

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

The Case of Mexico

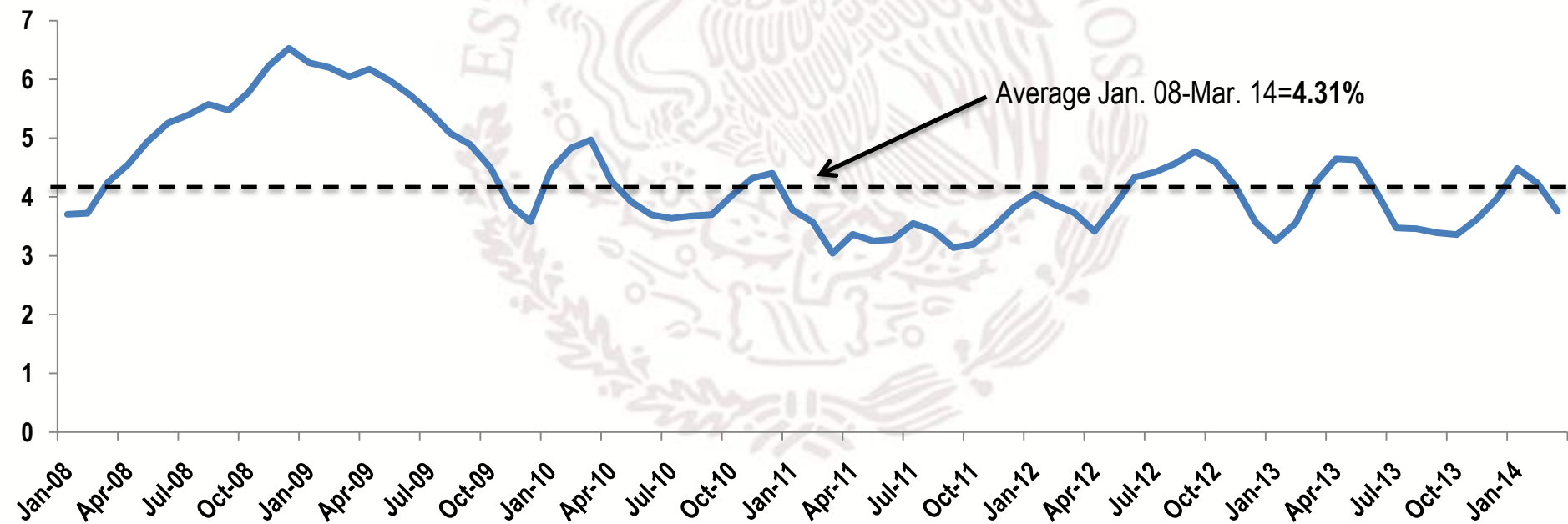
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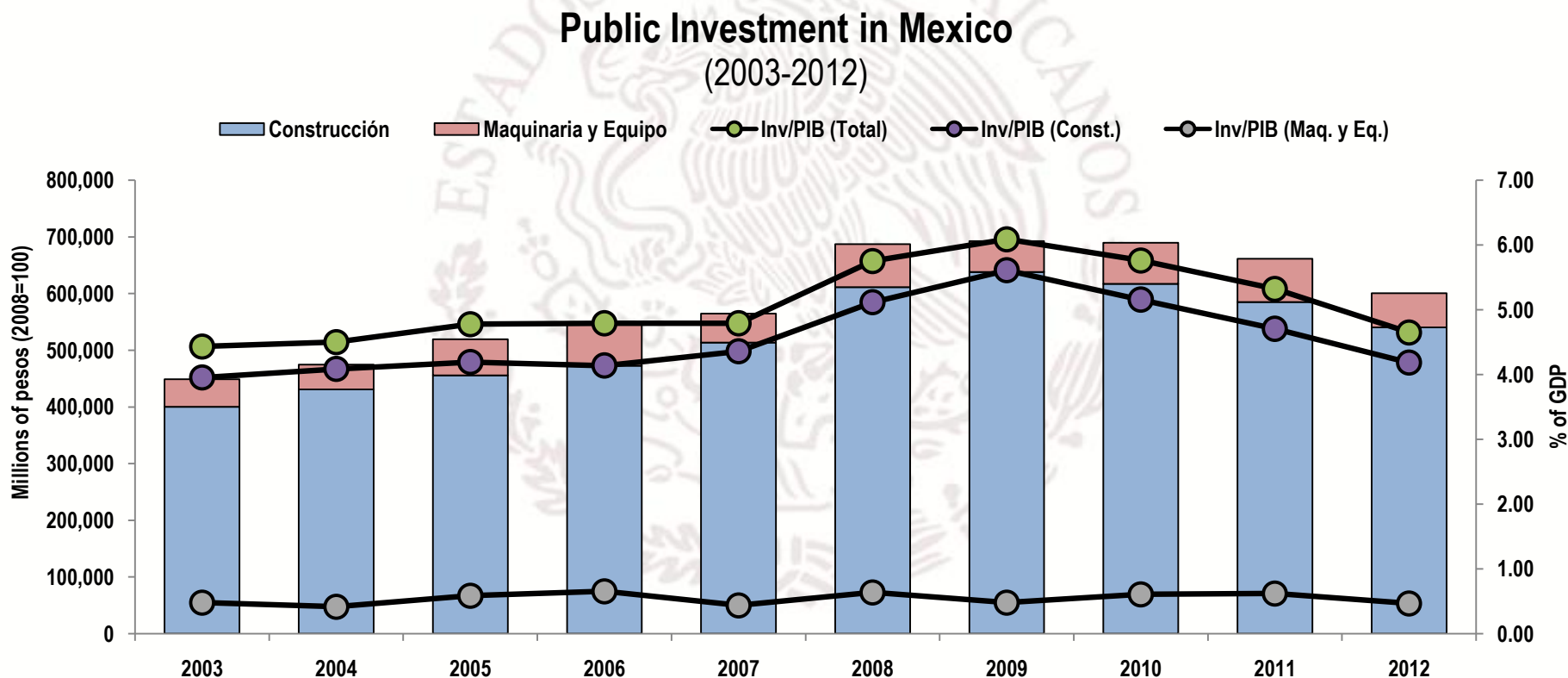
I. ECONOMIC ENVIRONMENT

- Average annual inflation in Mexico from January 2008 to March 2014 was only **4.31%**.
- After the 2009 period of volatility and starting in March 2010, inflation has remained within the range laid-out by the Mexican Central Bank (**2% - 4%**).
- During 2012 inflation remained below 5.0% generating confidence for both consumers and producers.

**Annual Inflation
(January 08 – March 14)**



- **Public investment in Mexico** has experienced a substantial increase over a 10 year lap. In 2003 this indicator was calculated at **450 billion pesos** or 4.43% of GDP and in 2012 it increased to **600 billion pesos** or **5.15% of GDP**. This represents a growth rate of **34%** for the 2003-2012 period.
- Construction and infrastructure has been the most important recipient of public investment.



Source: INEGI (2013).

Note: Public investment was proxied by the **gross fixed capital formation of the public sector**.

- Mexico received **337,595** million dollars in Foreign Direct Investment between 2000-2013, which represents a yearly average of **10.5%**.

Foreign Direct Investment (2000-2013) (millions of dollars)



II. INDUSTRIES REGULATED BY COFEPRIS

- The Federal Commission for the Protection Against Sanitary Risks (COFEPRIS) is the Mexican institution responsible to guard and preserve the citizen's constitutional right to Health through sanitary vigilance, regulation, and outreach.
- COFEPRIS was conceived by law as a macro sanitary regulator compared to other international sanitary agencies which regulate specific industries individually.

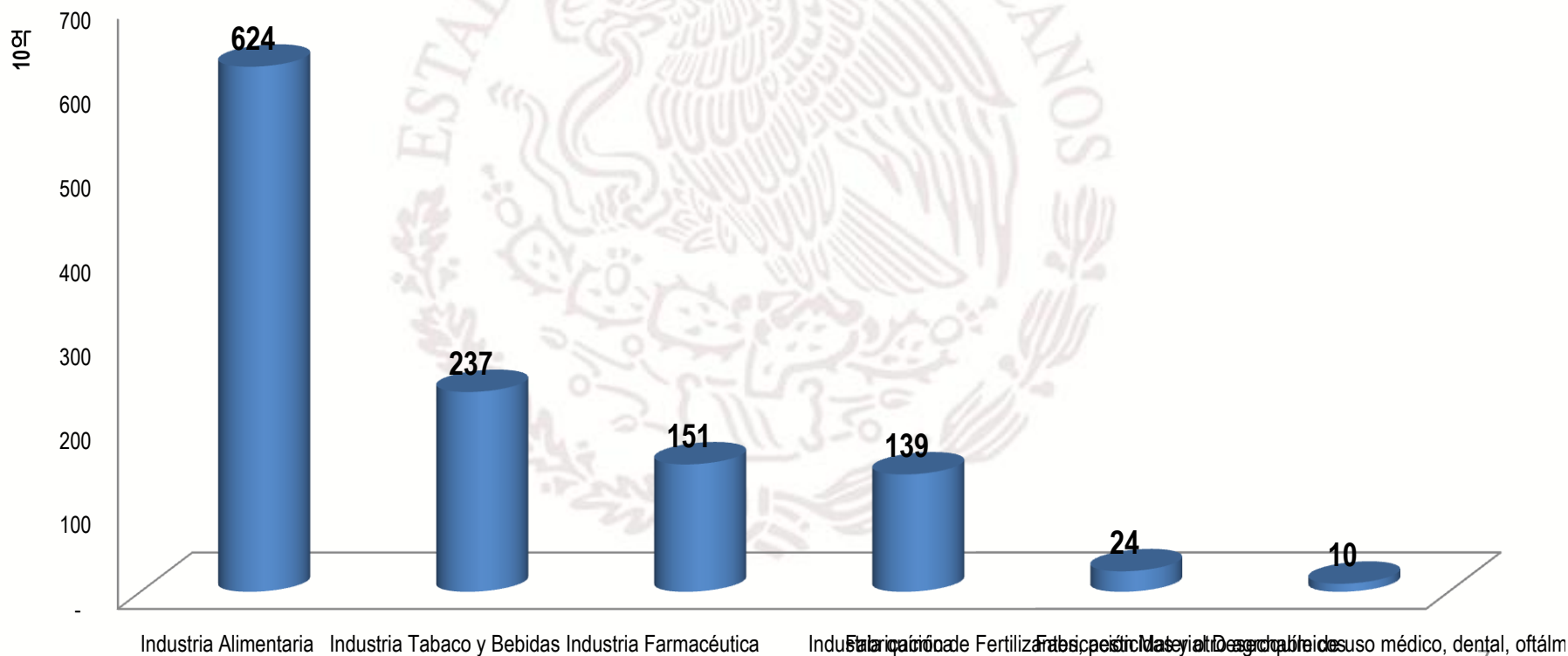
Regulated Sectors

1. Food and Beverages
2. Health Supplies
3. Health Services
4. Cosmetics and beauty products
5. Pesticides, Vegetable nutrients and Toxic substances
6. Emergencies
7. Labor Safety and Health
8. Environmental Risks



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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III. MEXICAN PHARMACEUTICAL DATA AND INDICATORS

- The pharmaceutical industry is strategic and of high priority in the country because of its close relationship with the economy and importance for the health of the population.

Macro Data of the Mexican Pharmaceutical Industry (last available data, INEGI 2013, OECD 2011, IMS Health 2012)	
Share of GDP	1.2%
Share of Manufacturing GDP	6.8%
Annual Exports (US million)	2,200
Health expenditures as a share of GDP	6.1%
Annual Health expenditures per capita (USD)	934
Value of the Pharmaceutical Market (billion USD)	13
Direct Employment	78,500
Indirect Employment	330,000

Source: Authors's elaboration with data from INEGI (2013), OECD (2011) and IMS Health (2012).

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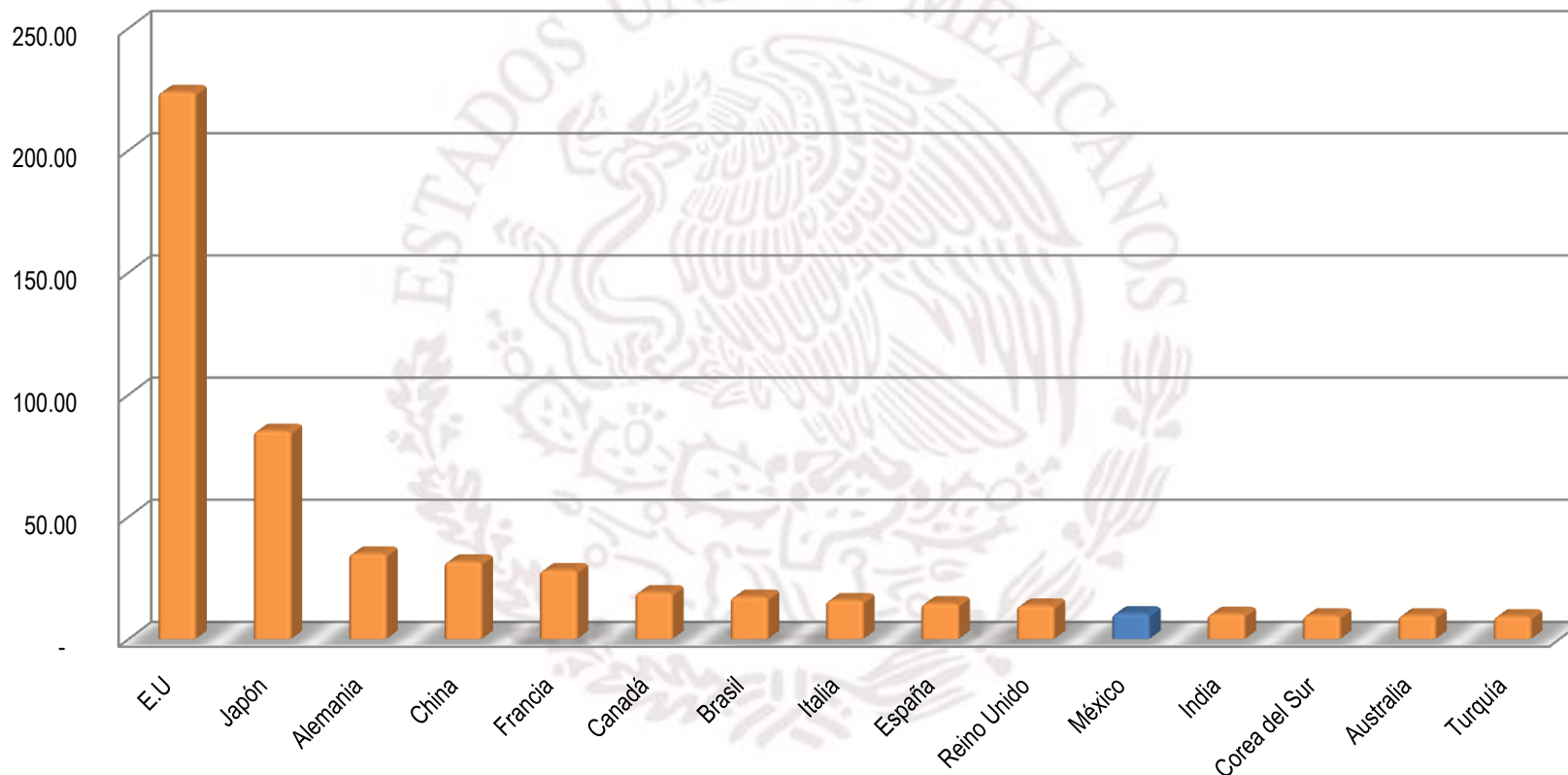


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- Mexico holds the 11th place within the 15 largest pharmaceutical markets.

Value of the 15 largest pharmaceutical markets, 2009
(Billions of USD)



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IV. PHARMACEUTICAL POLICY

Characteristics

- 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 efficacy 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.	

V. COMPREHENSIVE ADMINISTRATIVE SIMPLIFICATION PROGRAM

In the past, the pharmaceutical policy in Mexico was clearly weak due to:

- Backlog in the issuance of around **8,000** applications for health supplies.
- Administrative disarray that prevented COFEPRIS from providing timely and predictable service to its users.
- Pending regulations to eliminate market barriers and disarray on the legal framework.
- Lack of a clear and dynamic international agenda.

In March 2011, the Mexican Government launched a strategy to **reinforce the sanitary regulator** and **strengthen pharmaceutical policy**.

VI. BACKLOG REDUCTION

Drugs and Medical Devices Specialized Lanes

- In the past and before this strategy was implemented, every document filed before COFEPRIS was processed through a single authorization lane.
- To expedite the sanitary authorization process, specialized lanes considering a risk-based approach were implemented:

Lane		Characteristics and Operation
LANE 1	Administrative Paperwork	
LANE 2	Pharmaceuticals, Classes I, II, III	Subdivided in 3 production lines: <ul style="list-style-type: none"> i) Extensions ii) Modifications iii) New sanitary registrations
LANE 3	Pharmaceuticals, Class IV	Subdivided in 3 production lines based on a risk point system
	Pharmaceuticals, Classes V, VI	Subdivided in 3 production lines: <ul style="list-style-type: none"> i) Extensions ii) Modifications iii) New sanitary registrations

Health Supplies

Simplified Vaccine Liberation



- The guidelines for the scheme were published in the Official Gazette of the Federation (DOF) on June 1st, 2011.
- The new scheme implies a **2-month waiting time reduction**.
- The maximum allowed response time was reduced from **three** to only **one month**.
- During 2013, a total of **40.5 million doses of vaccine** were released.
- Since the new guidelines were published, a total of **108.7 million doses** have been released.

Waiting time was reduced from
1 year to 3 working days for
administrative procedures

Pre-verification of administrative paperwork

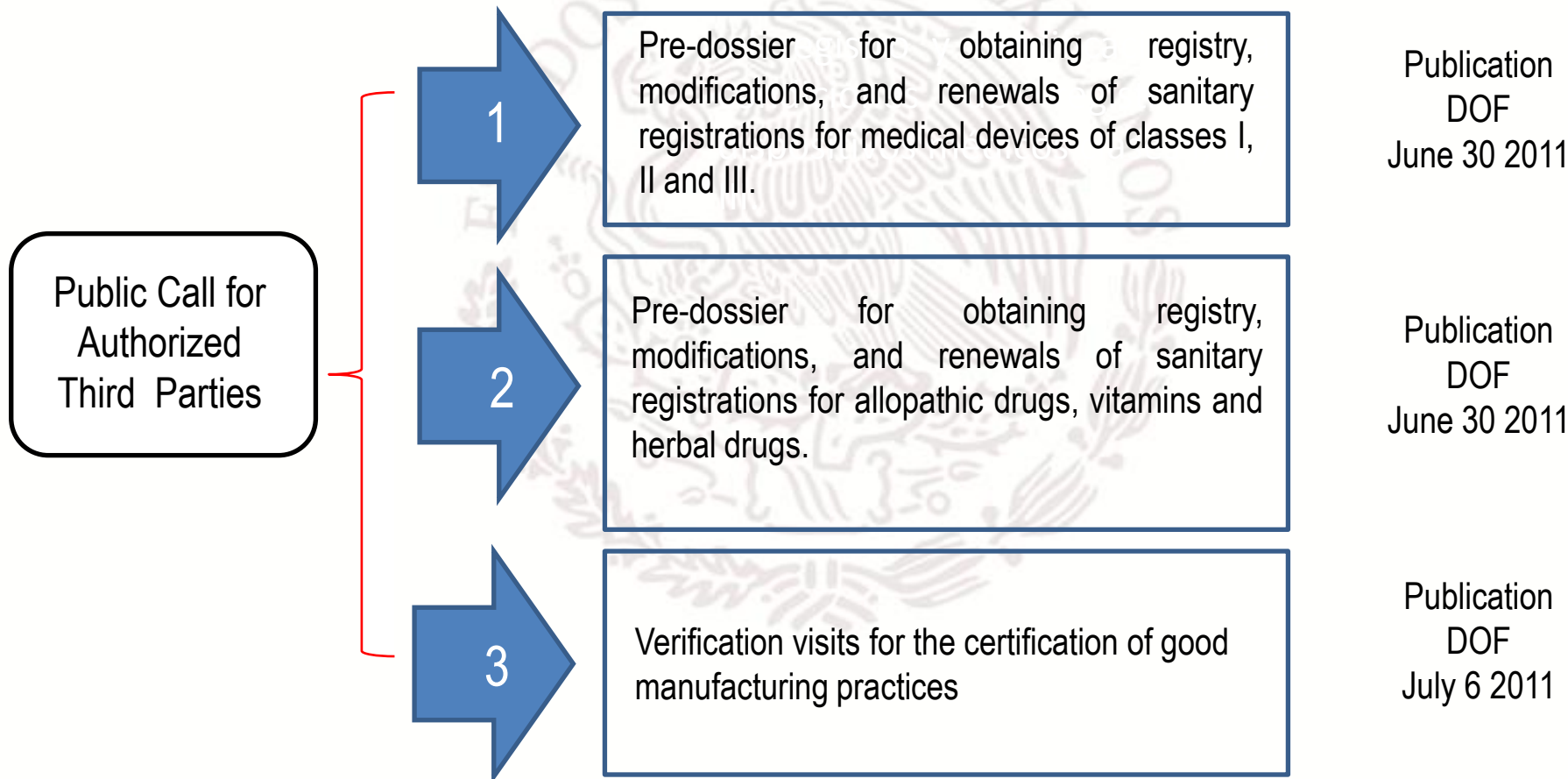
COFEPRIS has issued **8,762 sanitary registrations** under the simplified procedure within 3 to 15 working days.

	STATUS	NUMBER
Allopathic Drugs <ul style="list-style-type: none"> Lane started on June 16th, 2011 On average processes 112 files per month, or 4 per day 	AUTHORIZED	3,559
	WARNINGS	442
	IN PROCESS	188
	WITHDRAWALS	24
	SUB TOTAL	4,213
Medical Devices <ul style="list-style-type: none"> Lane started on August 5th, 2011 On average processes 107 files per month, or 4 files per day 	AUTHORIZED	3,480
	WARNINGS	39
	IN PROCESS	60
	SUB TOTAL	3,579
Instructions for Prescriptions <ul style="list-style-type: none"> Started on May 1, 2012 On average processes 37 files per month or 1 per day 	AUTHORIZED	767
	WARNINGS	130
	IN PROCESS	73
	SUB TOTAL	970
	TOTAL	8,762

Calls for Authorized Third Parties

Allopathic drugs, medical devices and plants

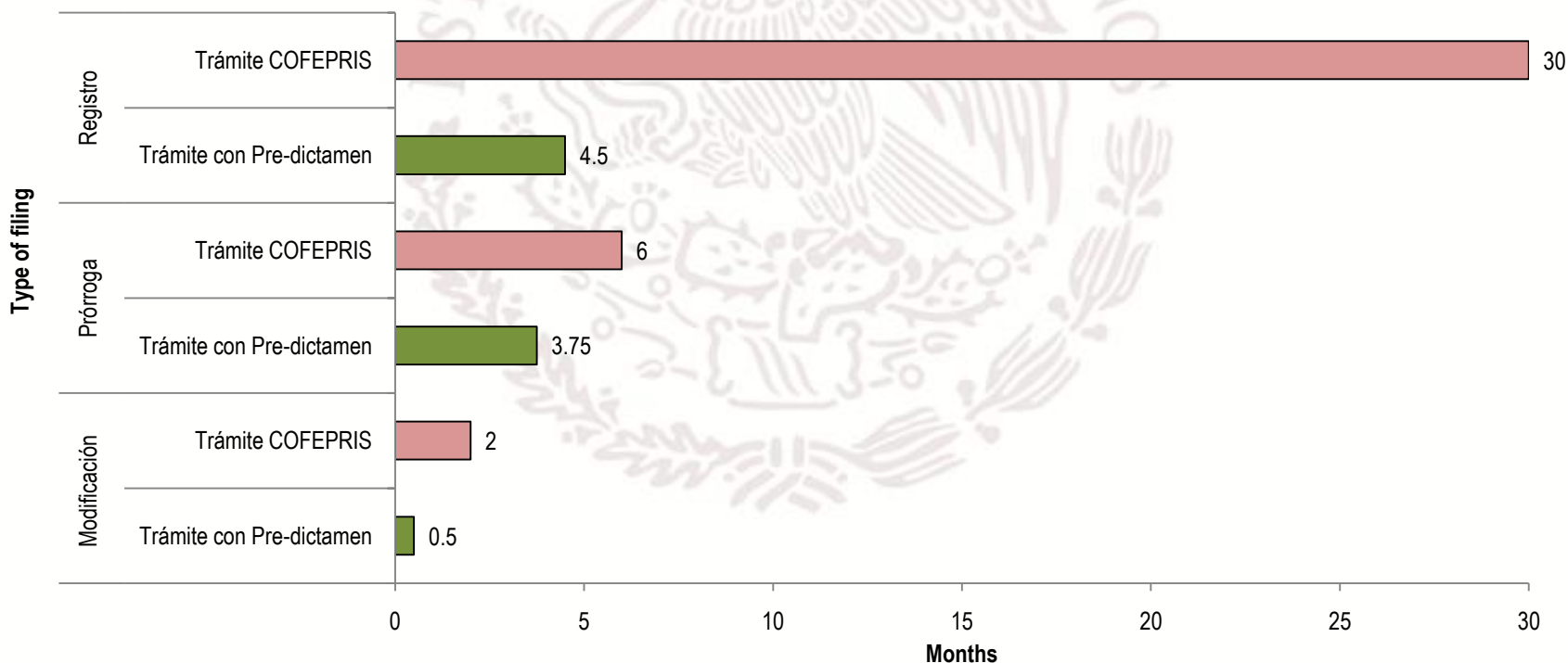
- Public calls were published with the objective of reducing the sanitary authorization waiting times by two thirds, (i.e. going from 2 years to 4 months).



Benefits of Authorized Third Parties

- The “**Pre-dictamination**” of Third Parties allows the authority to reduce significantly the processing time of each individual filing. For example, in the case of new registrations the processing time reduction is approximately reduced by **2 years on average**.

Average processing time for filings of drug products (months)



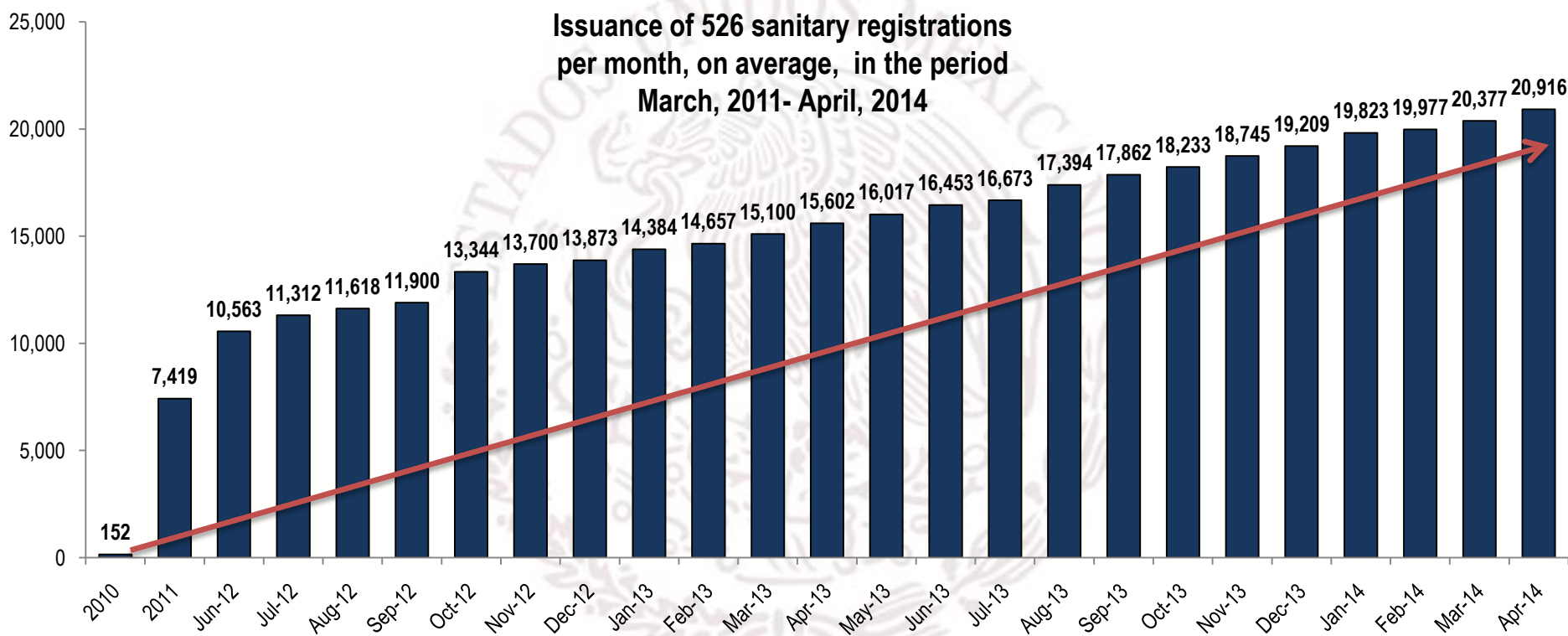
Authorized Third Parties

- There are **15 Authorized Third Party Companies** currently in operation and **1,701 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	739	374	644
	Extensions	255	128	233
	Modification	500	207	450
Medicines	New Registration	182	237	109
	Extensions	108	165	58
	Modification	296	273	207
Total		2,080	1,384	1,701

The issuance of **20,916** sanitary registrations from March 2011 to April 2014, represents a market value greater than **2.4 billion dollars**, and has a growth rate of **13,660%** relative to 2010. Progress has been as follows:



- A total of **10,353 sanitary registrations** have been issued from June 2012 to April 2014. This improvement implies an average of **450 monthly registrations**. The issuance of sanitary registrations will continue growing given that **COFEPRIS regulates 10% of GDP**.

VII. LEGAL FRAMEWORK TO ELIMINATE BARRIERS TO ENTRY

Introducing generics into the market increases savings for both the government and consumers

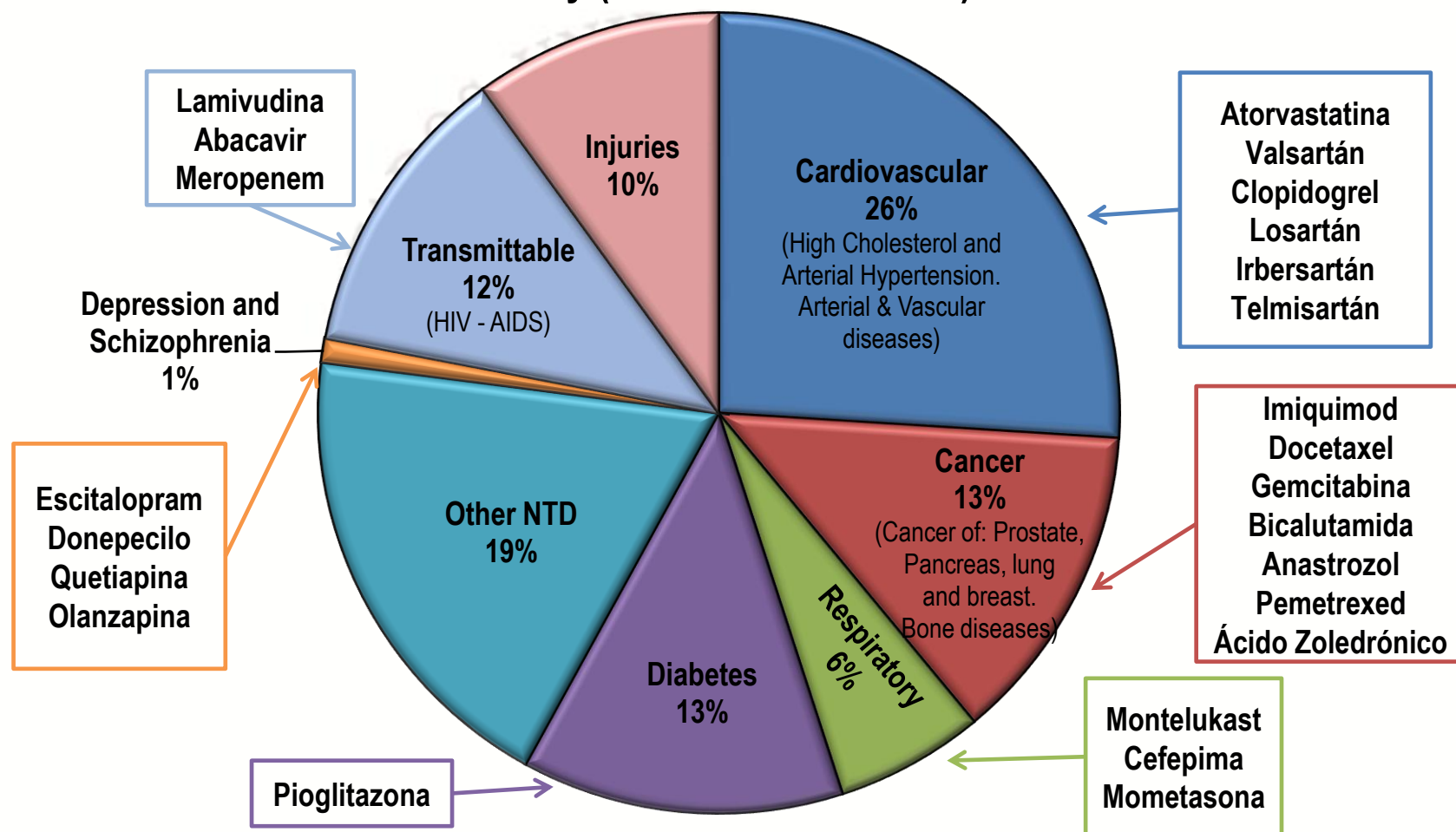
- Direct Benefits for the public sector:
 - Savings in government expenditures.
 - Increases in the capacity to receive more patients.
- Direct Benefits to the consumer:
 - Increases in the supply of drugs for all pathologies.
 - Decreases in the price of drugs.
 - Decreases in out-of-pocket expenditures.
- Direct Benefits for the producer:
 - Removal of barriers to entry into the pharmaceutical market once the patent has expired.

- **A total of 29 active substances have been released from October 2011 to February 2014. This corresponds to 261 new registrations of generic medications addressing 71% of Mexico's mortality causes:**

Number of Packages	Released Substances	New Generics	Accumulated savings (billion dollars)	Additional Patients
10	29	261	1.50	1,084,300

In Mexico, 24 out of 29 active substances are related to 71% of the causes of death.

Mortality (% of total of deaths)



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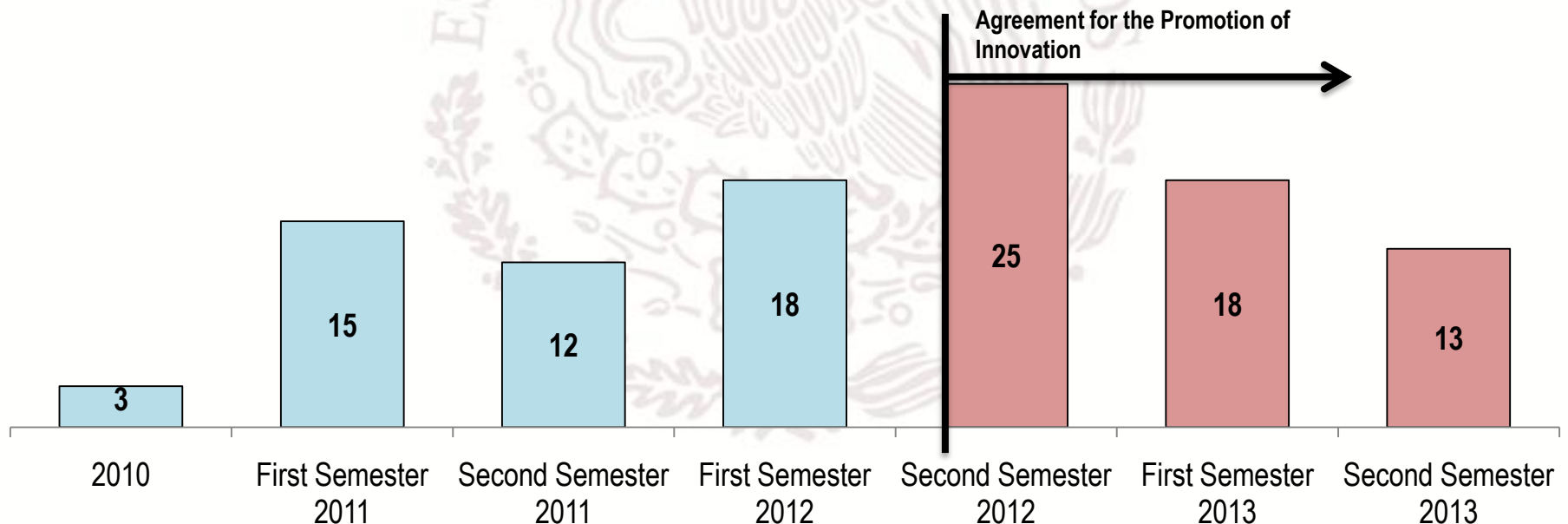
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Incentives for New Molecules

- Pharmaceutical innovation directly benefits consumers through: 1) lower drug prices; 2) reductions in hospital stay days; and 3) increases in the quality of life and life expectancy.
- During 2011 and 2013, COFEPRIS issued **101 sanitary registrations** for innovative drugs for the treatment of cardiovascular diseases, oncological diseases, and other medical conditions. This represents an increase of 3,267% relative to 2010.

Sanitary Registrations Issued for Innovative Drugs



VIII. REGULATORY REFORM AND DE-REGULATION

Removal of the requirement 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 **298** 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 next five years.

100% increase in the workforce of the firms involved.

Deregulation of Medical Devices

Due to this simplification procedure:

- 1,669 products** will no longer be considered medical devices, reducing the regulatory burden by **12.1%**.
- The implementation of this scheme will represent savings of at least **4,021 million pesos**, which amounts to **0.031%** of GDP and **12.9 %** of the market of medical devices.
- 99% of the economic benefits is the opportunity cost of solving the administrative procedures.

BENEFITS OF DEREGULATION	
1,669 Products not considered as Medical Devices	
Concept	Million USD
Reduced Aggregate Administrative Burden	25.6
Reduced Aggregate Opportunity Cost	3,990.8
Total Economic Cost Reduction	4,016.5
Cost reduction to COFEPRIS due to lower consultations	5.0
Total Economic Benefits	4,021.5
Savings as a share of GDP	0.031%

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	3,748
Market Value of the applications	337 million dollars in the Mexican market (1.51 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)	35% Class 1 38% Class 2 27% Class 3

- To this date **2,930** sanitary registrations have been approved by COFEPRIS.

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.

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 GDP	0.015%

Protection of Intellectual Property

- An international comparison shows that Mexico is a trailblazer regarding the protection of intellectual property rights. Mexican Legislation awards Data Protection for a period of 5 years.
- The **Linkage system** is also included in the Mexican Legislation. When COFEPRIS receives a sanitary registration application the agency verifies that patent rights are not being violated. **Both patents for active substance and formulation are included.**

Data Protection and Linkage in various countries

	Mexico	Argentina	Brazil	Colombia
Data Protection	100%	0%	0%	100%
	<ul style="list-style-type: none"> • The Legislation contemplates exclusive rights for data protection. • Data Protection is awarded for 5 years. 			<ul style="list-style-type: none"> • Data Protection is included in Colombian legislation. • Data Protection is awarded for 5 years.
Linkage	100%	0%	0%	0%
	<ul style="list-style-type: none"> • The scheme is featured in article 167 bis of the RIS. • Protection to Intellectual Property: <ol style="list-style-type: none"> 1. Patent for Active Substance. 2. Formulation Patent. 			
Member of TPP	YES	NO	NO	NO

IX. NTERNATIONAL HARMONIZATION

Recognition of Sanitary Registrations by Abroad

- **Ecuador:** Sanitary registrations issued by COFEPRIS are accepted by Ecuador through an expedited mechanism that reduces sanitary authorization times.
- **El Salvador:** Sanitary registrations issued by COFEPRIS are accepted by El Salvador through an expedited mechanism that reduces sanitary authorization times. To date, 150 Mexican products have been sold in this country.
- **Colombia:** With the Interagency Agreement between Sanitary Agencies of members of the Pacific Alliance, INVIMA and COFEPRIS recognize their GMP certificates, which avoids costs derived from verification visits to factories of health products and supplies.
- **Peru:** The Interagency Agreement between Sanitary Agencies of members of the Pacific Alliance establishes the obligation for the Peruvian regulatory agency to be certified as NRA IV, National Regulatory Agency of Regional Reference Level IV, in order to be able to benefit from trading.
- **Chile:** Through agreements with CENABAST and the enactment of a new law on drugs, Mexican companies are in a position to obtain an accelerated access to the Chilean market of government purchases.
- **Panama:** Mexico and Panama already signed a Mexico-Panama FTA., on April 3rd, 2014.
- **Costa Rica:** COFEPRIS and the sanitary agency from Costa Rica are pursuing the implementation of a procedure for administrative coordination.

Country	Colombia	Ecuador and El Salvador	Chile	Costa Rica	Panama	Total Currently	Peru	Total Expected
Population, 2012 (millions)	47.7	21.8	17.5	5	4	96	30	126

Source: COFEPRIS with data from World Bank (2013).

Recognition by the WHO of COFEPRIS for vaccines and pharmaceutical products

COFEPRIS began the process of recognition regarding vaccines which is granted by the WHO:

- 1) With the process that led to the recognition as a «national regulatory agency of regional reference» regarding medicines and vaccines, COFEPRIS has completed 80% of the WHO evaluation procedure regarding vaccines.
- 2) Seven critical steps have been defined in order to obtain the recognition of the WHO:

STEP 1	Reunion with representatives of the WHO about future colaboration and execution of the cooperation agreement.	FEBRUARY, 2013
STEP 2	Harmonization of procedure and evaluation tools WHO-PAHO.	FEBRUARY
STEP 3	Informal review in COFEPRIS with colaboration of WHO staff.	APRIL
STEP 4	Internal auditing on the fulfillment of the evaluation tool and on the quality management system	MAY – JUNE
STEP 5	Revision by the PAHO to assure level IV of COFEPRIS as a «national regulatory agency of regional reference» regarding medicines and vaccines.	AUGUST
STEP 6	Certification of Institutional Quality Management System based on international norm ISO 9001:2008.	NOVEMBER
STEP 7	Formal auditing to COFEPRIS by WHO regarding vaccines.	MARCH, 2014

The result of the audit was positive. Currently, COFEPRIS is in the period of resolution observations generated during the evaluation visit by WHO. June 14 is the date set by the WHO for the official delivery of results from the audit.

X. CONCLUSIONS

- Mexico's sound economic policies and stable macroeconomic indicators confirm that Mexico is a safe and attractive destination for investment all around.
- The Mexican Pharmaceutical industry has shown steady and dynamic growth to consolidate as Latinamerica's second largest market.
- The comprehensive strategic action plan applied by COFEPRIS directly attacked and eliminated the sources of inefficiency and opened the path to PAHO's certification.
- Transforming COFEPRIS into an efficient regulator has made the Mexican Pharmaceutical Sector ripe for investment and a launchpad for firms looking towards South America.
- These policies reduce distortions to the market providing certainty and predictability.
- Due to PAHO's certification, COFEPRIS' sanitary registrations are opening new markets throughout South America.

THANKS FOR YOUR ATTENTION