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COFEPRIS: Using regulation to better protect the population's health and transform the market.

The Case of Mexico

September 2016

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Regulated Sectors by COFEPRIS

COFEPRIS is an agency with broad regulatory powers, which main activity is the prevention against sanitary risks. It is related with industries that represents 9.8% of GDP, and 10.94% of foreign Mexican trade.

Regulated Sectors
1. Food and beverages
2. Health supplies
3. Health services
4. Emergences
5. Pesticides, Vegetable nutrients and Toxic substances
6. Cosmetics and beauty products
7. Environmental Risks
8. Labor Safety and Health

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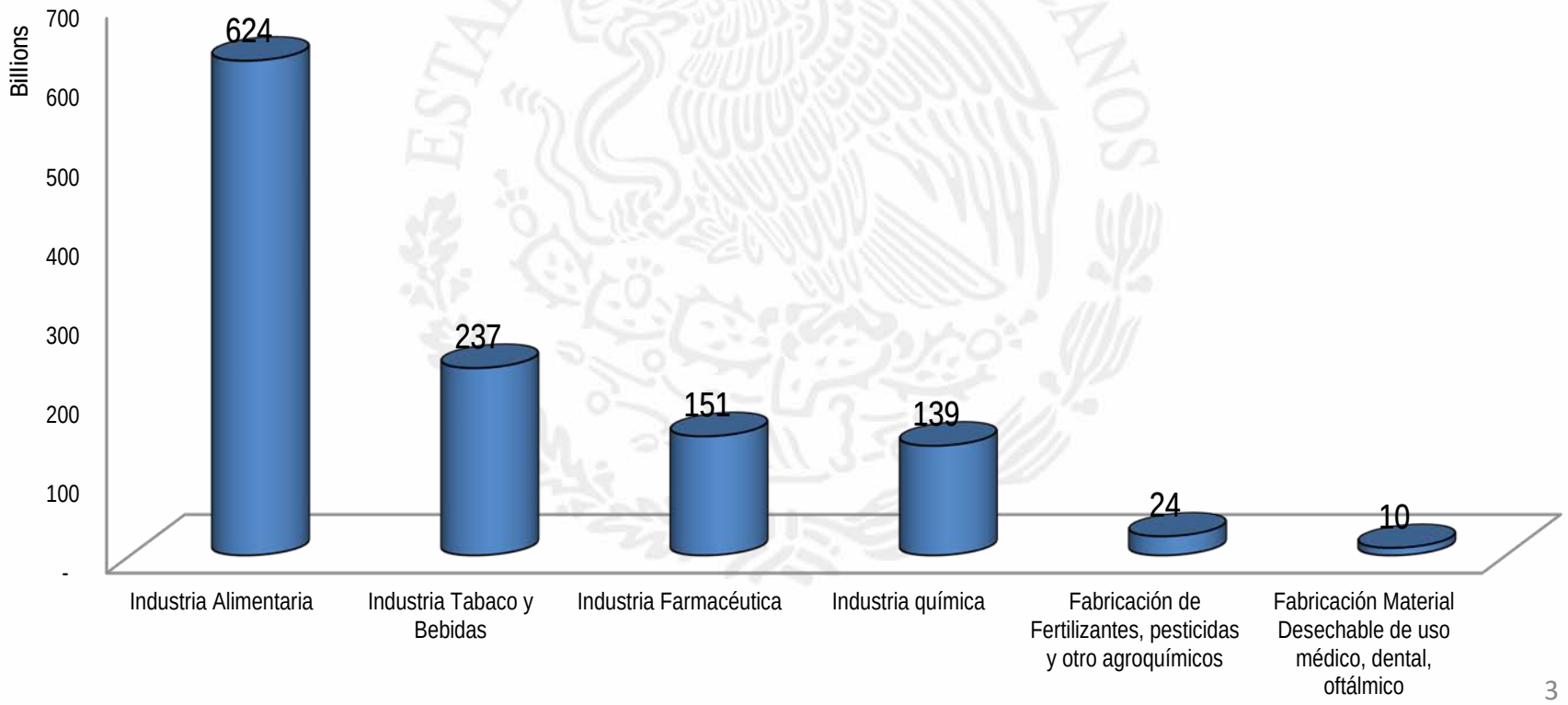
The value of the products regulated by COFEPRIS represents **9.8% of Mexican GDP.**

Industries Regulated by COFEPRIS
(2009 last available year)



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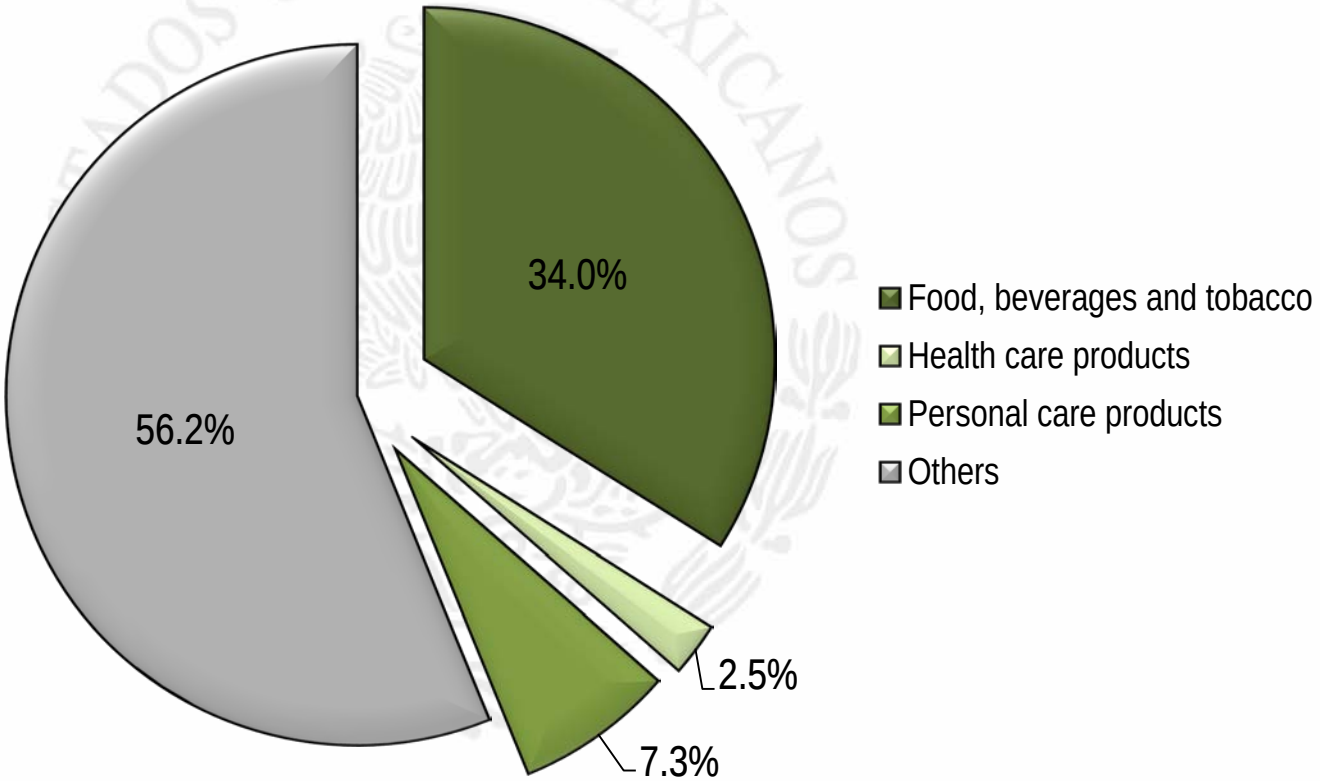
COFEPRIS regulates 44 **cents out of every peso** spent by households in Mexico through 3 categories: Food, beverages; health care; and personal care products.

Household Expenditures per Category
(as a % of total household expenditures)*



Source: Encuesta Nacional de Ingresos y Gastos de los Hogares (ENIGH, 2012). INEGI (2013).
* Only current monetary expenditures are considered.

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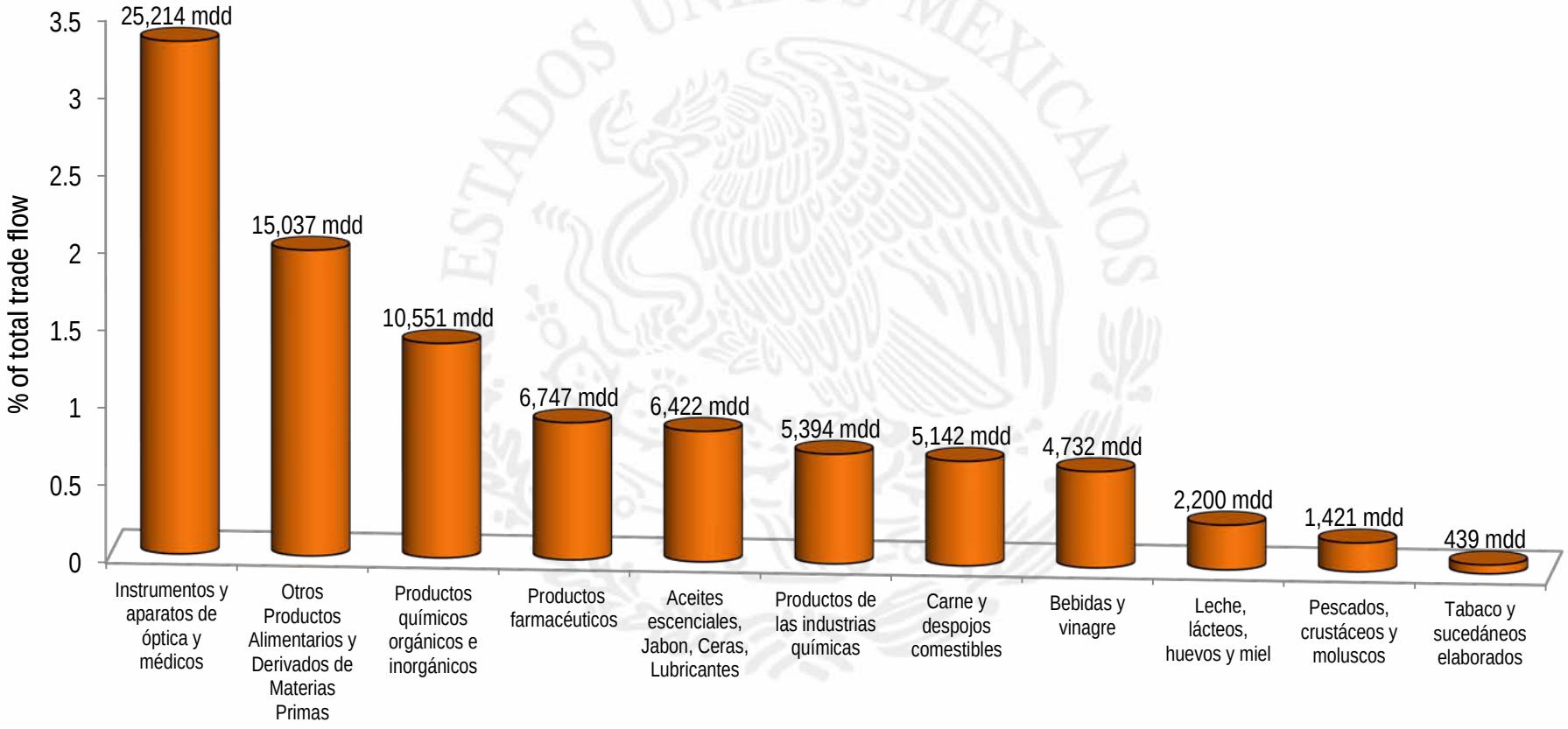
COFEPRIS regulates about 11% of the total trade flow between Mexico and the rest of the world (64% of GDP).



Source: DEOI with data from Banco de Mexico (2014).

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Pharmaceutical Policy

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Characteristics of pharmaceutical policy

- Rests on four fundamental pillars
- The pillars are aligned with the 3 **priorities of health policy** established by the Federal Government.
- Its main objective is to improve access of the population to a well-supplied drug market that offers innovative and generic medicines at the best prices.

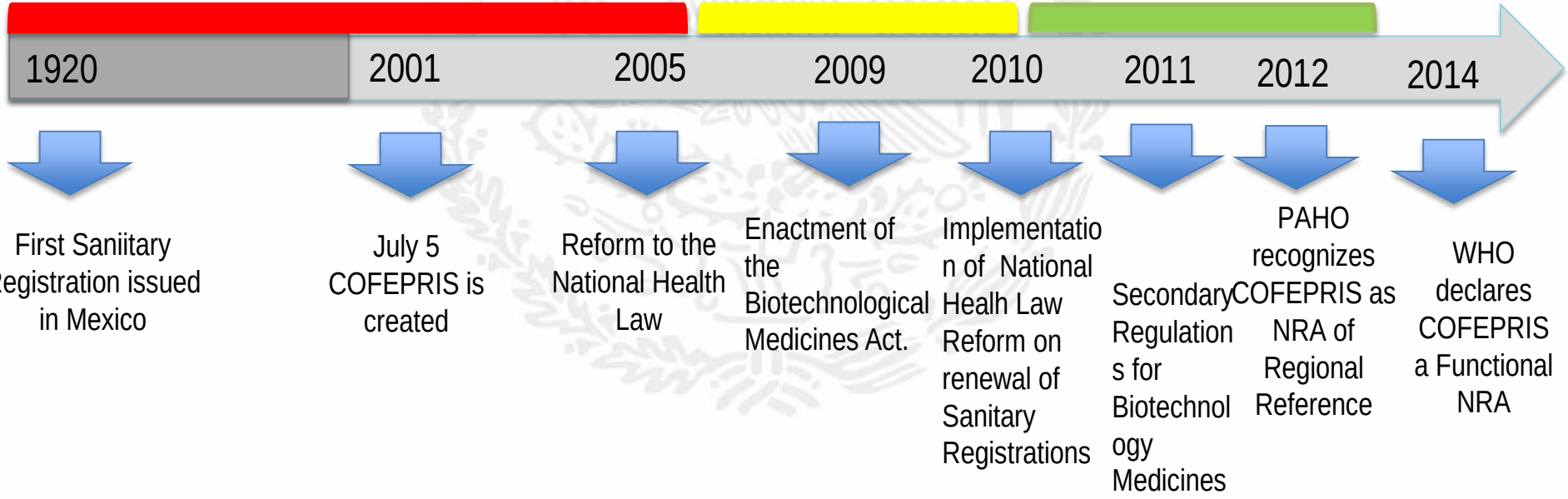
Pillars of Pharmaceutical Policy	Government's Health Policy Priorities
A **regulatory agency that guarantees the safety, quality and eficacy** of all drugs.	1. Effective Access 2. Service Quality 3. Prevention
A reliable scheme to **authorize sanitary registrations.**	
Removal of barriers to market entry for products that are safe and of high quality.	
Harmonization of the sanitary agency with best international practices.	

Evolution of the Mexican Pharmaceutical Regulation

During this period the market authorizations for medicines had indefinite duration and without the legal obligation to be bioequivalent.

1. The legal requirement of bioequivalence is implemented.
2. A netwrork of laboratories is created to perform bioequivalence tests through Authorized Third Parties.

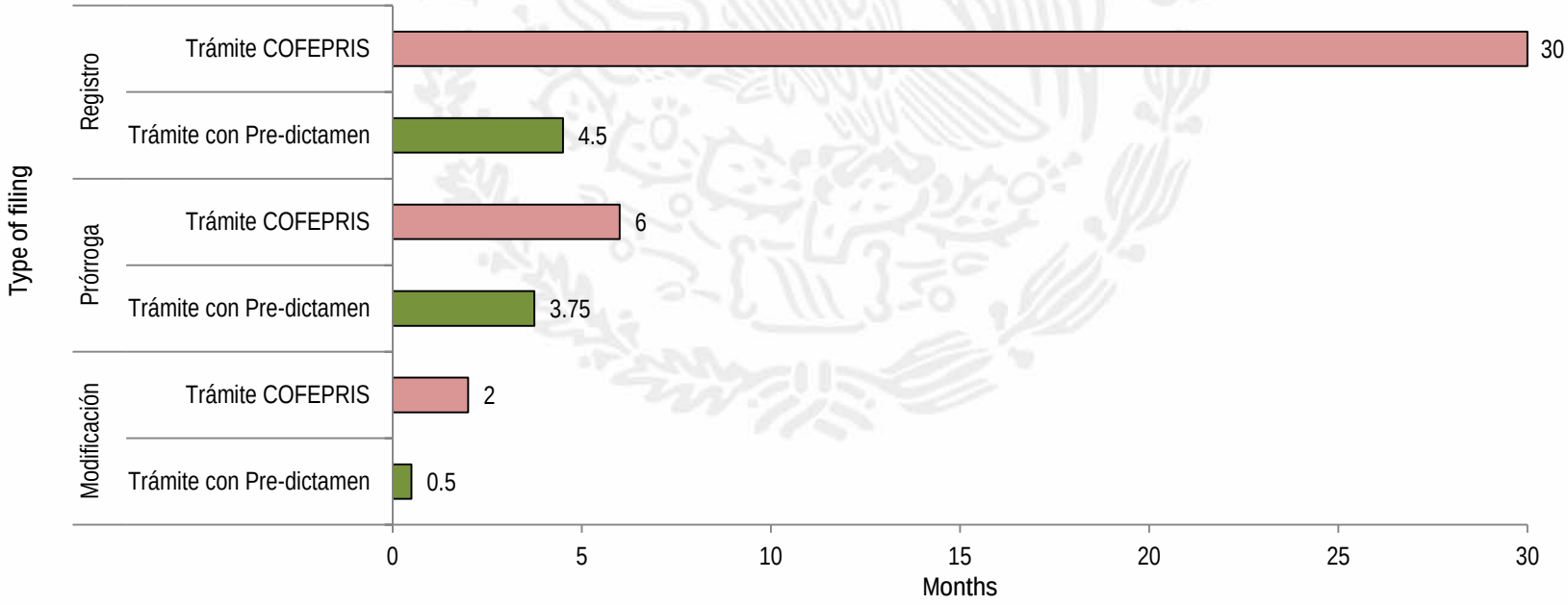
Domestic market with only two types of medicines:
1. Innovative Drugs
2. Generics



Benefits of Authorized Third Parties

- **Third Parties** issue a **"Pre-dictamination"** certificate, which must be submitted together with the complete paperwork when filing for a **New Registration, an Extension or a Modification to an existent Registration** to Cofepris.
- The **"Pre-dictamination"** certificate of Third Parties allow to reduce signifcantly the processing time of each individual filing. For example, in the case of new registrations the processing time was reduced by an average of approximately **2 years.**

Average processing time for filings of drug products (months)



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Authorized Third Parties

- There are **19 Authorized Third Party Companies** currently in operation and **8,456 products** have been authorized in an average of less than 20 days.
- The following table shows the type of procedure, the total number of filings submitted and its composition between approved and in process.

Filings submitted with Pre-dictamination of Authorized Third Parties				
	Procedure	Number of Filings	In process	Approved
Medical Devices	New Registration	3,342	410	2,931
	Extensions	772	36	736
	Modification	2,189	182	2,007
Medicines	New Registration	715	95	592
	Extensions	495	58	425
	Modification	2,046	254	1,765
Total		9,559	1,035	8,456

The approval of those registers have been achieved with a team of **105 evaluators** in the verification units; they also contribute to the activities performed by the **141 evaluators from** COFEPRIS, in order to increase the productivity in the issuing of registers.

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Generics Policy

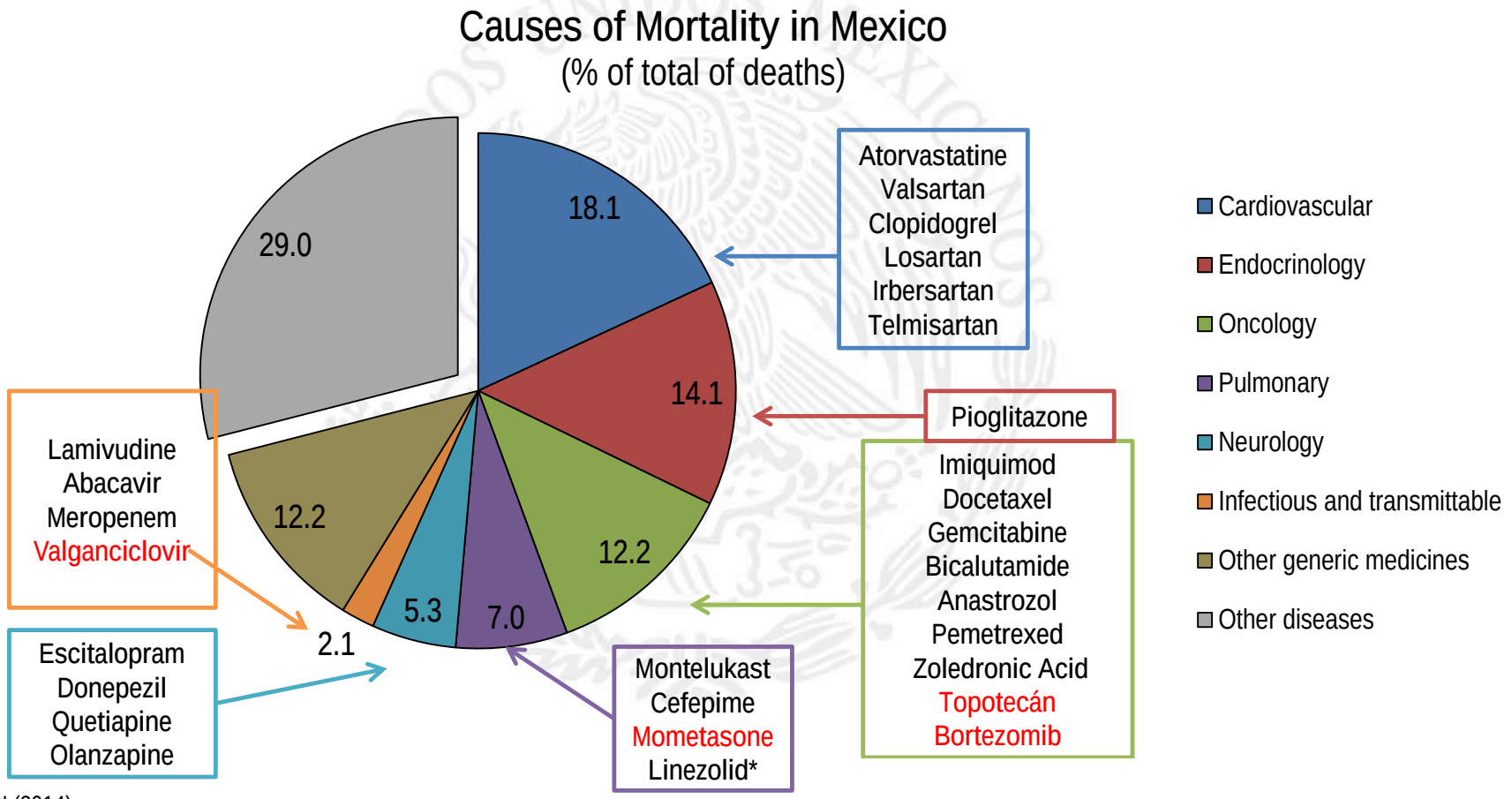
- The **Mexican Government** has released **37 active substances.** This corresponds to **491 new registrations of generic medications, which** address 71% of Mexico´s mortality causes.

- The **Generics Policy of the Mexican Government** has allowed an average reduction of 61% in medicines prices, which represents average savings of $1,047 pesos for the consumer.

Number of Packages	Released Substances	New Generics Options	Accumulated Savings (billions of dollars)	Mortality causes attended, as a % of total of deaths	Additional Patients
14	37	491	24,632	71%	1,998,202

- There is no international record of a generics releasing strategy of such magnitud and in a reduced period of time.

- With this increse in the supply of medications, the most frequent and costly diseases, which correspond with 71% of mortality causes in Mexico, are covered.



Source: INEGI (2014).
* Linezolid is a wide spectrum antibiotic used mainly in pulmonary diseases.

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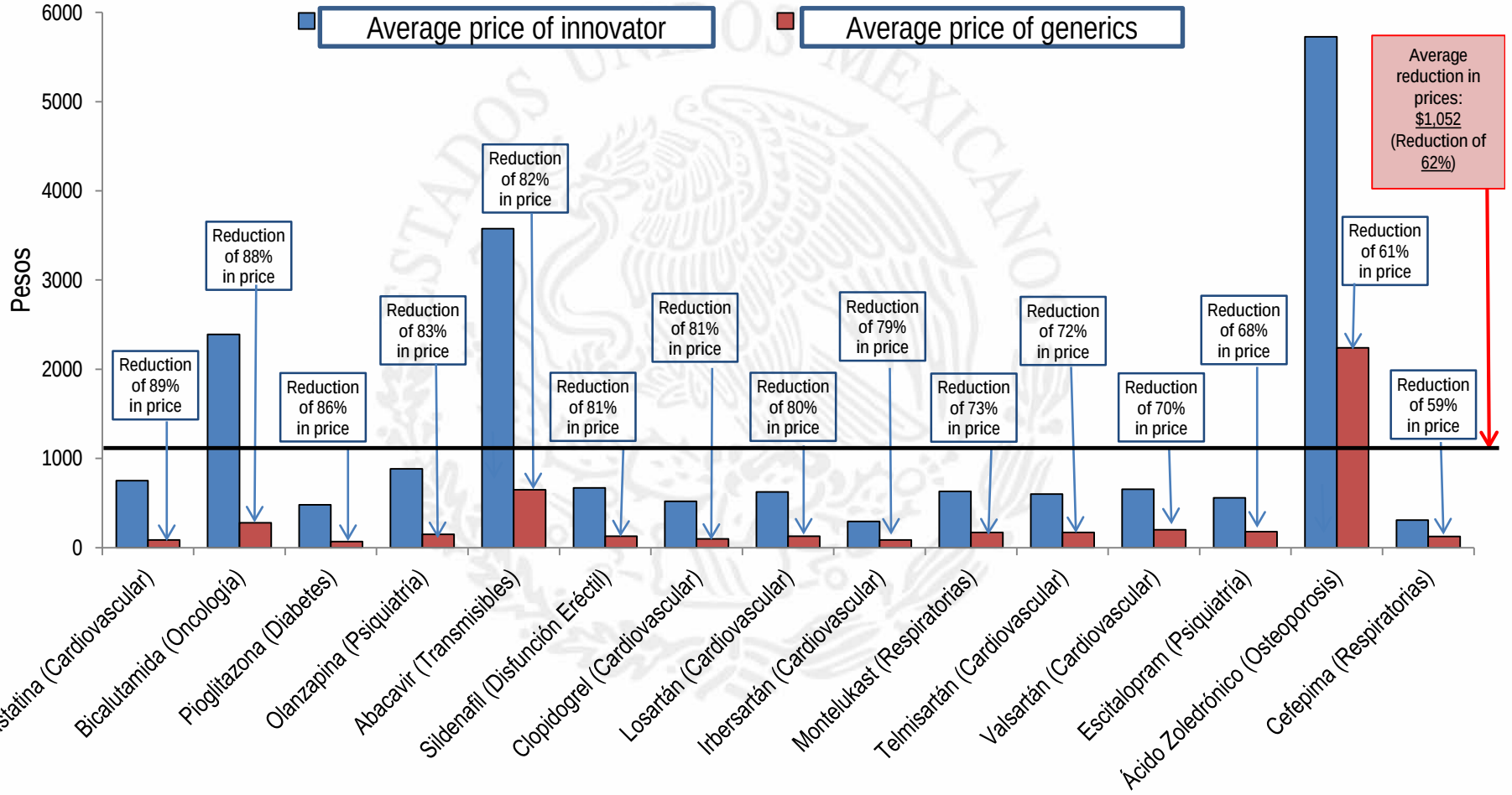
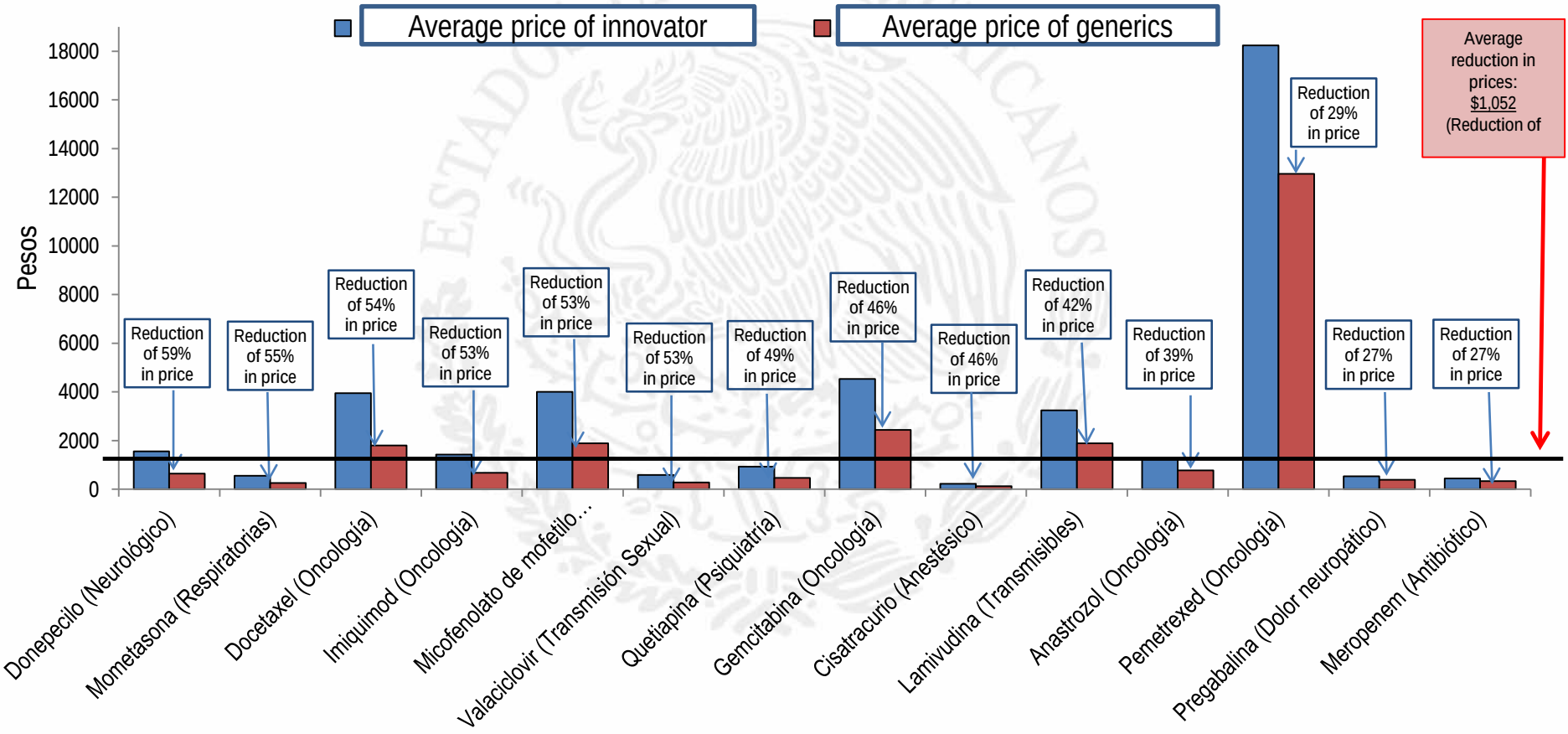
Private Market

The average reduction in prices of generics has been 61%, which represents an average saving of $1,047 pesos for the consumer.



Source: COFEPRIS (2015).

- For example, treatments for cardiovascular diseases have decreased 89%, for oncological diseases, 88%, and for diabetes mellitus, 86%.



Source: COFEPRIS (2015).

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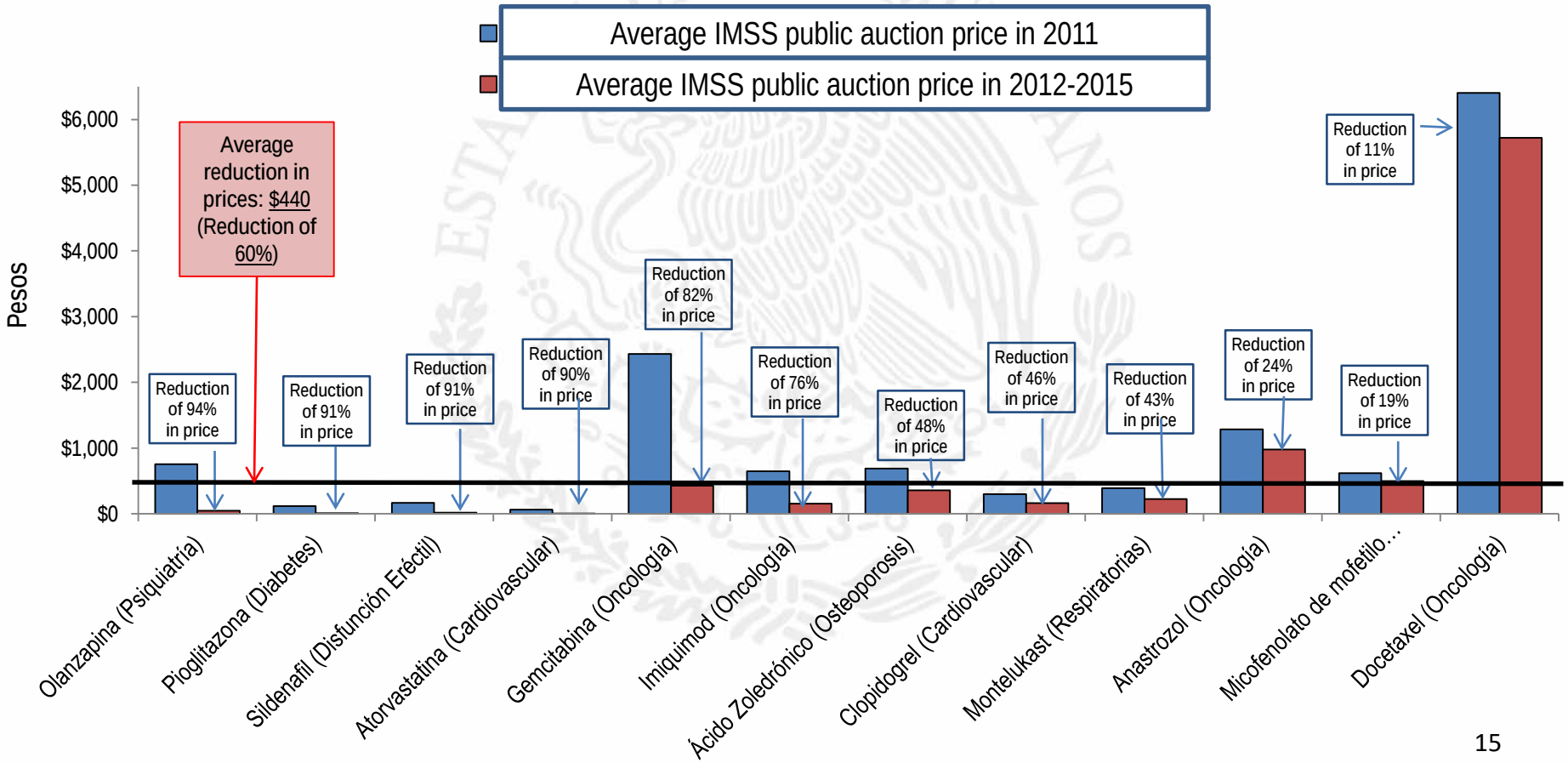
Public Tender prices

Price reduction of generics averaged 60%.

The largest decreases are related with cardio vascular diseases (90%), Diabetes (91%) and oncological diseases (82%).



Source: IMSS (2012, 2013) and COFEPRIS (2015).

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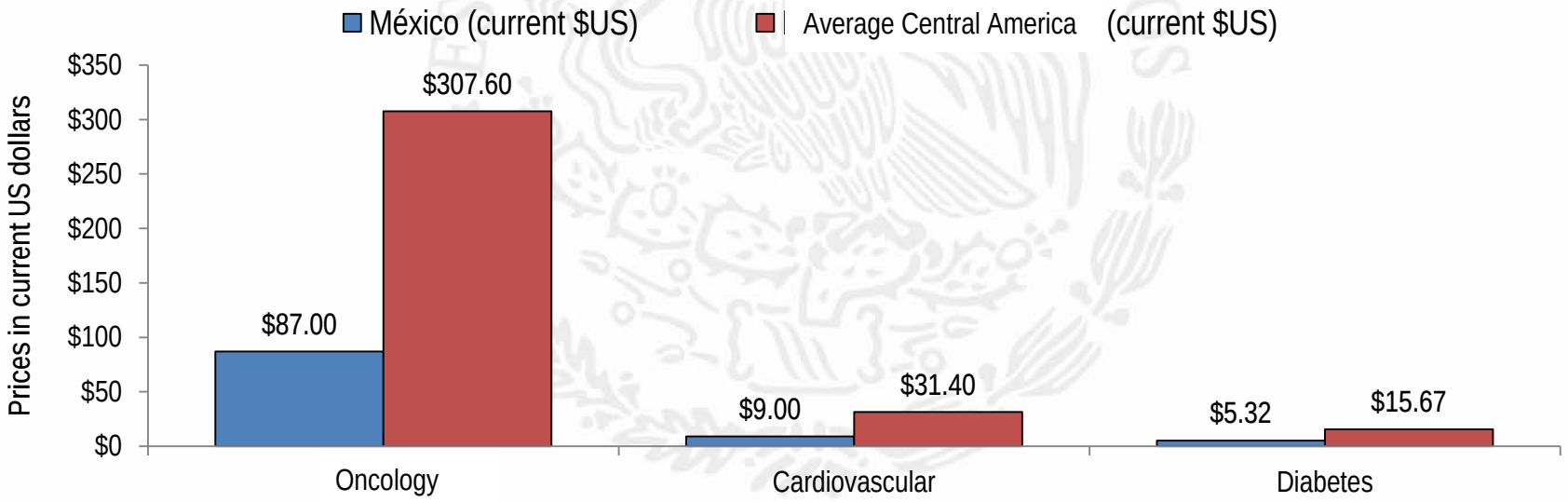
Price Comparison between Mexico and Central America

- A comparison between the generics market of Mexico and Central America shows that medicine prices are 71% lower in Mexico for drugs used for oncological and cardiovascular diseases.
- Moreover, medicines used in the treatment of type 2 Diabetes show prices that are 66% lower in Mexico than in Central America.

Price Comparison in the Generics Market in Mexico and Central America (2014)*



Source: COFEPRIS (2015) with data from the pharmaceutical market in Mexico and IMS Health (2014).
* The following countries are considered for Central America: Panama, Costa Rica, Honduras, Guatemala, El Salvador and Nicaragua.
The following active substances were considered by therapeutic group: Oncology (Bicalutamide, Imiquimod and Gemcitabine); Cardiovascular (Atorvastatine, Clopidogrel, Valsartan, Irbesartan and Losartan); Diabetes (Pioglitazone).

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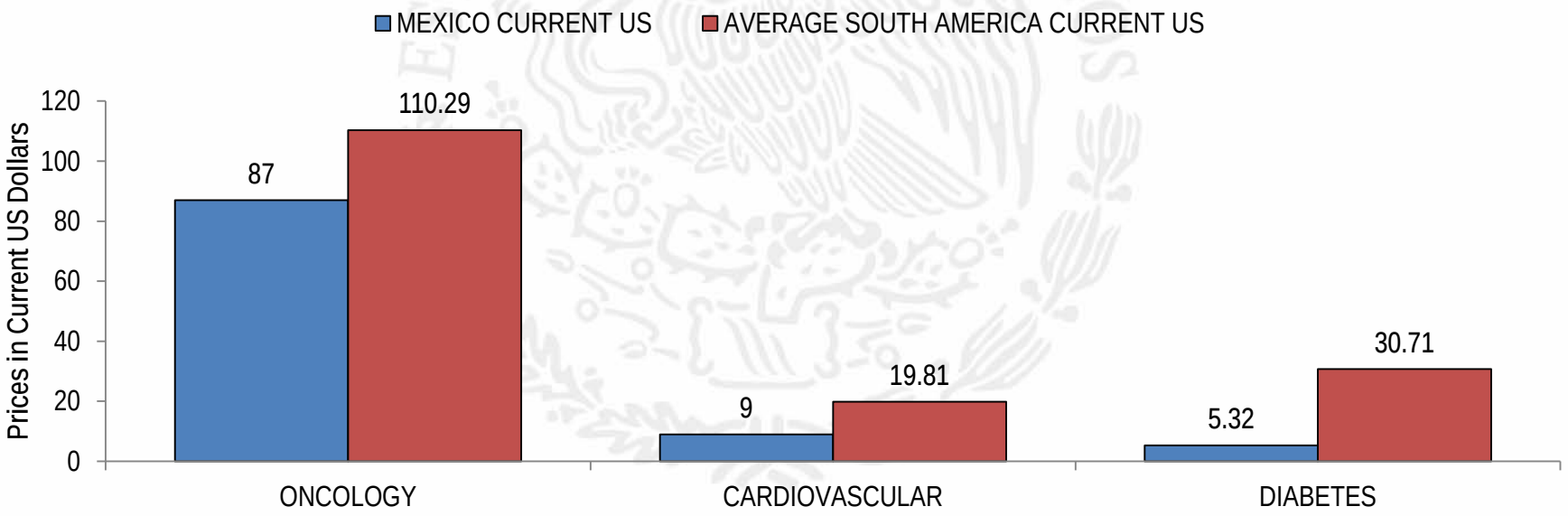
Price Comparison between Mexico and South America

- A comparison between the generics markets of Mexico and South America shows that, on average, the prices of medicines for **cardiovascular diseases** are 55% lower in Mexico.
- Moreover, medicines used in the treatment of **diabetes** are 83% lower in Mexico than in South American countries.

Price Comparison in the Generics Market in Mexico and South America (2014)*



Source: COFEPRIS (2015) with data from the pharmaceutical market in Mexico, Argentina, Brazil and Colombia (2014).
* The following countries were considered for South America: **Argentina, Brazil and Colombia.**
The following active substances were considered by therapeutical group: **Oncology** (**Bicalutamide**); Cardiovascular (**Atorvastatine**); **Diabetes** (**Pioglitazone**).

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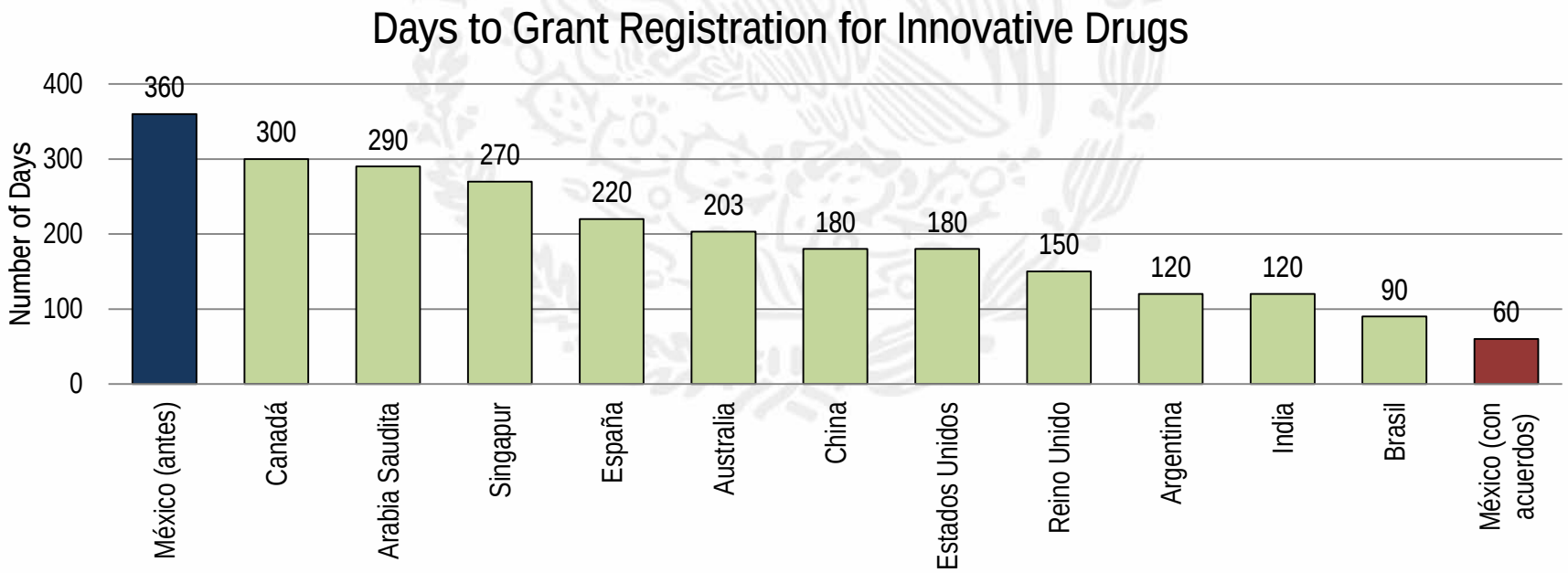
Innovation policy
Agreement for the promotion of innovation

- The Mexican Government established an innovation policy relying on regulatory cooperation among different sanitary agencies in order to expedite the entry of new drugs to Mexico. This policy consists of:

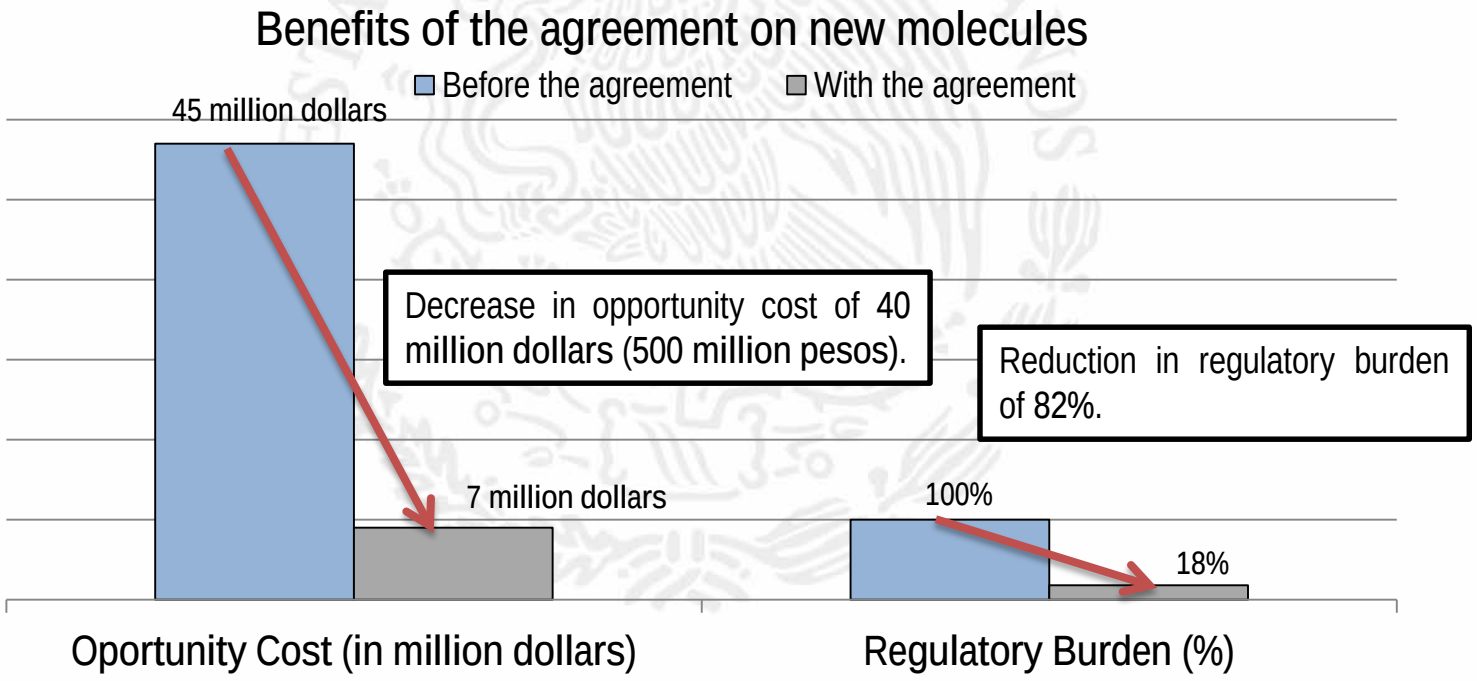
1. **Equivalence Agreements** of new drugs with the **US**, **Canada**, **Australia**, **Switzerland** and the **European Union**.

2. To encourage **clinical research**, Mexico substituted the requirement of a foreign free sale certificate with a report of clinical studies in Mexican population.



Agreement for the Promotion of Innovation

- The **opportunity cost** associated with the days a file is processed has decreased in approximately 40 **million dollars** (500 million pesos). This cost was estimated in 45 **million dollars** (570 million pesos).*
- Further, with the equivalence agreement on new molecules, the **regulatory burden** for each file decreases in 82%.



* Calculation of the opportunity cost consists of the daily administrative cost to process registrations for new molecules multiplied by the number of days requeried to grant authorization.

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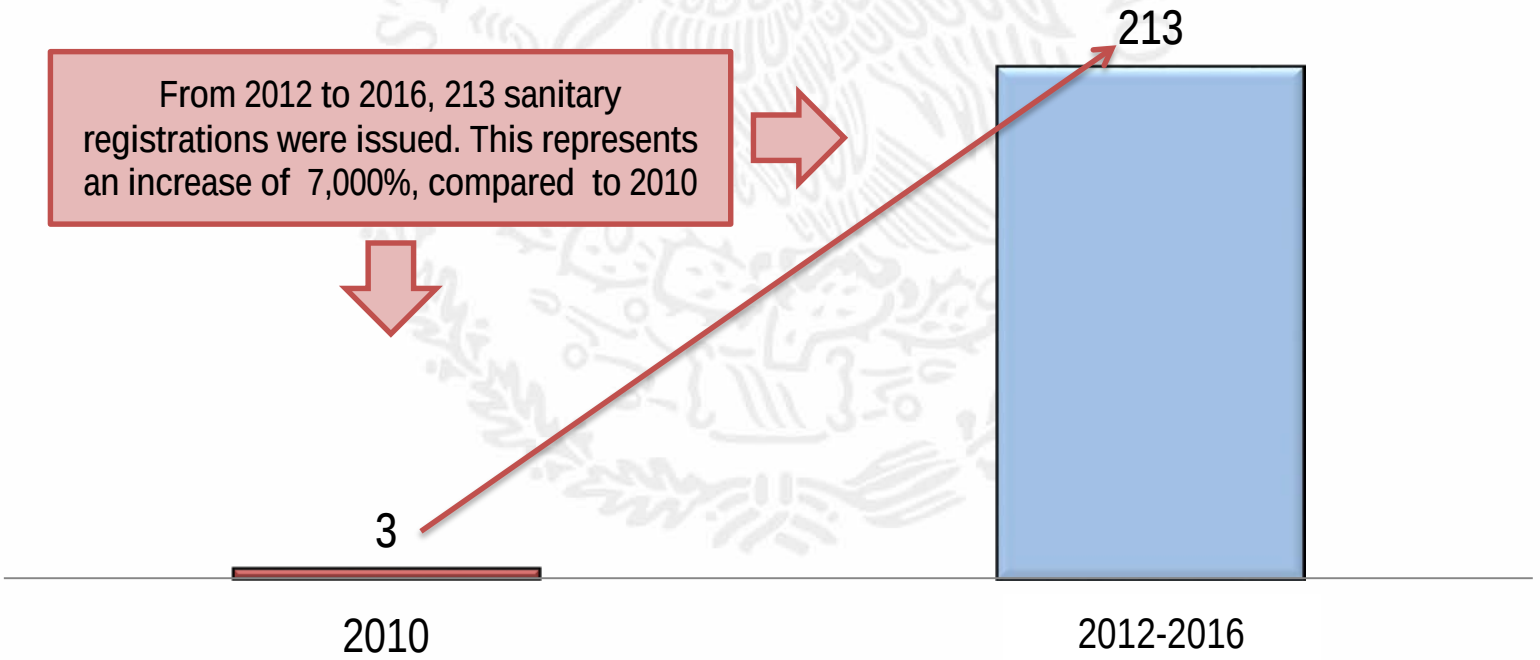
Innovation Policy

- As a result of the **innovation policy**, from 2012 to 2016, COFEPRIS issued **213 new marketing authorizations for innovative medicines**, treating **21 different therapeutical classes** representing **73%** of mortality causes in Mexico.
- This represents an increase of 7,000% in the supply of medicines with respect to the 3 registrations issued in 2010.
- .

Registros emitidos a medicamentos innovadores
(2010-2016)



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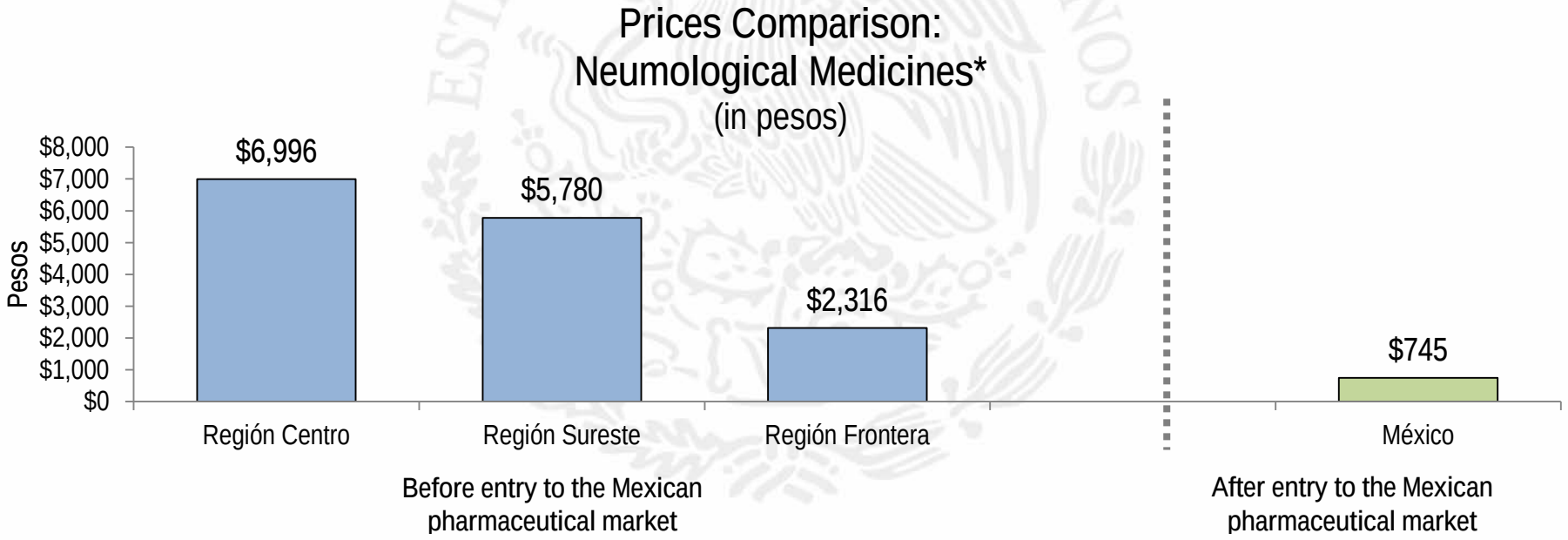
Prices Comparison: Neumological Medicines

- Before the entry of the drug **Eklira Genuair** (**Aclidinium bromide**) to the Mexican pharmaceutical market, consumers paid, on average, **$5,031 pesos** for this medication.

- Currently, as a result of the **equivalence agreements** derived from the innovation policy, the price of this medication in the Mexican market is **$745 pesos** (a price reduction of 85%).



* For cardiovascular medicines, the active substance **Apixaban** is considered. Transportation costs and time used to obtain the medicine are considered.

- Central Region: Mexico City and its Metropolitan Area.
- Southeast Region:Yucatan Península and Cancún.
- Border Region: Includes the city of Tijuana.

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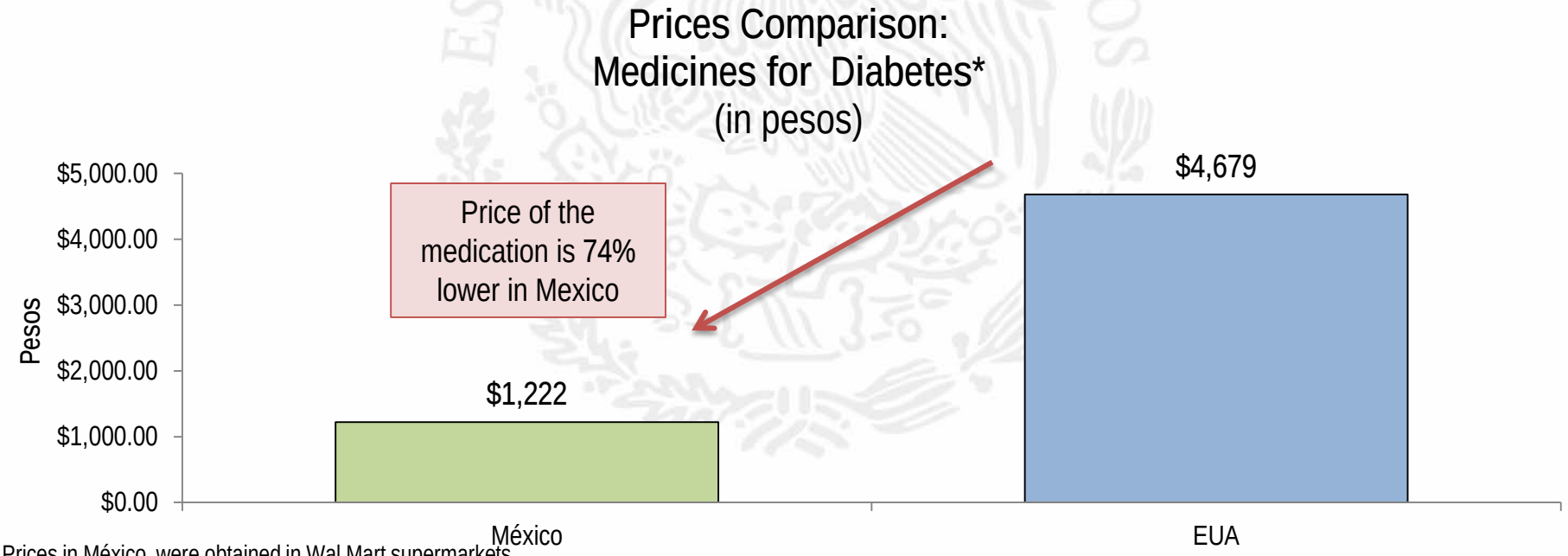
Prices Comparison: Medicines for Diabetes

- The Mexican Government has introduced **five new medications** to the Mexican pharmaceutical market as a platform of global launching: two are used in the treatment of **Type 2 Diabetes**; one more is used in the treatment of **Chronic Obstructive Pulmonary Disease** (COPD). Another medication is used in the treatment of **pulmonary hypertension** and the last medicine is used, in combination with a medical device, in the treatment of **prostate cancer**.
- The drug **Empagliflozine** is currently sold in the United States at a price of **$316 USD ($4,679 pesos)**. The price of this medicine in Mexico is **$1,222 pesos**, that is, 74% lower than in the United States.



* Prices in México were obtained in Wal Mart supermarkets.
Prices in the United States were obtained in Wal Mart supermarkets.

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Removal of the requirements to have a manufacturing plant on national soil

- In 2011 the Mexican Government removed the requisite to have a manufacturing plant in Mexico to market a medicine

- Approval of the first 633 registrations in this category which had been requested more than 10 months before.

BENEFITS:

- Increase the supply of pharmaceuticals.
- Availability of new molecules for research and development.

Impact:

Investment above 100 million dollars in the following five years have been made.

100% increase in the workforce of the firms involved.

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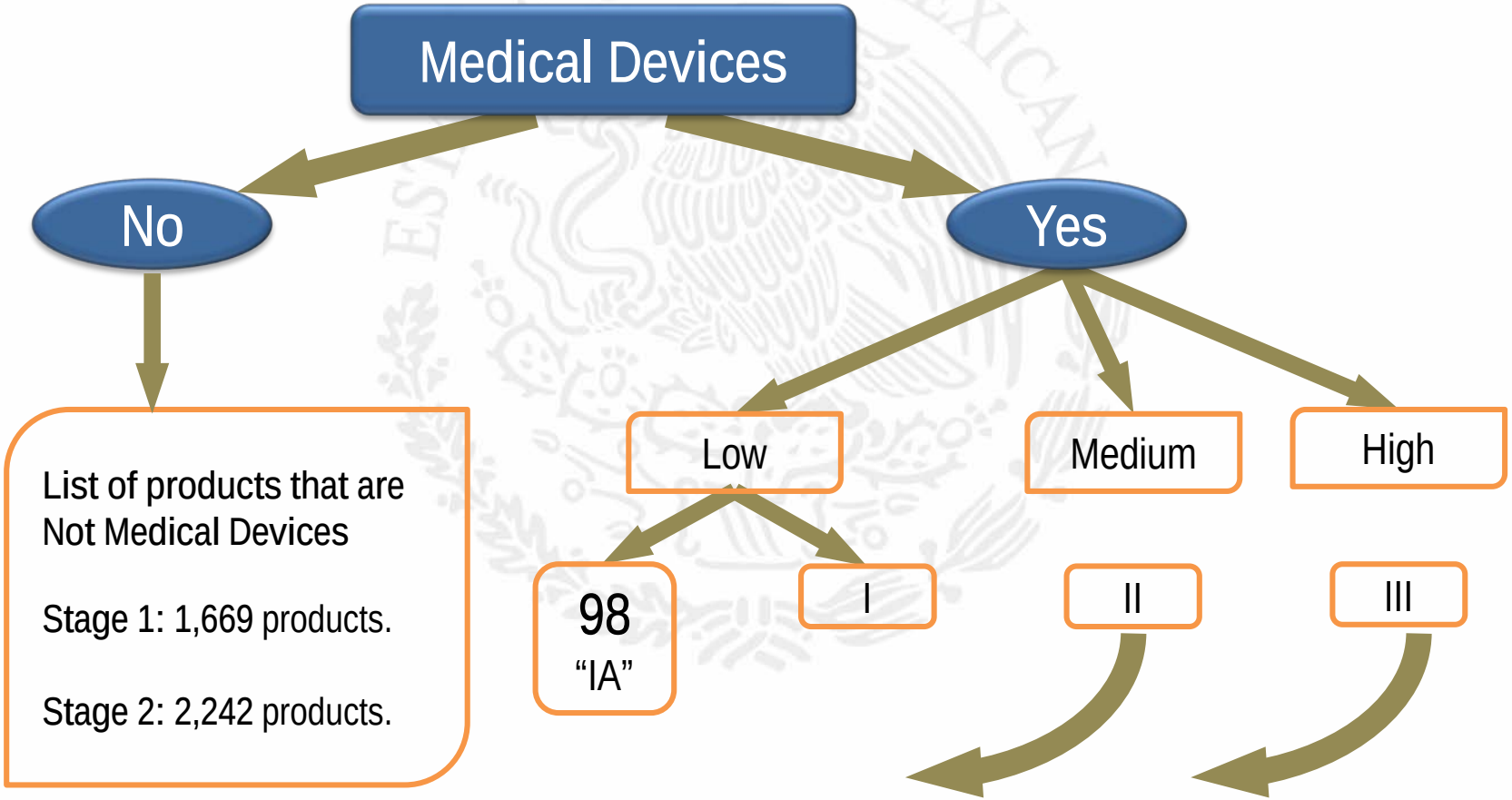
Deregulation of Medical Devices

The new scheme for the Medical Devices clasification was performed in two stages:

1. Stage 1: December, 2011 (1,669 products).
2. Stage 2: January, 2015 (573 products).



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Deregulation program of Medical Devices

- The **Medical Devices Desregulation program** implemented by COFEPRIS, gives the following results:

Deregulation of Medical Devices Comparative Staged			
	Stage 1	Stage 2	Total
MD excluded from registration (units)	1,669 products	573 products	2,242 products
Reduced in the regulatory load (%)	12.1%	4.1%	16.2%
Releasing of economic resources	4,021 million of pesos	1,414 million of pesos	5,435 million of pesos
Releasing of economic resources (% of GDP)	0.031% of GDP	0.007% of GDP	0.038% of GDP
Releasing of economic resources (% of MD market)	12.9% of MD market	4.5% of MD market	17.4% of MD market

- These actions allow a more efficient use of economic resources for the industry of medical devices.

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Issuance of Registrations through Equivalence Agreements

- The scheme is based upon the recognition of the registrations issued by FDA, Health Canada, and Japan for medical devices of any class and COFEPRIS will issue the corresponding registration in a maximum period of 30 working days.

Received Applications	4,824
Market Value of the applications	417.5 million dollars in the Mexican market (2.09 million pesos each registration).
Reduction in the Regulatory Burden	40%
Approved Applications	64% from FDA 33% from Health Canada 3% from Japan
The Incoming Applications Correspond to: (Medical Devices)	33% Class 1 40% Class 2 27% Class 3

- To this date 3,681 sanitary registrations have been approved by COFEPRIS.

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Recognition of foreign Certificates for Good Manufacturing Practices

Considering the high impact of the on site visits on the process of approval and renewal of sanitary registrations, Mexico published on June 22, 2011 guidelines to expedite and facilitate the process:

1. The certificates of GMP´s issued by FDA (USA), ANVISA (Brazil), Health Canada, Pharmaceutical and Food Safety Bureau (Japan), TGA (Australia) and EMA independently of the country where the manufacturing plant is located will be recognized by COFEPRIS.

2. The on site verification of GMPs from COFEPRIS will be issued in favor of the manufacturing plant or the firm in question and not the firm doing the import.

3. Consequently, the recognized GMPs by COFEPRIS could be used by any economic agent to obtain the sanitary registration or the corresponding extension.

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Recognition of Certificates of Good Manufacturing Practices
Savings derived from the measure

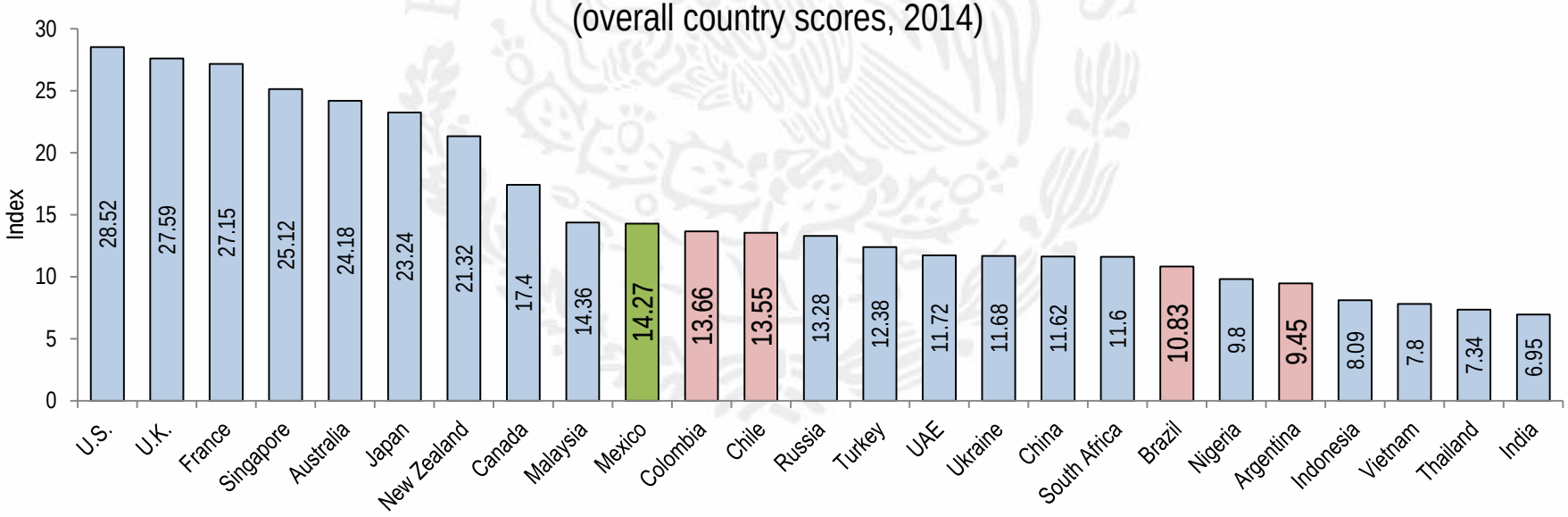
- The economic benefits are composed in 99% of the opportunity cost of the termination of the administrative process and represent about 200 million dollars.
- Each day the termination of an administrative process is delayed it has a cost between $50,000 and $60,000 pesos for the industry.

ESTIMATED BENEFITS OF DEREGULATION 1,339 GMP applications eliminated	
Concept	Million USD
Reduced Aggregated administrative burden	15.2
Reduced Aggregated Opportunity Cost	1,850.4
Total Economic Benefits	1,865.6 0
Savings as percentage of domestic GDP	**0.015%**

Intellectual Property Rights in Mexico

- An international comparison shows that Mexico is a trailblazer regarding the protection of intellectual property rights.
- According to the Global Intellectual Property Center (GIPC) Index of the U.S. Chamber of Commerce, Mexico is ranked the highest among Latin American countries.
- This index measures three different types of intellectual property rights: patents, trademarks and copyright. It indicates the gaps between advances in legislations and their enforcement.

Global Intellectual Property Center (GIPC) Index
(overall country scores, 2014)



Source: Global Intellectual Property Center (GIPC, 2014). U.S. Chamber of Commerce.

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International Harmonization

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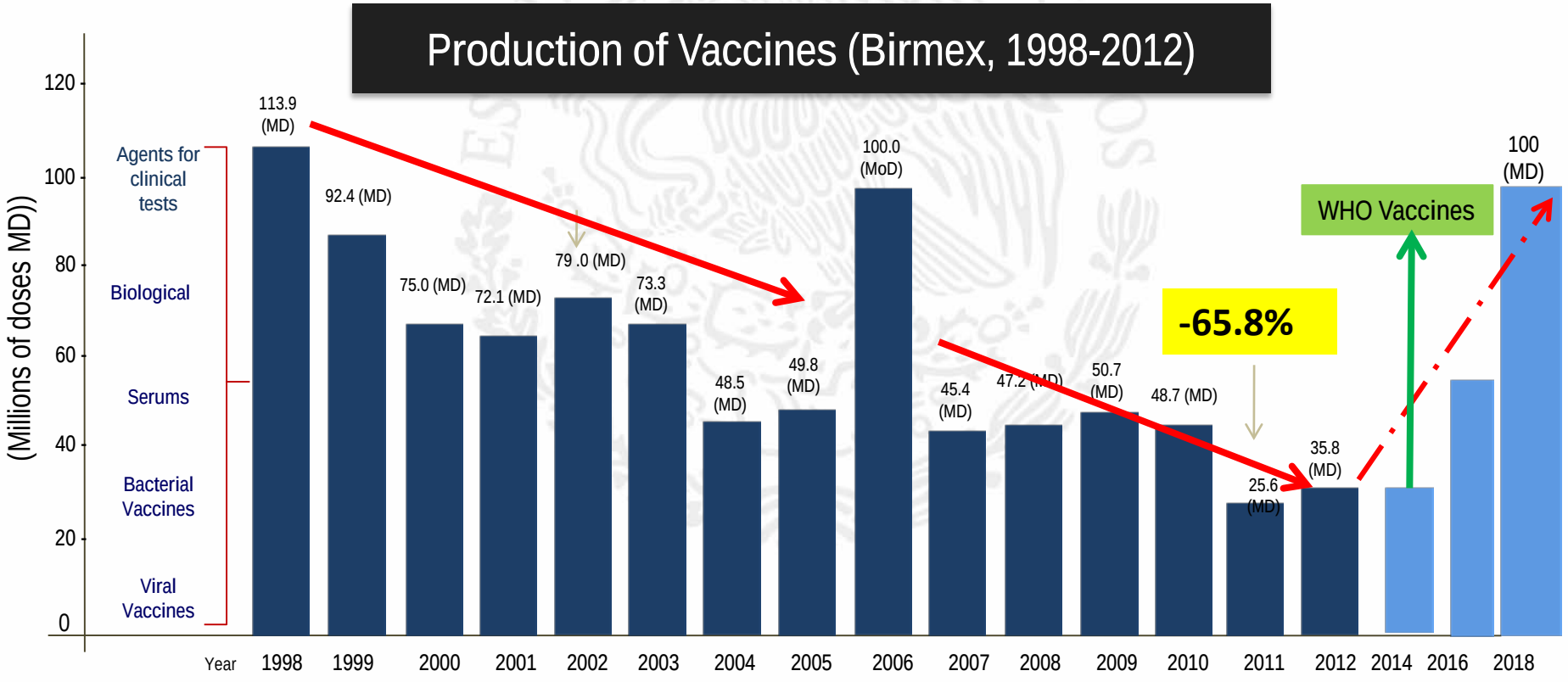
Recognition of COFEPRIS by the WHO for Vaccines

- In 2014, COFEPRIS was recognized by the World Health Organization (WHO) for vaccines and was declared as a FUNCTIONAL agency for the period June 2014 - June 2017.
- As a result, Mexico entered to the elite group of 28 countries holding this recognition, equivalent to only 14% of the world sanitary agencies.



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Recognition of sanitary registrations abroad

- In 2012, COFEPRIS became the fifth Latin American Agency to receive the PAHO Certification as regional reference body.
- As a result of this Certification, sanitary registrations issued by COFEPRIS are currently recognized in 7 countries: Ecuador, El Salvador, Colombia, Chile, Costa Rica, Panama and Belice.

COUNTRY	Population, 2012 (in millions)
Colombia	47.7
Ecuador	15.5
El Salvador	6.3
Chile	17.5
Costa Rica	5
Panama	3.8
Belice	0.3
TOTAL	96.1

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Sanitary Market Surveillance

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Regulation of advertisement versus «miracle» products

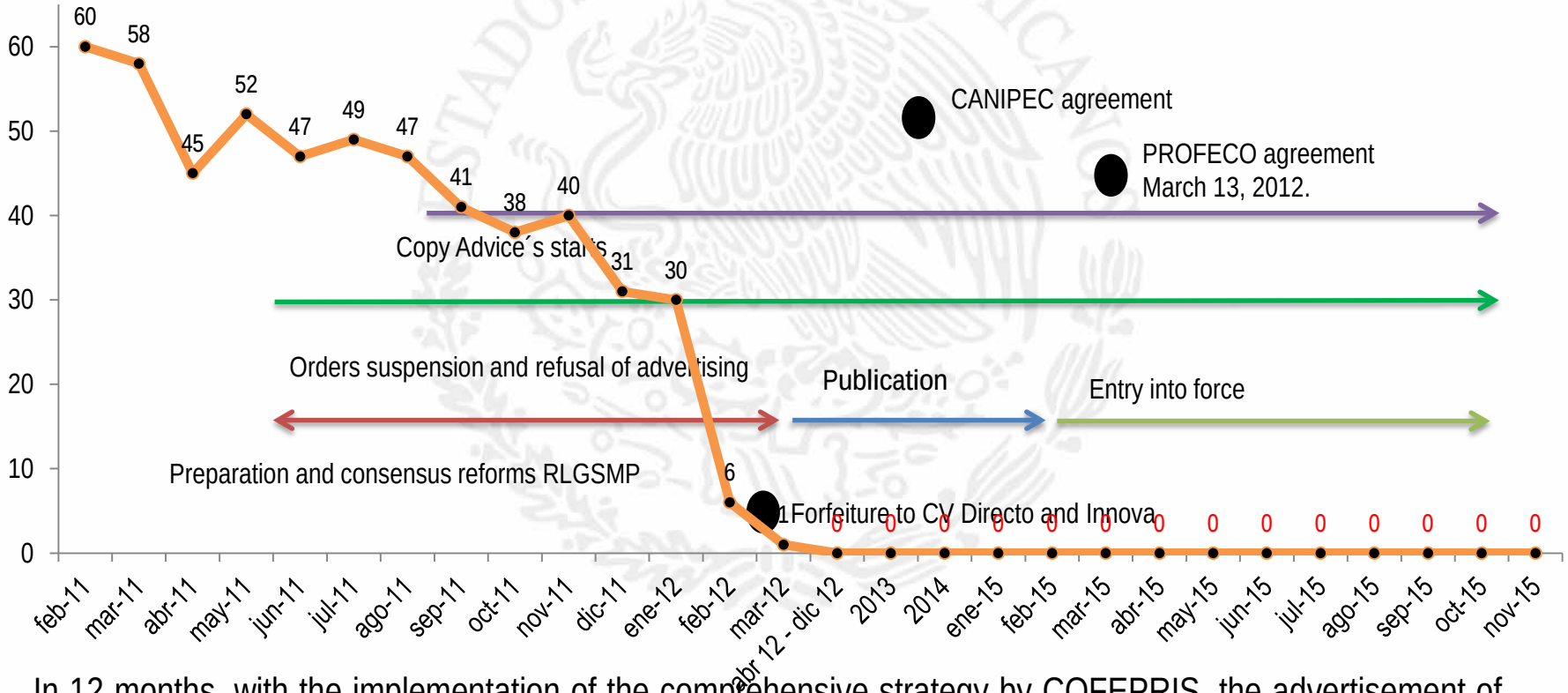
In its fight against informality, the Ministry of Health proposed the following reforms to the regulation of the Health Law regarding advertisement:

- To require sanitary registration and/or advertisement permission to announcers in order to advertise products.
- To require the media to cease in 24 hours the advertisement for a product or service that does not comply with the legal provisions.
- Increase in 400% the sanctions imposed for not complying with the provisions of the regulation.

The reform was published in the Official Gazette on January 19, 2012 and it was enabled on March 2, 2012.

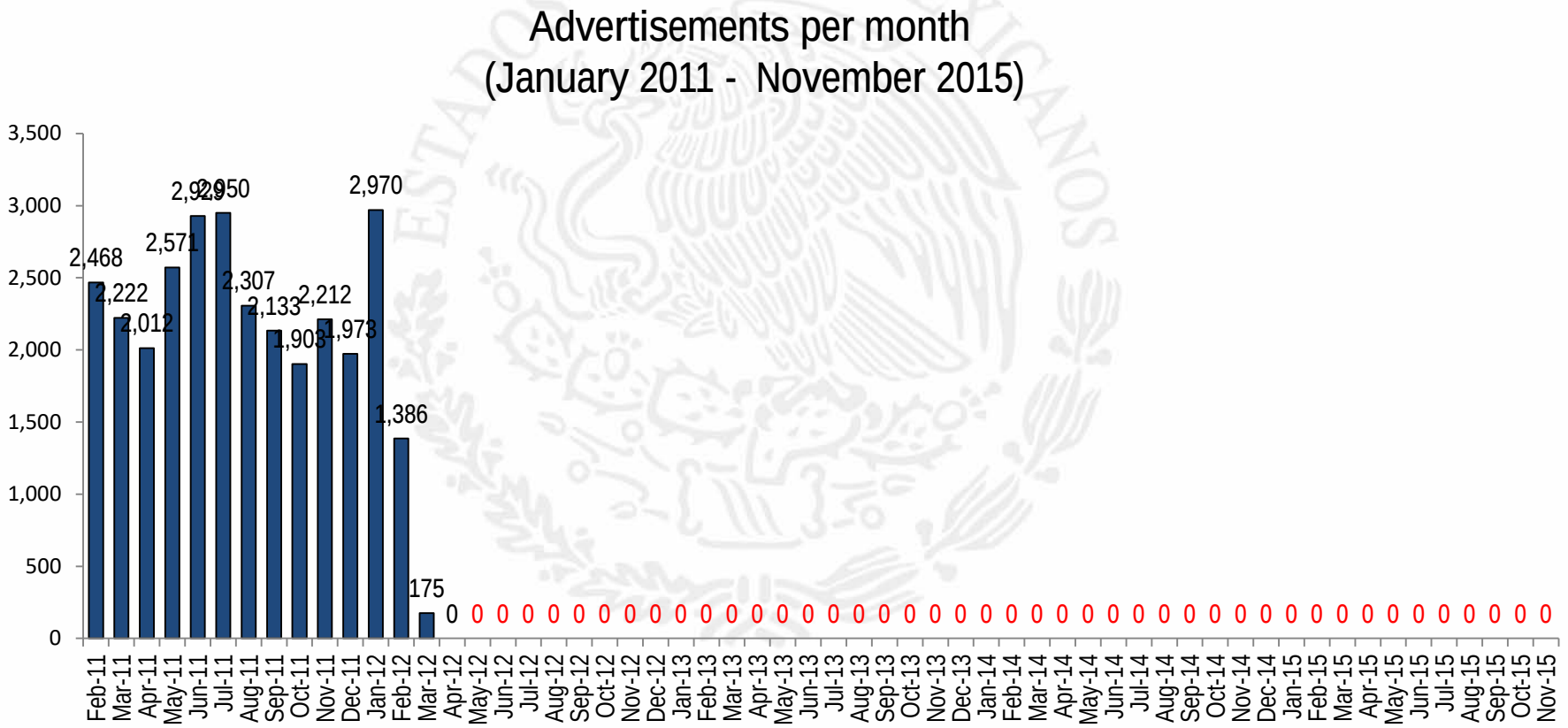
Regulation on advertisement of «Miracle» Products

- On January 18, 2012 the Health Law was amended aiming to prevent and stop misleading advertisement of fake miracle cures.



In 12 months, with the implementation of the comprehensive strategy by COFEPRIS, the advertisement of unauthorized products was reduced in 100%, from 58 to 0 products with media appearances.

From **January 2011 to March 2012**, media appearances of such "miracle" cures was reduced about 87.4%. In november, 2015 there were no media appearances.



- The strategy of sanitary surveillance includes seizures of **tobacco**, **alcohol**, **clenbuterol**, **«miracle» products and health supplies.**
- From 2011 to Junly 2016, a total of **58 slaughterhouses** have been suspended.
- With this strategy COFEPRIS has increased its efficacy in **67,885%** during **2011 – July 2016** compared with **2010**, on average.

Sanitary surveillance: Inspections and forfeiture of products (2010-2016*)					
Product	2010	2011-2016	Total	Growth rate	Average growth rate
Tobacco	40,000 cigarettes	301,419,072 cigarettes	301,459,072 cigarettes	515,581%	67,885%
Alcohol	87,175 litters	5,127,615 litters	5,215,331 litters	2,340%	
Clenbuterol	0 suspended slaughterhouses	58 suspended slaughterhouses	58 suspended slaughterhouses	-	
«Miracle» products	40,000 units	3,944,772 units	3,984,772 units	6,268%	
Health Supplies*	2.5 tons.	381.57 tons. (medicines); 9,005,785pieces (med. devices)	384 tons. (medicines)	14,513%	

Source: COFEPRIS (2014). Includes data from 2010 to July, 2016.

* On medicines comparison is between 2009 and the sum of inspections from 2010 to 2016.

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Conclusions

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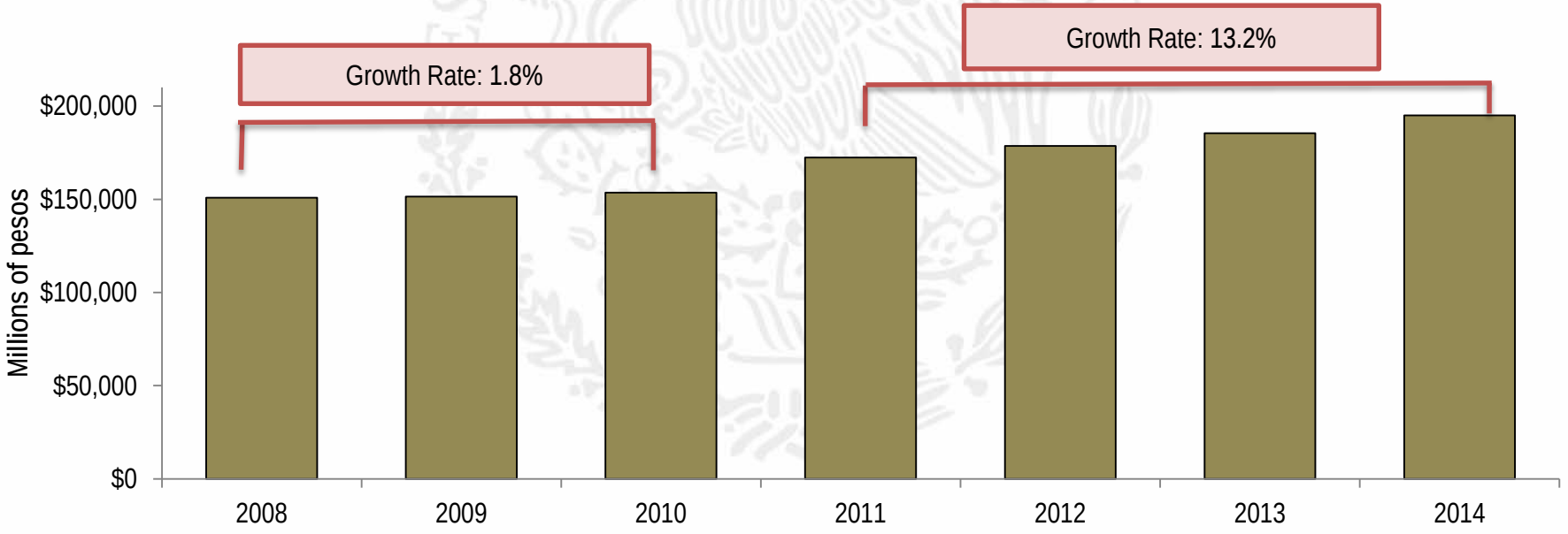
- The Mexican pharmaceutical market, estimated at 195.1 billion pesos in 2014, ranked among the 15 most important world markets and the second in Latin America.

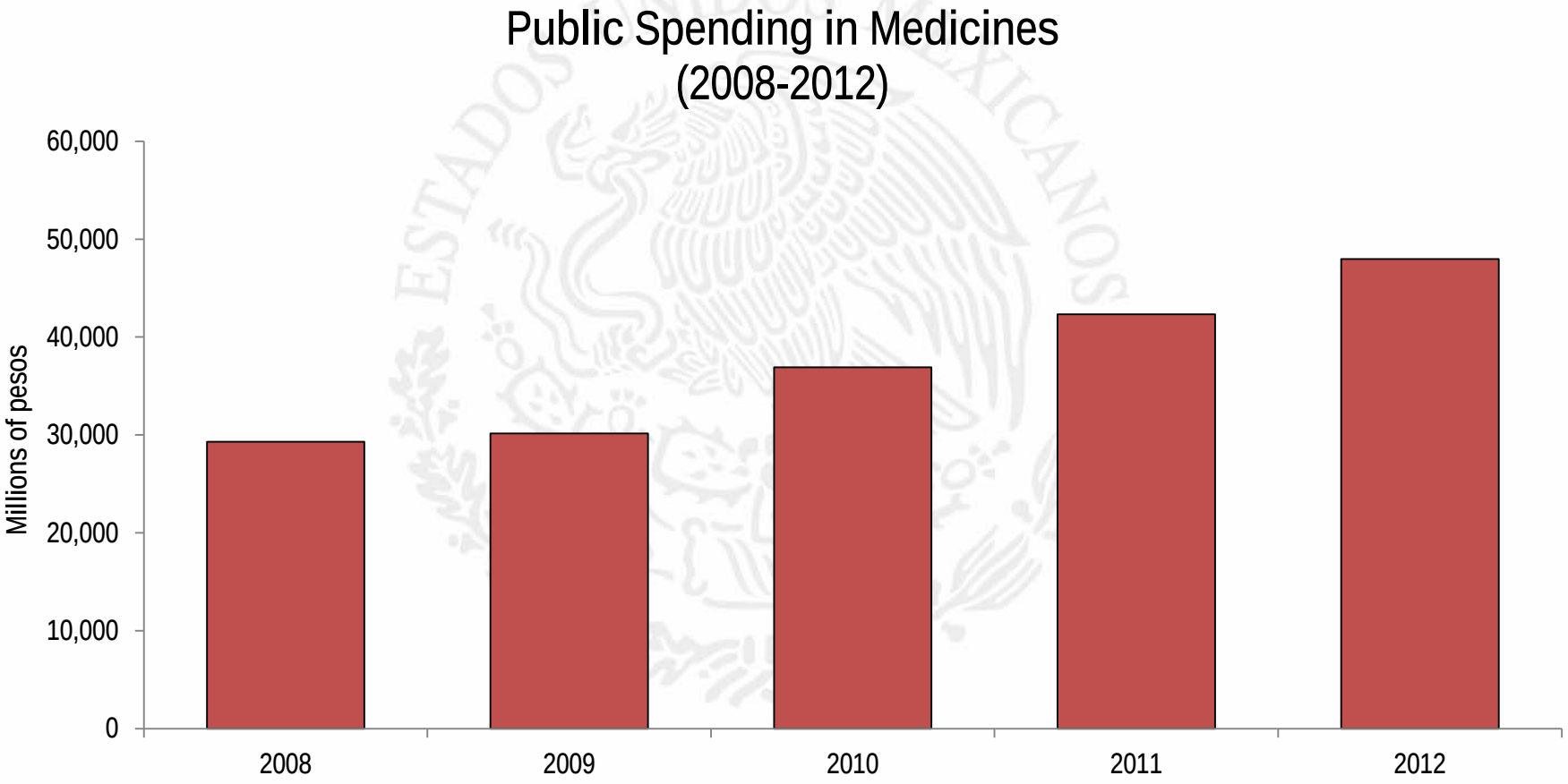
- Between 2011 and 2014, the growth of the mexican pharmaceutical market was of 13.2%, while in the period of 2008-2010, the rate reached only 1.8%.

Value of the Mexican pharmaceutical market, 2005-2014*
(millions of pesos)



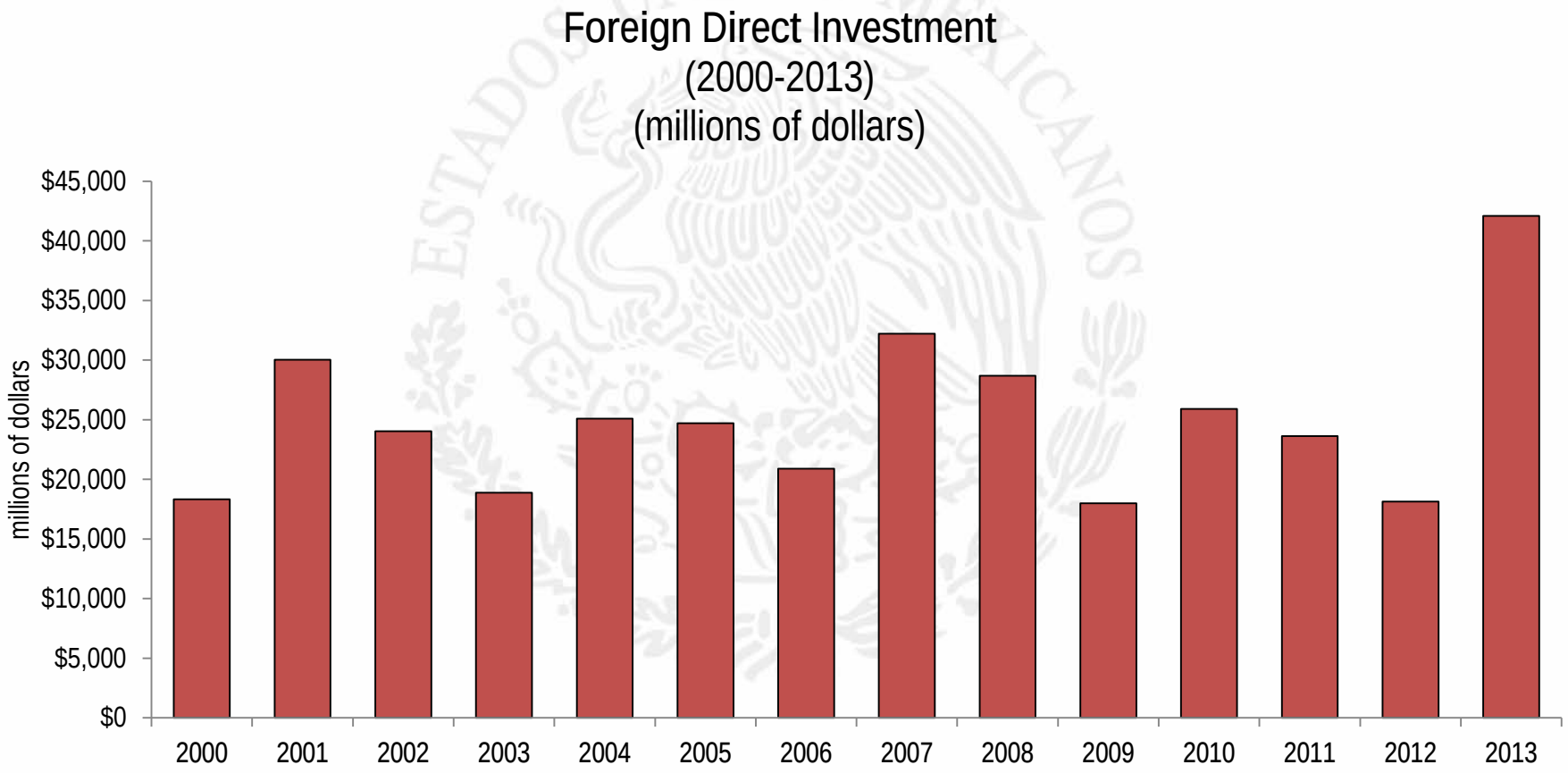
Source: COFEPRIS, witth data from INEGI (2011) and CANIFARMA (2015).
*Estimated value for 2014.

- From 2008 to 2012 government spending in medicines increased by 64%.



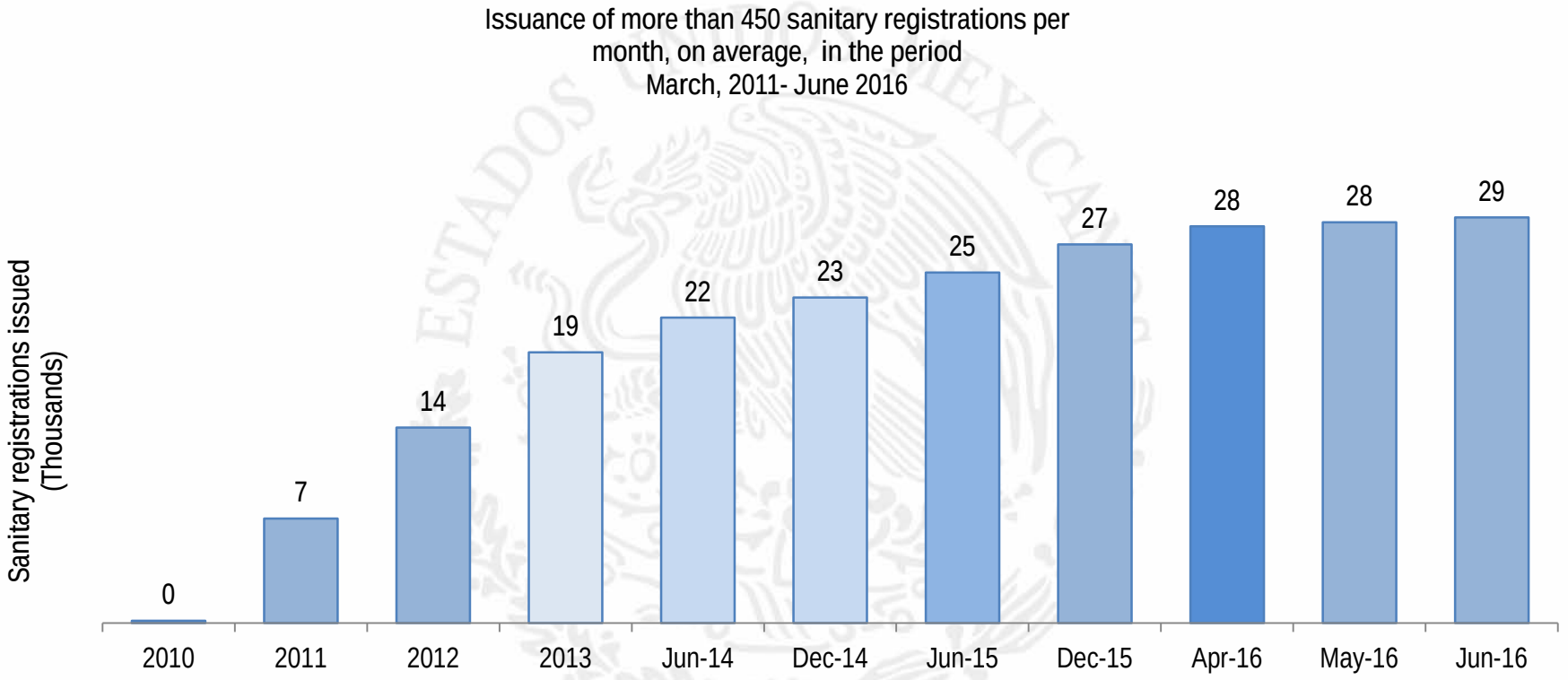
Source: Author´s elaboration with data from SINAIS, SS.

- Mexico received 337.6 billion dollars in Foreign Direct Investment between 2000-2013, which represents a yearly average of 10.5%.



Source: INEGI (2015).

- The issuance of 28,802 sanitary registrations from March 2011 to June 2016, represents a market value greater than 2.4 **billion dollars**. Progress has been as follows:



- A total of 18,556 **sanitary registrations** have been issued from June 2012 to June 2016. This improvement implies an average of 379 **monthly registrations**. The issuance of sanitary registrations will continue growing given that **COFEPRIS regulates 10% of GDP**..

- The Ministry of Health has an important tool to impact the economy in a positive manner through the application of sanitary regulation with measures that increase the efficiency of operation in the regulated sectors.

- Through the use of simplified processes of authorization and sanitary regulation, growth and economic benefits for more than 100 billion pesos in those regulated sectors have been created, specifically in pharmaceutical, pharmaceutical chemistry, food and agrochemical industries.

- There is a causal relationship between the efficiency and transparency of health policy and the economic growth in the regulated sectors.

- For the implementation of these actions is crucial a permanent coordination between the Ministry of Health / COFEPRIS and the Ministries of Finance, Economy, Foreign Affairs, Environment and Agriculture in order to generate comprehensive public policies.

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COFEPRIS: Using regulation to better protect the population's health and transform the market.

The Case of Mexico

September 2016