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Working Party No. 2 on Competition and Regulation

COMPETITION IN THE PHARMACEUTICAL INDUSTRY

-- Mexico --

This note is submitted by the Delegation of Mexico to the Working Party No. 2 FOR DISCUSSION at its next meeting on 7 June 2000.

English text only

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COMPETITION IN THE PHARMACEUTICAL INDUSTRY

Mexico

I. The Pharmaceutical Industry: Market Structure

Market Structure

(1.1) Please describe the market structure of pharmaceutical firms in your country – which firms are active, with what market share, in which therapeutic classes and with what level of R&D (including generic producers).

Manufacturing

1. As in many other countries, for a pharmaceutical company to be allowed to sell medicines and other medical products in Mexico a certain physical presence is required. For medicines that physical presence includes production and testing facilities, for medical devices storage facilities are sufficient. This is one of the reasons why most multinational pharmaceutical companies have a subsidiary in Mexico. Apart from that, there are many national pharmaceutical laboratories. These national laboratories are usually smaller and specialised in the manufacture of generics and other medicines whose patents have expired. Altogether, there are approximately 400 pharmaceutical manufacturers in Mexico.

2. The following table presents a list of the most important pharmaceutical firms that were active in Mexico in 1998. For each firm its share in total sales of medicines from April 1998 to March 1999 is indicated. The value of those sales amounted to approximately US$ 3,840 and covered both sales to the private and the public sector.

Table 1: Market Shares of the Main Pharmaceutical Firms
April 1998 – March 1999

Firm	Share in sales
Abbot	3.0%
Bayer	3.0%
Boehringer	4.8%
Bristol	2.5%
Glaxo Wellcome	3.6%
Hoechst	4.2%
Jansssen	2.7%
Lakeside	2.0%
Lilly	2.1%
Mead Johnson	2.7%

Table 1 (cont'd)

Firm	Share in sales
Merck	3.7%
Novartis	4.0%
Pfizer	2.7%
Pharmacia – UpJohn	2.6%
Rhône-Poulenc	2.0%
Roche	3.7%
Sanfer	2.1%
Senosian	2.6%
Syntex	3.3%
Wyeth	3.2%
Others	39.5%
Total	100.0%

Source: Anatomical Therapeutic Chemicals, International Medical Statistics, March 1999.

3. Evidently, relevant markets for antitrust analysis are much narrower than the market of all medicines. As a general rule, the degree of market concentration for antitrust purposes is much higher than what one would expect from the shares listed in table 1. In table 2 the sales of all medicines are split up according to therapeutic classes (level 1), which are still too broad for antitrust analysis.

Table 2: Sales of Medicines according to Therapeutic Classes (level 1)
April 1998 – March 1999

Therapeutic Class	Share
A. Alimentary Tract and Metabolism	19.0
B. Blood and Forming Organs	1.2
C. Cardiovascular System	7.7
D. Dermatologicals	6.1
G. Genito Urinary System Sex Hormones	6.5
H. System Hormonal Preparations (Excluding Sex Hormones)	1.8
J. General Anti-Infectives Systemic	19.3
K. Hospital Solutions	0.4
L. Cytostatics	0.5
M. Musculo-Skeletal System	6.6
N. Central Nervous System	11.9
P. Parasitology	1.0
R. Respiratory System	11.2
S. Sensory Organs	2.1
T. Diagnostic Agents	0.2
V. Various	4.5
Total	100.0

Source: Anatomical Therapeutic Chemicals, International Medical Statistics, March 1999.

4. In table 3 some of the therapeutic classes (level 1) are split up further and for several therapeutic classes (level 3) the main supplying manufacturers are listed together with their share in the sales of that class of medicines. For each class of medicines market concentration is calculated in terms of the Herfindhal and dominance indexes which are used by the Federal Competition Commission (FCC) in its merger analysis.

Table 3: Market Shares for Some Therapeutic Classes (Level 3)

Code	Therapeutic Class	Herfindhal Index	Dominance Index	Market Share
A3 Antispasmodics, anticholinergics and gastroprokinetics				
A3A	Plain antispasmodics and anticholinergics	2,318	3,933	BG: 32%, Boehringer: 31%, Senosian: 11%, Atlantis: 9%, Hoechst: 7%
A8 Antiobesity preparations, excluding diabetics				
A8A	Antiobesity preparations, excluding diabetics	3,354	5,250	Hoechst: 55%, Medix Corp.: 14%, Roche: 11%, Knoll: 9%, Searle: 5%
A11 Vitamins				
A11C	Vitamin A and D, including combinations of the two	3,737	6,849	Hoescht: 51%, Roche: 30%, RP: 14%, Sanofi: 1.5%, BG: 1.2%
C2 Antihypertensives				
C2A	Antihypertensives	1,452	2,967	AstraZeneca: 25%, Merck: 22%, BM: 13%, Bayer: 9%, Pfizer: 8%.
C3 Diuretics				
C3A	Diuretics	2,245	4,696	Hoechst: 43%, Searle: 19%, Novartis: 14%, Senosiain: 7%, Roche: 6%.
C10 Hypolipidaemics/Anti-Atheroma preparations				
C10A	Cholesterol and Triglyceride reduction preparations	1,957	3,411	Merck: 31%, BM: 23%, WL: 12%
D1 Antifungals, dermatological				
D1A	Antifungals, dermatological	1,132	2,390	Janssen: 20%, Bayer: 17%, RP: 12%, Plough: 11%; PG: 6%
D6 Topical antibiotics, sulphonamides and antivirals				
D6A	Plain topical antibiotics and /or sulphanomides	1,344	2,521	SB: 23%, Senosiain: 15%, CIC: 10%, Hoescht: 9%, Pfizer: 9%.
H2 Systemic corticosteroids				
H2A	Systemic corticosteroids, plain	2,162	5,910	Key Farma: 41%, Essex: 11%, PU: 9%, Chinoin: 9%, Cilag: 9%
J1 Systemic antibiotic				
J1C	Broad Spectrum Penicillins	1,809	3,856	BM: 31%, Sanfer: 22%, SB: 12%, Bayer: 11%, Wyeth:5%
J1F	Macrolides and similar types	2,492	4,103	PU: 38%, Abbot: 21%, Pfizer: 18%, EL: 14%, Hoechst: 5%
J1G	Fluoroquinolones	1,777	4,196	Bayer: 33%, Senosiain: 20%, Cilag: 12%, Janssen: 9%, Merck: 6%
J1H	Medium and narrow spectrum Penicillin V Penicillin G	3,395 3,366	6,303 6,966	Sanfer: 51%, Bristol: 24%, Wyeth: 12%, SB: 5%, Bayer: 3%, FL: 55%, Wyeth: 20%, Grossman: 15%, Grunenthal: 3%, Rimsa: 2%
M1 Anti-inflammatory and anti-rehumatic products				
M1A	Anti-rehumatic non-steroidal	1,113	1,276	Novartis: 20%, Syntex: 20%, Roche: 8%, SB: 5%, Boehringer: 5%
	Anti-inflammatory non-steroidal	1,891	1,031	Syntex: 26%, CG: 20%, PU: 5%, FL: 5%, SB: 4%
N2 Analgesics				
N2B	Non narcotics and anti-pyretics	1,320	2,493	Roche: 23%, Hoechst: 14%, BM: 12%, Merck: 11%, Bayer: 8%.
N5 Psycholeptics				
N5A	Antypsychotics	2,225	4,571	JJ: 38%, RP: 16%, Novartis: 14%, Armstrong: 13%, EL: 5%
R6 Systemic antihistamines				
R6A	Systemic antihistamines	1,317	2,953	Essex: 26%, GW: 14%, Plough: 12%, Jenssen: 11%, Hoechst: 6%

Source: Merger files of pharmaceutical firms, Federal Competition Commission.

Abbreviations.
BG: Byk Gulden; RP: Rhône-Poulenc; PG: Procter and Gamble;
PU: Pharmacia Upjohn; THE: Eli Lilly; SB: Smithkline Beecham; GW: Glaxo Wellcome;
BM: Bristol-Myers; CIC: Compañía Inter-Comercio México; JJ: Johnsons & Johnsons;
CG: Ciba Geigy Mexicana; FL: Pharmaceutical Lakeside; WL: Warner Lambert.

5. Although level 3 therapeutic classes may still be too broad for proper market definition (and occasionally too narrow if there is cross-substitutability among different classes), table 3 gives a much better picture of market concentration in the Mexican pharmaceutical industry than does table 1.

Wholesale Distribution

6. Wholesale distribution of medicines and medical devices is fairly concentrated in Mexico. The six main wholesalers account for approximately 90 percent of the market. First is Casa Autrey (three percent), second Nadro (27 percent) and third is Marzam (twelve percent).

7. However, it should be recognized that many medicines reach the final consumers without passing through wholesale. In the first place, the public sector (social security system, Ministry of Health) buys most of its requirements through public tenderings directly from the manufacturers. In the second, large chains of pharmacies at the retail level also buy directly from manufacturers. In much the same way, an increasing number of supermarkets with a pharmacy department jumps the wholesale link by buying directly from laboratories. Evidently, this circumvention of wholesale trade limits the abuse of market power by wholesalers considerably.

Retail Distribution

8. Unlike in many other countries, pharmacies in Mexico only sell the medicines, they do not mix them, dosify them or prepare them in any other way. That is, medicines leave the pharmacies in exactly the same presentation as they entered. In view of that, entry barriers into retailing are kept very low. Any person can run a pharmacy. He does not need to possess an academic title or similar professional degree.

9. As a consequence, there are many pharmacies and competition is very intense; too intense according to a great number of small traditional pharmacists that claim protection against upcoming chains of pharmacies that are in a better position to take advantage of economies of scale (jumping wholesale, volume discounts) and economies of scope (running broad assortments). Still, in far-away rural areas there is a lack of pharmacies. This may be partly due to traditional price control policies which did not allow for upmarks necessary to run a pharmacy in a thin market profitably.

Which firms co-operate to jointly undertake R&D or to jointly market certain products?

10. There is little information about R&D in pharmaceutical firms in Mexico. The development of new medicines is usually done in the laboratories of multinational companies abroad. Part of the testing of new medicines may take place in Mexico, however. No joint ventures for R&D or for joint marketing agreements have been notified to the FCC, so far.

Is there one or more associations of pharmaceutical manufacturers in your country?

Is this association politically important?

11. The main producers association is the National Chamber for the Pharmaceutical Industry (CANIFARMA). Although membership is no longer compulsory since 1997, most manufacturers belong to this association and it is the CANIFARMA that acts on behalf of the industry in the dialogue with regulatory bodies.

II. Regulation of Supply

Protection of Intellectual Property Rights

(2.1) Please describe the regulatory framework established for the protection of intellectual property rights in the pharmaceutical industry.

12. In Mexico there are no special provisions for pharmaceutical products and processes in the legislation on industrial property; i.e. pharmaceutical products are subject to the same regulations as any other product. In the Law of Industrial Protection patents for products expire twenty years after the filing of the request. In most cases the date of registration is the priority date, i.e. the date of registration in the first country where it was registered.

13. If a patent is not commercially exploited during three years following its registration, the Mexican Institute of Industrial Property (MIIP) has the power to oblige the patent holder to grant a license. In principle, any person can apply to the MIIP for such a license. Commercial exploitation does not require that the product be produced in the country. Importation of the product is sufficient to shield the patent holder from the obligation to license.

New Drug Approvals

(2.2) Please provide an overview of the drug approval process

14. Both the private and the public sector can apply for the approval of a new drug or pharmaceutical input. Upon approval it is included in the Pharmacopoeia of the United States of Mexico or in the corresponding standards. The pharmacopoeia is a legal document in which general methods of analysis are established and the requirements to guarantee the identity, purity and quality of medicines and pharmaceutical inputs.

15. Applications for approval must be filed with the Ministry of Health (MH). For well-known drugs not protected by patents the resolution must be issued within 40 days. For drugs patented in other countries the approval period is 60 days. For new drugs without patents in other countries the deadline is of 90 days. These approval periods compare favourably with those of many other countries. Sanitary registration is issued for indeterminate periods.

Trade Regulation

(2.3) Please describe any barriers to international trade or investment in pharmaceuticals. Are there restrictions on international trade in drugs by third-parties (such as parallel trade or re-imports)? Are there restrictions on mail-order or Internet supply of drugs? Does the regulatory regime distinguish between domestic and foreign firms in any way?

Regulation of Imports

16. The importation of many medicines is subject to a sanitary permit by the Ministry of Health (MH). Such permits are only granted to importers who have production and testing facilities in Mexico. It is not necessary that the production facilities refer to exactly the same product as the imported one, but the testing facilities must be adaptable to the product under consideration. In practice, this makes reimportation

or parallel trade by third parties very difficult for those products. The regulation of imports does not distinguish between foreign and domestic firms.

17. Medicines and pharmaceutical prime materials that are not subject to sanitary permits by the MH must carry sanitary certification from the country of origin in accordance with international agreements to which Mexico has subscribed or certification by laboratories, Mexican or foreign, accredited by the MH and the Ministry of Commerce and Industrial Development (MCID). The MH has the right to take samples of imports in order to verify the content of the merchandise and its compliance with Official Mexican Standards. The importation of narcotics, psychotropics and products containing them, is subject to stricter regulations. They can be realised through certain specially designated airports and never by mail. Also some biological products and blood derivatives need a permit from the MH for their importation.

Regulation of Exports

18. For the export of medicines and prime materials the exporter does not need a sanitary license, but only an export certificate from the MH. If the acceptance by the importer in the country of destination can be accredited no sanitary registration is necessary. The MH does not grant export certificates for narcotics, psychotropics or blood derivatives. For the exportation of narcotics, psychotropics and blood derivatives an permit by the MH is required. Such exportation can only be realised from the airports referred to earlier.

Foreign Investment

19. There are no restrictions on foreign investments in the pharmaceutical industry. I.e. foreign firms can fully participate in the social capital of Mexican firms in the industry and can establish their own subsidiaries. In the regulation applicable to the pharmaceutical industry there are no discriminatory provisions favouring national companies over foreign firms.

Industrial Policy

(2.5) Please describe any industrial policy objectives in this sector. Describe the objectives and effects of any tax concessions or subsidies that exist.

20. No sector-specific policies are applied to promote the pharmaceutical industry in Mexico. There have only been systematic attempts to deregulate (i.e. regulate only the strictly necessary) and eliminate red tape in the registration and authorisation of new establishments and in foreign trade transactions. No subsidies are given to the industry. There is only a general exemption from the value added tax for medicines.

III. Regulation of Demand: Controls on Pharmaceutical Prices, Quanties and Consumption

Health Insurance Coverage of Pharmaceuticals

(3.1) We invite you to discuss how the predominant forms of health insurance in your country (whether public of private) affect the demand of health consumers for pharmaceuticals.

Public Insurance

21. Public health institutions in Mexico, include those of the social security system and those run by the Ministry of Health.

22. The social security system covers both public and private sector employees. It is financed by compulsory contributions by employees, employers and the government. It covers the costs of all services provided, related to illness, accidents, childcare and maternity. Prescribed medications are also included.

23. Institutions of the Ministry of Health attend everyone; i.e. not only employees. It is financed out of the government budget. Prescribed medications are not given free but sold at subsidised prices.

24. Although the public heath institutions cover in principle the whole population, only a part of the pharmaceutical demand is supplied by them. Medication purchases by public institutions account approximately for 16 percent (measured in value terms) of the total pharmaceutical market. Thus, there is a significant demand for pharmaceuticals not supplied by public institutions.

25. There are several reasons for this. First, self-employed people are not covered by the social security system. Second, there is not much coverage of public clinics and hospitals in rural zones. Third, some people of the medium class and most people of the higher classes of the population don't take advantage of public health institutions, even if they are affiliated. This is due to long waiting times and sometimes low quality of service. These people prefer to consult private physicians and buy the prescribed medicines themselves.

Private Insurance

26. In Mexico private insurance companies have comparatively little influence upon direct consumer demand for medicines although they do effectively attempt to influence consumer demand. Most companies have negative lists of excluded medicines and services and positive lists of hospitals and physicians, but the penetration of private health insurance in Mexico is low. Moreover, most insurance contracts are for "major medical expenses" not covering expenditures in medicines as a rule.

27. No information is available to the FCC about whether and, if so, the way in which private insurance companies attempt to influence prescription practices by positively listed doctors and hospitals.

28. In the few occasions where privately consumed medicines are covered by insurance contracts the consumer pays first and is reimbursed by the insurance company afterwards. To our knowledge private insurance companies do not pay pharmacies directly as is the case in some other countries. This also limits the control insurance companies can exercise over pharmacies.

Formularies

(3.2) Please describe the main features of the formulary system in your country"

29. The social security system has positive lists of medicines that can be provided in the social security institutions. There are three lists: one for clinics, another for second level hospitals, and still another for third level hospitals. Second and third level hospitals are classified by the level of speciality they have. The list of medications of clinics and hospitals is named the Basic List for the Public Sector, and includes 500 generic medications, in 726 presentations. See also the answer to question 3.4.

Price Control Policies

(3.3) Please describe the operation of the controls on pharmaceutical prices in your country.

30. Since 1996 a mechanism of self-regulation of prices is in force, that was agreed between the Ministry of Commerce and Industrial Development (MCID) and the CANIFARMA. This mechanism is more flexible than previous mechanisms of price controls which were partly based on costs of production. In the new mechanism each manufacturer may increase the prices of its products freely but subject to a basket restriction. That is, the sales-weighted average of the price increase may not be larger than some inflation indicator. The inflation indicator may be a consumer price index, a producer price index, an exchange rate, labour costs or the like, provided it be published officially, or a weighted average of them. The manufacturer may himself select which indicators apply to its company and which weights. If at a certain moment he wishes to change indicators or weights, he is free to do so, but not retroactively. To monitor the system the pharmaceutical firms that participate in the mechanism must report sales (prices and volumes) to the MCID on a regular basis.

31. A special feature of the self-regulation mechanism is that it is not producer prices but *maximum consumer* prices that is restricted. Such maximum consumer prices are printed on the parcel and retailers are not allowed to sell at higher prices. They may sell at lower prices if they wish. Producer and wholesale prices may freely be negotiated among the parties involved. In other words, maximum retail prices are set by manufacturers under the self-regulation scheme but then they negotiate the price they receive with wholesalers or directly with retail chains.

32. It is interesting to mention that there are many retail chains selling at considerable discounts. This may be considered as an indication that the price control system is not overly restrictive.

33. Another feature of the self regulation scheme is that it includes some incentives for investments, training of personnel, research and development, etc. Such expenditures, when appropriately proven, may lead to special allowances in the inflation indicator adopted by the manufacturers.

34. It is also interesting to mention that medicines are comparatively cheap in Mexico. In a not so recent study[1] it was found that in Mexico medicines are five times cheaper than in the US and three times cheaper than in Europe on the average. Evidently, such comparisons depend critically on the medicines included in the compared basket. However, the fact that many US residents in the frontier with Mexico cross the border to buy medicines in Mexico seems to confirm this finding.

[1] See World Review, the Pharmaceutical Market, 1995. The figures refer to 1994.

Control of Physician Prescribing Practices

(3.4) Please describe the systems in place to encourage high-quality cost-effective physician prescribing practices

35. Only professionals (specialists, physicians, nurses, etc.) are allowed to prescribe medicines. There is a Catalogue of Substitutable Generic Medicines (CSGM). If the involved medicine is in the CSGM, the prescription must necessarily include the generic name of the medicine and can optionally include, along with the generic denomination, a pharmaceutical brand name.

36. This form to promote the substitution of generics for branded products is fairly recent and has not changed traditional prescribing practices very much. In practice, there are few doctors that follow these rules. I.e. many of them only put a brandname in the prescription.

37. Only certain specialised physicians can prescribe medicines that contain narcotics, psychotropics or similar substances. Physicians working in public and social security clinics or hospitals can only prescribe generic denominations of medicines included in the Basic List for the Public Sector. Due exemptions are allowed. These generic medicines have different presentation from those of the private market.

Regulation of Pharmacies and Pharmaceutical Distribution

(3.5) Please describe the nature of any controls on pharmacy margins, entry and/or ownership structure. Please describe also the nature of any rules governing the discretion of pharmacists in substituting other products.

38. There is no control on pharmacy margins. As explained under question 3.3 it is the consumer price that is controlled to a certain extent. Retail margins result ex-post from the price at which the retailers acquire the products from manufacturers and wholesalers, and from eventual discounts applied by the retailers.

39. There are no restrictions on ownership in pharmaceutical distribution. Entry barriers are very low. See answer to question 1.

40. As regards the discretion of pharmacists to substitute other products for prescribed medicines, it is useful to distinguish between six classes of medications:

a. those that can only be sold with a special prescription or permit by the MH (narcotics, psychotropics, blood derivatives)

b. those that can be sold with a prescription one single time; the prescription is held back and the sale is registered in the control books of the pharmacy.

c. those that can be sold with a prescription up to three times; the prescription is stamped each time and held back after three times.

d. those that can be sold with prescription as many times as the patient wishes

e. those that do not require prescription but can only be sold by pharmacies

f. those that do not require prescription and can be sold by establishments other than pharmacies

41. Although the system in itself seems to be well-designed, in practice the control over pharmacies is not very tight, so that it is fairly easy to obtain medicines of group c and d even without a prescription at all.

42. In the first two classes of medicines, which are under severe control, there is practically no discretion for pharmacist to substitute medicines. In the last two classes there is only a small role for the pharmacist because the patient is free to choose. The pharmacist can only suggest substitution. For medicines of classes c and d, as explained before, if the medicine is contained in the CSGM the prescription includes at least the generic name and the pharmacist is allowed to provide the generic instead of the branded product. If the medicine is not contained in the CSGM, there is no generic equivalent and the pharmacist is obliged to sell the prescribed (branded) product.

Policy towards Generics

(3.6) What share of the non-prescription/over-the counter, prescription and hospital markets are held by generics? Please describe the programs you have adopted to promote the consumption of generics.

43. There is no information available about the relative importance of generics in the markets mentioned. Very rough proxies and trends might be derived from the fact that most national laboratories specialise in generics or branded products whose patents have expired, but even then a precise definition should be given of the concept of "generics".

44. The main steps that have been taken to promote the consumption of generics versus branded medicines are three: (i) publication of the equivalencies, (ii) the obligation to mention generic equivalents in prescriptions and (iii) the ban on non-generic medicines in public and social security hospitals.

IV. Competition Issues in the Pharmaceuticals Sector

(4.1) Does the competition law apply to the different components of this sector (manufacturing, health insurance, health services, distribution and pharmacies) without exemption or exception? Which agency is responsible for enforcing the competition law in this sector?

45. The Federal Law of Economic Competition (FLEC) fully applies to the different stages of the pharmaceutical industry (manufacturing, wholesale and retail distribution) and to related fields (health care and health insurance). No exemptions are applicable. The FLEC prohibits monopolies, monopolistic practices and anticompetitive mergers. Mergers and acquisitions exceeding certain thresholds must be notified. The Federal Competition Commission (FCC) is the public entity in charge of the administrative application of the FLEC. It is technically and operatively autonomous.

Market Definition Issues and Barriers to Entry and Exit

(4.2) Have you had the occasion to address the definition of the relevant market in the pharmaceuticals sector? Did you find that the relevant product market could be approximated by commonly-accepted therapeutic groups? What techniques did you use to determine whether certain products were effective substitutes? Did you find it necessary to distinguish the market for drugs consumed in hospitals from the market for drugs prescribed by physicians and/or the market for over-the-counter (non-prescription) drugs? Was the relevant geographic extent of the market national or international?

46. The FCC has considered the anatomical therapeutical classes at level 3 a useful approximation of relevant product markets in the pharmaceutical industry. According to that classification products in one class are clinical substitutes and only differentiated by brand, presentation and dosification. Occasionally the market had to be refined further. This was the case in the analysis of the merger between Rhône-Poulenc and Hoechst which is discussed below.

47. Sales to the private sector and sales to the public sector are considered to belong to different relevant markets. Sales to the private sector comprise sales to private hospitals and clinics and sales to pharmacies. Sales to the public sector comprise sales to public health institutions. In the private sector wholesale traders play an important role, whereas the public sector institutions buy directly from the manufacturers often through public biddings. The geographic dimension of markets has been taken national.

48. For wholesale distribution the FCC has defined the relevant market as the distribution and commercialisation of pharmaceutical products, cosmetics, and personal care products. I.e. the products that are usually sold by pharmacies. Its geographic extension has been assumed national. For retail distribution the markets are considered local (municipal) arguing that consumers are not willing to travel long distances to acquire their medicines.

(4.3) Did you consider that the pharmaceutical industry is characterised by barriers to entry/exit? What barriers did you identify?

49. The FCC has considered that the most important economic barriers to entry in the pharmaceutical industry are investments in R&D, patents and publicity. Research and development is not very important in Mexico. The development of new medicines is mostly undertaken in laboratories of multinational companies abroad. Only the later stages of clinical testing is sometimes done in Mexican hospitals. Patents are usually registered first in other countries.

50. As regards publicity, on one hand there is massive advertising of popular medications in the media. On the other hand, there is a more targeted promotion directed to physicians aimed at influencing their prescription habits. The first type of promotion is mostly limited to non-prescription drugs. The latter kind of promotion is done by advertising in specialised magazines, personal visits to physicians, inviting them to medical congresses and free samples, and concentrates upon patented medicines. There is little difference between Mexico and other countries in this respect.

51. Normative barriers include, apart from a number of non sector-specific requirements, sanitary licenses to operate a plant for the manufacturing of medications or biological products, and the sanitary registration of the medicines.

52. As mentioned earlier, there are no significant normative entry barriers in retail distribution. However, there are some economies of scale and scope in retailing which constitute economic barriers to

entry. Economies of scope imply that every pharmacy must have a broad assortment of medicines to avoid frustrated visits by customers. Thus, pharmacies must have a minimum size. Economies of scale imply sufficient turnover to negotiate favourable terms in the acquisition of medicines from wholesalers and manufacturers.

Anti-competitive Agreements

(4.4) Have you had the opportunity to address questions of explicit or implicit collusion in the pharmaceuticals sector? What forms of collusion have you found? Have you found that pharmaceutical manufacturers deliberately choose to target different therapeutic classes or geographic markets, in order to avoid competition? Does the fact that the large pharmaceutical manufacturers compete in many different product and geographic markets have a tendency to lessen competition? Have pharmaceutical manufacturers or pharmacies acted in combination to attempt to increase (or resist decreases in) pharmaceutical reimbursement rates in health insurance plans?

53. In June 1999 the FCC started an ex-officio investigation against the multinational companies Roche, Basf and Rhône-Poulenc for collusion in the markets of some vitamins which are used as inputs in the pharmaceutical industry. The investigations followed similar antitrust actions against those companies in other countries. The investigation has not yet been concluded.

54. In February 2000 the FCC started an investigation upon a complaint about collusion by pharmaceutical companies in public biddings for the acquisition of surgical sutures by the Public Health Sector. The investigation is still under way.

55. There is no information about whether pharmaceutical manufacturers have deliberately targeted different therapeutic classes or geographic areas in order to avoid competition or whether the fact that they were competing in many markets has lessened their competition in each of them. However, such avoidance and lessening of competition may be perfectly compatible with the market mechanism and Mexican competition law would not prohibit it. It only prohibits *agreements* between competitors aimed at avoiding or lessening competition. If a manufacturer decides on his own not to enter a market or to withdraw from it considering that competition is already very strong in that market while in others it is not, that is part of normal business behaviour and does not violate competition principles.

56. The FCC has not investigated any collusive behaviour between pharmaceutical manufacturers or pharmacies to improve their terms of reimbursement of medicines in health insurance plans.

(4.5) Co-operative or collaborative ventures (such as co-marketing and co-promotion agreements) seem to be an important component of the pharmaceutical industry. Have you had the opportunity to examine the competitive effects of such agreements? What features of these agreements give rise to competition concerns? Have you opposed joint research and development and/or joint marketing arrangements?

57. The FCC has not investigated such co-operative or collaborative ventures; neither has the FCC opposed any joint ventures in R&D or in marketing arrangements in the pharmaceutical industry.

Mergers and Acquisitions

(4.6) What cases of mergers or concentrations have you addressed in the pharmaceutical industry? In what markets were concerns over market power most focused? In the pharmaceuticals industry where competition is primarily by way of new innovation (as opposed to competition on prices), what are the primary anti-competitive effects of a merger? Have mergers been opposed on the grounds that the merging companies might be competitors in the future (although they were not actually competing at the time of the merger)?

58. Most mergers in the Mexican pharmaceutical sector have been a consequence of mergers of multinational pharmaceutical companies which affected their subsidiaries installed in Mexico. All mergers analysed have been of horizontal nature; the FCC has not evaluated vertical mergers. A list of the main mergers in the pharmaceutical sector resolved by the FCC is presented in the following table.

Main mergers of pharmaceutical firms resolved by the FCC

Firms	Year*
1. Rhône Poulenc and Hoechst A.G.	1999
2. Zeneca Group PLC and Astra A.B.	1999
3. Upjohn and Pharmacia de Mexico	1996
4. Novartis Farmacéutica and Wyeth	1999
5. Roche Mexicana de Fármacos, Syntex and Syntex Química.	1996
6. Latin America Pharmaceuticals Inc. and Roussel Uclaf	1995
7. Sandoz de México and Ciba-Geigy Mexicana	1996

*Refers to the year in which they were notified to the FCC.

59. The analysis of some pharmaceutical mergers in Mexico is briefly described in the following.

60. The FCC did not find probable anti-competitive effects in the merger of Upjohn and Pharmacia de Mexico, notified in 1996. These firms participated in 12 therapeutic classes, but they only competed in the markets of products classified in the anti-inflammatory non-steroidal class. However, the post-merger market share in this therapeutic class was low, so that there were no competition concerns. On the contrary, the merger of these two firms with small market shares would allow them to compete more vigorously with stronger competitors, and in this way, strengthen competition in the relevant market.

61. The international merger among Zeneca Group PLC and Astra A.B. had effects in Mexico because both firms have subsidiaries in the country. The merger was notified in 1999, it was considered to affect 12 therapeutic classes. However, the firms involved competed directly only in four of them: antihypertensive, cholesterol and triglyceride, and systemic antibiotics. The market share of the merged firm would be 25 percent in products of the antihypertensive class, and in the other classes the market share would not be significant. The FCC found no anti-competitive effects in any of the markets of the four therapeutic classes in which they compete, so the merger was approved.

62. In the wholesale distribution market, the FCC analysed the merger among two Mexican firms: the acquisition of Distribuidora Drogueros by Casa Autrey Group, notified in 1997. The merged firm would increase its market share up to 30 percent of the wholesale distribution market. The FCC determined that this merger would not bring anti-competitive effects. The wholesale distributors generally supply to the pharmaceutical private sector, that includes hospitals, clinics and pharmacies. Increasingly however, pharmacy chains and supermarket chains with pharmacy departments purchase directly to manufacturers. Small pharmacies do not generally buy from manufacturers, but they can join together to purchase directly to laboratories. They can also purchase to pharmacy chains. These possibilities limit the exercise of market power by dominant firms in the wholesale distribution sector. The FCC approved this merger.

Anti-competitive effects

63. The only merger that has raised competition concerns was that among Rhône-Poulenc and Hoechst AG which had effects in Mexico through the implied merger of their Mexican subsidiaries. This operation involved several therapeutic classes but the merging firms only competed directly in 13 of them. The competition analysis showed that concentration would increase significantly in products elaborated with vitamins A and D, which was the relevant market upon which the analysis was focused. The possibility of including products containing vitamin C was also considered, but it was determined that they were imperfect substitutes of the vitamin A and D products to cure illnesses like rickets and vitamins A and D deficiencies.

(4.7) What sorts of remedies have been imposed as a condition on merger approval? Have the merging companies been required to divest or license certain products to third parties?

64. As a remedy, the FCC conditioned the transaction of Rhône-Poulenc and Hoechst to the divestiture of either the brand Aderogil 15 owned by Rhône-Poulenc or the brand Adekon owned by Hoechst, both classified in the therapeutic class of vitamins A and D. Aderogil 15 is a medication that does not require prescription for its purchase and its massive advertising is not restricted. On the other hand, Adekon is subject to prescription and its massive advertising is restricted. Nevertheless, both products were considered to be in the same relevant market, because of their similar active substances and because both can be acquired easily by the consumers in pharmacies.

(4.8) Have pharmaceutical manufacturers sought to integrate into downstream components of the health industry, such as hospitals, insurers, pharmacies or so-called pharmacy benefits managers ("PBM's")? Have you found such actions to be anti-competitive? What remedies have you imposed?

65. No such attempts are known to the FCC

Abuse of Dominance

(4.9) What cases of abuse of dominance have you addressed? Have you addressed cases of tying or predatory pricing? In what ways can a pharmaceutical firm with a dominant position reduce competition from rivals?

66. The FCC has analysed two cases regarding presumable predatory pricing in retail distribution. The complaints were filed in 1997 by small pharmacy associations against pharmacy chains and supermarket chains with pharmacy departments, both offering discounts up to 50 percent of maximum consumer prices. These associations claimed that the chains sold pharmaceutical products at a prices below the costs of acquisition.

67. The FCC conducted investigations concerning those complaints. It found that chains buy big amounts of medications and operate with higher inventory turnover than small pharmacies. For these reasons, they can obtain considerable volume and prepayment discounts. Small pharmacies generally cannot obtain such discounts or to the same extent. Thus, the FCC did not find elements that proved the predatory pricing practice. Besides, there was a strong competition among the chains, and none of them had market power.

68. The FCC has not analysed other cases regarding abuse of dominance in the pharmaceutical sector.