The Mexican pharmaceutical industry

News

KPMG in Mexico

Content

Prologue

The pharmaceutical industry has become increasingly significant for countries due to the complexity of its actors and challenges. At KPMG, we have made efforts to find solutions regarding quality management of health services, providing guidance for the analysis of patient care data, designing strategies for the implementation of innovative technologies, and to establish controls that maximize the operation of all those involved in this industry in order to have a positive impact on the economy and business profitability.

With a firm commitment to this sector at KPMG, we seek to take advantage of opportunities that satisfy the expectations of all those involved in the health sector, through perspectives and solutions that add value to business models and benefit consumers of their products and services improving collaborative initiatives.

We are pleased to present this 2nd edition, addressed to the entrepreneurs and investors of our country, on the challenges and the most relevant aspects that the pharmaceutical industry will be facing, and what will need to be considered in the future based on observed trends.

Scope of a priority sector

Health is understood as a state of physical, mental and social well-being, not only the absence of affections or diseases. In order to achieve this, there are multiple determinants, including personal, environmental and social initiatives to prevent diseases, and even health care services[1]. Within the latter, medication is a resource of great relevance. Its impact can be enhanced by the ability of health professionals to provide timely diagnosis, a correct prescription and medicines working properly, as well as patients completing their treatment correctly.

A medication is a substance or mixture thereof -natural or synthetic- with physical, chemical and biological characteristics, used for therapeutic, preventive or rehabilitating purposes[2]. In order to be considered and registered as such by the corresponding authority, pharmaceutical companies go through different processes in which chemical, biological, physical and medical tests of the potential product are carried out. Simultaneously, different manufacturing and marketing processes and activities are performed, subject to reviews by the regulatory authorities, in order to be able to sell the product. During the promotion stage, companies should develop appropriate ethical practices[3]. During the sales stage, some requirements must be met, such as public sector bidding and contract compliance in general; as well as tracking the product through vigilance systems. All this to place a product in the market, so close to human beings, that must provide security and effectiveness.

For up to 10,000 substances that are researched, only one makes it to the market as medication, which implies investments close to 2.5 billion dollars

Launching a pharmaceutical product to the market involves great efforts in investments and project management. After a long time in exhaustive research stages, where very few initiatives go past the phases required to become a marketable product, procedures are carried out to register the respective patent if the company so decides. It has been observed that, for up to 10,000 substances that are researched, only one makes it to the market as medication[4], which implies investments close to 2.5 billion dollars[5] for an innovative product.

After the clinical development to obtain a marketable product is completed, the pharmaceutical company is required to obtain a Sanitary Registration (RS, by its acronym in Spanish) in Mexico issued by the Federal Commission for Protection Against Health Risks (Cofepris, by its acronym in Spanish) before the product can be sold. Another fundamental element is defining the market price, a decision that should be supported by a methodology that integrates simplicity, suitability in medical care and cost management, aimed at proving value for

payment, as suggested in the reference document[6]. In the case of a generic product, interchangeability[7] needs to be validated by Cofepris, which ensures the correct functioning as treatment for patients. When one seeks to market the product in the multiple institutions of the government sector, which represents about 27% of the market value[8], basic table codes granted by the General Board of Health[9] and public sector institutions are required, especially for high specialty products and sometimes even private organizations have their own catalogues.

In addition to being highly specialized, the pharmaceutical industry has a direct impact on 161 branches of economic activity, out of 259 in which the input-output matrix[10] is classified, which includes branches of the primary, secondary and trade/services sectors[11]. Pharmaceutical companies in Mexico generate about 74,000 direct jobs and just over 310,000 indirect[12]. Besides and because of the contribution to the health of the population, this industry generates a favorable multiplier effect; for example, on average, between 1993 and 2014 it contributed a little over 4% of the manufacturing Gross Domestic Product (GDP)[13] in Mexico. The size of the companies in this industry is larger than the average size of manufacturing companies, with nearly 116 persons employed by economic unit against around 10, respectively[14].

The pharmaceutical industry is exposed to strict regulations because of how sensitive its activities are, from the stages of research, development, health approval, promotion, sale and follow-up of products; up to the operation of synergies with commercial partners and other sectors involved in its performance. Its regulatory framework includes laws, official Mexican standards, decrees and agreements that can be found on Cofepris' website[15].

1 According to the General Health Law (LGS), it includes prevention, healing, rehabilitation and palliative activities.

2 LGS, article 221.

3 http://www.cetifarma.org.mx/codigos-y-documentos/quienes-somos/buenas-practicas-de-promocion

4 AMIIF, http://cdn2.hubspot.net/hubfs/2090481/DESCARGABLES/PDFs/AMIIF-Folleto_corporativo.pdf?t=1483556532728, revisado el 5 de enero de 2017.

5 PhRMA, http://phrma-docs.phrma.org/sites/default/files/pdf/prescription-medicines-costs-incontext-extended.pdf

6 KPMG, https://assets.kpmg.com/content/dam/kpmg/xx/pdf/2016/10/value-based-pricing-in-pharmaceuticals.pdf

7 According to the Health Supplies' Rules, it's pharmaceutical speciality with the same active substance and pharmaceutical shape, concentration and form of administration, among other traits describe on these rules.

8 II Statistic Abstract, Canifarma, 2015 (www.canifarma.org.mx)

9 http://www.csg.gob.mx/contenidos/CB2013/cuadro_basico.html

10 Statistics regarding the pharmaceutical industry, Inegi, 2016.

11 Note.- In general, the primary sector includes agriculture and livestock, the secondary sector includes industrial industries such as manufacturing, construction, electricity, gas and water; trading and services to transportation, communications and banking.

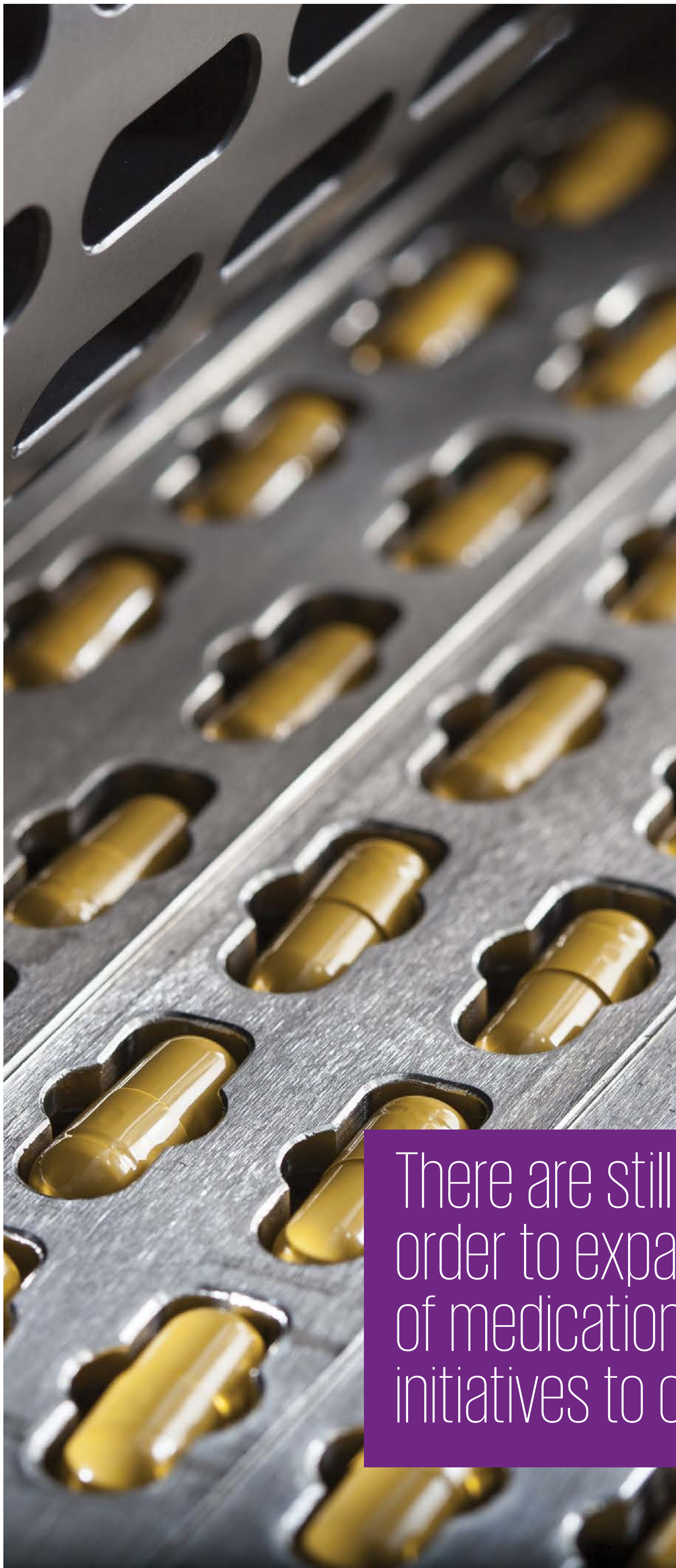
12 *Public health administration in Mexico,* Cofepris, 2015.

13 Inegi, 2016.

14 Inegi, 2016.

15 http://transparencia.cofepris.gob.mx/index.php?option=com_content&view=article&id=19

Impulse to the industry



The medication policy in Mexico dates back to late 40's when the list of basic substances for the Mexican Social Security Institute (IMSS, by its acronym in Spanish) was defined, and it was strenghtened in 1984 when the General Health Law (LGS, by its acronym in Spanish) was enacted. Such law stipulates the right to medical attention and to drugs, the first interchangeable generic medication catalog was defined in 1998[16]. Articles 168 and 170 of the Health Supplies Regulation were reformed in 2008 to eliminate the manufacturing plant requirement and to facilitate trading of pharmaceutical products, so they can reach the population that needs them.

In 2009, with the reform to article 222 bis of the LGS, the classification of biotechnological medications was defined in innovative and bio-comparable[17]. The general provisions to recognize Equivalence Agreements with other countries were established in 2010, to streamline the process to obtain RS[18]. The initiative for the Authorized Third Parties, aiding in the health control of medications to support companies preparing the reports required by the health authority, was launched in 2011[19]. Nowadays, this figure has been extended to medical device companies, research establishments and protocols[20] to ensure the monitoring of the correct effectiveness of the medical products.

Cofepris, the regulating authority, has made great efforts to contribute to the growth of both the pharmaceutical and medical device industries[21], such as the digitalization of procedures for issuing health records, for both generic and innovative medications, the impulse to scientific research in the country, the definition of agreements for cooperation with other countries, implementing and/or establishing regulations that improve the competitiveness of the sector, among other actions[22].

There are still challenges to be reached in order to expand the access to and coverage of medications, as well as strengthen initiatives to contain medical attention costs

This has allowed the widening of the population's access to health products. According to the 2016 National Halfway Health and Nutrition Survey (ENSN 2016 by its acronym in Spanish), 77% of the population received the medications prescribed to treat their illness, against 65% in 2012. There are still challenges to be reached in order to expand the access to and coverage of medications, as well as strengthen initiatives to contain medical attention costs linked to the services' management and administrative aspects[23], but significant advances have been made so far.

There are areas of opportunity to make Mexico more attractive as a manufacturer and exporter of medications. Part of Cofepris' efforts are directed to establishing regulations that allow us to be more competitive, considering Mexico currently holds the 25th place in the Export Market Rating (EMR)[24], as shown below:

Table 1. EMR[25]

1. Japan	---
2. Belgium	22. Poland
3. Switzerland	23. Greece
4. United Kingdom	24. Australia
5. Germany	25. Mexico

Furthermore, the population growth and the level of drug use show a potential for development due to the market size and demographic context of the country, where, in addition to the population growth in Mexico, it can be observed an increase in its average age, which has direct implications in healthcare.

16 Cofepris, 2015.

17 Biotechnology is the technique involving the use of biological processes and live cells or parts thereof in manufacturing products (Coferpris, 2015).

18 Cofepris, 2015.

19 Federal Gazette, June 30, 2011.

20 http://www.gob.mx/cofepris/documentos/convocatoria-para-ser-tercero-autorizado

21 In Mexico, medical devices are defined as the substance, mixture of substances, material, equipment or instrument used alone or in combination for the diagnosis, monitoring or prevention of diseases or aiding in the treatment thereof and disability, AMID. http://www.amid.org.mx/wp-content/uploads/2013/10/AMID_FACTSHEET.pdf, consulted on January 9, 2017.

22 http://www.gob.mx/cofepris/archivo/prensa, revisado el 9 de enero de 2017.

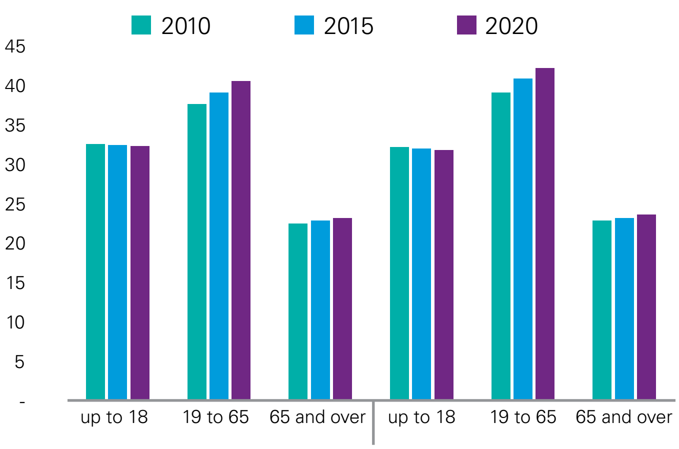
23 *Fiscal sustainability of health systems-why is it an issue, what can be done?*, OECD, 2015.

24 *2016 ITA Pharmaceuticals Top Markets Report, U.S. Department of Commerce -DC/USA, 2016, http://trade.gov/topmarkets/pdf/Pharmaceuticals_Executive_Summary.pdf, consulted on January 25, 2017.*

25 The methodology includes economic development, value of US exports, proportion of older adults, per capita drug spending, level of price control, intellectual property protection, among others, included in market growth. DC/EUA, 2016.

As a result of the decline in mortality, which results in a higher life expectancy for the population during the next couple of decades it is expected that the group of population of 65 years and over will have an increase in their relative weight. It is anticipated that the overweight population will represent 7% in 2010, and 10% in 2030.

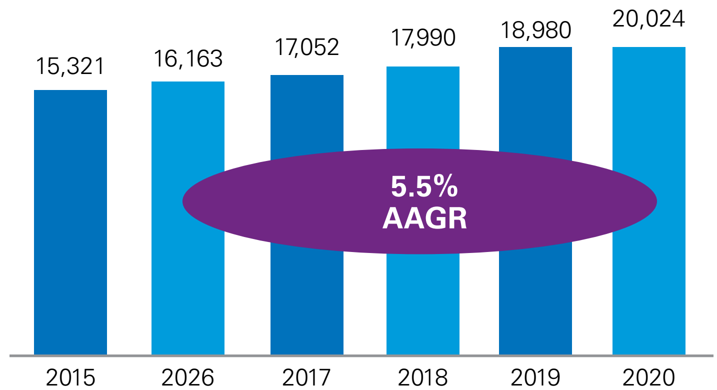
Mexican population
Millions of people



Source: CONAPO

On one hand, a combined growth of the economy with increasing per capita income support projections about the purchase of medicines.

Projection of the use of pharmaceutical products in Mexico (millions of dollars)



Source: INEGI (2015). AAGR.- average annual growth rate.

On the other hand, Mexico enjoys an infrastructure of great depth to take advantage of its regional positioning in commercial matters, both towards other regions of the world and internally.

The country has maritime ports, enormous biodiversity and large human resources that will be described in the following pages.

Table 2. Infrastructure[26]

	2010	2011	2012	2013	2014	2015
Paved roads_a	138.4	141.4	146.2	148.3	155.2	155.2
Telephones_b	91.3	94.6	100.7	103.7	102.2	102
Hotel deals_c	638.5	651.2	660.5	627.3	692.4	701.7
Electricity_d	274.7	290.8	294.6	296.3	301.5	320

Notes: _a/thousands of kilometers, _b/thousands of lines in service, _c/thousands of rooms, _d/thousands of gigawatts-hour, 2015 estimate

26 Compilation of Quarterly Reports for 2015, Banco de México (Banxico), 2016.. http://www.banxico.org.mx/publicaciones-y-discursos/publicaciones/informes-periodicos/anual/%7B2E95603A-807F-5308-402E-1D0CD179C999%7D.pdf, consulted on January 10, 2017.

Demographic trends

According to projections, world's population will be close to 9.7 billion[27] by 2050; in Mexico, it will be around 150 million. By then, nearly a fifth of the inhabitants of the world will be over 60 years old, which means pressures and opportunities for the health system. In order to cope with this demographic transformation, combined with an increase in chronic diseases of high complexity, the increase in the cost of treatment, health conditions inherent to inequality in economic development (such as infections and malnutrition), the health sector is required to match the circumstances with a solid pharmaceutical industry that can interact with all the elements that move the health sector.

The population growth rate in Mexico is slightly higher than 1% per year, with an average fertility rate of 2.2 children per family[28]. We are about 121 million people, 51% women and 49% men[29]. The current life expectancy in Mexico reaches about 75 years against 80 for the average of countries in the Organization for Economic Cooperation and Development (OECD)[30].

To cope with demographic trends, a solid pharmaceutical industry is required, to interact with all the elements that move the health sector

Table 3. Summary of demographic characteristics[26]

Population	121 million
Annual population growth rate	1%
Fertility	2.2 children per women
Life expectancy	75 years

[27] World Economic Forum (WEF), 2017. http://www.weforum.org.mx/system-initiatives/health-andhealthcare, consulted on January 25, 2017.

[28] Banxico, 2016.

[29] INEGI, 2017. http://www.beta.inegi.org.mx/temas/estructura/, consulted on January 9, 2017.

[30] OCDE, 2016. http://www.oecd.org/els/health-systems/health-statistics.htm, consulted on January 3 2017.

There are nuances between the states, where the population of some of them surpasses 76 years of life expectancy, such as Nuevo Leon and Mexico City, when in other states it is only 73, such as Chiapas, Chihuahua, Guerrero, and Oaxaca[31].

Mortality in Mexico reached an average annual gross rate between 2010 and 2015 of 5.7 deaths per 100,000 inhabitants; only in the last year it reached 655,000 persons[32]. The states with a greater rate than the national average are Chihuahua, Mexico City, Guerrero, Hidalgo, Michoacán, Nayarit, Oaxaca, San Luis Potosi, Veracruz and Zacatecas.

According to the National Institute of Statistics and Geography (Inegi, by its acronym in Spanish), the main causes of mortality classified by sex are the following:

Table 4. Mortality

Women	Men
Heart disease	Heart disease
Diabetes mellitus	Diabetes mellitus
Malignant tumors (cancers)	Malignant tumors (cancers)
Cerebrovascular diseases	Accidents and aggressions
Lung diseases	Liver diseases
Represent 80% of mortality	**Represent 85% of mortality**

[31] Inegi, 2016. http://cuentame.inegi.org.mx/poblacion/esperanza.aspx?tema=P, consulted on January 3, 2017.

[32] Inegi, 2017. http://www.beta.inegi.org.mx/temas/mortalidad/

[33] Annual IMSS report, 2016. *IMSS and ISSSTE correspond to social security. Pemex to the State oil company. SEDENA and SEMAR to armed forces. Popular Insurance is also publicly funded. **The percentage exceed 100% due to mutiple coverage.

As for infectious diseases, they are in eighth place for women and ninth for men as causes of mortality, with influenza and pneumonia as the main diseases. In order to respond to the needs of the population, there are different systems of affiliation. The population covered by different institutions, both public and private, is distributed as follows:

Table 5. Coverage plans in Mexico[33]

Plan*	% de population**
Social security: IMSS, ISSSTE, Pemex, SEDENA and SEMAR	63
Popular insurance	59
Private	1.8

In relation to the medical services provided under the systems indicated in Table 5, social security covers from pregnancy, childbirth, individual development, palliative care and even death, as well as disabilities due to work risks, pensions and retirements. *Seguro Popular* (Popular Insurance) is a system to finance health services defined in a specific and limited catalog. Private institutions offer coverage depending on the type of policy, whether preventive care, minor medical expenses, major medical expenses or for some specific condition. In this sense, the population is covered based on the corresponding system. Only in some parts of the world does the health system cover the entire population, especially the European Union, Australia, Canada and Japan.

In addition to the medical aspect of the benefits provided by the pharmaceutical industry, society is also paying attention to the aesthetic aspects of the individual. Some pharmacy chains have opened alongside the traditional product counters, spaces for dermatological checkups, which makes skin care products take on greater relevance. Weight watching has also gained more interest so that

nutritional products have an increasing presence in the market, coupled with the food supplements and vitamins already in development.

There are still many challenges for the health system: for example, strengthening coordination to expand access to quality services and improve cost structure, as well as aligning the distribution of resources to the states according to the needs of the population and the results achieved, among others[34].

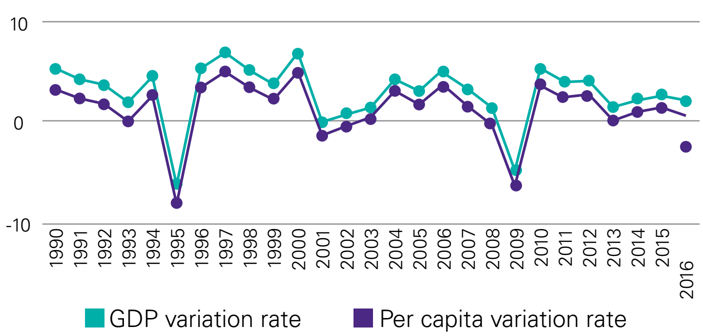
Infectious diseases are in eighth place for women and ninth for men as causes of mortality, with influenza and pneumonia as the main diseases

[34] Economic Surveys: Mexico, OECD, 2017. http://www.keepeek.com/Digital-Asset-Management/oecd/economics/oecd-economic-surveys-mexico-2017_eco_surveys-mex-2017-en#. WHZ4lHIzVMs#page57,consulted revised on January 11, 2017.

Macroeconomy

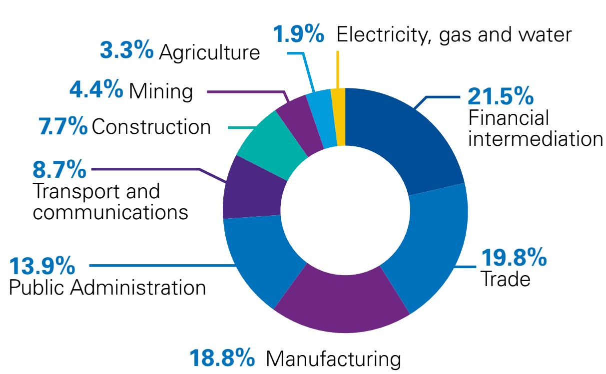
The economy in Mexico continues to expand at a rate of 2.5% per year during 2015 and early 2016, with a slight fall toward the end of the year, as shown in the following diagram.

Diagram 1. Change in Gross Domestic Product (GDP)[35]



As can be seen from diagram 1, since 2010, the Mexican economy has shown a recovery. Although it has not been enough to generate more employments and to attract more investments, it has remained stable as did inflation and exchange rate fluctuations. As for the composition of economic activity, the main sectors contributing to the vitality of activity are the financial and commerce sectors with over 40% and industry with just under 20%.

Diagram 2. Breakdown of economic activity[36]



On the expenditure side, as a proportion of GDP, the variables are as follows:

Table 6. Expense[37]

Variable	% of GDP
Private consumption	68.4
Government	12.5
Investment	23.0
Exports	35.2
Imports	-37.2

In general, the above parameters have maintained a growth rate, except public investment which showed a fall from 2011 to 2015 and the private one in 2013[38].

[35] Economic Comission for Latin America and the Caribbean (Eclac), 2017. http://estadisticas.cepal.org/cepalstat/Perfil_Nacional_Economico.html?pais=MEX&idioma=spanish

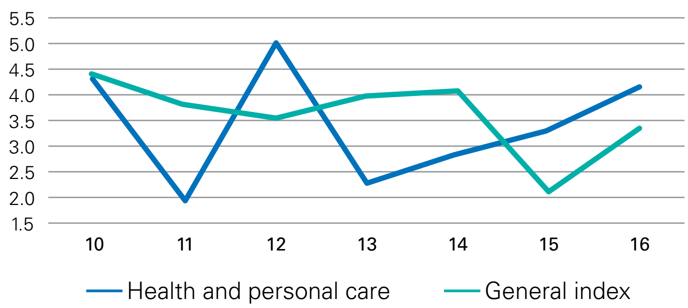
[36] Eclac, 2017.

[37] Eclac, 2017.

[38] Banxico, 2016.

Inflation has remained below 4.5% since 2009, which has facilitated project planning as well as increased purchasing power. In the case of health and personal care, which includes medications, the price level has had ups and downs, although the annual average level in the period is 2.2%. CETES' (treasury certificates) 28-day interest rates have remained in the range of 3% to 4.2% over the past seven years. The exchange rate of the peso against the US dollar has registered a devaluation from 2011 to 2016 of 35.72%.

Diagram 3. Price level
(Annual percentage change)



The macroeconomic picture, in general, is stable and solid with some risks derived from exchange rate parity.

Table 7. Summary of added variables[39]

	2011	2012	2013	2014	2015	2016e
GDP (annual change, %)	4.0	4.0	1.4	2.2	2.5	2.3
Inflation (annual NCPI)	3.8	3.6	4.0	4.1	2.1	3.2
CETES 28 days (rate)	4.2	4.2	3.8	3.0	3.0	3.8(a)
Exchange rate	14	13	13.1	14.7	17.2	19(a)
Unemployment rate	5.2	4.9	4.9	4.8	4.3	3.9

It can be observed in Table 7 that macroeconomic stability has been a constant in recent years, with slow but increasing growth levels and low inflation. Now the challenge is to maintain stability, accelerate growth and take care of the macro fundamentals of the economy.

39 Banxico, 2016: e/For 2016 it is a preliminary value of: Inegi, 2017. http://www3.inegi.org.mx/sistemas/temas/default.aspx?s=est&c=23824; (a) Banxico, value as of June.

Initiatives

The closest trade relationship for this industry is with the United States, a country that imports just over 20% of the products and exports a little more than 26%[40] of the national production. In this sense, the future of the relationship with the US becomes very important, but so does the opening of new commercial ties with other nations. The positioning and regional recognition of Cofepris establishes strong bases for the expansion of the domestic industry and the qualification for foreign companies to consider Mexico as an expansion platform for the preparation and trading of its products.

It will be of great importance to pay special attention to the negotiation of current and future trade agreements, especially regarding the rules of origin, as well as to take advantage of other initiatives that have been taking shape, such as the Pacific Alliance and more than 50 treaties and commercial agreements with countries around the world[41]. We have, among other strengths, trained human capital and very competitive production costs[42].

Furthermore, it is worth taking advantage of the strategy of Special Economic Zones, through the Law enacted by the Federal Government, to develop the domestic industry, facilitate the dynamics of foreign investment and boost the multiplier effect of the pharmaceutical industry. The manufacturing clusters in Mexico City, the State of Mexico and Jalisco, which concentrate around 60% of the economic units for the manufacture of medicines are also seen as having big potential[43].

Furthermore, it will be very relevant to identify spaces for effective collaboration, to make supply chains more efficient, to seek greater synchrony between manufacturers, distributors and payers of products. Although the OECD indicates that there is progress in the development of the health sector, there are also challenges that can become opportunities for process improvement, cost alignment, and financial planning design[44]. The goal is to contain the risk factors that drive the advance of chronic diseases and also to expand the access to quality products and services for medical care, based on a solid, innovative, swift and dynamic industrial platform, among other fundamental elements of the health system.

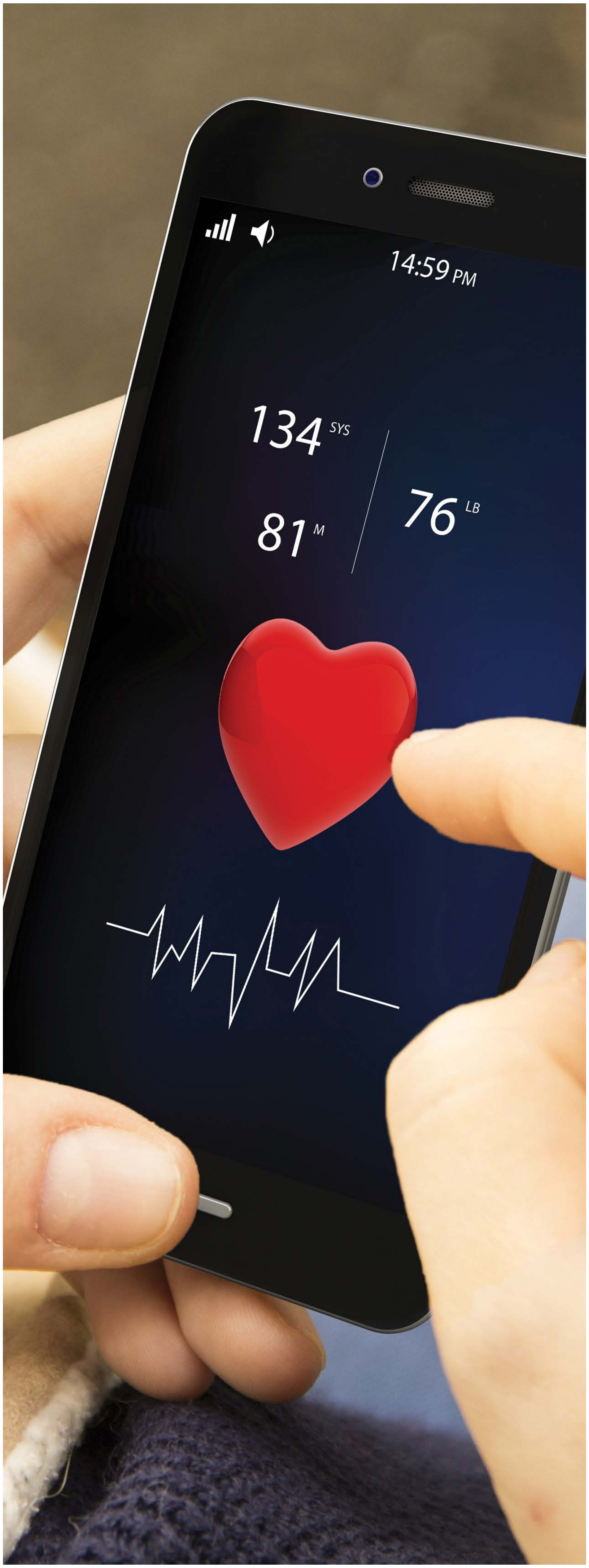
40 Inegi, 2016.

41 http://www.gob.mx/se/acciones-y-programas/comercio-exterior-paises-con-tratados-y-acuerdos-firmados-con-mexico

42 ProMéxico, 2015.

43 ProMéxico, 2015. https://www.gob.mx/cms/uploads/attachment/file/76324/111115_DS_Farmaceutico.pdf

44 OECD, 2017.



Industry challenges in numbers

The importance of health for the well-being of people and the performance of organizations implies challenges for the industry itself, among which are the readiness of supply chains to make them more flexible, swift and effective, turned to the service of their customers[45]. Another aspect that is relevant is taking advantage of technological platforms to link the different actors for medical care more closely and collaboratively[46]. We also recommend promoting public-private alliances and partnerships, which generate a formidable space for the successful development of initiatives[47], looking towards resolving the needs of the population, strengthening companies that generate value in the economy and the positioning of the pharmaceutical industry.

Health as a necessary condition for productivity

When people are healthy, they can perform their daily duties. At a personal level, health facilitates the optimal performance of the human being, and in the organizational field it drives productivity, trade, investment and innovation. This requires trust, as well as adequate coordination and integration of initiatives, efforts, processes and activities.

For this to flow effectively and relevantly to drive growth, people are required to find the care they need; developers, manufacturers and input traders are required to be driven by goals, strategies and project follow-up; regulation needs to drive public-private collaboration plans; optimal financing sources need to be consolidated to develop infrastructure; and there need to be incentives that boost the economic output that health brings.

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[45] *Fast forward–Future proofing the life sciences supply chain*, KPMG, 2016. https://home.kpmg.com/xx/en/home/insights/2015/05/future-proofing-the-life-sciences-supply-chain.html

[46] *Digital health: heaven or hell?*, KPMG, 2016. https://assets.kpmg.com/content/dam/kpmg/pdf/2016/03/digital-health-heaven-hell.pdf

[47] *Partnerships, networks and alliances-Global lessons and trends*, KPMG, 2016. https://assets.kpmg.com/content/dam/kpmg/pdf/2016/04/what-works-partnerships-networks-alliances.pdf
Beyond the hype: Separating ambition from reality in i4.0, 2017. https://assets.kpmg.com/content/dam/kpmg/xx/pdf/2017/05/beyond-the-hype-separating-ambition-from-reality-in-i4.0.pdf

Disease control for economic well-being

In Mexico, initiatives are being promoted to strengthen the health sector, such as clinical research, swiftness in regulatory procedures, transparency in the mechanisms for public purchase of inputs, promotion of programs for disease prevention and the search for efficiencies in healthcare processes.

Furthermore, there are many opportunities that can be taken advantage of, including controlling risk factors such as obesity, containing the advance of chronic illnesses such as diabetes and cardiovascular diseases, pushing for new payment methods based on results and identifying more opportunities for public-private collaboration.

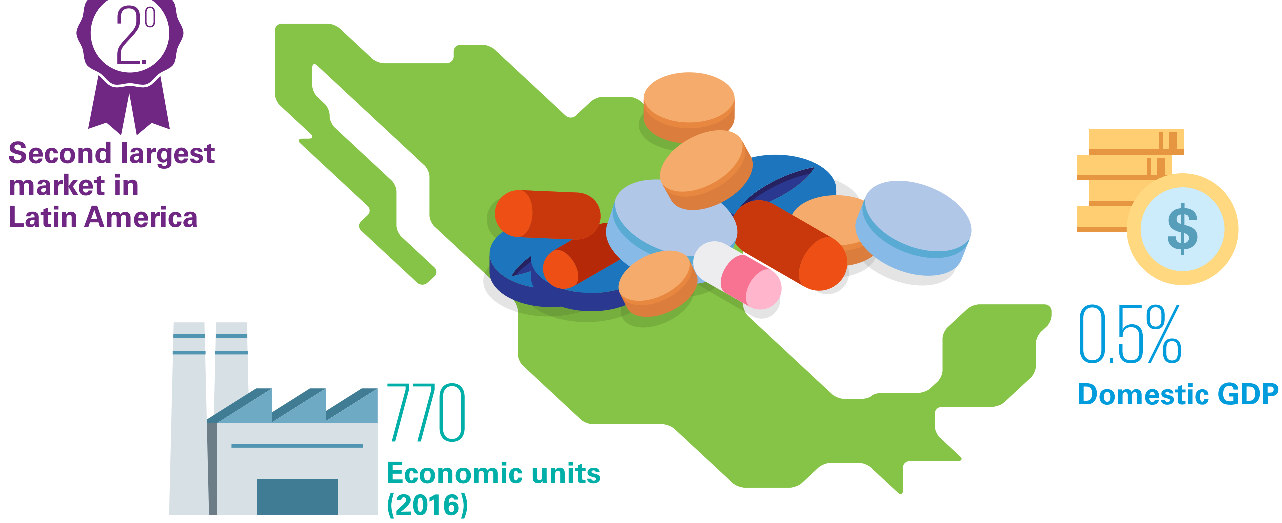
Local dimensions of the health sector

The economic value of the health sector represents about 6% of the Gross Domestic Product (total GDP) in Mexico. About 40% of health spending is paid out of pocket[50], the highest level within the group of OECD countries, where the average is 20% . A major challenge for the health system is to curb chronic diseases - diabetes, cardiovascular and kidney diseases - that have advanced significantly to account for 20% to 25% of the causes of death in our nation, and that place Mexico as one of the countries with the highest mortality rate for these reasons[51].

To meet such challenges, the country has, among other resources, nearly 2.5 doctors and 1.6 beds for every 1,000 people; the average for OECD countries is 3.3 and 4.8, respectively[52]. It also has manufacturers of medicines and medical devices, domestic and global companies, which positions us as a large market, both for manufacturing and for exports. In terms of pharmaceuticals, the country ranks among the top 15 in the world, and is the second largest in Latin America. In exports of medical devices, Mexico is located in the top ten[53].

The pharmaceutical industry is a priority sector for the country[54]. Even more with the possible departure of investments in some sectors, turning their eyes thereto seems attractive. The health of the population requires products that generate favorable, innovative, and cost effective results; strong and flexible companies that can adapt to a dynamic and volatile environment, having the operational processes under control and ensuring a management of risks of different nature, both regulatory and fraud, for instance; and that can maximize their fiscal positions and structures, from administrative to production and commercial.

The Mexican pharmaceutical industry



48 Satellite account of the healthcare sector of Mexico, Inegi, 2015.

49 Direct payment made by households for healthcare services at the moment of being attended. Programa Sectorial de Salud 2013-2018.

50 OECD, 2016.

51 http://www.healthdata.org/mexico, consultado el 3 de enero de 2017.

52 OECD, 2016.

53 Gestión de la Salud Pública en México, Cofepris 2015. http://www.amid.org.mx/wp-content/uploads/2013/10/AMID_FACTSHEET.pdf, AMID, 2015, consulted on January 3, 2017.

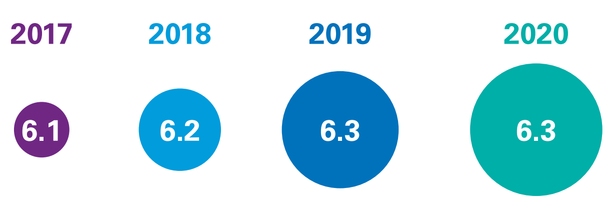
54 Cofepris, 2015.

Perspectives

The main drivers that will mark the trend for the pharmaceutical industry within 3 years are:

- The effectiveness of preventive programs and programs for the control of chronic and degenerative diseases, both by the increase of age in the population and those derived from obesity
- High market saturation of generic and biocompatible medications for some therapeutic areas that will tend to reduce the cost of medicines in the care of common diseases and open opportunities for specialized treatments
- International trade rules to be defined and their impact on the cost of active substances to manufacture medications and finished products to be marketed and opening opportunities for developing manufacturing of active substances
- The budgetary capacity of the government and the people to purchase medications, as well as the efficiency in the management of the medical care, widening opportunities for innovative schemes in the private sector
- The ability of the pharmaceutical industry to adapt and generate synergies with other sectors, at both ends of the chain: supply of raw materials, purchase and distribution of finished products
- Socio-demographic trends will continue to impact medication demand in the coming years
- New criteria for the definition of medication prices based on the value generated for the patient and the buyer
- The growth in the industry will be through inorganic growth (mergers and acquisitions), as well as through the arrival of new investments taking advantage of Mexico's competitiveness in the costs for the industry

Diagram 4. Health expenditure as a percentage of GDP



According to data from the Economist Intelligence Unit[55], growth in health spending is forecasted for the coming years, from US $500 per capita in 2016 to 570 in 2020, which would represent about 6.3% of GDP.

The main accelerators of the industry are linked, on one hand, to the demographic and epidemiological characteristics of the population, as well as to the effectiveness of health services; and on the other hand, to public spending aspects, income per capita, efficiency in supply chains for the distribution and procurement of products, incentives to develop research projects, maintaining competition certainty and expanding it in security aspects of both information and transfer of products.

Some of the key challenges we identified for the pharmaceutical and medical device industries are listed below:

- Sustaining the manufacturing quality of generic drugs before the expiration of patents for the innovators, in such a way as to maintain a sustainable balance between both products
- Expanding supervision of consolidated product purchases, so as to take care of the aspects of product quality and sufficiency in relation to the financial sustainability of both the acquiring institutions and the manufacturers and distributors
- Promoting evidence-based medicine to take care of the technical and scientific operational aspects in the application of therapeutic diagnostic guides to support the maturity of our health system in terms of cost-effectiveness of care and access to services of high social impact

Mexico has an industrial tradition in the manufacturing of pharmaceutical products of many years, at least 70, in which the National Chamber of Pharmaceutical Industry (Canifarma, by its acronym in Spanish) was created; and with great presence in several countries where products manufactured in the country are exported under strict standards. Internally, collaboration between government and industry has evolved favorably: both sectors agree on more visionary partnerships for the benefit of both parties, and especially of patients. The pharmaceutical industry is in a context of great momentum for growth and strengthening.

[55] *Industry Report Healthcare Mexico,* Economist Intelligence Unit (EIU), 2016.

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