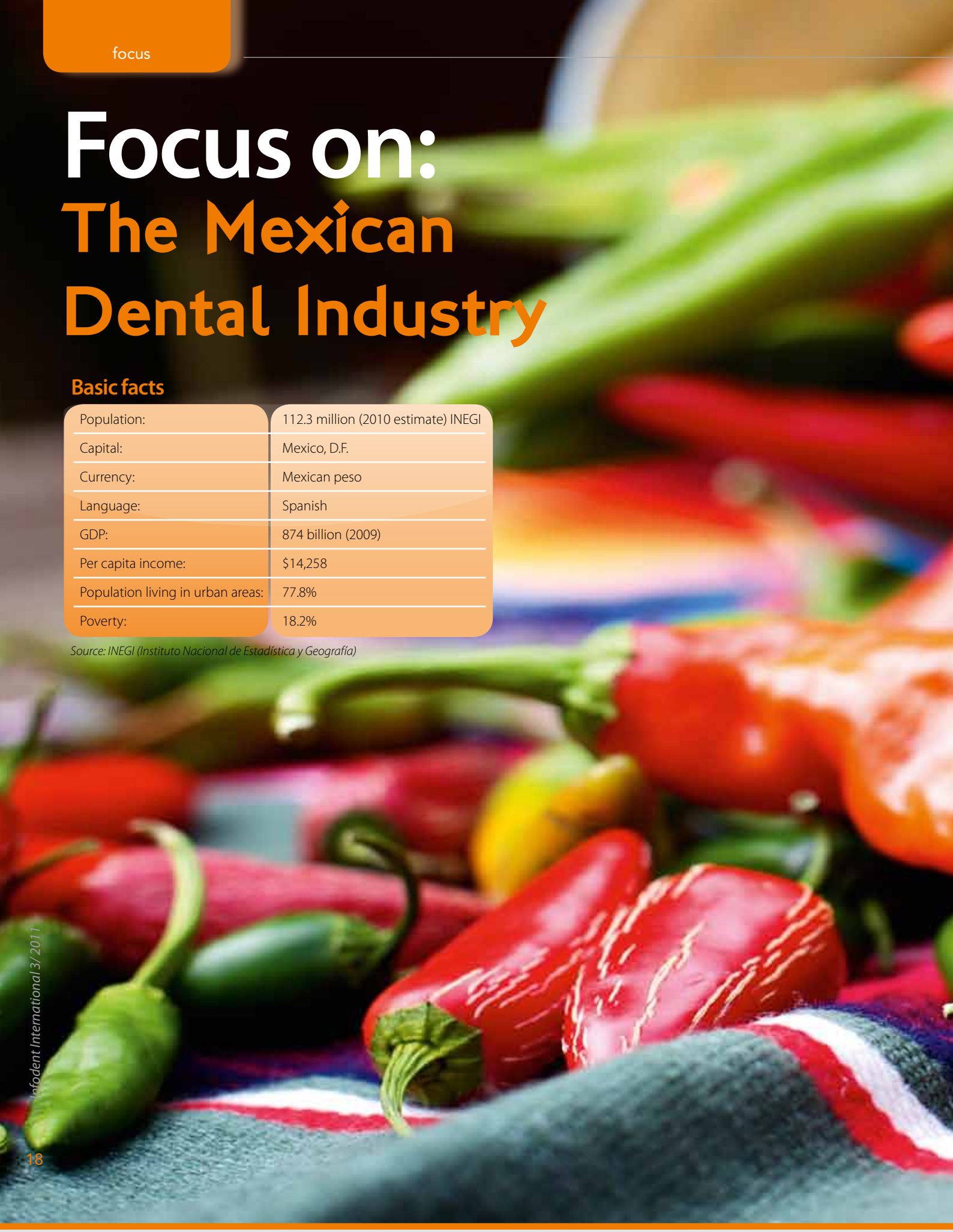
Focus on: The Mexican Dental Industry

Basic facts

Population:	112.3 million (2010 estimate) INEGI
Capital:	Mexico, D.F.
Currency:	Mexican peso
Language:	Spanish
GDP:	874 billion (2009)
Per capita income:	$14,258
Population living in urban areas:	77.8%
Poverty:	18.2%

Source: INEGI (Instituto Nacional de Estadística y Geografía)



Mexico consists of 32 federative entities and its capital is the Federal District. The country borders with the United States for over 3,000 km to the north, and with Guatemala and Belize to the south, represent an important gateway to Central and South America strong cultural and linguistic ties.

Mexico has established free trade agreements with 52 countries. The main one is the North American Free Trade Agreement (NAFTA) established in 1994 with the United States and Canada, followed by the EU-Mexico Free Trade Agreement in 2000. Besides removing tariff duties from the export of industrial goods, this agreement allows EU companies to participate to public tender offers. Many EU companies use Mexico as a low-cost manufacturing or assembling base to export their products to the US under favourable conditions provided from the NAFTA, to other Latin American countries or back to their own market. Moreover, Mexico is carrying on negotiations with other Central American countries for a regional free trade agreement.

Considered as the second largest Latin American economy, Mexico is ranked 35th out of 183 countries in the World Bank "Ease of Doing Business" chart, and 44th in the Protecting Investors rank. These benchmarks account for the efforts made by the Mexican government to attract foreign investments and create an open business environment by supporting administrative simplification and deregulation. From the social point of view, the country has improved life standards, education rates and distribution of essential services, in the meantime reducing unemployment to 5.2% and consolidating democracy, although violence and corruption are still widespread plague and drug traffic accounts for the majority of violent deaths in the country. Although poverty rate has in general been reduced, it is still high in less developed areas and among indigenous communities. The gap between a large low income group and the richest part of the population is partially being filled by the growth of the middle class; however, the distribution of wealth, access to basic services and opportunities is uneven, especially in the poorer states such as Chiapas, Oaxaca, Guerrero, Hidalgo and Veracruz, located in the country's southern region, with higher concentration of rural and indigenous population groups.

As regards merchandise trade, Mexico is trying to diversify its industry and to expand its commercial relationships beyond the US that traditionally represents the main trade partner. Exports have increased almost six-folds in the last two decades, reaching US$ 298 billion in 2010, the greatest part of which were directed towards the US. Imports totalled US$ 301 billion, half coming from the US while the other major suppliers were EU, China, Japan, Canada and Brazil.

However, by evaluating import-export figures for Mexico, it must be considered that maquiladora activities account for a relevant share. The term "maquiladora" refers to a Mexican company entitled by the Mexican government to temporary duty free import equipment or materials and components. The maquiladora company manufactures or assembles the temporarily imported parts in order to re-export the product, or sell it to another exporting company. Before the NAFTA came into force, maquiladoras were mainly located near the US border, but in the last 15 years they have spread across the country and their role in the Mexican industry increased along with their share in Mexican exports (about half of the total, with the US as main destination due to geographic proximity). The government has provided further support to the maquiladora industry by establishing preferential tariffs on raw materials in key manufacturing sectors and by reducing length and costs for administrative procedures concerning maquila corporations.

Healthcare system

The Ministry of Health (Secretaría de Salud) funds public hospitals, specialised institutes and the National Institute of Public Health, under guidelines issued by the General Health Council. On the regulatory side, the most important institution is the COFEPRIS (Comisión Federal para la Protección contra Riesgos Sanitarios) who is in charge of sanitary controls and surveillance of all health-related products and services.

The Mexican Institute of Social Security (IMSS) is the largest social security provider for private sector employees and their family members, covering almost 51 million people. The Institute of Social Security and Services for Public Employees (ISSSTE) provides coverage for 11.2 million state workers and their families. The Army, the Navy and the national oil firm have their own programs and together with states or other local social security institutions they have about 2.7 million people affiliated. About 44 million people are covered by Seguro Popular (Popular Insurance Scheme), a voluntary public insurance system for low income families or people working on their own who can't afford other forms of insurance. After a socioeconomic evaluation of the household, to be revised every three years, an annual fee based on income is determined, ranging from 0 to 11,378.86 pesos (about US$965). Funding for SP is also integrated by general tax revenues. Currently, the SP covers 275 procedures, including basic preventative and curative dental treatments. Only a few people can buy a private insurance, that contributes for a limited 2.1% to health financing.

Mexico is still facing diseases typical of developing countries including infections and undernourishment in the lowest income groups of population, but the growing standards of life for the middle class have also increased the incidence of diseases such as cancer, obesity, cardiac problems and diabetes. The access to quality medical services is still unequal and needs to be targeted by structural efforts and investment to guarantee that universal coverage is achieved, as reported in the National Development Plan 2007-2012.

Public expenditure on health is about 48% of the total health spending, accounting for 12% of government budget. At current prices, per capita health expenditure is US$ 515. The priorities set by Mexican government include modernisation of hospital infrastructure, expansion of coverage and services to underserved rural and indigenous communities, increasing the supply of quality equipment for the 21,887 medical units that are present on the national territory and a national promotion and prevention strategy. The private sector is also expanding its network of facilities (3,151 in 2008) and it is estimated to provide services to about 25 million patients. Large public and private hospitals usually invest in modern equipment and they are not allowed to buy used or refurbished equipment. Instead, some smaller private hospitals choose

this channel because of their limited budgets, or in some cases they even hire the equipment necessary for a specific intervention from companies offering so called "integral surgery services", thus avoiding to spend a larger sum to purchase it.

Oral Health

The incidence of dental diseases is very high among the poorest groups and in rural regions, reaching tops of 90%, as dental care is mainly available in urban areas, and only to a limited extent in public facilities. Nonetheless, since the implementation of the National Oral Health Program, Mexicans have generally improved their access to dental prevention treatments. The caries and missing teeth indexes for children aged 6 and 12 have also been reduced, while the offer of public dental services increased by 80% in the years 2000-2006. In 2008 the Mexican Dental Association started a dental education and prevention program targeting 3,000 children between 3 and 6, including the provision of basic preventative treatments and raising awareness on oral hygiene habits among their parents and teachers. The program has now been extended to more than 25,000 preschool children. The Secretariat of Health has appointed mobile units to reach underserved areas, called Health Caravans, to be integrated with dental care provision in order to provide oral health services to people who has difficult (if any) access to health facilities. In addition to that, the "Tratamiento Restaurativo Atraumático (TRA)", or restorative non-traumatic treatment, was introduced to bring dental services in marginalised areas. This program employs 540 dentists using hand instruments and low cost materials for simple restorations, increasing the number of interventions in these areas from 177,000 in 2001 to more than 712,000 in 2006. Although the improvement in oral healthcare delivery in the last two decades, however, the public dental sector faces some challenges. As life expectancy rises, the percentage of citizens over 60 (currently one in 20) is going to increase along with the incidence of dental diseases typical of this age group. The quality of public dental services is frequently affected by the lack of modern, state of art equipment and inadequate continuous training for dental personnel. The decentralization of health services requires the allocation of resources that are insufficient in many local health institutions and federal or state administration do not always provide the proper support and information.

Export values and trends, 2008

Import Category	Value, US$
Preparations for dental filling made of acrylic resins	2,265,917
Preparations of precious metals for dental filling	477,109
Dental cements and other dental fillings; bone reconstruction cements	17,564,492
Tooth pastes	205,892,475
Dental floss made of Nylon	34,445,185
Other preparations for oral or dental hygiene, incl. denture fixative pastes/powders in retail packing	6,742,860
Preparations known as "dental wax"	78,426
Preparations for use in dentistry, with a basis of plaster or stucco either in powder or paste	999,476
Dental impression compounds with a basis of rubber/synthetic plastic materials, an accelerator, and an adhesive, in retail packing	588,468
Photographic plates for dental X ray	4,057,101
Electric tooth brushes	3,948
Electric dental drill engines (flexible, hanging transmission, speed up to 30,000 RPM)	75,569
Other dental drill engines, whether or not combined on a single base with other dental equipment	390,725
Dental equipment on pedestal	2,965,453
Dental hand pieces (speed equal to or greater than 230,000 R.P.M.)	1,027,177
Dental drills	4,831,242
Other dental instruments and apparatus	25,132,050
Artificial teeth	1,512,976
Other dental fitting articles and apparaturs	7,749,725
Dental x-ray machines	1,712,967
Tooth brushes including dental plate brushes	34,823,871

The market for dental equipment and supplies

The Mexican market for medical devices is estimated as the largest in Latin America, and it is mainly supplied by foreign manufacturers. The US Commercial Service estimates that imports meet about 90% of the demand for medical equipment and instruments and about 20-30% of demand for medical disposables, with the US accounting for about half of the total value. However, Mexican import and export figures are influenced from maquiladora activities and a percentage of medical equipment imported into Mexico is destined to re-export, not to meet the country's healthcare needs. This also happens for dental products such as toothpaste, which is widely imported for packaging and re-export to other Latin American countries. Medical devices industries are concentrated in the states of Baja California, Chihuahua, Nuevo Leon, Tamaulipas, Estado de México and Morelos.

The dental industry, according to the Mexican Dental Trade and Industry Association (AMIC), contributes for 2.1% to Mexican GDP. The dental market grew by 10% last year but a large share of Mexican population has still little access to dental care and those who are covered by social security programs must pay out-of-pocket for more advanced treatments not included in their benefits.

With approximately 75,000 practicing dentists and about 4,000 new graduates every year, the need for dental equipment and supplies is increasing year-on-year as proved by the 12% growth of dental imports between 2007 and 2009 when they reached US$174 million (according to data released by the US Commercial Service). The US supply 45% of the total dental imports, nearly US$79 million. However, US predominance has diminished for some categories such as x-ray machines, dental floss, dental specula and rubber or gutta-percha based dental waxes. These products are now supplied also from Germany, Brazil, Japan, Korea and China, even if global sourcing by multinational companies accounts for a relevant share of imports from these countries.

Local production destined to the domestic market is small and limited to materials and disposable products, except for some basic equipment, and most purchases of new technology come from private dentists, while upgrade and replacement of equipment in the public sector is slower and subject to more constraints. Public institutions can purchase products and equipment under US$3,100 directly from a selected provider, but over that amount all purchases must be done through public, price-oriented bid tenders.

The dental distribution network is mainly composed of depots, with a minor number of large distributors extending their activity across the whole country. As medical devices, dental equipment and products need to be registered with the Mexican Secretariat of Health (SSA) in order to be imported and marketed in Mexico. The distributor or representative of the foreign manufacturer is in charge of the registration process.

Regulations on medical devices

The agency in charge of medical devices registration is known as COFEPRIS (Federal Commission for the Protection against Sanitary Risk), acting in the framework of the General Health Law. COFEPRIS issues regulations for health products import and export and advertising permits. It also collects information regarding manufacturers, importers, and distributors.

Dental supplies are included in the list of six categories (together with medical equipment; prosthetics, orthotics and functional aids; diagnostic agents; surgical and healing equipment; hygienic products) that require a Sanitary Registration in order to be produced, sold or distributed in Mexico, as described in article 262 of the General Health Law. In 2008 an amendment was introduced, requiring that all existing medical device registrations be renewed every 5 years and by 24 February 2010. By then, there were about 30,000 registrations of medical devices who were more than five years old and those who did not comply with the renewal requirement have been removed from the market.

A large share of medical devices that are marketed in Mexico obtain their pre-registration in the US or Canada, therefore the Mexican government has set up a mechanism to expedite the introduction of these devices on the Mexican market by recognizing them as equivalent to devices regulated by the General Health Law.

Medical devices are classified in three groups according to their risk level: Class I devices are "very well known in the medical field, with proven effectiveness and safety, and generally not introduced into the human body"; Class II devices are "well known in the medical field, but may have a variation in the raw materials of which they are made, or different component composition or concentration, and introduced into and kept in the human body for less than thirty days"; Class III devices include "new products or products recently approved in the medical field, or products that are introduced and kept in the human body for more than thirty days".
In order to register a medical device, a foreign manufacturer needs to appoint an entity based in Mexico and registered with COFEPRIS as its local representative. Manufacturers usually use their distributors in Mexico as registration holder, since their warehouse facilities can be inspected by COFEPRIS.

The registration submission (Formato de Solicitudes) includes all scientific and technical information demonstrating compliance of the medical device with safety and effectiveness characteristics, as well as the description of its manufacturing process, structure, materials, parts and functions. Moreover, the label in Spanish must be included, bearing the generic and specific names of the device, country of origin, sanitary registration number, expiration date, serial or lot number and contents. If a medical device is manufactured by a third party for the registration holder, the label should also include the name of the third party. Other important documents for registration submission are the instructions for use in Spanish, laboratory tests and bibliographical references, as well as any relevant references to corresponding official Mexican norms.

Foreign manufacturer must provide some additional information including:
- a certificate of free sale and good manufacturing practice certificate (or any equivalent medical device quality system certification) issued by the health authority of the country of origin;
- an authorisation letter from the manufacturer, certified according to the legal procedures in the manufacturer's country of origin, either written or officially translated in Spanish, if the medical device is not manufactured by the registration applicant;
- a copy of the certificate of analysis issued by the manufacturing company.
Any change of address should be immediately submitted to COFEPRIS as well. The registration process can take several months especially due to the mandatory re-registration required for medical devices after the amendment of the validity period and also due to a shortage in the number of reviewers. Hoewever, on 19 June 2009 an amendment on review times was introduced, requiring COFEPRIS to respond within 30 working days for Class I devices, 35 for Class II devices and 60 for Class III devices applications.
Once the medical device registration has been approved, the Mexican registration holder or the manufacturer can appoint other distributors for the registered product by transferring the registration and informing the Health Secretariat. Manufacturers with multiple distributors can give certified copies of the sanitary registration to each distributor which may then apply to COFEPRIS for an import licence for the registered device.

A manufacturer wishing to supply its product to public health institutions should submit an application to the General Health Council in order to receive a "CB" code, which is a 10-digit code with a generic description identifying the type of products that can be included in the category. The CB code is the same for all public health institutions and their formulary only include technologies that have previously obtained this code. Further details on how to prepare the submission dossier in order to obtain the CB code are available on the General Health Council Website: www.csg.salud.gob.mx.

• Sources:

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