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Pharmaceutical Pricing and Reimbursement Policies
in Mexico

Pierre Moïse and Elizabeth Docteur

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Health Working Papers

Pharmaceutical Pricing and Reimbursement Policies in Mexico

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DIRECTORATE FOR EMPLOYMENT, LABOUR AND SOCIAL AFFAIRS

OECD HEALTH WORKING PAPERS

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ABSTRACT

This paper examines aspects of the policy environment and market characteristics of Mexico's pharmaceutical sector, and assesses the degree to which Mexico has achieved certain policy goals. This paper questions the effectiveness of the maximum price regulation. It notes that retail prices for pharmaceuticals are relatively high, although proximity to the United States may have some influence. Although not wholly successful in containing overall drug expenditures, the federal government can claim some measure of success for the public sector market. A high reliance on out-of-pocket spending brings into question the sustainability of financing pharmaceuticals in Mexico. It also contributes to greater inequality, although a new health insurance scheme, the *Seguro Popular*, is addressing the latter with some success as it endeavours to provide coverage for the half of Mexico's population without health insurance. Finally, the paper acknowledges the government's efforts in improving efficiency of expenditures and quality of care through new bioequivalency requirements for generics. However, an unintended side-effect of the loss of low cost, non-bioequivalent drugs may be higher average prices for pharmaceuticals.

RÉSUMÉ

Le présent document examine certains aspects touchant l'environnement politique et les caractéristiques du marché du secteur pharmaceutique du Mexique, et évalue la mesure dans laquelle le Mexique a atteint certains objectifs politiques. Il met en doute l'efficacité de la réglementation sur les prix maximums et fait observer que les prix de détail des produits pharmaceutiques sont relativement élevés, mais que cette situation est peut-être due en partie à la proximité des États-unis. Bien que le gouvernement fédéral n'ait pas totalement réussi à maîtriser les dépenses globales de médicaments, il peut revendiquer d'un certain succès en ce qui concerne le marché du secteur public. Un large recours aux versements directs amène à s'interroger sur la viabilité du financement des produits pharmaceutiques au Mexique. Un tel recours contribue également à un accroissement des inégalités, bien qu'un nouveau dispositif d'assurance maladie, le *Seguro Popular*, remédie dans une certaine mesure à ce problème en s'efforçant d'offrir une couverture maladie à la moitié de la population du Mexique qui n'est pas assurée. Enfin, le document fait état des efforts déployés par le gouvernement pour rationaliser les dépenses et améliorer la qualité des soins moyennant l'adoption de nouvelles dispositions en matière de bioéquivalence des médicaments génériques. Cela étant, la disparition des médicaments peu coûteux non bioéquivalents risque d'avoir pour effet involontaire une augmentation des prix moyens des produits pharmaceutiques.

Classification JEL : I18, I11

Mots clés : Politique du médicament ; fixation des prix ; remboursement ; marché ; Mexique.

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1. THE POLICY ENVIRONMENT

1.   Mexico's pharmaceutical policy environment is in a period of rapid evolution, with simultaneous policy development, refinement and ongoing implementation. This handicaps Mexico's efforts to achieve policy goals efficiently at the present time, and also makes policy assessment and even accurate description difficult.

2.   The Mexican government recognises the need for a comprehensive framework and coordinated set of policies to achieve policy goals. An important step towards this was the publication in 2005 of *Hacia una política farmacéutica integral para México*, or Towards a Comprehensive Pharmaceutical Policy for Mexico, produced by the Ministry of Health as a statement of intent and direction. Some of the policy proposals and the goals they imply are controversial among experts, stakeholders and officials involved in Mexico's pharmaceutical sector, however.

3.   This first section of the report describes pharmaceutical pricing and purchasing policies in Mexico, as well as some of the most important related policies and practices, including policies to protect intellectual property rights, drug approval processes, health insurance coverage arrangements and policies to influence pharmaceutical use. The presentation focuses on present policies, but provides a glimpse of future policy directions and past policy history where this is critical to understanding the status quo.

1.1   Intellectual property rights

4.   Establishment and enforcement of intellectual property rights (IPR) provides economic incentives for private investment in research and development. Mexico's IPR protections are relatively new by OECD standards, as protection for pharmaceutical products was not implemented until the early 1990s. Although enforcement is improving, important problems remain.

5.   Intellectual property rights in Mexico are in line with the regulations of other developed countries. However, it is only within the past 15 years that Mexico has legislated strong IPR protections. Industrial property legislation prior to their enactment excluded patent protection for pharmaceuticals and chemical products in general, being confined to protection for industrial processes (Zuniga, 2002). At the time, it was government policy to make Mexico self-sufficient in the production of most pharmaceuticals.[1]

6.   Loose patent protection helped to foster a domestic generic pharmaceutical industry, encouraging many firms to specialise in producing "copy products," copies of drugs that are still under patent in other countries (see Box 1). Laboratories that produced copy products benefited from the same industry conditions that have allowed generics firms to flourish: avoiding large development costs, relying on clinical trial test data from the original product for asserting the safety of the generic version and capitalising on the low production costs to produce cheaper versions of original products. They also had

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[1] Like many Latin American countries in the period between the Depression of the 1930s and the 1980s, Mexico pursued a policy of import substitution industrialisation, i.e. it should strive to be self-sufficient in goods which it normally imports (Zuniga, 2002).

the added advantage of not having to wait for the expiration of the original product's patent before bringing their product to market.

7.   In 1987 Mexico amended the only legal ordinance that applied to patents and trademarks and added a new law, the *Ley de Invenciones y Marcas*, or Law on Inventions and Trademarks. Under the new law, patents for pharmaceuticals were to be allowed, but with a 10 year transitional period (Zuniga, 2002), ostensibly to allow producers of copy products time to adjust to the new realities of no longer being able to produce copies of on-patent products.

Box 1. Differentiation of the Mexican pharmaceutical product market

Original product. The first version of a medicinal product, developed and patented by an originator pharmaceutical company which receives exclusive rights to market the product for a specified period of time. An original product is a branded drug sold by an originator or by a company licensed or authorised by an originator, whether on- or off-patent. In Mexico, such products are also commonly referred to as "innovative" drugs or "reference" drugs.

Interchangeable generic (also referred to as GI - *genérico intercambiable*). Since 1998, a generic version of an original product that has gone off-patent can be certified as bioequivalent and interchangeable with the reference product.

Non-interchangeable generic.[1] A generic version of an original pharmaceutical product that is not proven to be bioequivalent to the reference product nor therapeutically interchangeable with it. The government has recently introduced directives that will eventually lead to the elimination of non-interchangeable generics from the market.

Copy product. A drug that is ostensibly bioequivalent to and interchangeable with a reference product that is on patent in another country. These drugs were common in Mexico prior to the strengthening of intellectual property rights in the nineties. Since then their numbers have been progressively diminishing.

1. The term *similares* (similars) is often used to denote these products. The term has been widely used by one retailer of non-interchangeable generics who sells his products in the private market.

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8.   This strengthening of its IPR regime was not enough for Mexico's future NAFTA (North American Free Trade Agreement) trading partners, Canada and the United States, who insisted that Mexico further strengthen its IPR law. Therefore, prior to ratifying NAFTA in 1994, Mexico signed into law the *Ley de Fomento y Protección de la Propiedad Industrial* (LFPPI, Law on the Promotion and Protection of Industrial Property) on 27 June 1991. This law provided for the standard patent protection for pharmaceuticals of 20 years from the date of patent application in Mexico. As a result of the enactment of the LFPPI, from July 1991 onwards pharmaceutical companies were able to patent products in Mexico as in other countries that explicitly recognised pharmaceutical patents.

9.   An important provision of the LFPPI was the granting of "pipeline patents" for pharmaceuticals, patents granted for pharmaceuticals in Mexico that were patented in other countries prior to the amendment of the LFPPI (See Box 2)[2]. The granting of pipeline protection for pharmaceuticals is a requirement of NAFTA, which goes further than the "limited marketing rights provided during the transition periods by TRIPS"[3] (Maskus, 1997). Under Article 12 of the LFPPI, applications for pipeline patents could be made for any pharmaceutical patented prior to 1991 in any country that was a signatory to the Patent Cooperation Treaty,[4] provided that no firm in Mexico was already producing copied versions of the pharmaceutical or

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[2] The following discussion on pipeline patents in Mexico borrows heavily from a legal opinion written by Hector E Chagoya and Sergio De Alva (Chagoya, 2003).

[3] TRIPS (Trade-Related Aspects of Intellectual Property Rights) is an international treaty administered by the World Trade Organisation (WTO) which sets down minimum standards for most forms of intellectual property regulation within all member countries of the WTO.

[4] The Patent Cooperation Treaty provides a unified procedure for protecting patents worldwide.

importing it into the country.[5] The priority date (the date of the first filing of the application for patent) for patents granted under the pipeline provision is considered to be the date of patent application in the country where the patent application was first made. Therefore, the expiration date for the patent in Mexico is the same as the expiration date in the country of first application.[6] This effectively gave the holder of the patent in Mexico a patent term equal to the expiration date (less the date of filing for the pipeline patent in Mexico).

Box 2. Pipeline patents

An important provision of the Law on the Promotion and Protection of Industrial Property was the granting of "pipeline patents" for pharmaceuticals. Under this provision, pharmaceutical companies must apply to the Mexican Institute of Industrial Property for a pipeline patent. Pipeline patent expiry dates are set equal to that of the foreign patent on which they were based. By law, terms cannot exceed 20 years as of the filing date of the application in Mexico.

Pipeline patent polices provide protection for pharmaceutical products that have already been patented in other countries. Shadlen refers to this as "retroactive patent protection" as it provides protection to pharmaceuticals that are not new for the duration of the patent in the country of origin (Shadlen, 2003). For example, if a patent was applied for in Canada in 1989, Mexico would offer pipeline protection to that product until 2009, the point at which the 20-year patent expires in Canada.

Pipeline protection is awarded from the date of the original filing of an application for a patent in the country of origin, even if the conventional term for patent recognition has expired (i.e., in most cases, patents are awarded only to new products, meaning that if a product has been patented in another country and the patent was issued more than one year ago, a patent will not generally be issued in another country).

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10.   The pipeline provision itself did not generate much controversy, but one aspect that did was the granting of extensions to patents. Patent extensions are often provided in many countries due to administrative delays during the application period or as compensation for the length of time required for conducting clinical trials necessary for obtaining marketing authorisation.[7] The LFPPI is ambiguous on the granting of term extensions to pipeline products (Chagoya, 2003). One interpretation of the law states that the term of the patent in Mexico depends on the expiration date in the country where the application for patent was first made. Under this interpretation, if a term extension is granted to the patent in the country of first application then the patent term should be extended in Mexico. Another interpretation is that the expiry date is fixed in the patent title and cannot be changed because the law does not allow for patent extensions. Under this cloud of confusion the *Instituto Mexicano de la Propiedad Industrial* (IMPI, Mexican Institute of Industrial Property) granted patent extensions in 17 cases.[8] For about half of these, no firms produced copies; however, 8 of the drugs were so-called blockbusters. Some firms went ahead and produced copies of these contested drugs despite the legal imbroglio that would inevitably ensue, judging

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[5] Thus, if a producer of an on-patent product, which was marketed in Mexico as a copy product prior to 1991, wishes to sell that product in Mexico it will not have the market exclusivity that patent protection provides. This situation will continue until 2011, at which time all patents of pharmaceuticals subject to the proviso will have expired.

[6] The patent could also expire if the original patent was abandoned due to litigation.

[7] For example, market exclusivity similar to patent protection can be extended by up to a maximum of five years following the expiration of a patent in EU member countries through a Supplementary Protection Certificate. The SPC is designed to provide a maximum of 15 years of market exclusivity from the date of marketing authorisation.

[8] The US Trade Representative has repeatedly used the "issuance of marketing approvals for patent-infringing copies of pharmaceutical products" (USTR, 2006), among other suspected IPR shortfalls, to place Mexico on its Special 301 Watch List of countries in which it suspects piracy is prevalent or tolerated by governments. These patent infringements were cited as reasons for placing Mexico on the Special 301 List in 2003 and again in 2005 and 2006 (USTR, 2003; USTR, 2005; USTR, 2006).

that the rewards of future profits from selling these drugs outweighed the costs of legal action and possible financial reparations.

11.   To deal with the confusion that resulted from the extension of patents due to the pipeline policy, the federal government issued a decree, with amendments in the *Ley General de Salud*, or General Health Law, and the *Ley de la Propiedad Industrial* (LPI, Law on Industrial Property), which replaced the LFPPI in 1994, to establish better coordination between the Ministry of Health (*Secretaría de Salud*), the authority responsible for granting marketing authorisation, and the Mexican Institute of Industrial Policy.[9] The amendment to the LPI imposed upon IMPI the obligation to publish a special version of the *Gaceta de la Propiedad Industrial* or Gazette of Industrial Property, a listing of trademarks, inventions and patent applications. The special version of the *Gazette of Industrial Property,* referred to hereinafter as the *Gazette,* is a non-exhaustive listing of active ingredients of pharmaceutical products that are under patent.[10] Second use patents and process patents are not included. The purpose of the *Gazette* is to reduce IMPI's burden in resolving pipeline cases by providing a link between the patent information on drugs that IMPI holds and the requests for marketing authorisation received by the Ministry of Health. Marketing authorisation for a pharmaceutical cannot be granted if the active ingredient is listed in the *Gazette*, except if the applicant is the patent holder. In cases where there is controversy regarding the title of the patent with respect to the substance or active ingredient, there is a provision under Article 227 of the LPI whereby interested parties may submit their arguments to arbitration. The *Gazette* has been produced for three years, during which time about 200 products under patent have been listed along with their International Nonproprietary Names, patent expiry date, the owner of the patent, some technical information and observations which in many cases include the current status of any litigation with respect to the product.

12.   The *Gazette* has reduced the number of litigious cases,[11] but has not completely resolved all problems pertaining to the granting of pipeline patents. There are still coordination problems between the Ministry of Health and IMPI that result in marketing authorisation being granted to generics firms for producing pharmaceuticals that are still under patent.

13.   Authority to manufacture generic copies of patented medicines can be granted through compulsory licenses, which are possible in Mexico under Articles 70 and 77 of the LPI. Under Article 70, a compulsory license may be granted if a patented product has not been produced in Mexico within 4 years from the priority date or 3 years from the granting of the patent. If, however, the product is being imported by the patent holder or a company licensed to import the drug, then no compulsory license can be granted. Although theoretically possible, these two waivers make it extremely difficult to obtain a compulsory license using Article 70. A compulsory license can also be granted under Article 77 of the LPI which states that a license to produce a pharmaceutical under patent may be granted to another laboratory for reasons of a national emergency, such as a shortage of medicines or a health crisis. There has been no granting of a compulsory license in Mexico in the last 14 years, although several unsuccessful attempts to obtain compulsory licenses for HIV/AIDS drugs under Article 77 have been made. These have inevitably faltered on the grounds that it is exceedingly difficult to define what constitutes a shortage or a health crisis.

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[9] Prior to this legal amendment, marketing authorisations were sometimes granted for patented products to a manufacturer other than the patent holder.

[10] The *Cámara Nacional de la Industria Farmacéutica*, known by its acronym CANIFARMA, is the trade body that represents the interests of the Mexican pharmaceutical industry. See the Section on National pharmaceutical production for more information on CANIFARMA. See the following section for more information on the granting of marketing authorisation for pharmaceuticals.

[11] Patent infringement cases are much more technically complex than most civil cases but are nonetheless adjudicated within the same judicial system. The judges that oversee patent cases are generally not trained to deal with the technical complexities these cases impose. These factors contribute to lengthy trials which create a period of uncertainty that can be commercially harmful to both plaintiff and defendant.

14.   A much debated aspect surrounding patents is the moment at which a generic manufacturer can reproduce an original pharmaceutical during the patent protection period for the purpose of initiating registry proceedings and tests of interchangeability.[12] Article 22 of the LPI allows scientific experimentation with original pharmaceuticals by entities without commercial aims other than the patent holder. More importantly for the generics industry, the recent reform to article 167 bis of the *Reglamento de Insumos para la Salud* (Regulation of Health Inputs) allows generics producers to ask for the registration of a generic with respect to a product under patent three years prior to the expiration of the patent, for the purpose of conducting the corresponding studies, tests and experimental production. Even though the registration is only granted once the patent expires, the objective is to shorten the time required for the roll-out of production of the generic product.

1.2   Product approval procedures and outcomes

15.   Responsibility for the licensing of drugs in Mexico resides with the Federal Commission for the Protection against Sanitary Risks (COFEPRIS, *Comisión Federal para la Protección contra Riesgos Sanitarios*). The COFEPRIS is the regulatory authority responsible for authorising drugs for marketing in Mexico and is a semi-autonomous organ of the Ministry of Health whose mission is to protect the population against health risks through public-health regulation, control and promotion.

16.   In order to obtain a license to market a drug, or a sanitary license as it is referred to in Mexico, COFEPRIS requires the following from the applicant:

- Primary materials, especially active ingredients of the drug, must conform to accepted norms;

- Production must take place in duly authorised adequate facilities;

- A valid production procedure, as set out in NOM-164-SSA1-1998 *Buenas prácticas de fabricación de fármacos*, the official standards for good practice in the manufacture of medicines, must be followed;

- The quality of the pharmaceutical must conform with certain specifications, corroborated by appropriate analyses showing that the final product contains the proposed active ingredient in the necessary concentration and without any harmful impurities;

- Stability must be demonstrated, under conditions of normal usage, for a sufficient time period;

- Therapeutic efficacy must be verified through clinical trials;

- The product must be established as reasonably safe, in relation with expected benefits; and

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[12] This is known as a Research Exemption, also called a Hatch-Waxman exemption or Bolar provision. This exemption allows generics manufacturers to conduct research and tests on a generic version of an on-patent pharmaceutical before the patent expires. Without such a provision, the effective life of a patent would be extended beyond its original expiry date by the time required to conduct tests on the generic versions for market entry. A related legal issue is the protection of test data submitted by originator firms to health authorities for marketing authorisation which is covered by Article 39.3 of TRIPS. This clause protects the original applicant from the "unfair commercial use" of submitted data. In order to comply with the clause, countries allow a period of protection during which generics companies are not allowed to use these data for the market approval of their generic versions. In the United States and Mexico, this exclusivity period is 5 years; it is 6 – 10 years in EU Member States.

- Conditions of quality, efficacy and security must be maintained during the time of commercialisation of the product.

17. Mexico has neither the means nor the authority to investigate production facilities abroad, despite heavy reliance on imported pharmaceuticals. COFEPRIS is working with the Food and Drug Administration in the United States and Health Canada to arrive at mutual recognition of verification of pharmaceutical products manufactured in each country. It has also initiated a similar venture with the authorities in Argentina, Brazil and Spain.

18. Targets for approval times for new drugs are notably short. For generic drugs, approval is expected within 40 days. For drugs patented in other countries the approval period is 60 days. For new molecular entities without patents in other countries the deadline is 90 days (OECD, 2000). Data regarding actual approval times were unavailable.

19. Until recently, there has been no requirement for a generic manufacturer to prove the bioequivalency of a product with its reference drug. However, two recent developments mean this will no longer be the case. A recent change to Article 376 of the General Health Law stipulates that market approval for drugs will be limited to a period of five years. Upon expiration of the five year period, the manufacturer may apply for renewal and continue to do so every five years thereafter. The second development requires all manufacturers to submit proof of bioequivalency of their generic products as part of the process for obtaining market approval, including applications for the renewal of marketing authorisation.[13] Taken together, these developments will effectively eliminate all non bioequivalent generics from the Mexican market by the end of 2010.

20. Pharmaceutical manufacturers will have to provide plans establishing which of their products will have to undergo bioequivalency tests within each of the next 5 years. These tests are to be carried out by "third-party laboratories" authorised by the Ministry of Health for the purpose of testing the bioequivalency of generics.[14] Generics manufacturers may conduct their own bioequivalency tests provided they fulfil the same requirement demanded of authorised third-party laboratories by the Ministry of Health. There are currently 40 authorised third-party laboratories in place and the authorities have set a target annual growth rate of 20% starting in 2005.

21. As of September 2005 there were nearly 40 000 registered products, of which about 7 000 were on the market and only 3 109 were interchangeable generics (Ministry of Health, 2005).

1.3 Pricing policies

22. Pharmaceuticals are one of two industries in Mexico — the other being liquid petroleum gas — for which prices are still regulated. While strict price controls were a feature of past regulations, recent regulations have been aimed at opening up pharmaceutical pricing to allow more flexibility.

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[13] This is being implemented through corresponding amendments to the Mexican Pharmacopoeia (Farmacopea de los Estados Unidos Mexicanos) which specifies all requirements necessary for generics to obtain marketing approval. For a product to be defined as a pharmaceutical compliance with the Pharmacopoeia is mandatory.

[14] NOM-177-SSA1-1998 establishes the tests and procedures required for establishing bioequivalency. It also sets out the necessary requirements for third-party authorised laboratories. This norm is currently under revision in order to be consistent with recent legal amendments concerning bioequivalency, including those of the Mexican Pharmacopoeia. These changes will aid in the implementation of requesting bioequivalency proofs for market approval of a generic product.

23.   Regulation of pharmaceutical prices in Mexico dates back to 1951 when the Act on Federal Executive Attributions in Economic Matters established maximum prices for drugs and other products. In 1984 a separate regulation for pharmaceutical prices was established in the General Health Law. Article 31 of the law conferred responsibility to the *Secretaría de Comercio y Fomento Industrial* (SECOFI, Ministry of Commerce and Industrial Development) to fix maximum retail prices for drugs. Based on this regulation, the maximum retail sales price for a drug was based at that time on analysis of the manufacturer's cost and operating expenditures with predetermined margins for manufacturers, wholesalers and retailers.

24.   In a bid to modernise the pharmaceutical industry, SECOFI, which is now the Ministry of the Economy (*Secretaría de Economía*), entered into negotiations on a number of issues with CANIFARMA, the latter on behalf of the pharmaceutical industry. One of the issues was to loosen the rigid price setting regulations by establishing new guidelines for setting the maximum retail prices for pharmaceuticals in the private market.[15] Participation by manufacturers in the price regulation scheme was voluntary.[16] The main characteristics of the regulation were as follows:

- Innovative pharmaceuticals – price determined by the manufacturer, but the price could not exceed a vaguely defined international price;[17]

- Newly introduced products whose active ingredient already existed in the market – price not to exceed that of the comparable product with the highest price;

- Existing products – price based on a formula defined by the manufacturer in accordance with its cost structure. The calculation of the maximum price is based on the weighted average of the sales of all the manufacturer's existing products, with the annual increase limited by an inflation factor of the manufacturer's choosing, based on at least two officially published indicators.

25.   It soon became apparent that there were flaws in this maximum retail price regulation. Basing costs on local production costs appealed more to the logic of compensating laboratories for the accords they signed in 1984, when the government's objective was to reign in the high inflation rates of that period, than as an explicit strategy to limit unjustified price increases in the absence of a competitive market (González-Pier, 2004). Moreover, an analysis prepared for the Economic Analysis Unit of the Ministry of Health in 2002 demonstrated low compliance in maintaining retail sales prices below the maximum retail price. Based on a sample of products, the analysis revealed that actual retail sales prices exceeded the maximum retail price in more than 43% of cases. Lack of reporting by firms and lack of sanctions also weakened the scheme.

26.   The latest maximum price regulation scheme, adopted in 2004, is an attempt to improve upon some of the failings of the previous one. The principal characteristics of the scheme, which is administered by the Ministry of the Economy, are as follows:[18]

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[15] The series of negotiations between SECOFI and CANIFARMA to modernise Mexico's pharmaceutical industry was initiated in 1990 and eventually became known as the *Programa para la Modernización de la Industria Farmacéutica* (PROMIF). As part of the PROMIF, the new agreement on the maximum price regulation scheme was signed on 12 September 1996.

[16] From September 1996 to November 1997, 104 pharmaceutical companies, whose sales represented 96.8% of total pharmaceutical sales in 1997, participated in the PROMIF (González-Pier, 2004).

[17] There were no specific guidelines that were followed to determine the international price. The SECOFI had released a circular of possible international prices, one of which was the price in the country with greatest sales and another was the average price of the product in at least 7 countries, calculated by eliminating the highest and lowest price.

- The regulation applies only to patent-protected drugs sold in the private-sector market;

- Participation by manufacturers is voluntary;[19]

- An international reference price serves as a benchmark for establishing a price threshold which the maximum retail sales price of a patented medicine cannot exceed;

- For new products with no comparators, the manufacturer can set the price, subject to re-evaluation three months after product launch; and

- Generic drugs and original products whose patents have expired are exempt from price regulation.

27.   There are three different prices defined in the price regulation. First there is the international reference price, known by its Spanish initials as PIR (*Precio Internacional de Referencia*). When a manufacturer registers a product with the Ministry of the Economy, the PIR is calculated as the weighted average of ex-factory prices from the previous quarter in the six countries where the product enjoys the highest sales penetration. The manufacturer has to submit to the Ministry of the Economy each year the international reference prices used for the PIR. The PIR is subject to annual verification by an external auditor.

28.   Next is the PRVP (*Precio de Referencia para Venta al Público*) or the reference price for sales to the public. The PRVP is derived from the PIR by multiplying the latter by 1.72 (PRVP = PIR x 1.72). The multiplication factor of 1.72 corresponds to what is typically considered the combined average wholesale and retail margins in Mexico. The PRVP is then converted into pesos using the average exchange rate as calculated by the Central Bank of Mexico, the *Banco de México,* for the quarter immediately preceding the date on which the firm registered its product in the reference-price scheme, i.e. the exchange rate corresponding to the period of time for which the PIR was calculated.

29.   Finally, there is the maximum sales price to the public (PMVP, *Precio Máximo de Venta al Público*). The PMVP, as the name suggests, is the maximum retail sales price allowable for an on-patent pharmaceutical product and is set by the manufacturer. This is the maximum price that the manufacturer stamps on the label of the pharmaceutical product.[20] When a manufacturer registers a patented product with the Ministry of the Economy it reports the PMVP as well as how it will calculate future price increases. If the PMVP or the proposed increases result in a PMVP that is greater than the PRVP then the former must adjust downwards to the PRVP. In this case there is a period of transition in which the manufacturer is allowed to bring the PMVP in line with the PRVP.

30.   The current scheme of price regulation applies to the following cases: (1) Patented medicines marketed prior to the signing of the agreement of October 2004, (2) products marketed in Mexico for the

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[18] Much of what follows of the description of the price regulation scheme comes from an unpublished analysis from the Ministry of Health (EAU, 2006).

[19] Firms failing to adhere to the new scheme could be subject to other price control mechanisms based on Article 7 of the Federal Competition Law (*Ley Federal de Competencia*). This article states that in the case of goods and services defined by decree as necessary for the national economy or general consumption and subject to price controls, and so long as there is a lack of effective competition, the Ministry of Economy can set maximum prices (based on criteria to avoid supply shortages).

[20] *NORMA Oficial Mexicana* NOM-072-SSA1-1993 Section 5.16 states that the maximum price to the public must be stamped on the labels of all pharmaceutical products produced for human consumption. The legend "Precio máximo de venta al público," followed by the corresponding amount must be legible and indelible.

first time after October 2004, (3) any updates of patented medicines prices for products registered within the framework of the agreement, i.e. updates to the retail sales prices in cases (1) and (2). Registered products that lose their patents after October 2004 are excluded, as are generic products, given that in both cases the prospect of price competition eliminates the rationale for price regulation. Moreover, in the case of new products, where the active ingredient does not exist in any other pharmaceutical form or it exists in a non-comparable form, the sales price to the public is solely determined by the manufacturer. Nevertheless, following a period of three months, a post-launch review is conducted to verify whether the product exists in the international market, and following confirmation that it does, the PRVP will be estimated and the regulation applied as per the agreement of October 2004.

31.   As with the previous price regulation, participation by pharmaceutical companies is voluntary and it only applies to pharmaceuticals sold in the private sector market. Once a manufacturer registers voluntarily in the new scheme, it cannot choose which patented drugs it will place under the scheme; all of the patented drugs it sells must be included in the maximum pricing scheme, without exception. The current accord is an agreement between the Ministry of the Economy, with support from the Ministry of Health, and the research-based pharmaceutical companies, represented by CANIFARMA and the Mexican Association of the Research-Based Pharmaceutical Industry (AMIIF, Asociación Mexicana de Industrias de Investigación Farmacéutica). As of October 2005, 231 different pharmaceutical presentations corresponding to 15 companies were registered under the reference-price scheme.

32.   Administration of the pharmaceutical price regulation scheme is the responsibility of the Ministry of the Economy. The Ministry regularly monitors prices, receiving information from the pharmaceutical companies once a year, where they report the price increases applied in the past year. The collected information represents estimated consumer prices at the point of sale, taking into account discounts offered by pharmacies. This information is included in a database and the results analysed within the Ministry of the Economy and then sent to CANIFARMA. Every three months officials of the Ministry of the Economy meet with those of CANIFARMA and AMIIF to discuss the analyses of the price data.

33.   While the Ministry of the Economy is responsible for administering the price regulation scheme, it is another organisation, the *Procuraduría Federal del Consumidor* (PROFECO, Federal Office of the Judge Advocate General of the Consumer), which is responsible for enforcing compliance with the maximum prices it establishes. PROFECO monitors pharmacies' adherence to the law by investigating reports of pharmacies selling drugs at prices exceeding the stamped maximum price. However, PROFECO's responsibility in this respect is only to make sure that pharmacies do not sell products at a price higher than the stamped price, it has no authority over how manufacturers set the maximum prices of their pharmaceuticals.

34.   It is too soon to make any definitive assessment of the latest maximum price regulation scheme. Nevertheless, there are some aspects of the scheme that can be assessed.

35.   The latest price regulation scheme is an improvement over the previous one in so far as it has de-regulated prices for generics and off-patent products, for which the economic rationale to impose a price ceiling is weak. However, the system is, by design, relatively weak as a price control mechanism. Most importantly, the system remains voluntary. The fact that most, if not all, manufacturers choose to participate suggests that the system is one that is perceived by manufacturers as ineffective: if the regulation had an impact by resulting in prices lower than what would otherwise be set in the absence of regulation, manufacturers would face strong economic incentives to not participate. A second indicator of weakness is that the pharmaceutical manufacturers' association has set up its own price monitoring system in an effort to ensure that individual manufacturers do not take advantage of the system by setting high prices and causing political pressure that would jeopardise the current arrangements.

36.   Indeed there is evidence that the maximum retail price established through the current regulation is generally not binding. An unpublished preliminary analysis by the Economic Analysis Unit of the Ministry of Health, based on data sent to the Ministry of Economy, examined pharmaceutical prices under the current maximum price regulation (EAU, 2006). An examination of prices in May 2005 reveals that of 273 examples examined, the maximum price established by the manufacturer was lower than the international reference price about 73% of the time, and equivalent in another 2% of cases.[21] When considered in light of the fact that retail discounts of 30 - 40% off the maximum price marked on the package are reportedly common, it is clear that the maximum price level set through the regulation is generally too high to serve as a binding constraint on the price paid by consumers.

37.   There may be a number of reasons why Mexico chooses to retain a retail price regulation system that is designed to have little impact on price levels. Perhaps the most likely consideration is that the Mexican public demands that some form of price controls on pharmaceuticals should be in place. In interviews with industry representatives, government officials and stakeholders, several mentioned that the complete elimination of price controls would have been anathema to the general public, given the historical policies in this area.

1.4   Coverage of pharmaceuticals

38.   Mexico is one of several OECD countries that does not have a single, national scheme providing health care coverage for the population as a whole.[22] About half the population enjoys social insurance coverage for health care, including pharmaceuticals, for which they have regular access to products dispensed at their respective social security agency's pharmacies. The other half of the population relies on federal and state funded services, with the exception of 3% of the population which has private health insurance.

39.   Social insurance is compulsory for all salaried workers in the formal labour market. The *Instituto Mexicano del Seguro Social* (IMSS, Mexican Social Security Institute) is the largest of the social insurance agencies. It provides coverage for all salaried employees of private companies. In 2002 IMSS covered about 46.2 million Mexicans. The other large social insurer is the *Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado* (ISSSTE, Institute of Security and Social Services for Government Workers), which covered 10.3 million people in 2002 according to the Institute's own estimates. Together these two institutes cover about 95% of Mexico's socially insured population.[23]

40.   IMSS and ISSSTE beneficiaries and their dependents are covered for most health care services, including most prescription pharmaceuticals included in their respective formularies, provided the drugs are dispensed from a pharmacy operated by the social security agencies.[24] They receive health care at no out-of-pocket cost from providers employed by their social insurance institution. There is no cost-sharing

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[21] It is possible that many or most of those drugs out of compliance were on the market prior to establishment of the new regulation, and are in the process of transition to a lower retail price.

[22] For a more detailed exposition of Mexico's health care system see the OECD review of Mexico's health system (OECD, 2005a).

[23] Other smaller social security agencies cover the remaining 5%. These include employees of the navy, the federal Ministry of Defence, and the national oil monopoly, PEMEX, as well as in Mexico City, the police, the federal district government and the Metro system.

[24] All drugs listed on IMSS' and ISSSTE's formularies are included in the interinstitutional basic formulary, the *Cuadro Basico*, which is used by the social security agencies and the government. The following section provides a detailed explanation of the basic formulary.

obligation for prescribed medicines. Health care coverage is governed by the General Health Law and the laws governing the social security agencies.

41.   For the other half of the population that does not enjoy social insurance coverage, there exist voluntary insurance programs operated by IMSS and the Ministry of Health as well as government schemes to improve access to care — used by approximately 40 million uninsured Mexicans. In 1997 two voluntary insurance programs were initiated by the government to expand coverage to two significant proportions of Mexico's working age population who do not fall under the net of social insurance: the self-employed and people who work in the informal sector,[25,26] i.e. who work for employers who do not declare workers and thus are not paying their social security contributions. The *Incorporación Voluntaria al Régimen Obligatorio* was established to provide a voluntary health-care benefits scheme for self-employed workers, while the *Seguro de Salud para la Familia* was started to provide coverage for workers in the informal sector. However, most of those eligible considered these programs too expensive to buy into and thus registration in them has been minimal.

42.   The uninsured can obtain health-care services through Ministry of Health or state health services facilities, subject to an evaluation of socio-economic status at the time of receiving the treatment, or through public programmes created to improve access to health care services. While drugs provided to patients in hospital are free of charge, patients must pay out-of-pocket for any drugs following discharge for the same episode of care. However, recent reforms have established a public health insurance scheme, the *Seguro Popular de Salud*, or Popular Health Insurance, which eventually will become the main vehicle for covering all individuals not covered through social security. This scheme now covers the costs of these drugs for patients enrolled in the program based on a catalogue of 249 essential (primary and secondary care) interventions and 17 interventions (mostly high-specialty) relating to catastrophic expenditures (González-Pier *et al.*, 2006).

43.   Private insurance in Mexico is very limited. At present, only 3% of the population, mostly individuals with high incomes, has private insurance with employer subsidised group plans accounting for half of private health insurance coverage.

44.   A consequence of having half the population without health insurance coverage is a large discrepancy in total disposable income devoted to health care (Ministry of Health, 2005). According to data compiled by the Ministry of Health, uninsured individuals contributed a greater share of disposable income to health care than the rest of the population regardless of the level of expenditure in 2000 and 2002, with the exception of the top 10% in 2000 (Ministry of Health, 2005). Sesma-Vázquez, *et al.* (Sesma-Vázquez, 2005), in a study of catastrophic expenditures on health (defined as health expenditures over 30% of a households' ability to pay), found that 69% of the total number of households that incurred catastrophic expenditures were uninsured whereas 31% were insured. Among uninsured households that had incurred catastrophic expenditures, 20% were related to pharmaceutical spending, while among insured households that had incurred catastrophic expenditures, 16% were related to pharmaceutical expenses.

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[25]Some of these individuals may be covered if they are dependants of someone who has social security cover (OECD, 2005a).

[26] There are an estimated 15 million people self-employed in Mexico (OECD, 2005b), almost ¼ of the working age population and it is estimated that there may be as many as 20 million people working in the informal sector (Cevallos, 2003).

1.5   Formularies used by coverage schemes

45.   The social security agencies and the Ministry of Health and state health authorities are obliged to purchase their pharmaceuticals from two sets of positive lists: the *Cuadro Básico*, or Basic Formulary and the *Catálogo de Insumos*, or Catalogue of Inputs.[27] The Basic Formulary and the Catalogue of Inputs are the culmination of a process that began twenty three years ago with a Presidential Agreement which established the need for a basic formulary to be used by public sector health institutions for their purchases of medicines.[28]

46.   The Basic Formulary is designed for medical care at the primary level. The Catalogue of Inputs is designed for care provided at the secondary and tertiary levels. They are not just drug formularies but reference sources for purchases of medical inputs with separate listings for each of the following: (1) medicines, (2) medical equipment and instruments, (3) treatment materials, (4) diagnostic aids. The medicines listed in the Basic Formulary and the Catalogue of Inputs are used by the public sector health institutions for their purchases of drugs. Altogether, these formularies comprise 23 therapeutic groups of pharmaceuticals. Products are identified by their generic name and a 4-digit code. The following pieces of information are included for each pharmaceutical: active and constituent ingredients, package, presentation, indications of use, mode of administration and dosage, risk in pregnancy, contraindications and precautions, adverse reactions and a general description of how the drug works. The 2005 editions of the Basic Formulary and the Catalogue of Inputs list a total of 776 generic names of drugs and 1 223 codes.[29]

47.   Responsibility for the development of these formularies rests with the *Comisión Interinstitucional del Cuadro Básico de Insumos del Sector Salud*, or Interinstitutional Commission of the Basic Formulary of Inputs of the Health Sector*)*, which meets at least three times per year. Representatives from the Ministry of Heath, IMSS, ISSSTE, the *Sistema Nacional para el Desarrollo Integral de la Familia* and the National Defense Ministry constitute the body of this commission. The Interinstitutional Commission acts as a working group under the auspices of the *Consejo de Salubridad General* (CSG), the General Health Council. Thirteen institutions sit on the board of the CSG which is presided over by the Council President, the Minister of Health. The President appoints the Council Secretary who oversees the functioning of the CSG. There are specific sub-committees for each type of listing comprised in these formularies. These sub-committees meet at least once a month.

48.   The Basic Formulary and the Catalogue of Inputs can be updated in response to: requests for listing products; for modifying the formula, packaging or presentation of a pharmaceutical already listed; and for de-listing.

49.   A request for listing a drug on the formulary can be made to the Interinstitutional Commission by public institutions providing health care, scientific organisations and pharmaceutical providers. All requests for inclusion on the formularies have to follow a bylaw specifically designed to accept requests. The bylaw stipulates three criteria that all drugs must meet for inclusion in the formularies. First, the drug must have been granted marketing authorisation. Second, the drug must have met all safety and clinical tests. Third, the drug must be cost-effective. With regards to the third criterion, the current regulation states

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[27] The Presidential Agreement of December 2002 states that "public institutions of the National Health System should only utilise inputs established in the *Cuadro Básico* (Basic Formulary) for primary level medical attention, and for secondary and tertiary level care, the catalogue of inputs."

[28] Published on 9 June 1983 in the Official Journal of the Federation. This agreement was itself the result of previous efforts, going back to 1975, to implement uniform coding for health inputs used in the public health sector.

[29] For each generic drug name there may be more than one code, each code corresponding to a different presentation.

that the applicant must submit with the request for submission all pharmacoeconomic tests pertaining to the drug. The bylaw is currently being revised to make the cost-effectiveness criterion, which has been in place for only two years, more explicit and to clarify its implementation.

50.   Once a request for listing has been submitted to the Interinstitutional Commission, all the information needed to make a listing decision is forwarded to each member institution. This information includes results of random, double-blind clinical trials, literature searches and pharmacoeconomic studies where these exist. Each member institution analyses the whole dossier and receives the analysis of the other member institutions.

51.   A listing decision is supposed to be made within 4 months of the initial request, although in reality, this is often surpassed. The final listing decision is based on majority vote. At least half of all requests for inclusion are rejected. If a drug is accepted for inclusion the Commission informs the manufacturer. The decision is then placed on the internet for 10 days for other groups to challenge its inclusion. It has not happened often, but there have been a couple of cases where a challenge to a drug's inclusion was successful.

52.   When a drug already listed is modified it must be done in such a way as to ensure that no other product's patent is infringed upon or that a similar product is displaced.

53.   The decision for de-listing a product is taken within the Interinstitutional Commission. There are several reasons for which a product can be de-listed. For example, a drug can be de-listed because it is no longer being prescribed. Another reason could be because the product is not being commercialised or traded, which happens sometimes with antibiotics. A third reason could be that the board knows that a product will not be used. A final reason could be if the board is aware of the availability of another product of greater efficacy and lower risk, toxicity or severe adverse side-effects. Pressure from pharmaceutical companies to keep a product on the formularies can make de-listing very difficult.

54.   Although the public sector health institutions must purchase only what is included in the Basic Formulary and the Catalogue of Inputs, they can choose not to purchase listed products. For example, at one point even though statins were included in the formularies, some social security organisations chose not to purchase them; it was not until a less expensive statin was launched that the same social security organisations purchased the cheaper product.

55.   The social security agencies must use the Basic Formulary (CB) as the foundation for any drug purchases, but this does not preclude the creation of institution-specific formularies so long as these are subsets of the formulary. In the case of IMSS, its formulary has 30% fewer drugs than the Basic Formulary. The formularies for ISSSTE and the Ministry of Health are similar to IMSS' formulary.[30]

56.   The decision process for listing drugs on the IMSS formulary is similar to the process for listing drugs on the Basic Formulary and Catalogue of Inputs. The decision is based on scientific evidence, including cost-effectiveness studies. Although no pharmaceutical companies are directly involved in the decision process, their lobbying of IMSS-affiliated physicians, who can request that certain drugs be added to the IMSS formulary, provided they are already included on the CB.

1.5.1   Hospital formularies

57.   The medicines listed in the Catalogue of Inputs is the formulary used by public hospitals, though they have the flexibility to go off formulary.

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[30] It is not known whether the other social security agencies have created their own formularies.

58.   Large private hospitals establish their own formularies through a Pharmacy Committee composed of physicians and pharmacists. Drugs are included in the formulary in accordance with the needs of a particular hospital's different specialties. The formularies of large private hospitals are quite different from the Catalogue of Inputs due to significant differences in patient populations. Smaller private hospitals are not likely to have established formularies for their drug purchases.

1.6   Purchasing

59.   Public purchasers procure pharmaceuticals for dispensation in publicly owned and operated pharmacies. All medicines purchased by public-sector institutions must follow the regulations set out in the Law of Acquisitions, Leasing and Services of the Public Sector. The law stipulates three methods by which pharmaceuticals can be bought: through public biddings, invitation to at least three people/organisations or direct negotiation.

60.   Most products listed in the Basic Formulary and the Catalogue of Inputs are supplied to the purchasing institution through a bidding process. The main bidding process is national, i.e. open only to manufacturers of products for which more than 50% of the constituent ingredients have been manufactured in Mexico. In the case of the Basic Formulary, this is not necessarily an undue restriction on supply since most of the products are generics which benefit from a well-developed domestic industry. Nevertheless, this limited bidding process can place restrictions on the availability of drugs to public sector institutions. To help alleviate this problem the law allows for international bids, where foreign companies can take part, in several cases, including: if the purchasing institution cannot find any domestic supplier for the drug it wishes to purchase, if the price of the drug revealed through the bidding process is deemed to be too high or if the bidding process fails to produce any bids. There are two types of international bidding processes, one in which national and international firms proffer bids for a given drug based on a national tender process, and one in which a tender is put out to the international community. International bids are especially useful for complicated generic drugs that would be difficult to produce domestically.[31] Each bidder must include a minimum and maximum volume of drugs it is willing to supply at its bid price.

61.   The law also allows for the purchase of patented medicines, for which a bidding process is inappropriate since there is only one producer. For patented medicines, the purchasing institution can enter into direct negotiations with the producer.

62.   Each social security institute has its own structured procedure through which it requests the drugs it wants to buy. Budget constraints are taken into consideration, but medical necessity is the most important criterion.

63.   In 2005 IMSS purchased 883 different pharmaceuticals, of which 99 (11%) were patented products, 367 were interchangeable generics (42%) and the remaining 417 (53%) were non-interchangeable generics (based on presentation by IMSS officials). In volume terms, interchangeable generics (GIs) figured prominently; 89% of pharmaceuticals purchased by IMSS were GIs compared to 10% that were non-bioequivalent generics and only 1% patented products.

64.   The drug purchasing process of the IMSS is decentralised to its 35 state delegations and 25 Medical Units of High Specialty (Tertiary Level Hospitals). IMSS purchases drugs by their International Nonproprietary Name, as listed in the Basic Formulary and the Catalogue of Inputs. For each drug, the purchasing unit first calculates the needs of its medical units, taking into consideration established medical

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[31] The law also stipulates that international bids must be used if an international treaty to which Mexico is a signatory obliges it to do so. This has been used with Mexico's NAFTA partners, Canada and the United States, to increase competition during the bidding process.

goals. Once the amount of the drug required is determined, this amount is set against the estimated inventory at the beginning of the contract period to determine the net required amount. IMSS then solicits bids, in accordance with the Law of Acquisitions as set out earlier in this section, for manufacturers to supply it with the net required amount. The winning bid(s) is that (those) with the lowest costs which is deemed technically feasible. Finally, a contract is signed by both parties wherein the purchasing unit agrees to buy a fixed amount at the bid price and the supplier guarantees to supply said amount.

65. There is a website where the delegations can view the drugs that IMSS has purchased and those that it is about to purchase. These data, including prices, stretch back to the past 5 years. Thus, delegations can compare the prices they paid with the winning bids in other regions to help them obtain the lowest prices possible.

66. Jointly with Nacional Financiera,[32] IMSS has a policy of using small and medium firms to supply its pharmaceutical products.

67. IMSS's decentralised system is a way for the delegations to purchase drugs according to local needs, an important consideration given Mexico's diverse epidemiological and socio-economic regional diversity. However, the system may also reinforce regional inequalities by creating prices that correlate with regional disparities. The regions with the worse market conditions, remote populations that are difficult to access, have low required volumes and frequency of provisions, inevitably attract the highest prices. These regions would benefit most from a centralised purchasing system where IMSS would take full advantage of its power as a large purchaser to extract the best prices possible.

68. Another criticism of the bidding process, one related to the process for the whole of public sector institutions, is the lowest bid requirement, which it is felt could result in a significant amount of non-interchangeable generics being bought by the purchasing organisations in place of more costly bioequivalent generics. This undermines the government's goal of purchasing only bioequivalent generics, however, the mandatory requirement that all generics be fully bioequivalent within 5 years will likely reduce significantly the number of non-bioequivalent drugs in the public sector.

69. For the moment, IMSS does not envisage moving to a reimbursement system since it believes the decentralised purchasing system is efficient. In fact, up until recently, reimbursement of pharmaceuticals has not been a feature of publicly provided health care services in Mexico. However, the *Seguro Popular de Salud* will be moving to a system of reimbursement as part of its new program (Box 3). The move to a reimbursement system should lead to greater availability of pharmaceuticals. The current distribution system, which is plagued by problems of mismatched supply and demand, will be replaced by a system which relies more on individual pharmacies, which should be better equipped to provide the right quantity of medicines and distribute them where they are needed. Accessibility should improve as the limited number of points of access where public-sector pharmaceuticals are dispensed are replaced by the growing number of private pharmacies signing-on to serve beneficiaries of the *Seguro Popular*. A potential downside is that it may be more difficult to obtain prices that are equally low under a system of reimbursement.

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[32] *Nacional Financiera* is a banking institution which promotes the development and modernisation of the industrial sector.

Box 3. *Seguro Popular de Salud*: **From Public Procurement to Reimbursement**

Started as a pilot programme at the end of 2001 and formally implemented in 2004 as part of the *Sistema de Protección Social en Salud* (System of Social Protection in Health), the *Seguro Popular de Salud* (SPS), or Popular Health Insurance, is a voluntary public health insurance scheme targeted to low-income families outside the social security system — 45.2% of individuals affiliated with the SPS are in the lowest 20% of income earners.[1] It is intended to provide uniform, subsidised health insurance for a defined set of essential primary and secondary services and care for selected catastrophic health conditions. The benefits package is gradually being expanded and services covered under the catastrophic expenditures fund are updated annually. Though the essential benefits package is standardised at the national level, the responsibility of providing the SPS essential benefits is that of the individual state authorities. The catastrophic expenses portion of the SPS scheme is financed by a fund that aggregates risk at the national level. Services are accessed through state health services and federal Ministry of Health facilities. Although not yet in place, the reform will allow for the use of private sector and social security providers on the basis of service provision agreements. By the end of 2006, 5.1 million families (about 22 million people) will have been enrolled in the scheme [2] (Frenk, *et al*.; 2006; Ministry of Health, 2006). Financing of the SPS is through a tripartite arrangement between federal and state contributions, and progressive household contributions through income-tested premiums. The objective is to extend coverage to the entire uninsured population (approximately 11 million families) by 2010.

From public procurement …

The current, decentralised drug procurement process has been criticised as being overly lengthy (averaging 4 months) and fragmented, and for consistently leading to supply shortages of necessary medicines in the first quarter of every year (Kearney, 2004). To shorten the lengthy procurement process, the government is in the process of implementing a system of reverse auctioning. Under this system, individual states specify the volume required for a 6 month supply of each drug it wishes to purchase, the lowest price at which it will accept a bid, and the geographic region of coverage. Both generics and brand-name drugs are included in the process. Manufacturers are invited to submit bids/proposals over a two-week period. Proposals will be analysed by a working group that will recommend those proposals that best meet the states' required volumes, while guaranteeing a national supply according to projected demand. The contract may be awarded to multiple suppliers. Each state will be autonomous in its purchasing of drugs and will be obliged to sign up one supplier. The result will be more heterogeneous prices across states, but, hopefully, lower average prices for the entire country.

… to reimbursement

A long-term reform on the SPS pharmaceutical agenda will focus on shifting away from public procurement to pharmacy reimbursement through the use of private-sector pharmacies and a "smart card" reimbursement system. Under the first part of the reform, private pharmacies will assume responsibility for storing and dispensing medications to SPS beneficiaries, and will receive a fixed price per drug from the state. The second part of the reform is a sophisticated reimbursement system that involves the use of patient identification cards (smart cards). Health and prescription data are stored on electronic chips housed in the smart cards that can be accessed by physicians and pharmacies through smart card readers. Smart cards will contain patient and prescription information. Notably, physicians will be able to prescribe medications on the card. Patients will then take the card to a participating private pharmacy, [3] where the card is swiped in the smart card reader and the prescription details (but not the price of the drug) are revealed to the pharmacy. The card reader requires that the prescribed drug is the one dispensed, and pharmacies will receive reimbursement from the government only for prescriptions registered on the card. The pharmacy is reimbursed by the government for the drug at the point of sale. Any pharmacy that violates the process will be banned from the system.

Objectives of the reimbursement policy

There are a number of objectives the reimbursement policy is intended to address. Overall, the shift from public procurement to reimbursement is expected to eliminate government responsibilities in storing and distributing pharmaceuticals and associated costs. Moreover, determining the appropriate mix and quantities of drugs is administratively costly and time consuming.

The second objective of the reimbursement policy is to increase the probability that patients receive the correct medication, and that they only receive medications for which they have a prescription. Since the pharmacy receives reimbursement only for medications registered on the card, this should reduce the amount of substitution while providing an incentive to dispense medications only to SPS beneficiaries with a prescription.

The third objective is to equate the number of prescribed medications with the number of prescriptions dispensed. Under the current system, only 70% of drugs prescribed actually reach the patient (i.e., because the drugs were unavailable in the pharmacy, because the patient was unable to access to designated pharmacy, and other factors).

The fourth goal is to reduce out-of-pocket spending by SPS beneficiaries. The reduction in out-of-pocket spending will be achieved in part by addressing the widespread perception that state provided pharmaceuticals are of lesser quality than private sector drugs. This will be achieved in part through the provision of drugs to SPS beneficiaries in private pharmacies, but also by standardising the packaging of all drugs so that there is no visible difference between public and private sector drug products. It is hoped that these reforms will raise public confidence in the scheme and lead to high enrolment levels.

The smart card scheme will be implemented in phases, and is currently being piloted in Tabasco and seven other states. Three and a half million cards have already been ordered and were to have been distributed to each household enrolled with SPS in June 2006.

1. Based on estimates from the 2005 Census made by the Economic Analysis Unit, Ministry of Health.

2. The majority of the families that have enrolled are from the lowest two deciles of the income distribution (as these individuals face extremely low to no premiums for coverage) and the third lowest decile (for whom the premiums are very low).

3. Pharmacies may choose to join the scheme or not. Those that do will receive training and a special license to operate.

1.6.1 *Packaging of products sold to public purchasers*

70.   Manufacturers package their drugs in such a way that all drugs destined for consumption in the public market, where procurement prices are much lower than private market prices, are clearly distinguishable from those sold in retail pharmacies. The latest reforms to the *Seguro Popular de Salud* will change this convention. In a bid to reduce the public's perception that drugs provided in the public sector market are inferior to those sold in the private market, manufacturers will be obliged to standardise the packaging of all drugs so that there will be no differentiation between public sector and private sector drugs (Box 3).

71.   While the government sees the new packaging requirement as an essential tool in combating prejudices about the quality of public sector drugs, manufacturers see it as a potential way for distributors to divert lower priced public sector market drugs to the private market where they can obtain higher prices. Not only would this boost the rents of distributors, at the expense of manufacturers who would not receive the higher private sector prices, but it could also exacerbate the undersupply of drugs in public sector pharmacies, driving more public-sector consumers into the private sector where they pay out-of-pocket for higher price drugs.

1.6.2 *Hospital purchasing*

72.   Tertiary level hospitals within IMSS devote 15% of their budgets to drugs purchases and 80% to labour costs.

73.   Private sector hospitals in Mexico are quite diverse. On the one hand, small physician-owned clinics with fewer than 5 beds account for 27% of private hospital beds (Ministry of Health, 2001). Over half of private hospitals do not have x-ray units, about one-third do not have a full-time doctor and less than a fifth do not have a full-time nurse (OECD, 2005a). These hospitals function more as ambulatory care clinics providing basic surgical procedures. It is unlikely these hospitals can exert significant buying power when purchasing pharmaceuticals.

74.   On the other hand, only 3% of private hospital beds are in hospitals with more than 50 beds. These hospitals provide high-tech and highly specialised care. Their purchases of drugs work through negotiations with both distributors and manufacturers. Typically, hospitals buy the latest drugs directly

from the manufacturers and as the volume of purchases becomes significant they move towards purchasing from a distributor. Group purchases with other private hospitals are rare occurrences.

75. Within a hospital each department requests which drugs it wishes to be included on the formulary. There is flexibility in the application of the formulary. It is not unusual for a physician to request that the hospital purchase a drug that is not included in the formulary and quite often the request is accepted. Private hospital pharmacies can purchase drugs not on the formulary as well. All told, off-formulary drugs can account for as much as one-quarter of a private hospital's pharmaceutical purchases, which is not an insignificant amount since roughly one-fifth of a hospital's budget can be expected to go towards the purchase of drugs.

1.7 Policies and other initiatives intended to influence pharmaceutical consumption

76. There do not appear to be any policies in Mexico designed to influence the use of medicines by patients nor do there appear to be any that seek to influence pharmacists' dispensation habits. Where policies that seek to influence pharmaceutical consumption do exist, they are aimed at influencing physicians' prescribing practices.

77. Generic substitution is the most widely used policy for influencing physicians' prescribing practices in Mexico. In the public sector, the Basic Formulary and the Catalogue of Inputs list drugs by their International Nonproprietary Name, including original products. IMSS provides its physicians with a copy of these formularies, which, in its view, makes doctors more aware of writing down the generic name when prescribing drugs for their patients.

78. IMSS has also produced guidelines for treating 42 common diseases. Although these are not directly aimed at influencing prescribing practices, they do contain guidelines that emphasise the use of generics.

79. The public sector institutes actively encourage the use of interchangeable generics. This policy can be considered quite successful in so far as the public sector overwhelmingly buys generics, however, it may inadvertently lead to many beneficiaries paying out-of-pocket for drugs purchased in retail pharmacies, given that many consider the generic drugs to be of inferior quality.

2   PHARMACEUTICAL MARKET CHARACTERISTICS

80.   This section reviews various components of the pharmaceutical market in Mexico, including expenditure trends and components of spending, pharmaceutical production, supply and trade.

2.1   Expenditure

81.   In 2004 Mexico spent almost 14.4 billion USD[33] on pharmaceuticals, more than most OECD countries. However, when size of the population is taken into consideration, Mexico comes last, having spent only 138 USD per capita in 2004 (Figure 1).[34]

Figure 1. Pharmaceutical expenditure per capita, public and private spending, 2004
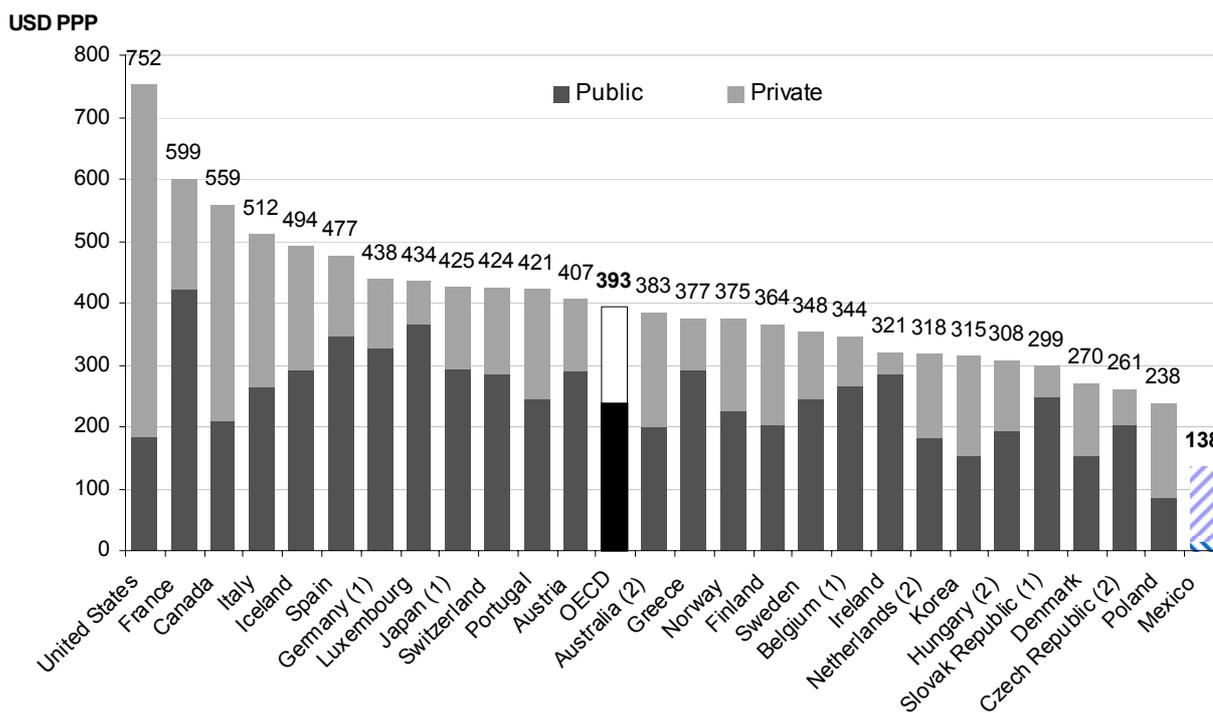
 (1) 2003; (2) 2002

Source: OECD Health Data 2006, version 06/26/2006

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[33] All currency figures are quoted in US dollar purchasing power parity (7.24 pesos = 1USD), unless otherwise stated.

[34] This does not include Turkey, for which the latest data available were for 2000. However, even in 2000 Mexico spent less per capita than Turkey (98 USD vs. 112 USD).

82.   Spending on pharmaceuticals in Mexico was 1.3% of GDP, which is slightly below the OECD average of 1.5% (Figure 2). While Mexico has the lowest per capita income among the countries shown in Figure 2, it still spends more on drugs as a percentage of GDP than half of them.

Figure 2. Share of pharmaceutical expenditure in GDP and share in total health spending, 2004
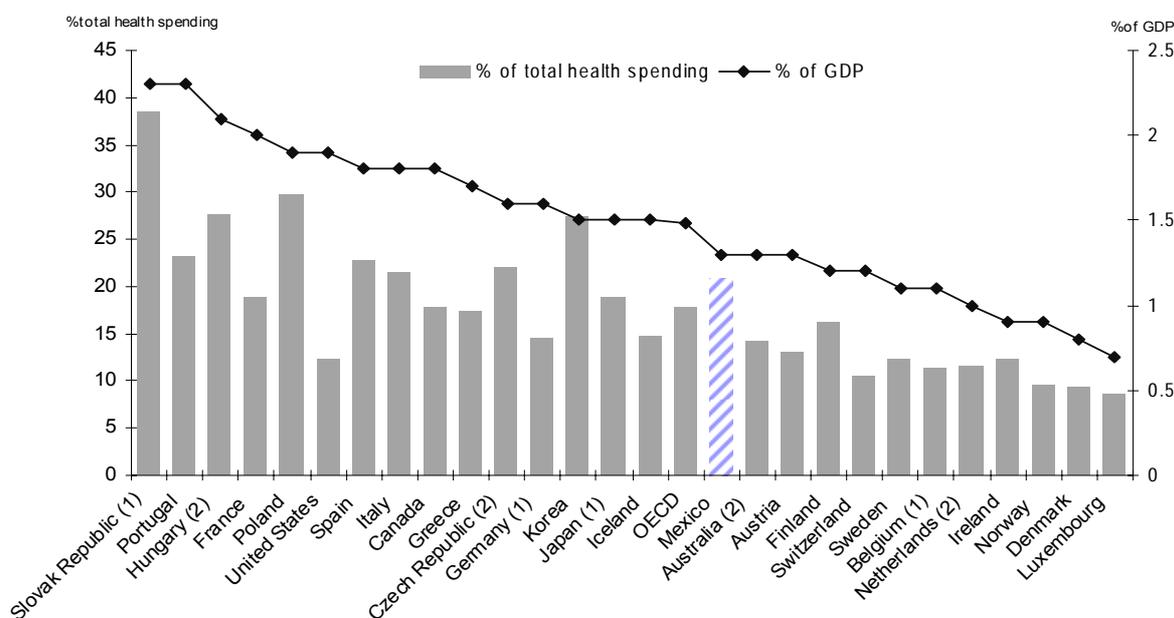
(1) 2003; (2) 2002

Source: OECD Health Data 2006, version 06/26/2006

83.   Pharmaceutical expenditures are an especially important component of overall health expenditures in Mexico. Pharmaceutical spending in Mexico represented 20.9% of total health expenditure, above the OECD average of 17.7% (Figure 2).

84.   Mexico, along with almost all OECD countries, has witnessed growth rates in health expenditures that have surpassed general rates of inflation and, as in many cases, a main driver has been spending on pharmaceuticals. Between 1999 and 2004, the real annual growth rate in pharmaceutical spending in Mexico was 8.0% (Figure 3), the 5th highest among the 24 OECD countries for which data were available for this period. Like most OECD countries, annual growth in pharmaceutical expenditures in Mexico was greater than that for total health spending (net of pharmaceutical spending), which was only 4.9% for this period. The annual rate of growth of pharmaceutical spending was above the OECD average of 5.8%, in contrast to the annual rate of growth of total health spending in Mexico which was close to the OECD average of 4.6%.

Figure 3. Real annual growth in pharmaceutical spending and total health expenditure (net of pharmaceutical expenditure), 1999-2004
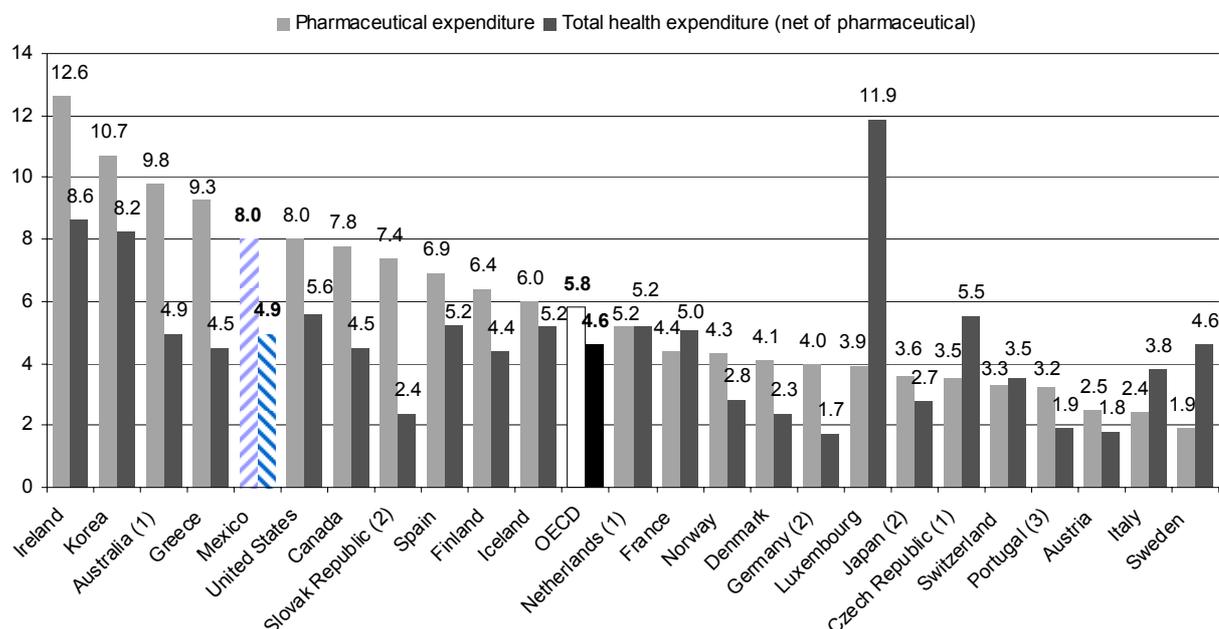
(1)1999-2002;(2)1999-2003;(3)2000-2005

Source: OECD Health Data 2006, version 06/26/2006

2.1.1 *Prices*

85.   There is a dichotomy in pharmaceutical prices that reflects the split in the health care system between a public market and a private one. In the public sector, the procurement prices for pharmaceuticals are estimated to be, on average, about 1/4 to 1/3 lower than they are in the private market (Gonzalez, 2002).[35] An evaluation by IMSS of the 20 most consumed drugs by IMSS beneficiaries showed that IMSS' procurement prices for these products were, on average, 80% lower than the stamped maximum price for the comparable products in the private sector (IMSS, 2004). However, given that pharmacies regularly offer discounts of anywhere from 30% - 40% on the maximum price, the difference between IMSS' procurement price and that actually paid by consumers in the private sector will be much smaller. Data for 2005 from IMSS and PROFECO seem to support this; calculations show that that IMSS' procurement prices were 83% lower than actual (observed) retail prices in the private sector, for a sample of 52 drugs.[36]

86.   Data collected by IMSS on the value and volume of drugs sold in the private sector can help shed some light on the procurement prices for pharmaceuticals in this sector (Ministry of Health, 2005). From

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[35] The source of this price differential was not indicated. While it is plausible that public sector market prices are lower than those of the private market, the price differential, if based on a decomposition of total sales into volume and value of sales, may reflect differences in type of pharmaceuticals consumed between the two markets rather than price differentials for similar products.

[36] Analysis undertaken by the Economic Analysis Unit, Ministry of Health. The aforementioned calculations consider a sample of strictly comparable active ingredients, which, although small, represents good evidence that price differentials between the two markets are substantial.

1997 to 2002 the volume of drugs sold in the private sector remained essentially flat. During this same period the total value of these drugs sales doubled. This suggests that prices of pharmaceuticals in the private sector rose. Indeed, it is hard to suppose that pharmaceutical prices would not have risen during a period when overall prices were rising. However, an increase in the value of drugs sold with the volume remaining constant can also come about if there is a substitution away from cheaper drugs to more expensive ones. The imposition of new intellectual property rights legislation, which made it more difficult to produce copy products, forcing consumers to switch from the lower cost copy product drugs to costlier patented drugs could have led to such a substitution. Changing epidemiology could also have induced a substitution towards more expensive drugs. In fact, officials from IMSS cite changing epidemiology of its beneficiary population, with marginal changes in consumption patterns, as a cause of a move towards more purchases of higher cost drugs by IMSS.

87.   Data compiled by the Central Bank of Mexico also indicate that prices for pharmaceuticals in the private sector increased during the latter half of the 90s and the beginning of the millennium (Figure 4). These data show double digit increases in prices for pharmaceutical products in the private sector from 1997 to 2000 with increases of about 5% per annum in 2001 and 2002.

Figure 4. Consumer price and pharmaceutical price inflation, 1987-2005
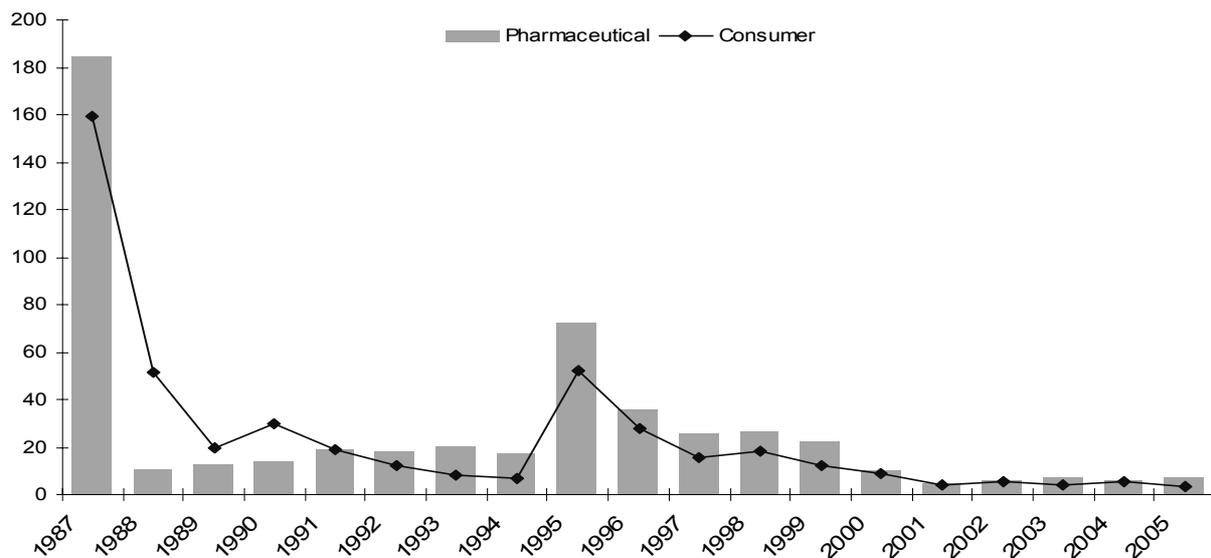
Source: Central Bank of Mexico

88.   The data on prices from the Central Bank of Mexico depict an evolution of consumer and pharmaceutical price inflation between 1988 and 2005, a period during which there were several changes in price regulations in Mexico. From 1988 to 1990 consumer price inflation was greater than pharmaceutical price inflation, at a time when the strict price controls of 1984 were still in place. In every year since 1991, when negotiations between the government and the pharmaceutical industry to replace the strict price controls with more flexible ones commenced, pharmaceutical prices have increased at a higher rate than general consumer prices. In the interim between the commencement of negotiations between the government and the industry, and the signing of the price regulation agreement of September 1996, the

trend rates of pharmaceutical price and consumer price inflation diverged.[37] Since the signing of the 1996 agreement, pharmaceutical price inflation has been on the decline, from a level of 35.8% in 1996 to 7.2% in 2005.

89.   Historically, pharmaceutical prices in Mexico have been low relative to other OECD member countries. In the early 1990s, prices in Mexico were estimated to be about 5 times lower than prices in the United States and about three times lower than in Europe (IMS Health, 1995). Since then successive governments have brought in initiatives to loosen up the pharmaceutical market, including liberalising imports, strengthening IPR and loosening, although not eliminating, price controls. These measures should have contributed to a narrowing of the gap between prices in Mexico and elsewhere in the OECD.[38]

90.   Danzon and Furukawa (2003) compared ex-manufacturer pharmaceutical prices[39] in 9 countries (Canada, Chile, France, Germany, Italy, Japan, Mexico, the United Kingdom and the United States), using 1999 data, looking at both generics and on-patent pharmaceuticals.[40] This study found that prices in Mexico (and in Chile) were about 80% of US prices — lower than prices in Germany, Italy and the United Kingdom, but higher than prices in Canada and France. Surprisingly, their results show that prices of generics in Mexico were greater than in the United States and on-patent pharmaceuticals were priced about 30% lower.

91.   However, Danzon and Furukawa found that when prices are adjusted for income, differences in pharmaceutical prices between countries roughly reflect income differences, with the exception of Mexico and Chile, for which the level of prices for pharmaceuticals are *more than 5 times* the level of income-adjusted prices in the United States. To the extent that income can be considered a proxy for the price elasticity of demand for pharmaceuticals, Mexicans are paying a far higher price for their pharmaceuticals than would be expected, given their relatively low level of income compared to the other countries. As the authors point out, in Mexico's case, price levels may reflect manufacturers' decisions not to offer prices more in line with Mexico's per capita income, used as a rough proxy for demand elasticity, for fear of importation into the United States. However, the use of income as a proxy for the price elasticity of demand is questionable, given the many prospective determinants of demand elasticity: income distribution, consumers' preferences, the level of out-of-pocket payments for pharmaceutical purchases, etc.

92.   With the exception of Chile, the other countries included in the Danzon and Furukawa study are much richer than Mexico. A comparison of pharmaceutical prices in Mexico against other Latin American countries with similar levels of purchasing power also found that prices in Mexico were relatively high.

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[37] An exception to this was the economic crisis in Mexico of December 1994 which led to a dramatic increase in prices — the inflation rate in 1995 was over 50%. This rising tide lifted all boats, including pharmaceuticals for which the price level increased by over 70%.

[38] According to a crude estimate by Gonzalez (2002) this appears to have occurred with US retail prices about 3 – 4 times greater than Mexican retail prices for pharmaceuticals in the private market. More thorough analyses of pharmaceutical prices would help to shed more light on whether these liberalisation measures did indeed help bring Mexican prices closer to those in the U.S., and consequently other OECD countries.

[39] Ex-manufacturer prices are the prices obtained by manufacturers in sales to purchasers (including distributors, large retailers and public schemes). They are lower than public prices or retail prices, which include mark-ups by pharmaceutical distributors and pharmacies.

[40] A significant drawback to this study from Mexico's point of view is that it compares a basket of leading products in the United States, which are likely not representative of the leading basket of pharmaceuticals in Mexico.

According to a 2003 sample of average prices to the public for drugs in Mexico, Argentina, Brazil, Chile and Venezuela, prices are highest in Mexico (Ministry of Health, 2005).[41]

2.1.2 Volume of consumption

93.   Comparisons of consumption volumes are also difficult to make. Different dosages and methods of administering drugs mean that calculations of volume for comparison purposes are exceedingly difficult, which is why comparisons of overall drug consumption, as opposed to within therapeutic class or specific molecule comparisons, rely on unit volumes of sales as a proxy for consumption. This has the added bonus of tying in directly with prices to total expenditures.

94.   There is almost no difference in the volume of consumption between the public and private markets; the total volume of pharmaceutical sales in Mexico is split 50/50 between the private market and the public market. However, the predominance of patented medicines in the private market and conversely generics in the public market, accounts for the huge discrepancy between the two markets in the split in value of sales (Table 1).

Table 1.   Public/private split of the pharmaceutical market, 2001

Sector	Value	Volume
Private	82%	50%
Public	18%*	50%

* If the share of pharmaceutical spending with respect to total health spending as reported in OECD Health Data 2003 is considered this figure increases to 21%. Industry sources estimate the Private/Public splits to be 85%/15% for value of sales and 43%/57% for volume of sales.

Source: Based on estimates from the Ministry of Health according to the output value as reported by the Instituto Nacional de Estadística Geografía e Informática in 2001.

95.   As noted in the previous section on prices, the volume of consumption of pharmaceutical sales in the private sector remained essentially flat between 1997 and 2002 (Ministry of Health, 2005). Data on the volume of pharmaceutical consumption in the public sector during this period were not available.

96.   One of the more striking differences between the public and private sector markets for pharmaceuticals is the greater reliance on generics in the former. Data collected by the World Health Organisation show that about half of all prescriptions in the public sector in Mexico in 1999 were for generic drugs. The corresponding figure for the private market was about 1% (data from Dr. Jonathan Quick, WHO, presented by COFEPRIS).

97.   Using the US consumption mix and volume as a standard, Mexico's consumption of drugs is relatively low.[42] Mexico's per capita consumption is only 12 percent of US consumption, when considering

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[41] Little is known about the data used for this comparison. If the data are based on a typical basket of pharmaceuticals from Mexico then the comparison does not suffer from the same drawback as the Danzon and Furukawa study (Danzon, 2003). At the same time, even if the basket is based on one of the other Latin American countries the problem will not be as great as with the Danzon study since these countries are likely to have pharmaceutical consumption baskets that are closer to Mexico's than that typical of the U.S. basket used by Danzon. There are other reasons, such as did the samples only reflect private market purchases or were they taken before or after pharmacy discounts, for which these data can present difficulties for comparing prices.

the molecules used most in the United States, and 6 percent or less for molecules launched within the past 10 years (Danzon, 2003). By comparison, Chile's per capita consumption is 22 percent of US levels overall, but 8 percent or less for molecules under 10 years old. And the 6 OECD countries other than Mexico that were included in the Danzon study all had per capita consumption of the leading US molecules of at least 53 percent (Japan) and up to 115 percent (United Kingdom).

2.2   Financing

98.   Of the 14.4 billion USD spent on pharmaceuticals in 2004, about 90% came from private agents, significantly above the OECD average of 39% (Figure 1). Mexico is one of only 5 OECD member countries for which private agents account for the majority of pharmaceutical expenditures. In fact, all three NAFTA countries are atypical with private sources accounting for 62%, 76% and 88% respectively of total expenditures on pharmaceuticals.

Figure 5. Distribution of total expenditure on pharmaceuticals by financing agent, 2003
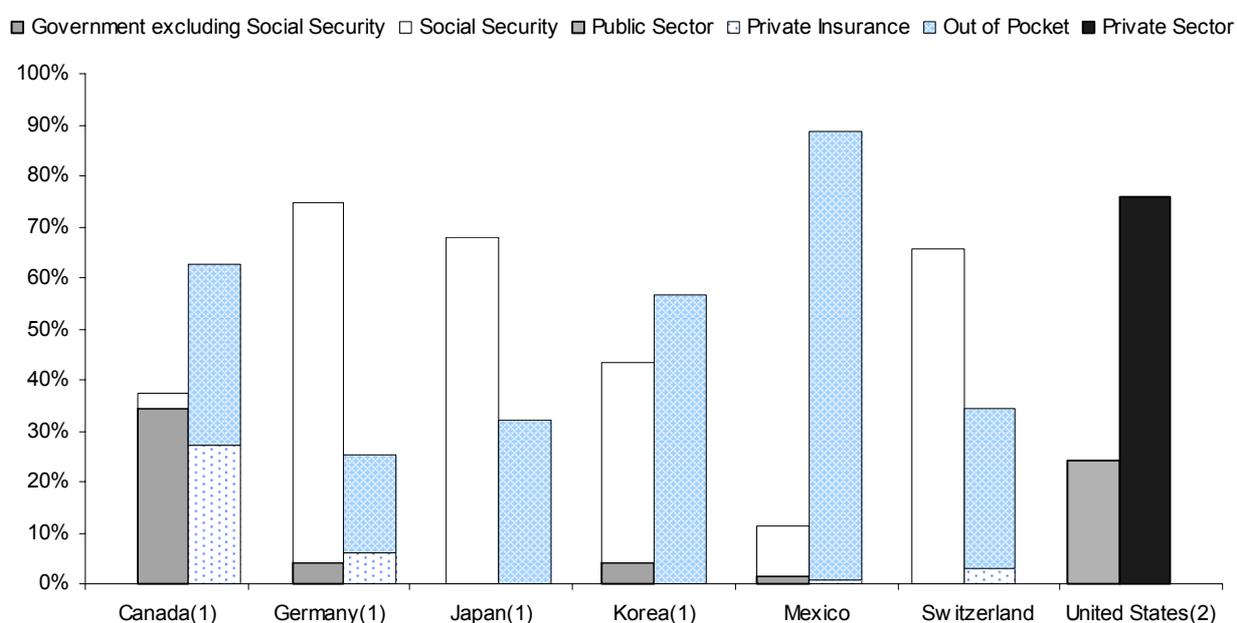
(1)2002; (2) 2004

Note: the left-hand side bars represent public sector expenditures and the right-hand side bars private sector expenditure. Data breaking down public and private sector expenditures for the United States were unavailable.

Source: 2006 Joint OECD-Eurostat-WHO Health Accounts (SHA) Data Collection

99.   Unlike its NAFTA trading partners, individual consumers in Mexico are the direct source of nearly all pharmaceutical expenditures. Data from Figure 5 show total expenditure on pharmaceuticals by financing agent for a select group of countries for which these data are available.[43] According to these data,

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[42] The US is not the ideal country to use as a benchmark for drug consumption in Mexico; however, the Danzon study is the only known, peer-reviewed comparison of drug consumption in Mexico with other countries.

[43] These data were compiled by officials in those countries which are in the process of implementing the OECD's System of Health Accounts methodology.

Mexicans spend considerably more out-of-pocket on pharmaceuticals than individuals in other countries. In 2003, 88% of total expenditures on pharmaceuticals in Mexico were out-of-pocket, compared to 57% in Korea, the only other country where out-of-pocket spending was greater than half of total spending on pharmaceuticals.[44]

100.   IMSS and ISSSTE account for respectively about 80.3% and 14.2% of public expenditures on pharmaceuticals, while the other social security agencies and the federal and state health services account for only 5.4% (Table 2). Public sector expenditures on pharmaceuticals as a percentage of total expenditure on pharmaceuticals were 8.2% in 2002, 10.4% in 2003 and 11.6% in 2004 (OECD, 2006).[45]

Table 2.   Distribution of total expenditure on pharmaceuticals, public and private sector, 2004*

	IMSS	ISSSTE	Federal and State Health Services
Public	12% of total expenditure on pharmaceuticals (16 USD per capita), of which:		
	80.3%	14.2%	5.4%
Private	88% of total expenditure on pharmaceuticals (122 USD per capita)		
Total	1.3% of GDP or 138 USD per capita		

* The data on the percent of pharmaceutical expenditures by IMSS, ISSSTE and the federal and state health services are from González-Pier (2004). The data on the public and private split in pharmaceutical expenditure and expenditure per capita are from OECD Health Data, (OECD, 2006).

Source: González-Pier, E. and A. González Hernández, "Regulación saludable del sector farmacéutico", *Competencia Económica en México*, Comisión Federal de Competencia, Mexico, D.F (2004) and OECD Health Data 2006, version 06/26/2006

2.3   Pharmaceutical industry activity

101.   With sales of 7.09 billion USD in 2003 the Mexican pharmaceutical industry is among the world's 10 largest markets and is Latin America's biggest (AMIIF, 2005). At the top of the distribution chain are about 300 pharmaceutical companies, both research-based, almost all of which are multinationals, and generics.[46] In the middle are a small number of wholesale distributors that control a large part of the distribution market. At the end of the distribution chain are thousands of retail pharmacies and drugstores where competition is intense.

102.   The pharmaceutical industry employs 45,000 people, about half of whom work in administration and sales, and about 40% in production, most of which is concentrated mainly in and around Mexico City (Ministry of Health, 2005).[47] The growth of the pharmaceutical industry in Mexico has been steady, if

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[44] Data for the United States breaking down private expenditures on pharmaceuticals between private insurance and out-of-pocket were not available, however, total private expenditures on pharmaceuticals in this case were 76%, so even if all of this was out-of-pocket, an unlikely scenario, Mexicans would still pay more out-of-pocket.

[45] Data for Mexico prior to 2002 are not comparable due to the use of a different methodology for calculating public expenditures on pharmaceuticals.

[46] Estimates of the number of pharmaceutical firms vary widely: about 300 domestic and 50 foreign firms (OECD, 2005a); 224 firms of which 46 are foreign firms and an additional 600 produce inputs for pharmaceutical production (Ministry of Health, 2005); 400 firms (OECD, 2000); 390 firms (Gonzalez, 2002).

[47] Based on data for 2003.

unspectacular compared to other OECD countries for which data are available. The mean annual growth rate in pharmaceutical industry production between 1980 and 2001 was 8.6%, below the average of the 16 countries for which data are available and below the figure of 9.1% for the United States (Figure 6).[48] A survey carried out for the industry association CANIFARMA shows that Mexico's pharmaceutical industry is producing at about 60% below capacity (Ministry of Health, 2005), which leaves plenty of room for the country's demand for drugs to be met by domestic production.[49]

103.   Chemical substances used in the manufacture of pharmaceuticals are a significant component of pharmaceutical industry production in Mexico. Approximately 40% of total pharmaceutical production is related to producing the constituent ingredients of drugs. The number of firms producing active ingredients has diminished in recent years: in 1987 there were 94 firms producing active ingredients, by 1994 this figure had dwindled to 48 and by 2005 there were only 26 companies (Ministry of Health, 2005).

Figure 6. Mean annual growth in pharmaceutical production in OECD countries, 1980-2001
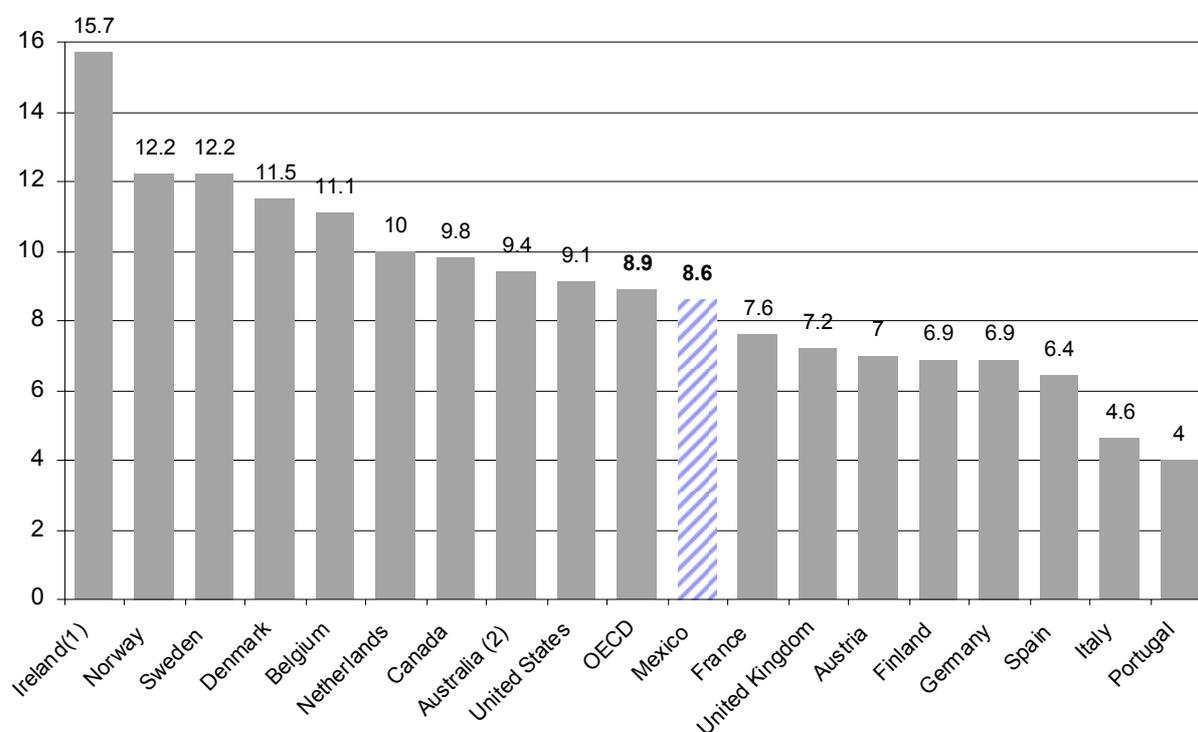
(1)1980-1999; (2)1985-2001

Source: OECD Health Data 2006, version 06/26/2006

104.   As mentioned earlier, the interests of the Mexican pharmaceutical industry are represented by the *Cámara Nacional de la Industria Farmacéutica* (CANIFARMA). In the past affiliation was mandatory, but today pharmaceutical manufacturers are not obliged to be members of the CANIFARMA. Nevertheless, the firms in CANIFARMA represent 95% of the pharmaceutical market in Mexico. There

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[48] These data include the production of pharmaceutical preparations for veterinary use.

[49] Pharmaceutical companies with a presence in Mexico supply 86% of domestic needs (Ministry of Health, 2005).

are two sub-groups within the CANIFARMA, namely the *Asociación Mexicana de Industrias de Investigación Farmacéutica* (AMIIF) which represents all the research-based pharmaceutical companies and the *Asociación Nacional de Fabricantes de Medicamentos* (ANAFAM) which represents the generic manufacturers. Formerly, AMIIF's members were strictly multinationals and ANAFAM's only domestic manufacturers, but within the past few years this distinction has evolved with Mexico's pharmaceutical market so that some of the research-based firms in AMIIF are Mexican firms and there are several international generic manufacturers within ANAFAM. There are also many pharmaceutical manufacturers who are affiliated to the CANIFARMA but are not members of either AMIIF or ANAFAM.

105.　　Almost all of the major multinational research-based pharmaceutical companies are present in Mexico. These firms accounted for 84% of the total value of pharmaceutical sales in Mexico in 2003 and invested an estimated 200 million USD in 2004 on modernising production facilities and clinical trials (AMIIF, 2005).[50] These firms produce almost all of the original products manufactured in Mexico.

106.　　Occasionally, manufacturers choose Mexico as the country of first launch: between 1995 and 2001 Mexico was the first-launch country for 16 drugs, which is more than Canada (10) but much less than the United States (163) or Japan (231) (Lanjouw, 2005); by contrast, many nations are not first-launch countries.

107.　　There are almost no research-based Mexican firms, a possible legacy of the lax patent laws that were in place up until the early 1990s which may have discouraged the development of a research-based pharmaceutical industry. It has also been argued that this same lax patent system may have helped foster the growth of a domestic pharmaceutical industry in a developing country where it otherwise may not have occurred (Zuniga, 2002). From about 60 firms in the 1940s, by the end of the 1980s there were over 200 firms in Mexico. While the lax patent laws may have helped a nascent production industry grow, it also provided the framework for the type of production the domestic industry would specialise in; mostly non-research based generics – with the notable exception of the steroid hormone industry, which drastically reduced the cost of synthesising progesterone, paving the way for mass production of the oral contraceptive.[51]

108.　　Domestic firms produce mainly interchangeable and non-interchangeable generics, and until recently, copy products, copies of drugs that are still under patent (see Box 1 for definitions of the types of pharmaceutical products available in Mexico). Strong patent laws have diminished considerably the number of manufacturers of copy products; there were 94 firms producing copy products in 1987, but, following the introduction of the patent law in 1991, this number had dwindled to 35 by 2002 (Zuniga, 2002). A clandestine counterfeit industry is believed to exist in the northern states; the size of which is unknown, although its operations are believed to be quite small when compared to industry production overall.

109.　　Nowadays ANAFAM no longer protects the interests of Mexico's domestic manufacturers against those of the multinationals, but rather protects the interests of the generic manufacturers, often it could be said, against the interests of the research-based pharmaceutical companies. The evolution of ANAFAM's role has generally coincided with the government's initiative to push the use of

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[50] These figures represent the member companies of AMIIF which include two Mexican based firms, Chinoin and Laboratorios Sanfer.

[51] The production technique for mass-producing the hormone progesterone was developed by Russell Marker, who found a way of synthesising progesterone from the Mexican yam, at a fraction of the cost of developing the hormone from animal extracts. Marker founded *Laboratorios Syntex SA*, which developed the first oral contraceptive in 1951.

interchangeable generics which started in 1998. ANAFAM's members accounted for 14.5% of total sales in terms of value and 19.9% of the total unit volume of sales in Mexico in 2002.[52]

110.   ANAFAM is a proponent of the government's program to make all generics bioequivalent. Currently 131 ANAFAM members produce interchangeable generics, which account for about 5% of total pharmaceutical sales in the private market.

111.   Within the CANIFARMA there also exists a body which represents Mexico's over-the-counter (OTC) producers, the *Asociación de Fabricantes de Libre Acceso* (AFAMELA). There are 18 members of AFAMELA, most of whom are multinationals or the OTC division of multinationals. Domestic OTC production represents about 1/3 of the total volume of pharmaceutical sales and about 1/5 total value.[53]

112.   Non-interchangeable generics, or *similares* as they are also known in Mexico, have a significant hold on the pharmaceutical market. From an almost negligible share of the market at the turn of the millennium, in 2005 they accounted for about 12% of total pharmaceutical retail sales in 2005 (IMS Health, 2005). Despite their popularity, the introduction of mandatory bioequivalence tests for generics should slow the growth of *similares* for the next few years, eventually eliminating them within 5 years.

113.   Competition among manufacturers in the public market is greater than in the private market. In the public market, 300 mostly domestic manufacturers compete to supply drugs to the social security organisations, and the federal and state-run health services. Multi-national research-based firms account for about 20% of the total value of pharmaceuticals sold in the public market. The private market is much more concentrated with about 70 firms competing to sell drugs. Here, the market share is reversed with multinationals making up 80% of the total value of sales and domestic firms making up the remaining 20%.

2.3.1   *Distribution channels*

114.   Manufacturers for the most part deliver their products through wholesalers. The largest companies commercialise and distribute pharmaceuticals through three distributors which account for approximately 70% of the wholesale market (OECD, 2005a). The remaining 30% of the wholesale market consists of small local distributors.

115.   Distribution channels differ somewhat between the public and private markets. In the public market, the social security organisations and the state and federal governments purchase most of their pharmaceuticals directly from manufacturers through tendered contracts, often bypassing distributors. In the private market, the three main distributors operate at a national level distributing 70% of wholesale drugs. Although they supply some drugs to IMSS, ISSSTE and the Ministry of Health, their main customers are pharmacies and hospitals in the private sector. There are many small and remote regions of Mexico that are not covered by the large national distributors, which are served by small local distributors. Increasingly, large pharmaceutical chains and an increasing number of supermarkets with pharmacy departments are taking advantage of economies of scale by purchasing their pharmaceuticals directly from manufacturers.

116.   Pharmaceuticals reach consumers through about 50 000 retail pharmacies, pharmacy outlets and drug stores (Ministry of Health, 2005). Retail dispensation of pharmaceuticals is different from other OECD countries. Pharmacies in Mexico can only sell medicines in the exact same form they received them; they cannot mix or prepare them in any way that alters their dosage. There is no requirement for a

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[52] www.anafam.org.mx/quienes/historia.html, accessed August 1, 2006

[53] See www.industria-farmaceutica.com/index.php?name=News&file=article&sid=652, accessed 1 August 2006.

trained pharmacist to be on the premises, although if a pharmacy dispenses psychotropics then it is required to have on the premises a professional with a degree in health sciences (pharmacist, pharmaceutical chemist or doctor). There are close to 17 000 pharmacies that own licenses to dispense psychotropics, meaning more than half of all pharmacies do not employ a health professional. These are mainly small, independent pharmacies that operate in much the same way as retailers of normal consumer goods. They also include pharmacies that sell *similares*. As noted earlier, they control about 10% of the pharmaceutical retail sales market. The largest chain, *Farmacias Similares*, with its ubiquitous mascot, Dr. Simi, has 3 720 retail outlets.

2.4   Innovation

117.   There is very little research and development (R & D) taking place in Mexico. Spending on all R&D as a percentage of GDP is 0.32%, less than half of the government's target of 1% of GDP and far short of the OECD average of 2.26% in 2002 (OECD, 2005c). Furthermore, R&D spending has been falling in recent years from a high of 0.43% of GDP in 1999. The pharmaceutical industry is estimated to spend on average 5% of revenue on R&D, which reflects the lack of research-based pharmaceutical firms based in Mexico. Some testing of new drugs does take place in Mexico; in 2004 the pharmaceutical industry had budgeted 680 million pesos (94 million USD) on clinical investigations,[54] but multinational firms generally conduct their new drug research abroad. Recently, pharmaceutical R&D has increased in Mexico, but this is mainly limited to clinical trials and other customisation-related activities (Zuniga, 2002; AMIIF, 2005).

118.   Despite fairly strong intellectual property rights protection, low R&D spending on the development of pharmaceuticals in Mexico has meant there is little in the way of innovative activity in this sector. In general, foreign patents account for 96% of all patents granted in Mexico. Since 1991 only 5 patents for pharmaceutical products have been granted to Mexican companies.[55]

119.   The factors that influence innovation in general are probably similar to the factors that affect innovation in the pharmaceutical industry: the availability of scientists and engineers, the amount of research conducted in the public sector, business-academic links,[56] the degree of product competition, a high level of available financing, and access to foreign inventions. An examination of these factors can lend some insight into the reasons why pharmaceutical R&D in Mexico lags behind that of the average OECD country.

120.   Based on the first factor, scientists and engineers, Mexico fares poorly compared to the OECD average. Using a broader measure, total researchers per thousand labour force, there were only 0.56 researchers per thousand labour force in Mexico in 1999, as opposed to an OECD average of 6.39 (OECD, 2005c). Mexico is also below average with respect to the second factor, the amount of research carried out in the public sector. In 2001 government intramural expenditure on R&D was 0.15% of GDP less than the OECD average which was 0.27% (OECD, 2005c).

121.   The third factor, business-academic links, is also fairly weak in Mexico. In interviews conducted for this paper officials from both government and the private sector were in agreement that co-operation

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[54] Figure estimated by the AMIIF. It is also estimated that 1135 clinical studies were conducted involving 37561 patients.

[55] Personal communication with officials from the Mexican Institute of Industrial Property

[56] In Jaumotte and Pain (2005) three separate variables were used to measure the influence of business-academic links on R&D, all of which were significant: R&D intensity in the non-business sector, the share of non-business research funded by businesses and business funding for non-business research as a share of corporate profits.

between industry and academia in research was not very strong. Available data tend to confirm these judgements. The share of higher education R&D financed by industry in 2001 was 1.1% which was far less than the OECD average of 6.4%. Weak business-academic links are also in evidence using Jaumotte and Pain's (Jaumotte, 2005) measures for business-academic links: Mexico was below the OECD average in both R&D intensity in the non-business sector and the share of non-business research funded by business.[57]

122.   The degree of product market competition, as measured through an indicator on product market regulations for 2003 shows Mexico to have one of the tightest regulated markets among OECD countries, with only Turkey and Poland having tighter regulations (Conway, 2005). Collecting information on the other factors that influence innovation, a high level of available financing and access to foreign inventions are beyond the scope of this paper. Nevertheless, the preceding information shows that there is plenty of room for improving the environment for innovation in Mexico.

123.   Jaumotte and Pain (Jaumotte, 2005) also estimated the impact of intellectual property rights (IPR) on R&D spending, finding that IPR increases patenting significantly but has little measurable impact on overall spending on R&D. However, in the case of the pharmaceutical industry the effect of intellectual property rights (IPR) may be more significant. In an empirical study of 100 US manufacturing firms, Mansfield (1986) found that patent protection was very substantial only for pharmaceuticals and chemicals firms. Combe and Pfister (Combe, 2001) found similar results in a survey of French manufacturers. In Mexico's case strong patent protection has not been a strong enough driving force for spurring innovative activity in the domestic pharmaceutical industry.

124.   Most pharmaceutical research is conducted by the large multinational firms and their research arms tend to be located in the country of origin. For Mexico, this means that the vast majority of the research done by multinationals based in Mexico is done elsewhere. Furthermore, there appear to be little or no sector-specific industrial policies to promote the pharmaceutical industry (OECD, 2000).[58] Mexico's epidemiological structure, a high prevalence of some diseases such as HIV/AIDS characteristic of developing countries, can also have an impact on pharmaceutical R&D. It is estimated that about 10-20% of worldwide health R&D is spent on diseases that primarily affect 80-90% of the world's population, mainly developing countries.

2.5   Supply of pharmaceuticals

125.   There are approximately 7 000 registered pharmaceutical products marketed in Mexico. Each year about 600 new products enter the market while approximately 5% fall into disuse, meaning the total stock of available pharmaceuticals increases by less than 1% per annum. While this number is comparable to many OECD countries, the mix of drugs is likely to be different and many of them may be older drugs that are no longer in use in countries with higher per capita incomes. At the very least, the drugs that are

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[57] R&D intensity in the non-business sector is calculated as the combined share of Expenditure on R&D in the Higher Education Sector (HERD) and Government Intramural Expenditure on R&D (GOVERD) as a percentage of GDP. In 2001 in Mexico this measure was 0.27% of GDP, well short of the OECD average of 0.64%. The share of non-business research funded by business is calculated as the percentage of HERD plus GOVERD financed by industry. On this measure as well Mexico's share of 3.7% is less than the OECD average of 5.0%. These measure were derived from data taken from *Main Science and Technology Indicators* (OECD, 2005c).

[58] The *Fondo Sectorial de Ciencia y Tecnología para el Desarrollo Económico* (Science and Technology Fund for Economic Development) provides financial support for pharmaceutical R&D, which it considers a strategic sector.

available in other OECD countries may be supplied to the Mexican market but they may not be consumed to the same degree.[59]

126.   Of all drugs released globally between 1995 and 2001, most new products had been marketed in Mexico within 4 years of the first world launch, and 73% were available within 5 years (Lanjouw, 2005). By this measure, launch of new drugs is slower than most developed countries (where a majority of new drugs were launched within 3 years), but similar to OECD countries such as Spain and Austria, and better than countries such as Portugal. To some extent, manufacturer's decisions regarding product launch (and pricing) in Mexico are likely to be affected by Mexico's proximity to the United States, which provides the largest market for pharmaceuticals in the world — and at the world's highest prices.

127.   It is estimated that about 60% of medical visits in Mexico result in a prescription for one or more drugs (Ministry of Health, 2005). A prescription must refer to the active ingredient and may also include the brand name. This is a requirement to promote physicians' prescribing the generic version of drugs, but often pharmaceutical company promotional activities influence prescribing behaviour such that the newer, brand-name drug is included on the prescription.

128.   Although it is not required, the prescription may also include information on adverse reactions and precautions on the use of the drug(s) prescribed, information that is not required on the drug label as in most other OECD countries.[60] This information is included in medical specialty dictionaries which private sector physicians will consult if they wish to communicate this information to their patients when prescribing medicines. Public sector physicians will consult the Basic Formulary and the Catalogue of Inputs. These reference sources include much of the information, such as contraindications, secondary adverse reactions and interactions with other drugs, normally found on drug package labels.

129.   Having to rely on physicians to impart information on adverse reactions and precautions on the use of the drugs they prescribe to their patients is not ideal. The sheer volume of available drugs makes it practically impossible for any physician to know all the harmful effects of each drug. Needless to say, for various reasons, this information is quite often not communicated completely and clearly to patients (Ministry of Health, 2005) and is very likely to be the source of many avoidable health problems. Indeed, one of the officials interviewed for this paper noted that the information in the medical specialty dictionaries supplied by pharmaceutical companies that many physicians use as a reference source when prescribing drugs contain many inconsistencies. It is expected the government will implement the recommendation from "*Hacia una política farmacéutica integral para México*" that the existing statute on labelling of pharmaceutical products be amended to include information on adverse reactions and precaution in use for all drugs sold in Mexico.

130.   Based on interviews of senior managers with experience in running both private and public hospitals, physicians in hospitals are reluctant to use generics, preferring to use the original versions of drugs for which they generally have more experience in using and know they work. Lack of information about, and incentives for, prescribing generics limits their use in hospitals. This is as true of public

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[59] In Danzon and Furukawa (2003) for example, from a sample of 249 leading molecules in the United States, 90% were available in Mexico, however even after 10 years, per capita consumption of these molecules was about 10 times lower in Mexico than the U.S.

[60] "*NORMA Oficial Mexicana NOM-072-SSA1-1993, Etiquetado de medicamentos*" is the medical labelling statute that governs the information to be included on the package. It stipulates that all drugs sold in Mexico must contain many of the information, such as form and dosage, normally found on drug labels and inserts in other OECD countries. Moreover, the rule requires that OTC packages must contain information on contraindications and adverse reactions, but does not state this requirement for prescription drugs, except when indicating that the product should not be used by pregnant women.

hospitals as it is of private hospitals. Despite the government mandate that public sector institutions must purchase interchangeable generics wherever and whenever possible (see following paragraph), public sector hospitals have the flexibility to go off formulary, i.e. purchase and provide patients with drugs not included in the Basic Formulary and the Catalogue of Inputs.

131.   Since 1998 the government has made a concerted effort to promote the use of bioequivalent or interchangeable generics (see Box 1). This effort was reinforced in 2002 when the General Health Council (CSG) issued a mandate that all public sector health institutions purchase interchangeable generics (GIs, *genéricos intercambiables*) whenever these were available. The result has been an increase in the number of listed GIs from 963 (OECD, 2005a) to 3 685 products as of July 2006.[61] There are currently 143 participating manufacturers and 27 authorised third-party laboratories.

132.   The GI programme is a collaborative effort between the CSG, the Ministry of Health and the pharmaceutical industry. The CSG and the COFEPRIS, the regulatory authority responsible for marketing authorisation, are responsible for oversight and implementation of the GI program. Manufacturers first submit their wish to be included in the GI program to the COFEPRIS. The types of bioequivalency proofs required are determined by the CSG and the tests are carried out by authorised third-party laboratories or by the generics manufacturers themselves provided they meet the demands required of them by the third-party laboratories.[62] Upon demonstrated proof of bioequivalency the COFEPRIS lists the generic in the *Catálogo GI*, or GI Catalogue, and the CSG subsequently announces the publication of a *Catálogo de Medicamentos Genéricos Intercambiables*, or Catalogue of GI Drugs, in the *Diario Oficial de la Federación* (Official Journal of the Federation).

133.   The government's promotion of bioequivalent generics in the public sector has not spilled over into the private sector where the number of non-interchangeable generics on the market has continued unabated.[63] It is estimated that 60% of drugs currently on the market have not demonstrated any proof of bioequivalency (Ministry of Health, 2005). The popularity of inexpensive non-bioequivalent generics pharmacies such as *Farmacias Similares* has grown significantly in recent years.

134.   The government's GI promotional efforts have also had mixed results in terms of prescriptions for generics. Almost half of all prescription in the public sector were for generics, which compares favourably to countries such as Denmark which also enjoy high generic penetration. However, this is in marked contrast to the private sector market where generic penetration in prescriptions is poor: less than 5% of prescriptions in the private market are for generics.

135.   The regulation of pharmacies from a public health perspective is almost non-existent. However, the commercial behaviours of pharmacies are subject to oversight. The pricing behaviours of pharmacies are monitored by the authority responsible for inspection and surveillance of commercial behaviour of all providers of commercial goods and services in Mexico, the *Procuraduría Federal del Consumidor* (PROFECO, Federal Office of the Judge Advocate General of the Consumer).

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[61] Based on the update to the *Catálogo de Medicamentos Genèricos Intercambiables* published in the Diario Oficial de la Federación on 21 July 2006. The list was obtained from the Ministry of Health website at the following address: www.salud.gob.mx/csg/publica/genericos.html, accessed 2 August 2006

[62] See footnote 13.

[63] Adherence to the GI program on the part of generics manufacturers is voluntary. The only requirement from a public health standpoint is that a drug meets all the requirements of quality, security and efficiency for marketing authorisation. This situation will change as new regulations requiring proof of bioequivalency come into force See Section 1.2 Product approval procedures and outcomes.

136.   There are three specific areas to which pharmacies must adhere to regarding their pricing behaviours. The first is that all prices must be clearly exhibited on the package. For pharmaceutical products, the maximum allowable retail price must be stamped on the box. This is a relatively minor area of concern since the stamp is applied on the box by the manufacturer.

137.   Of greater concern to PROFECO is retailers' adherence to the price stamped on the box. PROFECO has the right to inspect pharmacies to make certain that prices are exhibited properly and that the maximum allowable price is not exceeded. Pharmacies that are found to be in violation of exceeding the maximum price can be published in a "Who's Who" of violators of the maximum price law and may be required to display a consumer alert warning issued by the agency.

138.   The third area of concern, and the one where violations occur most often, is with respect to the discounts that are offered by pharmacies. Most pharmaceuticals are not sold at the maximum price. Price competition among pharmacies is very intense and discounts on the maximum price are a feature of this competition. Discounts from 30% to 40% on the maximum allowable price are quite common. PROFECO has the authority to make certain that any discounts offered are provided as advertised. A PROFECO intervention is usually the result of a complaint by a customer. The vast majority of violations occur most frequently with smaller retailers,[64] which, given the number of pharmacies in Mexico, makes surveillance quite difficult. One of the most frequent violations is the offering of discounts for a pharmaceutical, not based on the maximum price stamped on the box but on the price of the same product produced at a later date, which carries a higher maximum price than the purchased product which was produced earlier.

139.   PROFECO does have levers to force compliance. Following an inspection, a notification followed by an administrative procedure can result in the violating firm being hit with a sanction from 100 to 300 000 pesos (14 to 40 000 USD)[65].

140.   The lack of regulation of pharmacies extends to qualified personnel within establishments selling pharmaceutical products. As mentioned earlier, the only requirement for pharmacy personnel is that a professional with a degree in health sciences must be present if the pharmacy sells psychotropics. There are 33 000 establishments in Mexico that do not sell psychotropics but do sell prescription drugs. Personnel employed in these establishments are not required to have any special training in dealing with pharmaceuticals. Their function is to take the customers' orders, be they prescription or OTC drugs, retrieve the product from the shelves behind the counter and give it to the customer in exchange for payment.

141.   The fact that there are no requirements for trained pharmacists to work in retail pharmacies is a source of concern for many public health professionals.[66] The most frequently cited concern is with respect to inappropriate self-medication of prescription-only drugs, a significantly large phenomenon in Mexico (see following section). There is little scientific evidence of the extent of damages to health due to improper self-medication, but several individuals interviewed for this study suggested that it is a significant source of hospitalisations. The presence of professionally trained pharmacists could help reduce these avoidable hospitalisations. Another concern is that the lack of professional pharmacists leads to waste since many of the individual units within a pharmaceutical package are not consumed. Pharmaceuticals are

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[64] Although not as frequent, there have been violations by some of the larger national and regional retailers, including last year when two chains were admonished for offering improper discounts.

[65] 7.37 pesos = 1USD

[66] The only institutions that appear to employ professionally trained pharmacists are hospitals. At present there are only a handful of universities in Mexico that offer a degree programme that leads to a professional qualification as a pharmacist.

distributed to pharmacies pre-packaged. Pharmacy personnel are not allowed to open boxes and break down the contents into smaller units for sale. Finally, untrained pharmacists are likely to provide inappropriate or harmful advice to consumers, even though this advice is required in 9% of pharmacy visits (Wirtz, 2006).

142. The view that the lack of pharmacists is a source of concern is by no means universal. The costs of requiring the employment of qualified pharmacists in dispensation of medicines could be high, not only for the state and private institutions that would train them, but for consumers as well since it would undoubtedly add to the costs of pharmaceuticals leading to increased prices. It has been estimated that it would take about 20 years to train enough pharmacists to staff each pharmacy in Mexico (Ministry of Health, 2005).[67] The higher costs of hiring pharmacists would have a particularly negative effect on small retail pharmacies, reducing competition and possibly contributing further to increased pharmaceutical prices. Steps to strengthen training and employ professional pharmacists in hospitals would be less costly and more feasible in the short term.

2.6 Demand for pharmaceuticals

143. Many factors will affect the demand for pharmaceuticals. The prevalence of various health conditions, the breadth of insurance coverage for pharmaceuticals and pharmaceutical prices are the most obvious examples.

144. The epidemiological profile of Mexico has undergone a transformation during the latter half of the 20th century that parallels Mexico's evolution from a developing to an emerging-market country. In 1960, diarrhoea and pneumonia were the leading causes of death in Mexico. In 2000 the leading causes of death were heart disease and cancer. During this transformation Mexico has retained some epidemiological elements of a developing country in concomitance with epidemiological patterns more characteristic of a developed nation. On the one hand, infectious and parasitic diseases are much more prevalent in Mexico than in other OECD member countries, while on the other hand, chronic conditions and ageing-related diseases, such as diseases of the circulatory system, are the leading causes of mortality in Mexico as they are in other OECD countries. Concomitant with this mixed profile, the demand for pharmaceuticals should exhibit a slightly different profile with respect to other OECD countries. In a comparison of sales by therapeutic class for the three NAFTA countries, there are a number of similarities. The top five therapeutic classes in terms of sales in Mexico are the same as in the United States and represent four of the top five in Canada (Ministry of Health, 2005). However, while sales of drugs for treating cardiovascular disease represent 17.6% of total sales in the United States and 25.1% in Canada, they only represent 8.6% of total pharmaceutical sales in Mexico. Moreover, the sales of anti-infective for systemic use, which make up 15.7% of total sales in Mexico, account for only 8.4% and 5.3% of sales in the United States and Canada respectively. Drugs for treating infectious diseases accounted for 35% of all drugs purchased by the Ministry of Health for the *Seguro Popular de Salud* in 2005, more than double the next highest category.[68]

145. Additional information from IMSS on epidemiological patterns further demonstrates this epidemiological transformation, showing it to be an ongoing process. Among IMSS beneficiaries, chronic conditions have replaced infectious diseases as the most frequent causes of mortality and incapacity among Mexico's salaried workers in the private sector (Ministry of Health, 2005). More recently, changing

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[67] In 2001, there were 20 584 students enrolled in pharmaceutical sciences programs. It is estimated that about 40% will have graduated in 4 years time. This means that in any given year there are about 2 000 graduates. Even if each one of these were trained as pharmacists, it would take 20 years for there to be a sufficient number of pharmacists to supply each pharmacy in Mexico.

[68] Information from a presentation by Ministry of Health officials responsible for the *Seguro Popular* (April 2006).

epidemiology has led IMSS to purchases of higher cost drugs. IMSS officials believe that had purchasing patterns not changed, i.e. the epidemiological profile of beneficiaries remained the same, they would be spending less on drugs today because the bulk of purchases would be for relatively lower cost drugs.

146.   Much of the epidemiological 'residual,' a relatively high number of developed world communicable and infectious diseases in a nation with a developed country epidemiological profile, can be attributed to regional disparities in socioeconomic status (OECD, 2005a). Unfortunately, health care supply has not met demand where it is most needed. There is an unequal distribution of health-care services across Mexico, with services weakest in rural areas.[69] The problem is similar for access to pharmaceuticals, although may not be as acute since pharmaceuticals in general are more accessible than fixed capital infrastructure like hospitals and clinics. However, pharmaceuticals must be dispensed through pharmacies, which does place a limit on the accessibility to drugs.

147.   By many measures of health status, Mexico is worse off than most OECD countries, *ceterus paribus,* this should mean that the demand for health care services, including pharmaceuticals, should be greater in Mexico than most other countries. Of course, a limiting factor is Mexico's low per capita income. The ability of Mexican's to buy the drugs they need is limited by their inability to pay for these drugs; only Turkey spends less per capita on pharmaceuticals. Furthermore, if pharmaceuticals are a necessary good,[70] then one would expect spending on pharmaceuticals to exact a larger portion of per capita income in Mexico than most other countries. However, Mexico spends only 1.32% of GDP per capita on pharmaceuticals, less than the OECD average. These measures suggest that Mexicans may not be getting all of the drugs they need.

148.   It may be that the lack of universal healthcare insurance coverage in Mexico may be preventing many Mexicans from obtaining the drugs they need. If more Mexicans had health insurance coverage for drugs, they would demand more drugs because they would not have to pay the full cost. The *Seguro Popular de Salud* is a start in this direction, with the goal of extending coverage to all uninsured families by 2010 (see Box 3). However, even with universal health care insurance coverage, if financing is insufficient then a situation of unmet demand for pharmaceuticals can still exist.

149.   The ability of consumers to satisfy their demand for pharmaceuticals will depend on the accessibility of drugs. Outside the hospital setting, the point of access for consumers is the pharmacy. The more pharmacies that are easily accessible the easier it is to meet demand. Unfortunately, translating this notion into a pertinent and reliable indicator is difficult for a number of reasons (see Annex 1). The accessibility of pharmacies to persons living in urban areas, where there is a greater density of pharmacies, can be expected to be fairly high relative to those living in rural, and especially remote, areas.

150.   The demand for a particular pharmaceutical is usually the result of a visit to the doctor. However, there are circumstances where a patient decides for himself or herself to purchase in the private sector medicines without consulting a health professional. When people "self-medicate" they typically purchase over-the-counter drugs (OTC) for which they do not require a prescription. This is quite a common practice

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[69] See Table 2.1 in OECD 2005a. The health-care services measures include numbers per 1 000 population of doctors, beds, acute care beds, nurses and surgical units.

[70] There has been little empirical evidence about the nature of pharmaceuticals as either a necessary or luxury good. The jury is still out on whether health care, as exhibited by health expenditure data, is a necessary or luxury good. Earlier estimates tended to classify health care as a luxury good (Newhouse, 1977; Parkin, 1987), but more recent studies have shown it to be a necessity (Getzen, 2000). From a non-economics viewpoint, many people would classify health care, as well as its components such as pharmaceuticals, as a necessary good.

in Mexico and elsewhere.[71] However, self-medication can also occur in the absence of a prescription when one is required. This type of "irrational self-medication" is a particular problem in Mexico where many pharmacies sell pharmaceuticals without a prescription, even though by law they cannot dispense pharmaceuticals, apart from OTC drugs, unless the customer presents a prescription. It is estimated that in Mexico 45% of cases where the customer self-medicated were for drugs for which a prescription should have been provided (Ministry of Health, 2005). This type of behaviour can have grave consequences if customers are unaware of associated problems usually communicated to them by the prescribing physician such as adverse reactions, contraindications, restrictions on use or interactions with other drugs. While health problems emanating from irrational self-medication appear to be a problem for the health care system, very little hard data on the problem exist. Self-medication may also be a particularly important factor in Mexico's high out-of-pocket spending habits since drugs bought through self-medication are typically not covered by health insurance.

151.   In Mexico, self-medication is a phenomenon that reaches across all socioeconomic levels, even among social security beneficiaries, although those persons without social insurance or government-sponsored health insurance coverage are more likely to self-medicate (Pagán, *et al*. 2006). Another factor may be the consistent undersupply of medicines in the public sector. Many individual social security beneficiaries, rather than wait for the drugs to become available through their provider pharmacies will opt to buy the pharmaceuticals in the private sector, without a prescription, assuming the entire cost of the drugs. The perceived inferior quality of public sector drugs is often cited as another reason why social security beneficiaries often buy drugs in the private sector, without a prescription.

2.7   Competition

152.   At the manufacturing level, the pharmaceutical market in Mexico appears to be heavily concentrated. In 2001, about 10% of pharmaceutical firms, the leading multinationals, accounted for almost 80 percent of total sales (Gonzalez, 2002). However, based on the Herfindahl Index for the pharmaceutical market in Mexico as a whole, the index of 232.68 would point to an unconcentrated market.[72] However, the actual competitiveness of the market is a bit more nuanced.

153.   A problem with measures of competition is defining the market. Anti-trust regulators can segment a market in any number of ways when determining the level of competition. These include geographic scope, the different parts of the distribution chain and product group. For the latter, competition in the pharmaceutical industry can be examined by therapeutic class. When examined under this light, the market for several therapeutic classes is more concentrated than the overall market. For example, 94% of anti-obesity preparations, excluding dietetics (ATC A8A)[73] were produced by 5 firms, with one firm producing 51% of all drugs in this therapeutic class (OECD, 2000).

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[71] Sales of OTC products represented 33% in volume terms and 18% in value terms of total pharmaceutical products produced in Mexico in 2004.

[72] The Herfindahl index is a measure of the amount of competition within an industry. It is defined as the sum of the squares of the market shares of each individual firm. Generally, a Herfindahl Index of 1,800 or higher is considered an indicator of high concentration while an index of less than 1,000 indicates almost no concentration. The calculation of the Herfindahl Index in this paper was based on information on the share of sales of the top 20 pharmaceutical firms in Mexico in 2001 (Gonzalez, 2002). These firms accounted for 60% of sales so the remaining 40% was assumed to be allocated evenly among the remaining firms. As noted in footnote 14 the estimates of the number of pharmaceutical firms varies widely, however, the Herfindahl Index calculated for all estimates falls within the range of 229.30 to 239.47.

[73] ATC refers to the Anatomical Therapeutic Chemical classification system developed and maintained by the World Health Organisation.

154. As was observed earlier, there is a division in the pharmaceutical market in Mexico between a public market on the one hand and a private market on the other. In the public sector, which is dominated by trading in generics, there are several hundred manufacturers competing to sell their products to a handful of buyers: IMSS, which itself is responsible for about 80% of drug purchases in this market, ISSSTE, a few other social insurance agencies, the state health authorities and the Ministry of Health.

155. Manufacturing is more concentrated in the private market. There are about 70 manufacturers, with 20 firms accounting for about 60% of the market, ¾ of which are multinationals. Firms in this sector produce both generics and original products. On the one hand, competition among producers of on-patent pharmaceuticals is quite limited and, given the lack of domestic research-based firms, it is not surprising that a few firms dominate this segment of the market. This situation is likely to remain for some time. On the other hand, the large number of generics producers, each with a relatively small share of the market, should ensure healthy competition for the production of generic products.

156. By and large, the competitiveness of the manufacturing sector in the pharmaceutical industry is not a major concern of the competition authorities in Mexico. Where there is some concern, however, is in the wholesale segment, especially in the private market, where the pharmaceutical manufacturers distribute their products through three distributors which account for approximately 70% of the wholesale market. The remaining 30% of the wholesale market consists of small local distributors, which may also be cause for concern since some of these regional distributors operate alone in their respective regions.

157. In the private market, many large pharmacy chains and department stores with their own pharmacy departments are buying their products directly from manufacturers, thus circumventing the wholesalers. While information on the extent to which wholesalers are being bypassed is unavailable, this activity is likely growing as the large pharmacy chains continue expanding (IMS Health, 2005). In the public market, the social security agencies and the Ministry of Health often buy their drugs directly from the manufacturer through the bidding process, thus avoiding going through distributors. These activities in the public and private markets will have a tempering effect on the ability of distributors to capture rents arising from the inefficiency of the distribution system.

158. Unlike the wholesale and manufacturing segments, competition at the retail end of the market is intense. The retail pharmacy industry in Mexico is not as regulated as other segments of the health-care industry; the absence of a regulation requiring pharmacists to dispense drugs is an example. In fact, the amount of regulation faced by retail pharmacies is not much greater than for any other type of small retail business. Looser regulations facilitate easy entry into the pharmaceutical retail market. Operating a pharmacy under these circumstances is no different than running any type of retail store.

2.8 Trade, imports and exports

159. Mexico is a net importer of pharmaceuticals. In 2003 Mexico exported 1.9 billion USD worth of pharmaceutical products and imported 4.0 billion USD for a total net import of 2.1 billion USD (Figure 7). The United States is the largest single exporter of drugs to the Mexican pharmaceutical market, supplying about one-quarter of total imports in 2000, while countries of the European Union accounted for almost 50% of total imports. Mexico's exports are directed mostly to the Latin American market with Panama, Brazil and Colombia the three largest recipients of Mexican pharmaceuticals (Krazov-Jinich, et. al., 2003).

160. The domestic industry in Mexico is dominated by generics firms, which means that Mexico imports most of the original products it consumes. This explains why the largest exporters to the Mexican market are countries with a significant research-based pharmaceutical industry. By contrast, Mexico's largest export markets are to other countries with a similar lack of home-grown R&D-based pharmaceutical companies. The domination of generics firms in the domestic industry also means that

Mexican exports will be limited because they must compete in a highly competitive generics market, where entry costs are nowhere near as prohibitive as in the research-based pharmaceutical industry. This can be seen in the distribution of total pharmaceutical exports in the OECD by country. The top 5 exporting countries, Germany, the United States, the United Kingdom, Switzerland and France account for almost 60% of total exports in the OECD and are the countries with the largest presence of R&D-based pharmaceutical companies. Mexico, on the other hand, represents but 0.27% of total exports in the OECD, more than India but less than China, two non-OECD countries.

Figure 7. Pharmaceutical industry trade balance in OECD countries, million USD PPP, 2003
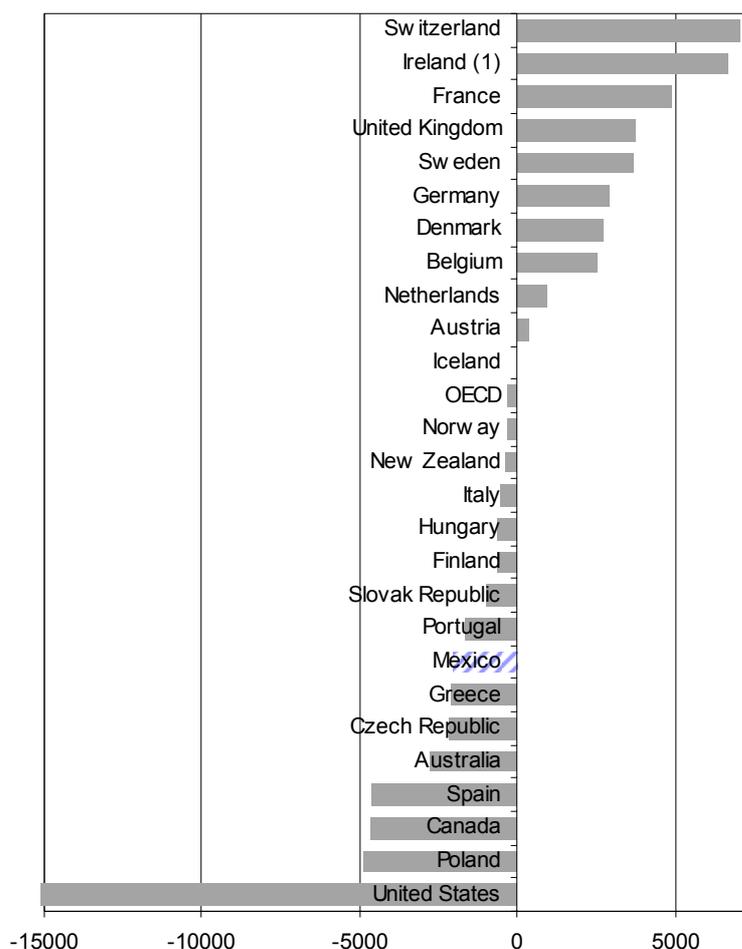
(1)2001

Source: OECD Health Data 2006, version 06/26/2006

161.   Mexico became a signatory to the General Agreement on Tariffs and Trade (GATT) in 1986. This reduced, but did not eliminate, tariffs on primary materials and active ingredients for pharmaceutical products. More importantly, adherence to GATT meant the elimination of the special law that refused import permits for drugs if there was a national producer.[74] This protective status was diminished when

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[74] This law also pertained to patented medicines, even though technically there should be only one producer, the holder of the patent. Mexico's intellectual property rights laws were very weak at the time and copy products, copies of drugs that were still under patent, were quite prevalent.

Mexico signed the North American Free Trade Agreement (NAFTA) with the United States and Canada, which came into effect in 1994. NAFTA brought with it the elimination of tariff barriers for pharmaceutical imports from the United States and Canada and helped to eliminate non-tariff barriers (ITA, 2004). However, pharmaceutical companies from outside NAFTA still face average tariffs of 18% providing both Canadian and American pharmaceutical firms with a competitive advantage over their overseas rivals. NAFTA has helped propel the United States to the number one exporter of pharmaceutical products to Mexico, past France and Switzerland who were the two largest exporters in 1997 (Krazov-Jinich, 2003).

162.   The opening up of trade in pharmaceuticals in Mexico has coincided with an expansion of both exports and imports of pharmaceutical products. Data from 1991 to 2003 show that exports and imports have increased more substantially over that period of time (Figure 8). Between 1991 and 1994 exports grew by 2.5 times, an average annual rate of growth of 19.5%, while imports almost doubled during the same period, an average annual growth rate of about 13%. The pace of growth in pharmaceutical exports was slower following the signing of NAFTA, with an average annual growth rate of 11.7%, although growth in imports also slowed to less to 12.1% per annum.

Figure 8. Trends in pharmaceutical imports and exports in Mexico, 1991-2003
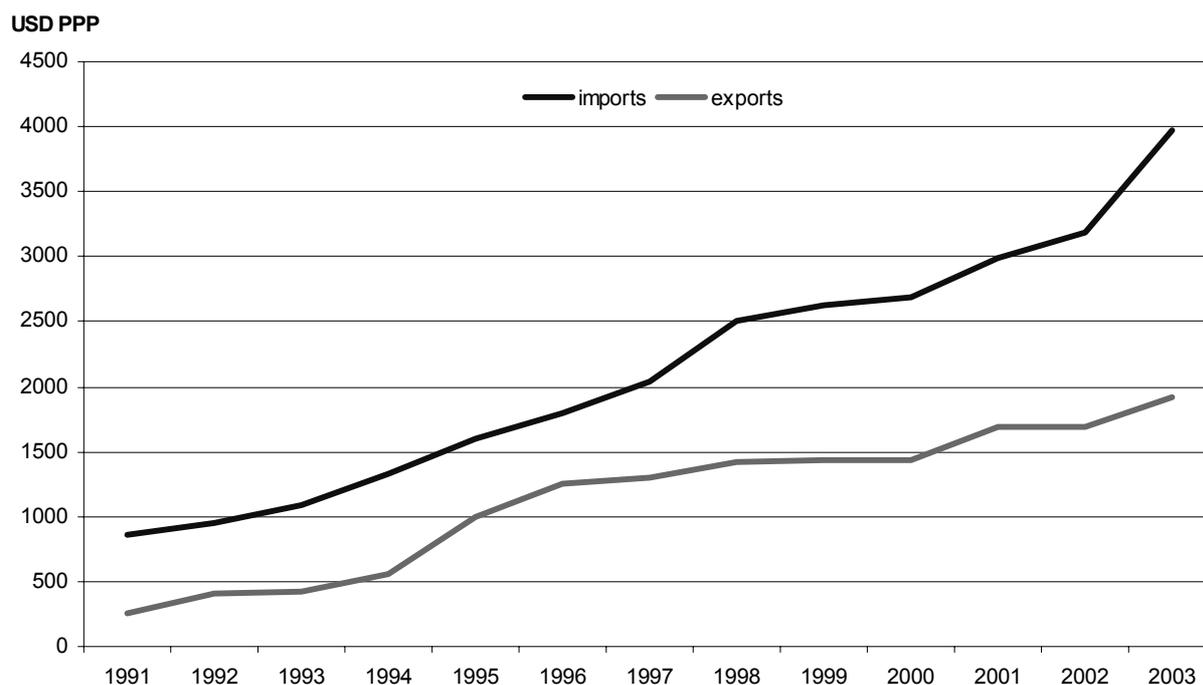
Source: OECD Health Data 2006, version 06/26/2006

163.   What is particularly interesting to note on the evolution of the trade in pharmaceuticals during the "free trade era" is the composition of exports and imports between final products (pharmaceuticals) and inputs (the chemical constituents in pharmaceuticals) (Ministry of Health, 2005). In January 1994, Mexico imported about 40 million USD worth of inputs, almost 100% of total importations of pharmaceutical products. By January 2003, imports of inputs (65 million USD) accounted for less than half of total

pharmaceutical imports; imports of final products had increased substantially to about 100 million USD. The story is completely reversed with respect to exports. In January 1994, exports of inputs were about 30 million USD, accounting for half of total pharmaceutical exports. Ten years later, exports of inputs increased more than 5 times to over 150 million USD, accounting for over 90% of total pharmaceutical exports; the export of final products during this period decreased to 10 million USD.

164.   Despite opening up its domestic pharmaceutical market to foreign competition, Mexico still retains non-tariff barriers to trade. The rules governing marketing authorisation for pharmaceutical products are still decided by the government of Mexico. This is not an aspect unique to Mexico; both of its NAFTA partners also have their own laws governing when and how drugs are authorised to be placed in their respective market. Indeed, all countries retain the right to determine the rules by which pharmaceutical companies must comply for their drugs to be marketed to the public. These rules are considered to be public health laws and generally outside the remit of trade agreement negotiations.

165.   Another non-tariff trade barrier that remains in place, one which falls under the marketing authorisation laws, is the requirement for all importers of medicines to have marketing authorisation for the product(s) they wish to import, from the Ministry of Health.[75] This law requires that any company importing a drug into Mexico must have duly authorised production and testing facilities in the country, in accordance with the requirements for obtaining marketing authorisation as set out by the COFEPRIS (See section 1.2).[76] The guidelines do not specify whether the importer is domestic or foreign owned. The testing facilities do not need to be specific to the drug being imported, but must be adaptable to the product under consideration. The public health aspect of this requirement is less obvious than for marketing authorisation. That being said, the public health claim is that since Mexico is not in the position to test drugs in facilities outside the country, it must retain that ability by forcing drug importers to have facilities in Mexico which can be easily inspected. The plant requirement in effect adds to the costs of imported drugs in Mexico, which also has the effect of making drugs for re-importation more expensive (OECD, 2000), having a dampening effect on parallel trade.

166.   Cross-border trade in the form of US residents purchasing medicines in Mexico for their personal use at home has been estimated to account for approximately 100 million USD in business.

167.   Parallel trade does not appear to be a significant issue in Mexico, not only because of the plant requirement. There are other, more compelling reasons why parallel trade is not an important problem in Mexico. The packaging and labelling of pharmaceuticals in Mexico requires that they be in Spanish only which acts as a significant deterrent to re-importing these products to a non-Spanish speaking country, most notably the United States, despite its significant Spanish speaking minority, which, due to its proximity, the relative high price of pharmaceuticals and the significance of its exports to Mexico is the most likely candidate for parallel trade. Furthermore, most parallel trade of pharmaceuticals in the United States occurs with Canada, much of which is due to the expansion of internet pharmacies. Mexico's relatively poorer Internet penetration puts it at a significant disadvantage vis-à-vis Canada at capturing this market, which anyway appears to have peaked in 2004. Finally, parallel trade became an important issue in the United States because a significant number of people became increasingly aware of the price differential between the United States and Canada. Currently there does not appear to be any evidence that a similar trend is taking hold vis-à-vis Mexico. Nevertheless, for the moment there does not appear to be as much of a concern by the industry to this practice in Mexico. One reason may be that US pharmaceutical companies are quite happy to allow the practice to continue so long as it allows them to segment the US

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[75] Article 131 of the *Reglamento de Insumos para la Salud* (Regulation of Health Inputs).

[76] This regulation only applies to importers who intend to sell the drugs on the market. A hospital, for example, can import drugs without fulfilling the requirement of having a plant in Mexico so long as the drugs are for use within the hospital itself.

market of demand for pharmaceuticals. Americans for whom incurring the transaction costs of a trip to Mexico to buy cheaper drugs is worth it are likely to have not bought the product. This type of cross-border trade provides a new market for pharmaceutical companies of customers who otherwise would not have bought the product.

3   ACHIEVEMENT OF POLICY GOALS

168.   This section considers the degree to which Mexico achieves certain policy goals for health-system performance and the pharmaceutical industry in Mexico. It also attempts to assess the impact of Mexico's pharmaceutical pricing policies on the attainment of these goals.

3.1   Containment of drug expenditures

169.   Although Mexico's total health spending has grown at a slower rate than the OECD average in recent years, its spending on pharmaceuticals has grown at an annual rate that is one of the highest in the OECD. This might be explained, in part, by the effect of strong growth in the retail prices of on-patent drugs, reflecting Mexico's relaxation of controls on the prices of pharmaceuticals for consumers purchasing drugs in the private market.

170.   At present, Mexican price regulation is ineffective in constraining manufacturers' prices and policies to control on volume or consumption are virtually non-existent in the private sector, leaving half of the pharmaceutical sector in Mexico essentially unregulated. High retail prices in Mexico may also reflect the country's geographic proximity to the United States, to the extent that manufacturers seek to diminish the extent of cross-border trade or the threat of encouraging legalisation of parallel imports to the United States. Because retail prices are very high in comparison with Mexico's income level, one-third of all private health expenditures are devoted to pharmaceuticals.

171.   On the other hand, Mexico has done very well in containing drug expenditure growth in the public sector through a combination of leveraging its purchasing power to obtain very low prices and strong controls on the supply of pharmaceuticals to those with publicly financed health care insurance coverage which also acts to shift some demand (and costs) to the private sector. Reflecting these factors, pharmaceutical spending represented only 5.2% of total public spending on health in Mexico in 2004, a notably low share by OECD standards.

172.   As publicly financed insurance coverage expands in Mexico, cost pressure in the public sector will increase. It is unclear whether manufacturers will continue to provide products at such low prices for a larger share of the total market. Furthermore, to the extent manufacturers fear that packaging restrictions will facilitate illicit re-sales in the private market of products manufactured for public purchasers, they may be less willing to sell their products to public purchasers at a significant discount.

3.2   Sustainability and equity of financing for pharmaceuticals

173.   Reliance on out-of-pocket payments by households as the primary source of financing for pharmaceuticals raises issues of both sustainability and equity. Relying to a greater extent on public coverage or private insurance would enhance both sustainability and equity, while offering the advantages of pooling risk and reducing financial barriers to care. As pharmaceuticals continue to play a larger role in health-care practice and total health expenditures, moving away from reliance on out-of-pocket spending will be increasingly important for Mexico.

174.   Nevertheless, given the large share of Mexicans who do not participate in the formal employment market, the financing implications of expanding publicly financed coverage are quite significant. In addition, increasing coverage can be expected to have a strong positive impact on demand for pharmaceuticals, as appears to be the case for health care services in general (Gakidou *et al.*, 2006).

3.3   Efficiency of expenditures

175.   Evidence suggests that Mexico's pharmaceutical expenditures do not result in the most cost-effective outcomes. At present, the main effort to obtain value for money in drug spending comes at the level of formulary decisions in the Basic Formulary and the Catalogue of Inputs and subsequent purchasing decisions by publicly financed coverage schemes. However, the use of economic analysis in such decisions is relatively new and standards are lacking.

176.   Improvements in efficiency could include a change from a purchasing model to a patient or pharmacy reimbursement model of drug expenditures, given the costs associated with purchasing, storing and distributing medicines to patients with publicly financed coverage. Such a model averts the need to accurately predict drug usage and to avoid problems such as expiration or loss of medicines due to poor storage. It could also improve efficiency by increasing the availability of medicines to patients, who would not need to rely on the supply of a small share of pharmacies affiliated with their coverage scheme. While increasing the match between need and availability will improve efficiency, it may also result in higher costs.

177.   Generic medicines have a high market share in Mexico, overall and in the public market in particular. While this would normally be indicative of cost-effective supply, in Mexico's case it is not clear, given that bioequivalency requirements have only recently come into effect. Effectiveness may be unduly compromised in the case of reliance on medicines not proven bioequivalent as substitutes for products that have passed extensive safety and effectiveness tests. If the high market share can be maintained in the light of bioequivalency demands, Mexico will be able to boast of a highly cost-effective product market.

178.   On the private side, the lack of competition in the wholesale market might be a source of inefficiency. However, supply shortages are not evident, the maximum price limits the practice of price gouging and evidence of inefficient distribution is lacking. Along the supply chain it is small pharmacies that are most likely paying the price of an uncompetitive wholesale market, except again in rural areas served by a single wholesaler. Small pharmacies operating in a highly competitive market lack the economies of scale of the large retailers that allow them to buy directly from manufacturers and they get squeezed between wholesalers who command higher prices than those in a competitive market and retail market forces which compel small pharmacies to compete on prices by offering significant discounts on the maximum price.

3.4   Availability of pharmaceuticals

179.   A number of factors suggest that most pharmaceuticals that are available in the developed countries of the world are also available in Mexico on a fairly prompt basis. First, approval times are reportedly rapid so that delays in access to the private market are minimal. Second, Mexico is one of the world's largest pharmaceutical markets from the perspective of manufacturer sales revenues, with significant growth potential given its low income relative to other large pharmaceutical markets. In order to achieve the global revenue targets on which profits depend, it stands to reason that few pharmaceutical manufacturers can afford not to do business in Mexico. On the other hand, product launch timing decisions may well be affected by Mexico's proximity to the United States, and the potential for cross-border trade.

180.   Although evidence of availability is limited, that which exists supports a finding of prompt availability of new products: Mexico is occasionally the first market in which a manufacturer chooses to launch a new product and most new products are adopted within four years after the first world launch.

181.   It is very likely that availability of original pharmaceutical products and bioequivalent generics vary widely across Mexico, according to a number of factors. Geographic variation in supply is likely large, given income differences across Mexico: pharmacies may well be lacking in poor rural areas. Similarly, availability differs for social security and publicly funded health insurance beneficiaries who lack the income to participate in the private market for drugs. It is also not clear that drugs included on formularies are always readily available in public clinics, reflecting factors such as cost constraints and poor planning in drug purchasing.

182.   For those who are not able to participate fully in the private market for drugs the alternative is non-interchangeable generics. However, these low cost and probably inferior quality products are imperfect substitutes. Moreover, their availability will diminish over the coming years as the regulation requiring bioequivalency of generics comes into effect. On the one hand, the absence of these drugs from the market will likely contribute to an increase in the overall average price of drugs, further exacerbating the problems of low-income individuals obtaining pharmaceuticals. On the other hand, to the extent that interchangeable generics are substitutable for higher cost on-patent medicines, their increased presence may contribute to lowering the overall average price of drugs. How the gradual displacement of non-interchangeable products with interchangeable generics will affect overall drug prices remains to be seen.

3.5   Accessibility of pharmaceuticals

183.   Despite what is probably reasonably good availability of medicines in Mexico, accessibility of pharmaceuticals is undoubtedly poor for many patients, particularly the poor living in remote regions.

184.   Those enrolled in publicly financed schemes should face no financial barriers to access, given the lack of cost sharing in the coverage schemes. However, the Basic Formulary and the Catalogue of Inputs and the scheme-specific formularies that are its subsidiaries restrict access to some medicines. Beyond this, all public schemes require patients to obtain their medicines from designated public clinics or pharmacies, reducing accessibility further, particularly when the supplies purchased may be insufficient.

185.   There is some evidence that patients are not achieving access to pharmaceuticals that is comparable with that of other OECD countries. For example, by the standard of comparison with the mix of molecules used by patients in the United States, Mexico's level of per capita use is very low — much lower than 6 other OECD countries studied and half the utilisation of Chile (Danzon, 2003a). Low volumes of use in Mexico likely reflect a combination of high prices in the private market and constraints on supply in the public market.

186.   Despite this evidence of poor access, there is also some promising evidence regarding accessibility of pharmaceuticals in Mexico. Disease-specific programmes have received high-levels of funding and, anecdotally, have greatly improved accessibility to medicines for patients with life threatening illnesses who are most in need of ready access to medicines. Recent evidence regarding the *Seguro Popular de Salud,* the government scheme for eventually extending health insurance coverage to all Mexicans, is also encouraging. Gakidou *et al.* (2006) show that affiliation to the *Seguro Popular* is increasing, especially among poor and marginalised communities. This is especially important for lowering barriers to access given that *Seguro Popular* affiliates were shown to be much less likely to pay out-of-pocket for medicines than uninsured people.

3.6   Quality of care, health outcomes

187.   There are a number of factors suggesting quality of care is hurt by Mexico's pharmaceutical policies, although specific evidence regarding impact on health outcomes is not available.

188.   First, the widespread incidence of patients obtaining prescription medicines in the private sector without seeing a doctor and obtaining a prescription is understood to lead to serious problems such as errors in medicine choice and dosage, and interactions with other medicines. Some such errors lead to patient injury. The problem is augmented by the lack of formal education or certification requirements for pharmacists, who are merely sales clerks in most cases, not qualified to help patients select and use medicines correctly. Further compounding the problem is lack of requirements for adequate information in packaging.

189.   The use of copy products and medicines similar, but not bioequivalent, to original products, creates an additional quality problem that may impair health outcomes, as does the existence of counterfeit products in the market.

190.   Finally, without question medicines are under-used in Mexico at present, in that many who could benefit from health improvements made possible by medicines fail to obtain them. The health impact of such under-utilisation cannot be quantified.

191.   Mexico's health status is very low by OECD standards. Improvements in pharmaceutical policy will undoubtedly improve the health status of many Mexicans, but as with all policies, there are both benefits and costs, which imply that there are trade-offs to be made. For instance, improved education and licensure of pharmacists has been proposed. While the prospective benefits of improvements in quality and safety of such a policy are clear, such a policy could entail increased costs and reduced access to medicines, caused both by increased prices and closure of retail pharmacies in the absence of a pool of qualified employees. The challenge for policy makers will be to implement a policy that increases consumer safety, while minimising impact on the public's access to affordable medicines. A gradual phasing-in of pharmacist requirements could meet such a challenge, perhaps beginning with a requirement that large hospitals hire professional pharmacists, where the need is the greatest.

3.7   Public satisfaction with pharmaceutical policies and outcomes

192.   Very little information is available to assess patient and consumer satisfaction with the results of pharmaceutical policy in Mexico. Anecdotally, there is a perception of poor quality of pharmaceuticals and service in the public sector. The government's proposed solution of requiring manufacturers to sell products in packages identical to those used in the private market may be a double-edged sword, in that quality perceptions may increase even as access becomes more restricted (given manufacturers' likely reactions to imposed packaging changes).

193.   In the private market, there may well be a dichotomy of perception between actual and perceived quality. Sales of non-interchangeable generics continue to be very strong in Mexico and popularity is high enough to encourage the owner of a leading business selling these *similares* to run for public office in Mexico. Yet products that are similar, but not necessarily identical, to known products produced by originators, have a higher risk of being ineffective or unsafe than do bioequivalent generics or originator products produced in special packaging for use by beneficiaries of publicly financed coverage schemes.

3.8   Industrial policy goals

194.   Mexico has shed its post-war policy of import substitution industrialisation and embraced business-friendly trade and intellectual property rights policies. Through GATT and NAFTA, Mexico has

significantly reduced restrictive trade policies. The opening up of trade has benefited trade in pharmaceuticals, as evidenced by the 650% increase in exports and 350% increase in imports of pharmaceutical products between 1991 and 2003 (Figure 8). The requirement for drug importers to have production and testing facilities in Mexico may constitute a non-tariff trade barrier, however it is unclear as to whether or not this constitutes an unreasonable barrier.

195.   Incremental strengthening of patent protection has gradually removed the financial disincentives to research-based pharmaceutical companies to limit their exposure in Mexico. Pfizer, for example, has recently built a new distribution centre in Mexico that covers all of Latin America. To help foster technology transfer, the Mexican Institute of Industrial Property, in cooperation with the Ministry of Health, has begun a programme for training academic researchers on how to write patents.

196.   Despite these positive developments, Mexico still does not have the resources to attract pharmaceutical manufacturers from the R&D-based portion of the industry. Trade may have opened up, but the comparative disadvantage of Mexico in the production of final products is evident: 90% of Mexico's pharmaceutical exports now are primary materials, while imports of final products have increased to 50% of total imports whereas they used to be less than 10%.

197.   In innovation, as well, Mexico is hard pressed to compete. Funding levels for R&D are low by OECD standards and have even decreased in recent years. Government funds most research in Mexico but, without increased revenues there will be little room for expanding R&D funding in the face of competing demands. Business funding of R&D is no better. Furthermore, the number of researchers is significantly below other OECD countries.

198.   These conditions will not change in the short-term. The greatest prospects for the Mexican pharmaceutical industry lie in using its competitive advantage over other Latin American countries; open trade and strong intellectual property rights. Competitive pressures from open trade will force generics producers to be more efficient and bioequivalency requirements will enhance the quality of their products vis-à-vis their Latin American competitors. Under these conditions the generics industry in Mexico is in a position where it can compete favourably with the industries of other OECD countries. In addition, strong IPR will force multinationals to look more closely at Mexico as a Latin American base.

199.   Research and development of the medicinal properties of natural products and their subsequent transformation into marketable pharmaceutical products offers the most promising area for developing a strong research-based pharmaceutical industry in Mexico. The treatment of ailments through natural products is widespread throughout Mexico with a tradition that dates back centuries. Furthermore, there exists a precedent for this type of industry in Mexico: the development of the oral contraceptive began with the synthesis of an extract of a yam found in Veracruz into progesterone, this eventually lead to the creation of Laboratorios Syntex SA to manufacture therapeutic steroids from the yams, from which developed an internationally competitive steroid hormone industry.

4   KEY FINDINGS AND CONCLUSIONS

200.   This paper has undertaken a comprehensive review and assessment of Mexico's pharmaceutical pricing and reimbursement policies and the market and policy environment in which those policies operate. The findings point to a number of successful accomplishments, as well as outstanding challenges. Among the key findings are these:

➢ Patented medicines is one of only two sectors in the Mexican economy still subject to price regulation. In some respects, pharmaceutical price regulation operates more as a symbolic initiative representing consumer protection than a functional mechanism responsible for consumer savings.

➢ To the extent that income can be considered a proxy for the price elasticity of demand, Mexican price levels are higher than would be predicted, in comparison with a sample of seven other countries of moderate and high income. Prices also have been found to be high relative to those of other Latin American countries. Possible explanatory factors include the relative weakness of the maximum price standard established in regulation, as well as the influence of the geographic proximity of the United States, to the extent that manufacturers take the threat of cross-border trade into account when establishing Mexican prices.

➢ Relatively high retail prices have implications for both the uninsured and those with public coverage, in that many of the latter make use of the private distribution system to avert prescription requirements, quality concerns and problems of shortages of products in public dispensaries.

➢ Mexico's social insurance programmes achieve very significant savings over the retail cost of medicines through a system on which manufacturers of interchangeable generics bid for business, designating the price at which a particular volume of medicines can be offered.

➢ The market penetration of generic products is fairly high. In the public sector this is due in large part to the purchase of interchangeable generics. In the private sector, potentially inferior, low cost non-interchangeable generics represent a large share of the market. A trade-off between safety and cost in the private market is inevitable as new bioequivalency requirements come into force.

➢ Some inefficiencies in the system of public procurement and dispensing, such as product waste due to expiration and storage failures, as well as shortages of products in public clinics, point to the prospective value of experimentation in the use of reimbursement of private pharmacies.

201.   These findings regarding Mexico's pricing and reimbursement policies have been drawn on the basis of an assessment of the direct impact of the policies in Mexico. However, an important consideration of ongoing work in the area of pharmaceutical pricing policy is the so-called global and cross-national impact of policies. Impacts of interest include the hypothetical effect of pricing and reimbursement policies in one country on prices and availability of medicines elsewhere, and the impact of pricing and reimbursement policies on investment in pharmaceutical R&D and the resulting impact on pharmaceutical innovation. These issues have been alluded to in this report without being directly assessed. This case

study of Mexico will provide input into OECD work to assess the hypothetical global and cross-national impact of different pricing and reimbursement schemes and policies.

REFERENCES

AMIIF (Asociación Mexicana de Industrias de Investigación Farmacéutica) (2005). Corporate brochure, Mexico, D.F.

Cevallos, D. (2003). LABOUR-MEXICO: 20 Million Informal Sector Workers, *Inter Press Service News Agency*, www.ipsnews.net/interna.asp?idnews=19946, accessed 25 July 2006.

Chagoya, H. and S. De Alva (2003), "Mexico: Using pipeline patents to protect pharmaceuticals", *Managing Intellectual Property Supplement - Patent Yearbook 2003*, www.managingip.com/?Page=17&ISS=12710&SID=473291, accessed 11 July 2006.

Combe, E. and E. Pfister (2001). "The Effectiveness of Intellectual Property Rights : New Evidence from French Survey Data" in R. Lipsey and J.L. Mucchielli (eds), *Multinational Firms and Impacts on Employment, Trade and Technologies : New Perspectives for a New Century*, London, Routledge.

Conway, P., V. Janod and G. Nicoletti (2005). "Product Market Regulation In Oecd Countries: 1998 To 2003", *Economics Department Working Papers*, No. 419, OECD, Paris.

Danzon, P.M. and M.F. Furukawa (2003), "Prices and Availability of Pharmaceuticals: Evidence from Nine Countries", *Health Affairs – Web Exclusive*, pp. W3-521 - W3-526, http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.521v1, accessed 11 July 2006.

EAU (Economic Analysis Unit, Ministry of Health) (2006). internal working document, Mexico.

Frenk J, *et al.* (2006). "Comprehensive reform to improve health system performance in Mexico", *Lancet*, Vol. 368, pp. 1524-34.

Gakidou E, *et al*. (2006). "Assessing the effect of the 2001–06 Mexican health reform: an interim report card", *Lancet*, published online Oct 25. DOI:10.1016/S0140-6736(06)69565-2.

Getzen, T.E. (2000). "Health care is an individual necessity and a national luxury: applying multilevel decision models to the analysis of health care expenditures," *Journal of Health Economics*, Vol. 19, No. 2, pp. 259-70.

Gonzalez, J. (2002), *Industry Sector Analysis (Mexico)*, U.S. & Foreign Commercial Service, Washington.

González-Pier, E. and A. González Hernández (2004), "Regulación saludable del sector farmacéutico", *Competencia Económica en México*, Comisión Federal de Competencia, Mexico, D.F.

González-Pier E, *et al*. (2006). Priority setting for health interventions in Mexico's System of Social Protection in Health. Lancet 2006; published online Oct 25. DOI:10.1016/S0140-6736(06)69567-6.

IMS Health (1995). *IMS World Review, the Pharmaceutical Market, 1995,* IMS Health.

IMS Health (2005). *Intelligence.360: Global Pharmaceutical Perspectives 2005*, IMS Health.

IMSS (2004), *Informe al Ejecutivo Federal y al Congreso de la Unión sobre la Situación Financiera y los Riesgos del Instituto Mexicano del Seguro Social*, IMSS, Mexico City.

ITA (International Trade Administration, US Department of Commerce) (2004), *Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation*, US Department of Commerce, Washington, D.C.

Jaumotte F. and N. Pain (2005). "From Ideas to Development: The Determinants of R&D and Patenting", *Economics Department Working Papers*, No. 457, OECD, Paris.

Kearney, A.T. (2004). "Health Mexico's Health Care System," *Executive Agenda*, 7(3): 69-75.

Kravzov-Jinich, J., *et al.* (2003), "R_x Price Control Methods in Mexico", in A. I. Wertheimer and M. C. Smith (eds.), *International Drug Regulatory Mechanisms*, pp. 151 – 180, The Haworth Press, Binghampton, NY.

Lanjouw, J. (2005). *Patents, Price Controls and Access to New Drugs: How Policy Affects Global Market Entry*, paper prepared for the Commission on Intellectual Property Rights, Innovation, and Public Health of the World Health Organization.

Maskus, Keith E. (1997). "Implications of regional and Multilateral Agreements for Intellectual Property Rights." The World Economy 20 (5), 681-694.

Ministry of Health (2004). *Boletín de Información Estadística: Recursos y Servicios*, No. 22, Vol. 1, Mexico.

Ministry of Health (2005). *Hacia una política farmacéutica integral para México*, 1st edition, Mexico.

Ministry of Health (2006). *Sistema de Protección Social en Salud. Elementos conceptuales, financieros y operativos*, 2nd ed., *Fondo de Cultura Económica*, Mexico, D.F.

Newhouse, J.P. (1977). "Medical-care expenditure: a cross-national survey", *Journal of Human Resources*, 12(1), pp. 115–125.

OECD (2000), *Competition and Regulation Issues In The Pharmaceutical Industry*, OECD, Paris.

OECD (2005a), *OECD Review of Health Systems – Mexico*, OECD, Paris.

OECD (2005b). *Labour Force Statistics 1984-2004*, OECD, Paris.

OECD (2005c). *Main Science and Technology Indicators*, 2nd issue, OECD, Paris.

OECD (2006), *OECD Health Data 2006*, Version 06/26/2006, OECD, Paris.

Pagán, J.A., *et al.* (2006). "Self-medication and health insurance coverage in Mexico," *Health Policy*, Vol. 75, pp. 170-177.

Parkin, D., A. McGuire and B. Yule (1987). "Aggregate health care expenditures and national income : Is health care a luxury good?" *Journal of Health Economics*, Vol. 6(2):109-127.

Sesma-Vázquez S, *et al*. (2005). "Catastrophic health expenditures in Mexico: Magnitude, distribution and determinants", *Salud Pública de México*, Vol. 47 Supl 1, pp. S37-S46.

Shadlen, K. (2003). "Regional vs. Multilateral Strategies for Economic Integration: NAFTA in the Context of the WTO" Working Paper prepared for the conference Features of Contemporary World Politics Affecting Mexico, Centre for Mexican Studies, Oxford University, www.mexico.ox.ac.uk/wp5.htm, accessed 25 July 2006.

USTR (US Trade Representative) (2003), *2003 Special 301 Report*, Office of the US Trade Representative Washington, D.C.

USTR (2005), *2005 Special 301 Report*, Office of the US Trade Representative Washington, D.C.

USTR (2006), *2006 Special 301 Report*, Office of the US Trade Representative Washington, D.C.

Wirtz V., *et al*. (2006). *Medicines in Mexico, 1990-2004: Review of research on use, access and quality*, unpublished paper, Instituto Nacional de Salud Pública, Mexico.

Zuniga, M.P. and E. Combe (2002), "Introducing Patent Protection in the Pharmaceutical Sector: A First Evaluation of the Mexican Case", *Revue Région et Développement*, No. 16, pp. 191 – 221, éditions l'Harmattan, La Garde.

ANNEX 1. PHARMACY SUPPLY AS AN INDICATOR OF PHARMACEUTICAL ACCESSIBILITY

202.   Looking at the number of pharmacies within a given area might provide some idea as to the accessibility of pharmaceuticals. The fewer pharmacies there are within a given area, the farther consumers are likely to have to travel to obtain needed pharmaceuticals. Ideally, this information would be examined at a municipal level, focusing on the more remote municipalities. Unfortunately, these data are not available so we have to rely on data aggregated to the smallest level possible, which in this case is the state-level. Table 3 provides data on the number of pharmacies for each state in Mexico and the number of pharmacies per square kilometre. As would be expected, the largest states in area tend to be those with the lowest number of pharmacies per square kilometre: five of the six states with the least number of pharmacies per square kilometre are the largest in size. The correlation coefficient for the number of pharmacies per square kilometre and the percentage of the population living in cities with less than 2 500 inhabitants is -0.341 (Table 4), suggesting a fairly strong negative correlation between the number of pharmacies and population density, i.e. states with larger urban areas tend to have a greater density of pharmacies.

203.   The density of pharmacies within a given population can be used as another measure of accessibility. Table 3 also provides data for each state on the number of inhabitants per pharmacy. The lower the number the more accessible pharmacies are. Here the relationship between the number of pharmacies and population density is less obvious than with geographical size and the number of pharmacies. On the one hand, the state with the lowest population density, Baja California Sur, also has one of the highest number of inhabitants per pharmacy (3 040) and Sonora, with the 4th lowest population density has the second highest number of inhabitants per pharmacy (3 902). On the other, the states with the second and third lowest population densities, Durango and Chihuahua, are closer to the middle in terms of inhabitants per pharmacy. This weaker relationship is reflected by the correlation coefficient between inhabitants per pharmacy and percentage of the population living in cities with less than 2 500 inhabitants which is 0.135 (Table 4).

204.   There may be an underlying cause for the fairly weak relationships noted in the preceding paragraphs. The anomalous states, Chihuahua and Durango are geographically large northern states, which are more affluent relative to the rest of the country. The large number of pharmacies relative to their population densities may be due to the greater purchasing power of the citizens of these states. The inhabitants of many of Mexico's remote regions, especially in the southern part of the country, are at a socioeconomic disadvantage compared to regions in the north or around Mexico City. The marginalisation index is a measure of the degree of social and economic deprivation and lack of access to services. When the index is set against the two measures of access to pharmacies, the results are somewhat ambiguous. For example, 4 of the 6 states with the lowest number of pharmacies per square kilometre are states where the degree of marginalisation is either very low or low. Furthermore, two of these states, Baja California Sur and Sonora, also have the lowest number of inhabitants per pharmacy. The correlation coefficients from Table 4 show medium strength relationships between the degree of marginalisation and the two measures of access to pharmacies.

Table 3. Number of pharmacies, population and socioeconomic indicators, by state, 2005

State	Population* (1)	km² (2)	Pharmacies (3)	Pharmacy / km2 * 1,000 (4)	Inhabitants / pharmacy (5)	GDP per capita (USD, 2000)** (6)	Degree of Marginalisation *** (7)
Mexico	103,088,021	1,934,194	51156	26.45	2015.17	5 289	
Aguascalientes	1,050,873	5,590	537	96.06	1956.93	6 597	Low
Baja California Sur	516,764	71,234	170	2.39	3039.79	7 037	Low
Baja California	2,842,199	71,098	1908	26.84	1489.62	8 006	Very low
Campeche	751,413	55,539	310	5.58	2423.91	8 852	High
Chiapas	4,255,790	72,177	1352	18.73	3147.77	2 116	Very high
Chihuahua	3,238,291	246,686	1676	6.79	1932.15	7 879	Low
Coahuila de Z	2,474,692	151,062	909	6.02	2722.43	6 902	Very low
Colima	562,277	5,545	295	53.20	1906.02	5 290	Low
Distrito Federal	8,669,594	1,480	8000	5405.41	1083.70	13 481	Very low
Durango	1,488,778	123,020	630	5.12	2363.14	4 129	Medium
Guanajuato	4,892,677	30,338	2534	83.53	1930.81	2 851	Very high
Guerrero	3,116,453	63,129	1000	15.84	3116.45	2 851	Very high
Hidalgo	2,333,747	20,749	1726	83.18	1352.11	2 965	Very high
Jalisco	6,652,232	77,138	4530	58.73	1468.48	5 209	Low
México	14,160,736	22,144	6454	291.46	2194.10	4 058	Low
Michoacán de Ocampo	3,988,295	57,862	1816	31.39	2196.20	2 765	High
Morelos	1,605,375	4,878	641	131.41	2504.49	4 419	Medium
Nayarit	942,589	27,380	461	16.84	2044.66	2 905	High
Nuevo León	4,164,268	64,069	1054	16.45	3950.92	9 640	Very low
Oaxaca	3,521,715	91,759	1228	13.38	2867.85	2 175	Very high
Puebla	5,391,484	49,998	2156	43.12	2500.69	3 852	High
Querétaro Arteaga	1,592,753	11,613	845	72.76	1884.91	6 436	Medium
Quintana Roo	1,134,209	42,545	670	15.75	1692.85	9 022	Medium
San Luis Potosí	2,412,196	60,995	930	15.25	2593.76	3 750	High
Sinaloa	2,609,976	54,727	1140	20.83	2289.45	4 082	Medium
Sonora	2,384,251	178,375	611	3.43	3902.21	6 271	Low
Tabasco	2,012,902	23,720	645	27.19	3120.78	3 280	High
Tamaulipas	3,020,225	76,574	1488	19.43	2029.72	5 947	Low
Tlaxcala	1,060,640	3,976	449	112.93	2362.23	2 833	Medium
Veracruz de Ignacio de la Llave	7,080,731	54,059	2842	52.57	2491.46	2 945	Very high
Yucatán	1,802,578	39,435	1009	25.59	1786.50	4 355	High
Zacatecas	1,357,318	75,300	1140	15.14	1190.63	2 616	High

Note:
* Population for 2005
** Ratio of state GDP to population where 9.46 Mexican pesos = 1 USD (based on 2000 estimates)
*** Marginalisation index ranges from -1.5 to -1.2 very low; -1 to -0.6 low; -0.4 to -0.1 medium; 0 to 0.8 high; and 0.9 to 2.25 very high.
Source:
(1) and (2): *Instituto Nacional de Estadística Geografia e Informática* http://www.inegi.gob.mx/inegi/ accessed June 13, 2006.
(3) *Comisión Federal para la Protección contra Riesgos Sanitarios,* (6) (OECD, 2005a), (7) *Consejo Nacional de Población*

Table 4. Correlation matrix of pharmaceutical density and socioeconomic indicators, 2005.

	GDP per capita (USD, 2000)(2) (1)	Degree of Marginalisation (2)	Percentage of the population living in cities with less than 2500 inhabitants (3)	Population Density (inhabitants per square kilometer) (4)	Inhabitants / pharmacy (5)	Pharmacy / km2 * 1,000 (6)
(1)	1					
(2)	-0.696	1				
(3)	-0.749	0.891	1			
(4)	0.549	-0.291	-0.351	1		
(5)	-0.135	0.223	0.135	-0.326	1	
(6)	0.563	-0.287	-0.341	0.998	-0.329	1

Source:
(1) (OECD, 2005a)
(2) *Consejo Nacional de Población*
(3) and (4) *Instituto Nacional de Estadística Geografía e Informática* (INEGI)
(5) and (6) INEGI (inhabitants and geographic area) and *Comisión Federal para la Protección contra Riesgos Sanitarios* (pharmacies)

205.   Table 4 also shows the correlation coefficients between the two pharmacy density measures and another measure of socioeconomic status, GDP per capita. The relationship between GDP per capita and inhabitants per pharmacy is not very strong, correlation coefficient of -0.135, but the data show a strong relationship between GDP per capita and the number of pharmacies per kilometre, the correlation coefficient being 0.563.

206.   Thus, the number of pharmacies does not appear to be a reliable measure of accessibility to pharmaceuticals (at least not at the state level). In Mexico's case this can be partly explained by the lack of regulation of pharmacies. It is not too difficult to obtain a permit to operate a pharmacy. Furthermore, many of the remote areas that are deprived of essential health-care services are serviced by small pharmacies, sometimes operating without a permit or owned by the local family physician. In these cases, accessibility may be more a question of timely access to medicines rather than access to the products themselves.

LIST OF ACRONYMS

AFAMELA	Asociación de Fabricantes de Libre Acceso (Association of Over-the-Counter Manufacturers)
AMIIF	Asociación Mexicana de Industrias de Investigación Farmacéutica (Mexican Association of the Research-Based Pharmaceutical Industry)
ANAFAM	Asociación Nacional de Fabricantes de Medicamentos (National Association of Drugs Manufacturers)
CANIFARMA	Cámara Nacional de la Industria Farmacéutica (Chamber of the National Pharmaceutical Industry)
COFEPRIS	Comisión Federal para la Protección contra Riesgos Sanitarios (Federal Commission for the Protection against Sanitary Risks)
CSG	Consejo de Salubridad General (General Health Council)
GATT	General Agreement on Tariffs and Trade
GI	Genéricos Intercambiables (Interchangeable generics)
GOVERD	Government Intramural Expenditure on R&D
HERD	Expenditure on R&D in the Higher Education Sector
IMPI	Instituto Mexicano de la Propiedad Industrial (Mexican Institute of Industrial Property)
IMSS	Instituto Mexicano del Seguro Social (Mexican Social Security Institute)
ISSSTE	Instituto de Seguridad y Servicios Sociales de los Trabajores del Estado (Institute of Security and Social Services for Government Workers)
LFPPI	Ley de Fomento y Protección de la Propiedad Industrial (Law on the Promotion and Protection of Industrial Property)
LPI	Ley de la Propiedad Industrial (Law on Industrial Property)
NAFTA	North American Free Trade Agreement
OTC	Over-the Counter
PIR	Precio Internacional de Referencia (International Reference Price)
PMVP	Precio Máximo de Venta al Público (Maximum Sales Price to the Public)
PROFECO	Procuraduría Federal del Consumidor (Federal Office of the Judge Advocate General of the Consumer)
PROMIF	Programa para la Modernización de la Industria Farmacéutica (Program for the Modernization of the Pharmaceutical Industry)
PRVP	Precio de Referencia para Venta al Público (Reference Price for Sales to the Public)
R&D	Research and Development
SECOFI	Secretaría de Comercio y Fomento Industrial (Ministry of Commerce and Industrial Development)
SP	Seguro Popular de Salud (Popular Health Insurance)
SPSS	Sistema de Protección Social en Salud (System of Social Protection in Health)
TRIPS	Trade-Related Aspects of Intellectual Property Rights

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