real terms. Therefore, the trade deficit rose from 19 thousand 291 million pesos in 2007 to 41 thousand to 141 million pesos in 2012. (See Table 3).

1 According to the study "Descripción del sector farmacéutico en México 2012" by FUNSALUD, the estimation of the size for the total market is 3,151 millones packs y 199,020 millones of pesos up to December 2012.

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Table 3. Trade balance: exports and imports, 2005-2013 (Million of pesos de 2013[1)])

Type	2005	2006	2007	2008	2009	2010	2011	2012	2013/p	Annual Growth 2005-2012
Exports	20,606	18,943	19,423	17,955	20,205	20,787	23,334	24,790	18,676	20.31
Imports	39,897	46,751	50,072	55,941	61,801	61,667	59,680	65,930	55,085	65.25
Trade balance	-19,291	-27,809	-30,650	-37,986	-41,597	-40,879	-36,346	-41,141	-36,409	-88.73

Notes: / p Figures as of October 2013.

1The values were obtained from the Foreign Trade Statistics and include only tariff item of pharmaceutical products (Chapter 30 in the Harmonized Commodity Description and Coding System according to the trade statistics of INEGI). The values are monthly thousands of dollars from January 2005 until October 2013. The FIX Exchange rate for Pesos per U.S. dollar (FIX) estimated by the Bank of Mexico was used. After obtaining the value in thousands of Mexican pesos, each monthly value is deflated using the producer price index. Finally, an annual estimation was obtained considering the sum of the monthly values.

Source: Own calculations based on data from INEGI, 2014.

10. Moreover, the origin of imported pharmaceuticals is concentrated in the United States of America, which accounts for 74% of the value of imports, followed by Brazil with 23%, Germany 0.5% and China 0.3%, the rest is divided into different origins. The share in the value of imports from these countries is not proportional to their share in terms of volume, because while countries like Brazil and China, increase their volume share, the United States and Germany exported a smaller volume of products with higher added value, increasing their share in terms of value.[3]

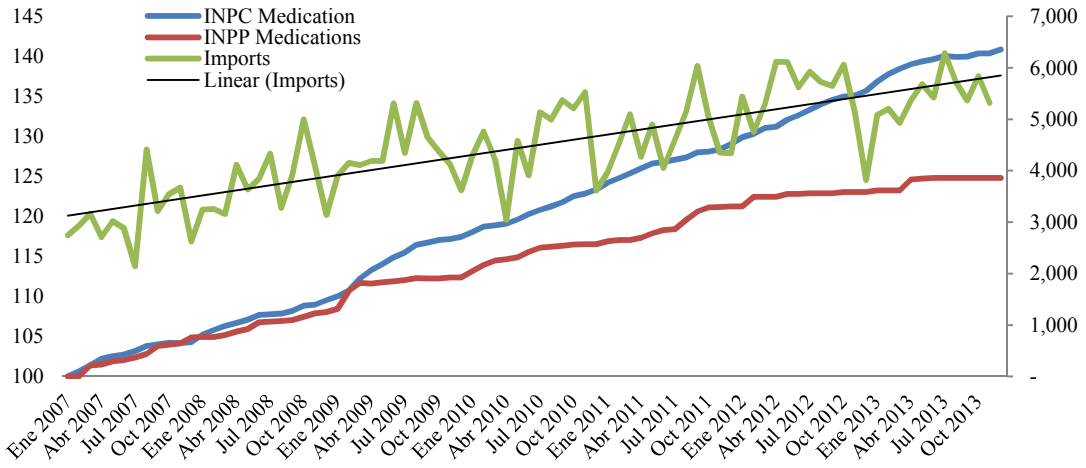
2.5 Producer and consumer price indexes

11. From January 2007 to February 2009, the national index of producer prices (INPP for its acronym in Spanish) for medicines had a similar growth to that of the index of the national consumer price index for medicines (INPC for its acronym in Spanish). However, from March 2009, consumer prices began to grow at a faster rate than producer prices.[4]

[3] Information obtained from the Commercial Information System Via Internet (SIAVI for its acronym in Spanish). Ministry of Economy.

[4] Since the enactment of the Cental Bank's Statistical and Geographic Information Law, the Central Bank and INEGI participated in a series of activities aimed at the transfer of national price indexes so that consistency is maintained. According to the Methodological Note on Sample Design of the National Producer Price Index 2012, INEGI considers the change in prices of a fixed basket of goods and services representative of the domestic industry. Unlike the National Index of Consumer Prices , which according to the Methodological Document (INPC for its acronym in Spanish) INEGI , the fixed basket of goods and services reflect the consumption pattern of the average home, so there is no difference whether it is produced domestically or imported . Therefore, the sample of goods covered by the two indices is different as an important component of the supply of medicines consists of imports and the price of these is not covered by the INPP.

Figure 2. National index of suppliers' prices of medicines and National index of consumers' prices based on January 2007[1]



[1]/ National Index of suppliers' prices of medicines (INPP) was calculated using the weights of the INPP general price for aggregate classes, 3274 Gastrointestinal Products, Nutritional Products 3275, 3276 Dermatological Products, 3277 Expectorants and decongestants, Antibiotics 3279 products, Cardiovascular products 3280, 3282 Anti-flu Products and Analgesics, and other medicines 3283. This derived from the lack of specific information for the sector.

Source: Own calculations based on data from INEGI, 2013.

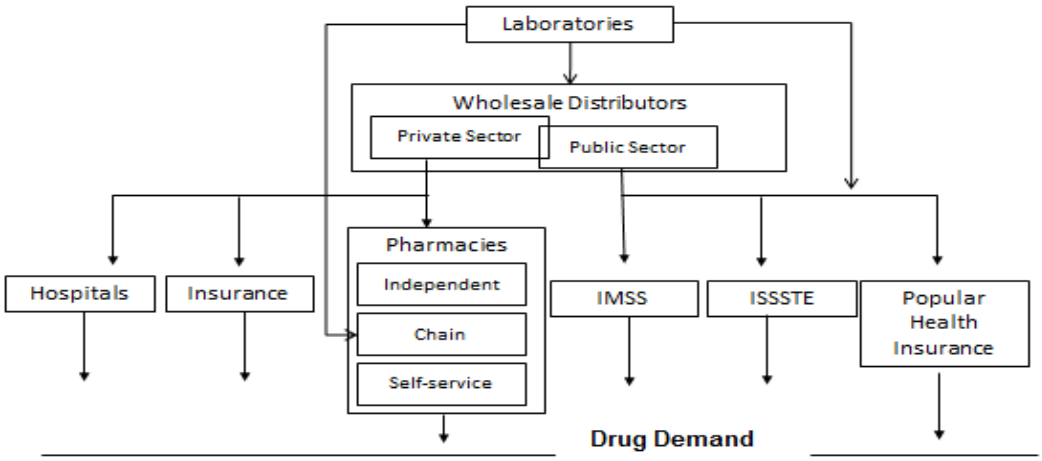
12. In the specific case of the public sector, medicines are bought through auctions called by: the Mexican Social Security Institute (IMSS for its acronym in Spanish), the Institute for Social Security and Services for State Workers (ISSSTE for its acronym in Spanish) and health institutions belonging to State Own Enterprises (SOEs) and the Popular Health Insurance. This sector reported a drop of 11% in prices of medicines from 2007 to 2009, according to information from the Institute of Pharmaceutical Research and Innovation, which made this calculation based on the Price Index of the Basic Medicines' Package (IPCBM for its acronym in Spanish)[5].

3. Description of the structure of the distribution systems and the supply chain

13. The value chain for the supply of medicines nationwide involves three stages: production, distribution and retailing (See Diagram 1).Demand in the pharmaceutical market comprises two segments: the public and private sectors. The public sector includes medicine purchases of social security institutions (IMSS and ISSSTE, etc.), and the federal government and state governments (National Institutes of Health, other federal hospitals and Popular Health Insurance). Households, hospitals and private insurance conform the demand in the private sector. Demand segmentation in turn, reflects the partial coverage of medical insurance in Mexico.

[5] IIIFAC (2009).

Diagram 1. Value chain for the supply of medicines in México



Source: Own research, 2014

3.1 Traditional distribution system

14. After laboratories produce medicines, distribution channels that allow products to reach the private and public sector demand are needed. Unlike other industries, where the same producer owns its distribution network, in the case of Mexico, the supply of medicines is done by a group of wholesalers that are responsible for the distribution process (purchase - storage – transportation - sale) and logistics. These wholesalers offer credit and collection of due payments, which allow them to finance their customers' inventory.

15. Aside from the distribution of domestic medicine production, distributors are engaged in the distribution of imported medicines. Under this system, the number of transactions between producers and retailers is reduced, and a concentrated structure of distribution of medicines translates into lower costs due to the high scale of operation. According to FUNSALUD information for 2012[6], Nacional de Drogas (NADRO), Casa Saba, Casa Marzam and Fármacos Nacionales, concentrated 58% of the distribution market. Followed by Proveedoras de Medicamentos and Almacenes de Drogas, the rest of the market is composed by 33 firms with regional participation. Meanwhile, government distributors are: Fármacos Especializados, Distribuidora Internacional de Medicamentos y Equipo Médico, Farmacéuticos Maypo, Savi and Comercializadora de Productos Institucionales, among others.

3.2 New players: pharmacy chains and supermarkets

16. In the retail segment there is an important number of pharmacies, which can be independent (popular), or belong to chainstores, supermarkets and government health institutes and are distributed throughout the country. In the past ten years, there has been consolidation of several pharmacy chains nationwide and at the regional level, as well as of supermarket pharmacies.

17. According to FUNSALUD (2013), currently 55.4 % of total sales in the private sector correspond to pharmacy chains, 16.8% pharmacy stores, 21.8% to independent pharmacies and other pharmacies that sell generic brands. In turn, public institutions have their own pharmacies dispensing free medicines to beneficiaries either within or outside hospitals and with the only requirement for a prescription in order to obtain the product.

6 See FUNSALUD (2013).

18. The growth of pharmacy chains and the increasing interest of supermarket chains to expand the sale of pharmaceutical products is largely explained by the expanding market of generic products, derived from patent expiration and a more flexible regulation in Mexico for their production, import and marketing[7]. This has reduced prices and thereby the cost of inventories needed to reach the final consumer. The interest of supermarkets, is explained not only by their ability to negotiate favorable price terms but by the gains from economies of scope.

3.3 Vertical integration of distributors and pharmacy chains: Casa Saba and Farmacias Benavides merger[8]

19. In 2010, the Mexican Federal Competition Commission (CFC, now extinct and substituted by the Mexican Federal Economic Competition Commission or COFECE for its acronym in Spanish) received a notification of a transaction that led to the vertical integration of Casa Saba, operating in the market for wholesale distribution of pharmaceutical products, and the pharmacy chain Farmacias Ahumada Benavides. In this transaction the Commission analyzed the likelihood of discrimination problems in the supply of product to downstream pharmacy competitors by the new vertically integrated operator. The relevant markets for the distribution of pharmaceutical products were defined as regional markets.

20. In addition, in the 26 August decision of the CFC it was established that: "…although Casa Saba has a nationwide coverage distribution of pharmaceutical products, it is considered that the geographic dimension of this market is regional and that once wholesale distributors receive the products in their collection centers they are responsible for distributing them to the various localities within their range of influence."

21. Related to the above the CFC estimated the market shares of the wholesalers in the regional markets and established that Casa Saba did not have substantial market power to set prices in the regions where it operated, therefore in its public decision "*the Commission concluded that the transaction does not create a situation of significant concentration in the retail market of pharmaceutical products in the various regions in which the parties coincide. Also, no elements were found that lead to assume that the presence of Casa Saba in the market of pharmaceutical product distribution could lead to anti-competitive behavior or restrictions to competition."*

22. According to the above, vertical integration can be explained in terms of the interest of the wholesaler to ensure downstream markets to compete more effectively with pharmacy chains.[9]

3.4 Upstream and downstream exclusivity between manufacturers, pharmacies, wholesalers, pharmacy chains and supermarkets

3.4.1 Upstream exclusivity

23. With respect to exclusivity contracts between wholesalers and laboratories, these are not considered to be the norm prevailing in the wholesale market. Since the shares of the four largest distributors are similar, in principle it might not be convenient for laboratories to celebrate exclusivity contracts. (See Section C)

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7 See Section II, Regulation of the supply chain and its effect on competition.

8 File CNT-030-2010, available at: http://www.cfc.gob.mx:8080/cfcresoluciones/Docs/Concentraciones/V343/604/1330300.pdf#search= saba

9 Casa Saba left the Mexican Stock Exchange in May 2013. It sought partnerships to maintain its business; however, it sold the assets of its distribution and wholesale division to two United States Investment Funds.

3.4.2 Downstream exclusivity

24. The supply chain system of pharmacies described above indicates that there is no exclusivity between wholesalers and pharmacy chains. Further, chains have access to online systems that allow them to choose the wholesaler that offers the best supply and price conditions. Furthermore, the formation of pharmacy chains described in the next section indicates the strengthening of their purchasing power, their lack of dependence on wholesalers, and their ability to directly purchase medicines from laboratories.

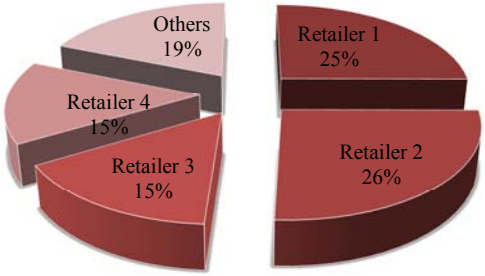
4. Market shares in the supply chain

4.1 Wholesale distribution market[10]

4.1.1 Private sector

25. In 2009 between 80% and 90% of the final sales in the private sector were made through wholesalers and the remaining sales were direct sales from manufacturers to several pharmacy chains, according to the Federal Commission for Protection against Health Risks (COFEPRIS for its acronym in Spanish) and FUNSALUD[11]. (See Figure 3).

Figure 3. Participation by distributor in wholesale in 2009



Source: Elaborated with reserved information COFECE'S CNT-030-2010.

26. In 2012, four firms dominated the wholesale market but their market share dropped to 58% while the rest of the market comprised smaller local companies with expertise at the regional level that have grown significantly in recent years, from 12 in 2009 to 33 in 2012.[12]

27. This could be the result of a gradual change in the medicine distribution system, generated by large pharmacy chains and supermarkets that are being supplied directly by manufacturers.[13]

4.1.2 Distribution in the public sector

28. According to a FUNSALUD (2010) , the major distributors in the private sector also supply the public sector but with the exception of one of them the other have less importance. Wholesale distributions

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10 The information of the market participation of the private sector per company is only available in confidential files. Therefore, the companies are referred to as 1, 2, 3 and 4.

11 See FUNSALUD (2011) and (COFEPRIS, 2013).

12 See FUNSALUD (2013).

13 Since 2007 Walmart started with 91 laboratories for the production of its own generic medicine brands. Available at: http://www.eluniversal.com.mx/finanzas/57582.html

to the public sector is a more specialized segment. This specialization, is partly due to the difference in government and pharmacies' requirements. Public institutions usually have local warehouses from which they distribute medicines to their medical units, which results in lower barriers to entry for distributors.

29. The specialized distributors of the public sector are Equimed del Centro, Savi Distribuciones, Selecciones Médicas, Farmacéuticos Maypo, Distribuidora Internacional de Medicamentos and Equipo Médico, Comercializadora de Productos Institucionales and Ralca, among others.[14] In addition, Fármacos Especializados is among the four largest participants in the private sector and is also one of the distributors with the higher sales to the public sector.[15]

30. Concentration of public procurement has been growing both in the Mexican Institue of Social Security (IMSS) and the Public Sector Workers Social Security Institute (ISSSTE). In IMSS, the concentration of the three major suppliers increased from 46.4% to 71.1% of the acquisitions made in 2009 and 2012 respectively. Also, the four major suppliers accounted for 80.4% of the acquisitions in 2013. [16]

31. Meanwhile ISSSTE shows a higher sales concentration of suppliers than IMSS between 2009 and 2011, although in 2012 sales concentration of IMSS exceeded that of ISSSTE (see Table 5).

Table 5. Concentration estimates of the public sector providers

Public institution	Concentration estimate	2009	2010	2011	2012
IMSS	CR3	46.4	50.4	50.8	71.1
	CR4	55.1	63.9	60.0	80.4
ISSSTE	CR3	62.2	70.2	69.8	67.2
	CR4	74.6	80.4	80.5	72.9

Source: IMSS and ISSSTE, 2013

32. Considering years 2009 and 2012concentration of distribution to the public sector was lower than in the private sector in 2009 and higher in 2012 since in the latter the CR4 fell from 81.2 % to 58%. Meanwhile in the IMSS and the ISSSTE, the CR4 was lower in 2009 but increased in 2012. This would indicate that while the entry of distributors reflects greater contestability in the private distribution market in 2012, the supply to the public sector, in this case represented by the IMSS and ISSSTE, concentration remains high.

33. Public procurement of IMSS and ISSSTE is carried out mainly from medicine distributors and not directly by laboratories. Distributors are organized in three associations according to their size and the markets they serve. Associations are presented in the following table.

Table 6. Main organizations of distributors of medicines (Main characteristics)

Organization	Main Characteristics
Association of Pharmaceutical Distributors of Mexico (DIPROFAR for its acronym in Spanish)	Founded in 1974. It brings together the largest distributors to the private pharmaceutical sector in Mexico.
National Association of Distributors of Medicines (ANADIM for its acronym in Spanish)	Established in 1944. It comprises some distributors and some smaller pharmacy chains that have their own distribution schemes.
National Association of Distributors of Health Products (ANDIS for its acronym in Spanish)	Brings together nine distribution companies focused on the public sector and often participate in public tenders.

Source: FUNSALUD 2013, page 10.

14 See FUNSALUD (2013).

15 See KPMG (2006).

16 IMSS publishes in its web page the sales per company. See. http://compras.imss.gob.mx/?P=imsscompro

4.2 Retail distribution

34. In the arrangement of associations, in addition to the aforementioned wholesale distributors, retail pharmacies (independent, or belonging to a chain or supermarket) comprise more than 23,500 locations in the country and represent the last link in the medicine distribution chain.[17]

4.2.1 Pharmacy chains

35. According to FUNSALUD (2011), wholesale distributors have faced increased pressure to deliver best prices due to a greater bargaining power of supermarkets and pharmacy chains that buy large volumes, and in some cases have chosen to use their own distribution chain. Also, some distributors specialized in the public sector have chosen to move into the private sector.

36. Moreover, some cases of vertical integration would be evidence of this competitive pressure. In this sense, some distributors have chosen to acquire pharmacy chains and there are also retailers, including supermarkets, have established partnerships with laboratories in order to launch generic versions of their own brand. In this context, it is clear that retail distribution channels have diversified rapidly, leaving the traditional system of individual pharmacy with a share of 21.8 %, versus the 31 % of 2007.

37. According to the National Pharmacy Association of Mexico (ANAFAMEX for its acronym in Spanish), which represents independent pharmacies, there are about 8,000 pharmacies owned by several chains, 33.98 % of which comprises the three major brands (Benavides, del Ahorro and Guadalajara) and the remaining 66.02 % is divided among small chain participants. This model in the retail pharmacy market has shown a significant growth in sales that has attracted entry of more national and regional competitors.

38. The Director of IMS Health reported in the press an increase in pharmacy chains share in the retail market from 45% to 59% between 2010 and 2012[18]. Some of the reasons for this growth could be greater economies of scale and more efficient supply systems. This could have influenced the fall in the share of the four major wholesale distributors from 81 % to 58 %, which could be complemented by a more contestable wholesale distribution market where the share of minor wholesale distributors' rose from 12 to 33 in that period according to estimates of FUNSALUD[19]. This change in retail supply may have imposed high pressure on distributors to retain their market, where some like Casa Saba are now vertically integrated.

39. The model of pharmacy chains show significant growth at the regional level, as in the case of Farmacias del Sureste, which owns140 branches in the states of Campeche, Chiapas, Quintana Roo, Tabasco, Veracruz and Yucatan, with more than 1400 employees. Moreover, they have begun to generate synergies in distribution since some supermarket chains have acquired pharmacy chains. One of these operations involved FEMSA, an operator ofOXXO convenience stores purchase of two pharmacy chains.[20]

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17 See COFEPRIS (2013).

18 Héctor Valle, Director of IMS Health México in his presentation of pharmaceutical trends IMS World Review 2013. Available at: http://www.lajornadamichoacan.com.mx/2013/07/24/consultas-en-farmacias-y-genericos-ganan-terreno-en-mexico/

19 See FUNSALUD (2011 y 2009).

20 In November 2012, FEMSA through its subsidiary Oxxo, acquired 75% of Farmacias YZA, a chain of 333 stores present in the southeast región. Also, last May it announced the purchase of Farmacias FM Moderna, based in the Sinaloa state, that controls over 100 point of sale. The CFC authorized the former transaction in April 2013.

40. Walmart is also entering the pharmacy chain market with 10off-site pharmacies, as part of its business strategy to position the Medimart generic brand in Mexico. Also, following the purchase of the two pharmacy chains, FEMSA has 433 pharmacies that account for a 5.41 % share of the market. However, FEMSA is below the 1,000 locations of Farmacias del Ahorro second in the chain model with 12.5 % of the market share, just below Farmacias Guadalajara with1008 pharmacies and a share of 12.6 %, followed by Farmacias Benavides that operates 710 locations, and Farmacias Unión with 200 locations (see Table 7).

Table 7. Participation of Pharmacy Chains 2012

Name	Number of establishments	Participation	
Pharmacy Chains (Patent and generic medicines) /[1]	**8000**	**32%**	
Farmacias del Ahorro	1,000		*12.50%*
Farmacias Guadalajara	1,008		*12.60%*
Farmacias Benavides	710		*8.88%*
Oxxo	433		*5.41%*
Unión	200		*2.50%*
Medimart (Farmacias Walmart)	10		*0.13%*
Other	4,639		*57.99%*
Main pharmacy chains (generic)	**5000**	**20%**	
Farmacias Similares	4,000		*80%*
Farmacias GI	1,000		*20%*
Supermarkets/[2]	**2164**	**8.7%**	
Walmart	1,157		*27.5%*
Comercial Mexicana	199		*4.7%*
Chedraiu	202		*4.8%*
Soriana	606		*14.4%*
Other	**9836**	**60%**	
National Total[3]	**25,000**	**100%**	

Notes: [1]/the 8000 locations mentioned by the National Pharmacy Association of Mexico (ANAFARMEX) are considered.

[2] / Corresponds to the number of branches of each store and not necessarily the number of pharmacies.
[3]/Considering 25,000 locations referred by FUNSALUD (2013).

Source: COFECE research and web-pages of companies, 2014

4.2.2 Supermarkets' retail distribution

41. Traditionally supermarket chains have found attractive the marketing of medicines as a way to attract customers. For example, Walmart currently operates about 1,157 medicine stores in its various store formats (Bodega Aurrerá, Walmart, Sam's Club and Superama). Meanwhile Comercial Mexicana has 199 branches across its store formats (Mega Comercial Mexicana, Bodega Comercial Mexicana, Sumesa, City Market and Fresko). The only regulatory restrictions for supermarkets to operate in the pharmacy market is established in Article 114 of the Regulations for Health Supplies (RIS for its acronym in Spanish) indicating that pharmacies should be installed in specific and independent areas within the stores and away from alcohol, perishable food and any substances that threatens the integrity, purity and conservation of medicines. However, supermarkets have recently diversified their market share to generate their own brands[21] of generic drugs through partnerships with laboratories. In 2007, Walmart launched its generic

[21] Walmart participates in the market with the brand Medimart and Comercial Mexicana participates with the brand Farmacom for generics of known laboratories.

drug Medimart and in 2011, the group opened the first pharmacy outside their establishments, which currently has 10 locations distributed in low income level neighborhoods in Mexico City, which allow them to set a low price strategy to market Medimart generic medicines.

5. Regulation of the supply chain and its effect on competition

5.1 Supply regulation

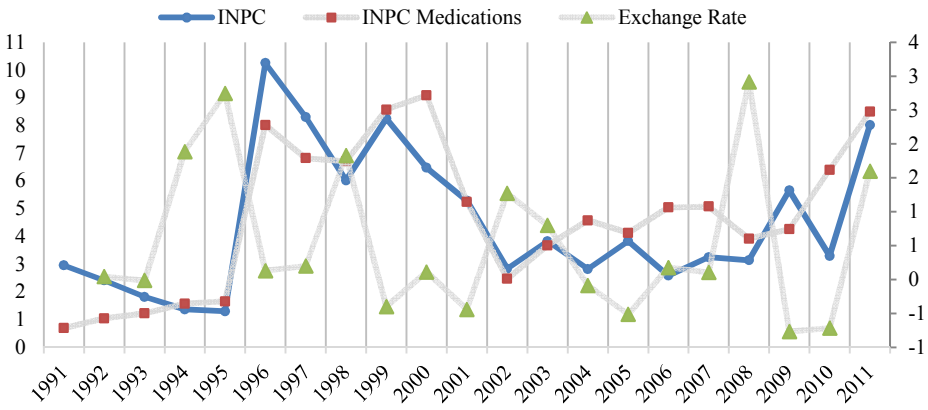
5.1.1 Upper retail price limit regulation

42. Price regulation of medicines began in 1951 in the State Law on Economic Matters that established maximum prices for medicines and other products. In the eighties the Mexican pharmaceutical industry was subject to significant price regulation. In fact, in the early 80's Mexico produced domestically most of the medicines, whereas medicine/chemical input imports reached 50 % of the sector's needs.

43. Specifically in 1984, a separate regulation established in the General Health Law gave the Ministry of Trade and Industry (SECOFI for its acronym in Spanish, now Ministry of Economy, SE for its acronym in Spanish) the responsibility to set maximum prices of medicines. Based on this regulation, the maximum consumer price of medicines was based on an analysis of the manufacturer's production costs, operating costs and default margins for producers, wholesalers and retailers.

44. In early 1991 the Agreement to Convene Medicine Prices established a gradual process to release the medicine prices starting August of that year. Prices of medicines increased below the INCP until 1993. However, since 1995, as a result of the devaluation of the exchange rate, prices of medicines, as well as consumer prices, had a stage of high volatility until 2000. From that year on the INPC and medicine prices increases began to slow down until 2002. However, from 2003 to 2011 the increase in medicine prices was above the increase in the INPC with the exception of 2009. (See Figure 4)

Figure 4. Evolution of medicines prices and the exchange rate (Annual change)



Source: Own elaboration with data from INEGI, 2014

45. The gradual price liberalization was complemented by the Federal Law of Economic Competition (FLEC) in December 1992 that allowed the Executive redirect pricing policy towards deregulation. According to competition law, regulators should seek the opinion of the COFECE when imposing maximum prices.

46. In 1996, SECOFI and the CANIFARMA signed a new Agreement to Convene Medicine Prices based on a scheme of self-regulation (non-mandatory) to set the maximum selling price to the consumer.

Those laboratories that do not adhere to the system could be regulated directly by the State in terms of Article 7 of the FLEC.

47. The agreement was applicable to patented and non-patented medicines and established that companies should define a representative cost formula.

48. The main features of the agreement were:[22]

- Companies define a representative cost formula, comprising at least two public economic indicators (INPC, exchange rate, etc.), and show that the price increase of medicines was a result of increased input prices;
- Flexibility to pharmaceutical companies to determine the amount and timing of price increase, provided it did not exceed that established in the formula for self-regulation.

49. It was soon realized that this regulation had significant difficulties. An analysis prepared by the Economic Analysis Unit of the Ministry of Health in 2002 showed poor compliance in keeping consumer prices below the established maximum. A sample from the analysis revealed that consumer prices exceeded the maximum price established in over 43% of cases. The lack of reports and sanctions to companies weakened the system.

50. The last regulatory scheme agreed with CANIFARMA in 2004 sought to improve some of the flaws of the former agreement. Currently outside the maximum public sale price (PMVP for its acronym in Spanish), no other regulation applies to prices offered by retailers and pharmacies. There is no regulation for the margins generated along the various stages of the supply chain.

- The regulation only applies to patent medicines sold in the private sector
- Participation is voluntary for manufacturers
- An international reference price serves as a parameter to set the maximum value of the price of the patented medicine.

51. In the case of new products with no reference price, the manufacturer can set the price subject to review over a period of three months after product launch. Also, medicines whose patent expired are not subject to price regulation.

5.2 Maximum price estimation

52. Current regulation of on-patent medicine prices offered to the private sector involves three definitions of prices. First an international reference price (PIR for its acronym in Spanish) is defined based on the weighted average of the ex-factory price of the six countries with the main market penetration for each product.

53. Producers provide such international prices. The PIR is multiplied by the factor 1.72, which incorporates the margin of wholesale and retail distributors to yield the reference retail price(PRVP for its acronym in Spanish).

54. In addition, laboratories are free to set the PMVP, with is required to be stamped in the labels of medication, but pharmacies are free to offer discounts on this amount. When a patented medicine is

[22] See PriceWaterhouse Coopers. "Convergencia y Oportunidades en el Sector Salud." *Doing Bussiness in México, Guía para una inversión inteligente*. 2012.

registered before the Ministry of Economy, laboratories propose a PMVP as well as the methodology to calculate its increases. If the PMVP is greater than the PRVP, companies must adjust prices downward.

5.2.1 Price regulation of public procurement

55. Procurement prices of patented medicines are not regulated by the upper price limit mechanism since these acquisitions are used to supply medicines to the public hospitals and not directly to the public in general. Through the Coordinating Commission for Medicines Price Negotiation (CCNPM for its acronym in Spanish)[23] the public sector annually negotiates purchase prices for the public sector of patent medicines and other single source medicines. The price negotiated by the CCNPM is binding in the procurement processes of the public health institutions involved in the negotiation.

56. The CCNPM is composed of the Ministries of Finance (SHCP for its acronym in Spanish) and SE; Public Health Institutions, the Ministry of Health, IMSS, ISSSTE, the Ministry of Public Administration (SFP for its acronym in Spanish) and COFECE, the two latter in their capacity of permanent advisors.

5.3 Flexible sanitary registry requirements and expansion of generic medicines

57. A key element that has determined a lower medicine price growth is the supply expansion policy by way of promoting generic medicines.

58. Recent regulatory changes have helped to significantly increase the importance of generic medicines in the domestic market. On the one hand , the reform of Article 376 of the General Health Law, published in the DOF in February 24, 2005 and the reforms to the RIS established that sanitary registry had a limited duration of 5 years renewable, and in the case of generic medicines, the extension will be subject to verification of interchangeability (RIS bis1 190).

59. With this regulation, unauthorized copies by the Ministry of Health were forbidden since the bioavailability and bioequivalence tests became mandatory for all medicines. This laid the groundwork for a major expansion of generic medicine manufacture. According to the above, by means of the "Agreement that adds and changes the relationship of pharmaceutical specialties likely to join the catalogue of generic medicines" (of February 21, 2008), 755 medicines of the "basic package of inputs" (for first, second and third level care) were added to the generics catalogue. Also, between October 2011 and August 2013, 28 patent medicines were released and recorded in 233 generic presentations.[24]

60. Another relevant change that increased competition in the generics market was the reform of Articles 168 and 170 of the RIS that consisted of the elimination of the "plant requirement" in Mexico, in August 2008. This requirement established the obligation that foreign producers have facilities in Mexico in order to export its products to Mexico[25]. The objective of this measure was to increase the access of Mexicans' to last generation medication and to increase the economic competitiveness of Mexico. The requirement was gradually eliminated by groups of medicines under a schedule provided by the Federal Government, from August 2008 to August 2011.

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23 Established in the National Registry (DOF for its acronym in Spanish) in February 28, 2008.

24 See COFEPRIS (2013).

25 The " Factory requierement", required a sanitary licence of the factory or laboratory established in Mexico. The latter in order to hold the medicine sanitary registry. With this the importer had to establish a factory or a laboratory in Mexico in order to trade its product in the domestic market.

5.4 Demand regulation

61. The demand for generic medicines has been negatively affected by physicians and consumers' confusion arising from ignorance of medicine quality[26]. Danzon (2013) shows that the problem arises from safety, quality and efficacy of medicines unobservable by consumers and is exacerbated by the existence of fraudulent copies of the so-called "similar" medicines that do not meet the tests to be interchangeable. This problem had to be addressed by the requirement that all registered generic medicines had to pass the interchangeability tests.

62. Since 2005, the obligation to prove interchangeability for all generic medicines in order to obtain the renewal of their registration was introduced. The coexistence of interchangeable generics (known as GI for its acronym in Spanish) and generic brand medicines (which up until 2005 were not required to show interchangeability) created confusion in the mind of patients and physicians on the efficacy and safety of generic medicines and their use as substitutes for patent medicines, thereby slowing its ability to generate competitive pressure and reduce average medicine prices at the molecule level.

63. To the extent that there is renewal of sanitary registries and information that all generic (branded or not) are interchangeable is disseminated, demand should be sensitized to the possibility of substitution. It is expected that in the public sector this effect would be stronger due to the obligation to prescribe generics, the existence of generic forms and the mechanisms of generic medicine procurement. The other aspect necessary to avoid distortions in demand refers to the regulation of prescription. On this, Article 31 of the RIS provides that for generic medicines the prescriber should write the generic name and if desired may indicate the distinctive name. So, if the physician writes the distinctive name or brand, the pharmacy must supply that brand, even though there is a cheaper generic medicine which could only be replaced if authorized by the prescriber, thus the customer will not have access to the generic despite the evidence of interchangeability ensures that it is a perfect substitute. When prescribing a non- generic, the brand or both brand and generic denomination may be written down.

6. Monopolistic practices in the chain

6.1 Horizontal practices: Collusion problems in public tenders

64. Public procurement through tender procedures is the market most widely affected by monopolistic practices. Collusive processes involved manufacturers and distributors supplying social security institutes directly.

65. COFECE has played an active role in the fight against bid rigging. Thus, in February 2000 the Commission investigated agreements between competitors in tenders for surgical sutures performed by the General Hospital of Mexico and the ISSSTE[27] and in February 2001 the Commission identified agreements between competitors in bidsto supply radiographic material to IMSS and ISSSTE[28].

66. However, the most important case of collusion in public procurement was initiated in August 2006[29], after conducting an investigation of the public procurement of medicines, affecting the price of high impact and very important medicines such as insulin. The practices identified were market segmentation, bid rotation and price fixing.

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26 See page 5. Danzón, P. "Competition and Antitrus Issues in the Pharmaceutical Industry". Final Report. Draft, December 2013.

27 See File DE-10-2000, 9 February 2000.

28 See File DE-10-2001, 28 February 2001.

29 See File IO-003-2006, 15 August 2006.

6.2 Vertical practices

67. In the private market, COFECE has never investigated illegal vertical restraints in the supply chain of wholesalers and pharmacies or wholesaler and laboratories.

68. Complaints against vertical restraints have been filed in the purchasing of medicines by the public sector. However, in 2003 COFECE analyzed a complaint for alleged abuse of a patented manufacturer to impose an exclusive distributor[30], but it resulted not illegal since it was a patented product. Moreover, in 2007 COFECE analyzed a complaint for possible monopolistic practices (established in sections VII and IX of Article 10 of the FLEC) related to predatory pricing and cross-subsidies, which resulted not founded since the alleged predatory prices were above the average cost and no cross subsidies were involved.[31]

69. The Casa Saba - Benavides merger explained above indicates that incentives to maintain exclusive distribution of medicines between wholesalers and laboratories have had a minimal presence in the domestic market. In order to ensure market participation, wholesalers have opted for vertical integration to compete with pharmacy chains more efficiently rather than imposing vertical restraints. Also, integration of pharmacy chains and their increased buying power have increased competitive pressure on wholesalers as they compete on-line, prevailing that who offers the best price and availability.

7. The use of competition to ensure an adequate supply of medicines

70. As noted in the first section of this contribution, wholesale distribution segment has high concentration indexes. Therefore, competition policy has an important role to bring efficiency to this market. The COFECE has acted to inhibit absolute monopolistic practices in public procurement of medicines, where offenders have been identified and sanctioned.

71. Regarding vertical conduct, the analysis of the Casa Saba - Benavides merger shows that exclusive distribution systems between wholesalers, pharmacies and laboratories are not a common practice. However, it is not possible to rule out that some products may be subject to undue territorial divisions and the imposition of resale prices by laboratories that may have market power.

72. Moreover, the enhanced presence of pharmacy chains probably responds to efficiency considerations and is creating incentives for vertically integrated wholesale distribution. Therefore, COFECE has analyzed vertical mergers with a view to rule out that they confer market power to participants. In this regard, merger review is considered an important policy instrument to prevent undue displacement of competitors at the retail level.

30 See DE-054-2003 September 2006.

31 See DE-33-2006 of 26 June 2007. As well as the complaint DE-054-2003 in the market for the production, distribution and comercialization of medicines for the treatment and secondary effect of chemotherapy.

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