

## The role of health regulations in the rational use of medicines

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### Abstract

The Federal Commission for the Protection against Sanitary Risk (COFEPRIS by its initials in Spanish) is the state body responsible for transversely regulating various sectors of the Mexican economy, among them health services and inputs. Both cases are related to the rational use of medicines. The pharmaceutical policy of the Mexican Government is to prevent health risks by strengthening the effective and timely access to a market supplied with safe, effective, and quality products at the lowest possible prices. To date, the regulatory mechanisms used by COFEPRIS to ensure access to medicines and quality health services have been effective. With the implemented measures, self-medication has been reduced and medical services provided by pharmaceutical clinics comply with the best practices. Finally, the regulatory framework has been strengthened to fight the illegal drug market and "miracle" products. So far, the present administration has increased seizures of illegal substances and, as of today, all advertising guidelines for health-related products comply with the regulations. (Gac Med Mex. 2015;151:640-7)

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### COFEPRIS

The Federal Commission for the Protection against Health Risks (COFEPRIS – *Comisión Federal para la Protección contra Riesgos Sanitarios*) was created by Presidential Decree as a regulatory agency with broad competences.

Unlike other international agencies that individually regulate the sectors of economy, COFEPRIS transversely regulates those sectors that can affect the population's health. Based on this, health protection is achieved by offering the consumer the best quality and

price alternatives in the market on health supplies, as well as intelligent and effective health surveillance.

According to its founding decree, the sectors regulated by COFEPRIS are:

- Foods and beverages.
- Health supplies.
- Health services.
- Other use and consumption products (cosmetics).
- Pesticides, vegetal nutrients and toxic substances.
- Emergencies.
- Occupational health.
- Environmental risks.

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## Pharmaceutical policy

With regard to the pharmaceutical policy, it is aligned with the 3 health priorities established by the Government of the Republic, and its main purpose is to strengthen effective and opportune access of the population to an adequately supplied market with safe, efficacious and quality products at the lowest prices, and the prevention of possible risks for health.

To accomplish this, the pharmaceutical policy rests on 4 fundamental axes, aligned with the aforementioned priorities of the Government of the Republic: 1) to consolidate a regulatory body that guarantees the safety, quality and efficacy of medications; 2) to establish a reliable regulatory approval system; 3) elimination of barriers for safe, efficacious and quality products to enter the market, and 4) standardization with the best international practices.

## Regulation of drug supply

### **Health regulation in the rational use of medications**

On August 25, 2010, the “Agreement establishing the guidelines that the sale and supply of antibiotics must obey” (henceforth “the Agreement”) was published with the purpose to prevent self-medication, by establishing that pharmacies should only sell antibiotics when the customer exhibits a medical prescription.

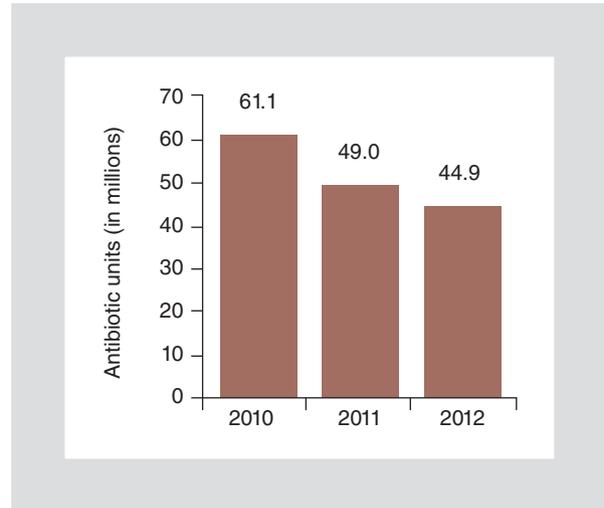
Professional guidance to the physician under this plan has the following benefits:

- To provide a medical diagnosis adequate to the diseases of the patients, guiding them in the purchase antibiotics and other medications such as antiviral drugs.
- To stop deleterious self-medication with antibiotics.
- To reduce the risk of bacterial resistance caused by inadequate medication.
- To reduce the risk of deviation of antibiotics to the informal market.

### **Effects of regulation in the antibiotic market in Mexico**

By virtue of the Agreement, antibiotics sales in Mexico dropped by 20%, shifting from 61.1 million units sold in 2010 to 49 million units sold in 2011. Additionally, between 2011 and 2012, antibiotic sales were decreased by 8.4%.

On average, the sales reduction in the antibiotic market for the 2010-2012 period is estimated in 14.1%, as shown in figure 1.



**Figure 1.** Sales reduction in the market of antibiotics during the 2010-2012-period (source: COFEPRIS, 2014).

## **Farmacias with consulting room in Mexico**

As a result of the same Agreement, some drugstore chains made an incursion in offering medical services through consultation rooms. The results showed that out of over 25,000 pharmacies existing in Mexico, more than 10,000 (40% of total) already have this modality available.

Thus, between 2010 and 2012, the supply of drugstores with a doctor's office in Mexico grew by 130%, as shown in figure 2.

Therefore, between 2010 and 2012, the existence of pharmacies with consulting room in Mexico grew by 130%, as shown in figure 2.

COFEPRIS has the legal mandate to guarantee for the patient not to be left unprotected in his/her medical care. Therefore, in view of the increasing offer of pharmacies with consultation rooms, it was fundamental for health authorities to make sure that both the pharmacies and the corresponding consultation rooms follow the corresponding regulation, in order to guarantee their correct functioning.

Thus, pharmacies and consultation rooms have to adjust to the following regulatory orders:

- In the first place, pharmacies are subjected to the pharmacopoeia of the Estados Unidos Mexicanos in the Supplement book for establishments dedicated to sell and supply of medications and other health supplies, fourth edition 2010.
- Second, consulting rooms are subjected to the NOM 005-SSA3-2010 standard, which establishes the minimal infrastructure and equipment requirement in establishments for ambulatory medical care of patients, in force since October 16, 2010.

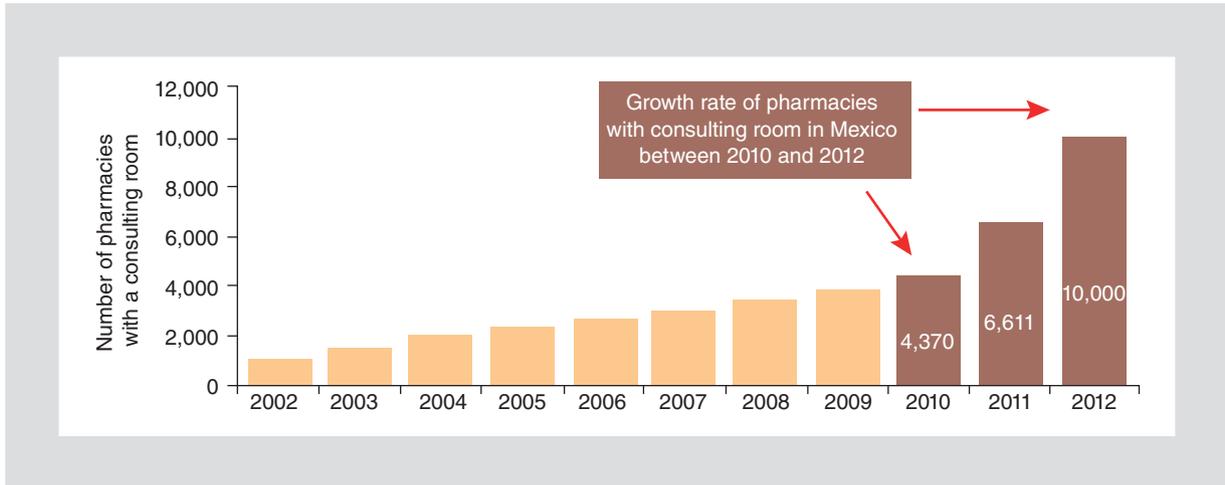


Figure 2. Growth rate of pharmacies in Mexico between 2010 and 2012 (source: COFEPRIS, 2014).

- Third, in case of being specialized medical care consulting rooms, they should meet the NOM 016-SSA3-2012 standard.

For the period from 2013 to 2014, COFEPRIS, in close collaboration with the pharmaceutical sector, used 2 main strategies for the adequate functioning of the modality of consulting rooms in pharmacies.

First, of Healthcare Promotion, based on the schedule of Healthcare Promotion visits where the "Guideline for Good Medical Practice in Pharmacies with Consultation Room" is applied, with the purpose to draw a compliance critical path in those cases where the guidelines are not followed and to consolidate a diagnosis of compliance with the regulatory framework.

In second place, of Healthcare Operation, which derives from the information acquired in the promotion visits and with which an intensive healthcare surveillance program is designed, with the purpose to sanction violations to healthcare regulations.

Finally, while the rational use of drugs is one of the foundations to ensure the efficacy of the pharmaceutical policy of the Government of the Republic, with regard to the access to drugs, the comprehensive strategy to ensure it was designed. It is based on three basic pillars: 1) the correct supply of drugs; 2) a strict surveillance of the market, and 3) elimination of asymmetric information in the market.

### Supply of drugs in Mexico

#### Household expenditure on health

In Mexico, households spend 2.05% of their total income on health-related expenses. Of the households'

expenditure on health, 40% is used to cover consultation fees and other health services, 30% for the purchase of medications and the remaining health expenditure is used in hospital care, clinical tests, purchase of medical devices, health insurances and others (Fig. 3).

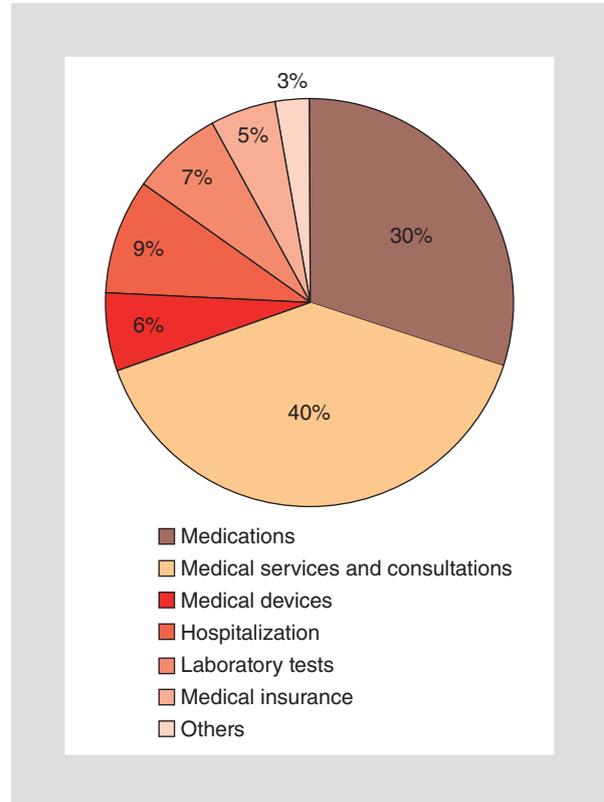


Figure 3. Households' health expenditure by type of goods and services, 2010 (source: Encuesta Nacional de Ingresos y Gastos de los Hogares [ENIGH], 2010).

**Table 1. Penetration and structure of pharmacies in Mexico**

Position	Type of economic unit	Number of economic units (2009)	Units per each 10,000 inhabitants (2009)
1	Temporary lodgement and food preparation services	392,242	35.66
2	Professional, scientific and technical services	84,695	7.70
3	Business support services	80,922	7.36
4	Real-estate and rental services	54,188	4.93
5	Educational services	43,286	3.94
6	Entertainment services	41,821	3.80
7	Pharmacies	25,000	2.27
8	Financial and insurance services	18,706	1.70

Source: Economic Censuses, 2009 (INEGI, 2013).

## Pharmacies in Mexico

In the private sector, between 80 and 90% of drug sales is carried out through wholesalers and the rest directly from the manufacturers to some of the big pharmacy chains.

With regard to retail sale (or general public dispensation), a large number of pharmacies participate (independent or popular, chains, in supermarkets and governmental sector) atomized in more than 250,000 dispensing points in the entire country. Only in the Distrito Federal there are more than 2,000 pharmacies.

### Penetration and structure of pharmacies in Mexico

Currently, in Mexico there are 2.27 pharmacies per each 10,000 inhabitants. This figure shows that pharmacies are in the seventh place with regard to the penetration of service establishments available to Mexican consumers. Today, pharmacies have an even higher penetration than banks, thus reflecting the potential of access to pharmaceutical and health services to the population (Table 1).

The structure of the pharmacy business has changed over the last decade. Retail selling in the private sector was carried out through small and independent pharmacies. Now, several pharmacy chains have consolidated at the national and regional levels, as well as the sale of drugs through supermarkets.

Currently, 34% of sold units are estimated to correspond to national chains, 25% to independent pharmacies, 21% to pharmacies in supermarkets and the rest to regional local chains.

Today, there are 10,000 pharmacies with consulting room in Mexico located throughout the extension of the Mexican Republic with the following characteristics:

- On average, each consultation room sees between 25 and 35 patients per day.
- These consulting rooms offer 250,000 daily consultations, whereas the Institute of Security and Social Services for State Workers (ISSSTE – *Instituto de Seguridad y Servicios Sociales para Trabajadores del Estado*) this figure is calculated to be 89,000 and in the Mexican Institute of Social Security (IMSS – *Instituto Nacional del Seguro Social*) it is estimated to be 290,000.
- This scheme allows for medical care to be provided to 8 million patients per month, i.e., 7% of the Mexican population in such period.
- The 10,000 consulting rooms are estimated to employ approximately 25,000 health professional physicians.

### Health promotion and health surveillance visits to pharmacies with consulting rooms

During 2011, 23% of medical consulting room visits in pharmacies were due to gastrointestinal conditions, whereas 21% was due to respiratory conditions. Other medical conditions that prompt visits to consulting rooms in pharmacies include headache, nausea, fever, high blood pressure, renal problems, trauma and pregnancy (Fig. 4).

Since September 2013, COFEPRIS, in collaboration with the Federal Healthcare System, managed to visit 6,939 pharmacies on order to apply the Guidelines of

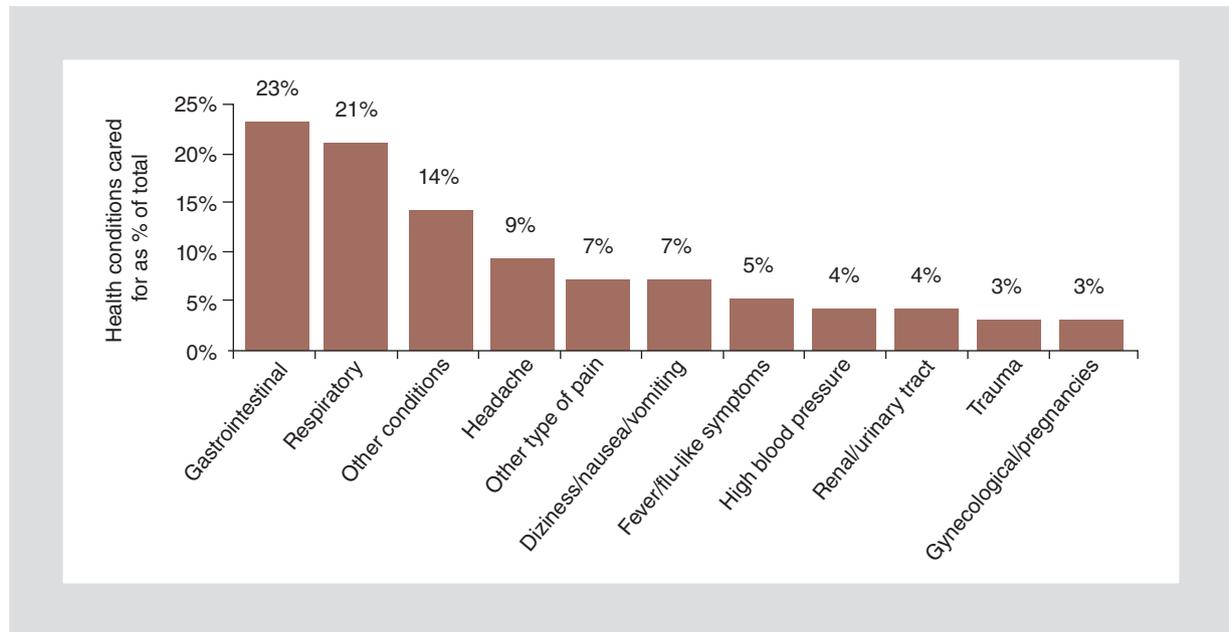


Figure 4. Main medical conditions cared for in pharmacy consulting rooms, 2011 (source: IMS health, 2012).

Good Practice in Pharmacies and Consulting Rooms out of which an average compliance of 75% was obtained.

With regard to health surveillance of consulting rooms in pharmacies, between November 2013 and May 2014, COFEPRIS conducted 311 inspections resulting in 58 suspensions, while the States conducted 3,933 inspections that entailed 185 suspensions. Overall, in the mentioned period, 4,246 inspection visits and 243 suspensions to establishments were carried out.

The above mentioned figures demonstrate the effects of the promotion visits to consulting rooms in pharmacies, since the ordered suspensions correspond to 3.47% of the establishments where the healthcare promotion visits were carried out.

## Health surveillance with regard to drugs

### Healthcare surveillance strategy with regard to drugs

During the 2011-2014 period, COFEPRIS implemented a strategy against the illegal market of medications through 2 key axes: substantial increase in illegal products seizures, and expired drugs elimination.

### Irregular drugs seizures

The fundamental principle of the strategy was to increase intelligence information together with the industry in order to markedly elevate the seized volumes. As

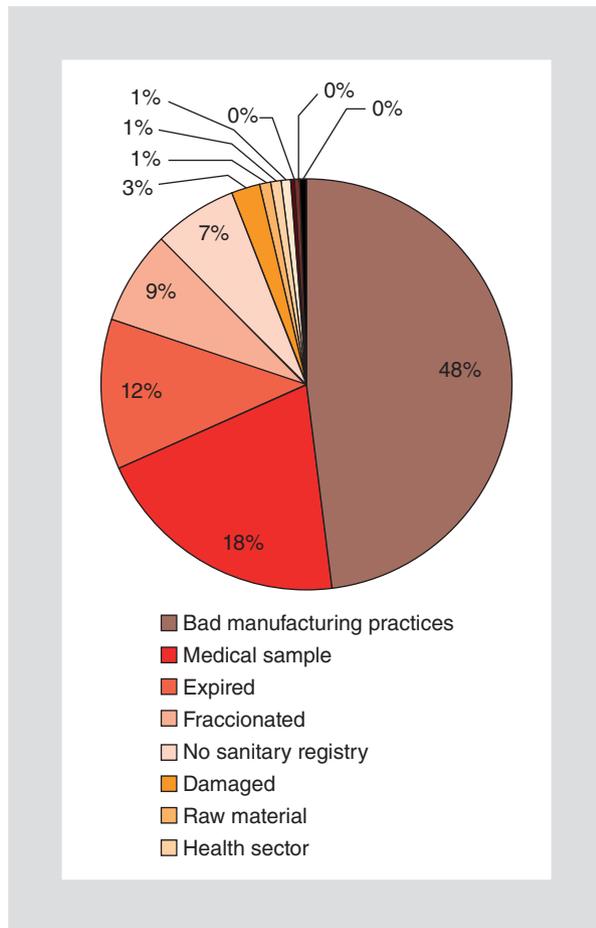
a result, between 2011 and 2014, 302.6 tons of irregular medications were seized, which represents a growth rate of 12,004% in relation to 2010 and nearly 1.9 million units of "miracle" products, which represents a 4,634% increase in seizures of such products in relation to 2010.

### Irregular medications: operatives and sanctions

During the period from January 2011 to June 2014, 88 health surveillance operatives were carried out for the seizure of irregular medications, which represented an increase of 417.6% with regard to the 17 operatives conducted in 2010.

In 2012, 44 fines were imposed on pharmacies, laboratories, warehouses, distributors and subway establishments for a total of 18 million 093 thousand and 720 pesos in comparison with 16 fines for a total of 4 million 220 thousand and 012 pesos in 2011. This represents an increase of 175%. In 2013, 51 fines were imposed with an amount of 20 million 693 thousand 340 pesos. Finally, between January and June 2014, 24 fines have been imposed for an amount of 11 million 765 thousand 304 pesos.

During 2011-2014, the largest amount of seized drugs was due to bad manufacturing practices (48%), followed by medical samples (18%) and expired products (12%), and only 1% of seized medications fell in the classification of presumably forged (Fig. 5).



**Figure 5.** Classification of seized medications (2011-2014) (source: COFEPRIS, 2014).

### Strategic actions against the use of expired drugs

In 2012, COFEPRIS published the Guidelines for the Reduction of Health Risk of Expired Drugs in the Mexican Market, with the purpose to prevent health risks by the use of substances that have reached their expiration date.

In tight collaboration with the organized industry of the pharmaceutical sector, distributors and suppliers of medications (pharmacies), COFEPRIS has maintained its policy of health promotion against expired drugs.

Thus, a strategy has been used to reaffirm and strengthen the application of the guidelines subscribed in 2012, for the prevention of sanitary risks resulting from expired drugs; to promote the inclusion of pharmacies to the National Drug Container Residues Management System A.C. (SINGREM – *Sistema Nacional de Gestión de Residuos de Envases de Medicamentos*)

and to promote adequate medication in the population taking into consideration the shelf life of medications and final disposal of expired products and their containers.

With the above referred strategy, an important lengthening of medications shelf life has been achieved, which was missed due to anticipated return.

In 2010 and 2011, between 80 and 85% of drugs were returned to the manufacturers with an average shelf life of 9 months. During the present administration, medications are returned with a shelf life of one month and hence the stability period of the drug out of the shelf has been reduced on average by 8 months, which implies an 88% reduction.

It should be noted that, in 2010, of the total of returned drugs, only 15% were returned through the chain of supply, under standardized principles and one month prior to expiration. Since 2012 and during the present administration, 80% of drugs are returned to manufacturers with one month of shelf life, which implies a deviation reduction higher than 700%.

On the other hand, a substantial reduction is observed in the number of companies that fail to comply with the guidelines. At the beginning of 2011, more than 40% of manufacturers, i.e., more than 64% were not in compliance with the guidelines, and by June 2014, less than 4% of them, i.e., only 5 are non-compliant with these guidelines.

Meanwhile, the SINGREM, a mechanism that facilitates for the medications end-consumer to dispose of their expired medications and their containers by placing them in containers located in pharmacies, has shown the following results and benefits:

- It reduces the risk for expired drugs in hands of the end-consumer being ingested, causing inefficient medication or health damages.
- Reduces the risk for expired drugs to generate harm to the environment when being disposed of in inadequate places.
- Ensures for expired drugs to be returned via the formal production route for destruction in special ovens authorized by the environmental authority.

In 2012, 75 tons of drug containers residues were collected using 1,891 special containers. In the present administration, more than 285 tons of residues have been collected using more than 3,485 containers, which implies a recollection rates growth of 280%, and 84% in terms of containers installment (Fig. 6).

The SINGREM has increased its services to the population by 1,150%, already providing benefits to over 50 million Mexicans (Fig. 7).

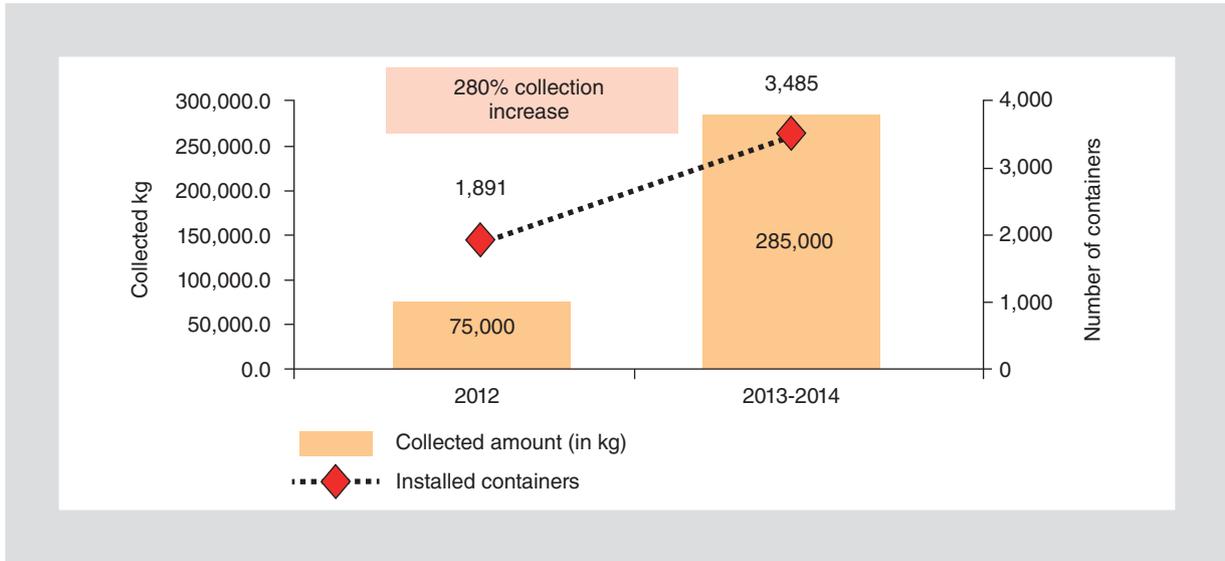


Figure 6. Drug Container Residues Management System (SINGREM): Results (source: COFEPRIS, 2014).

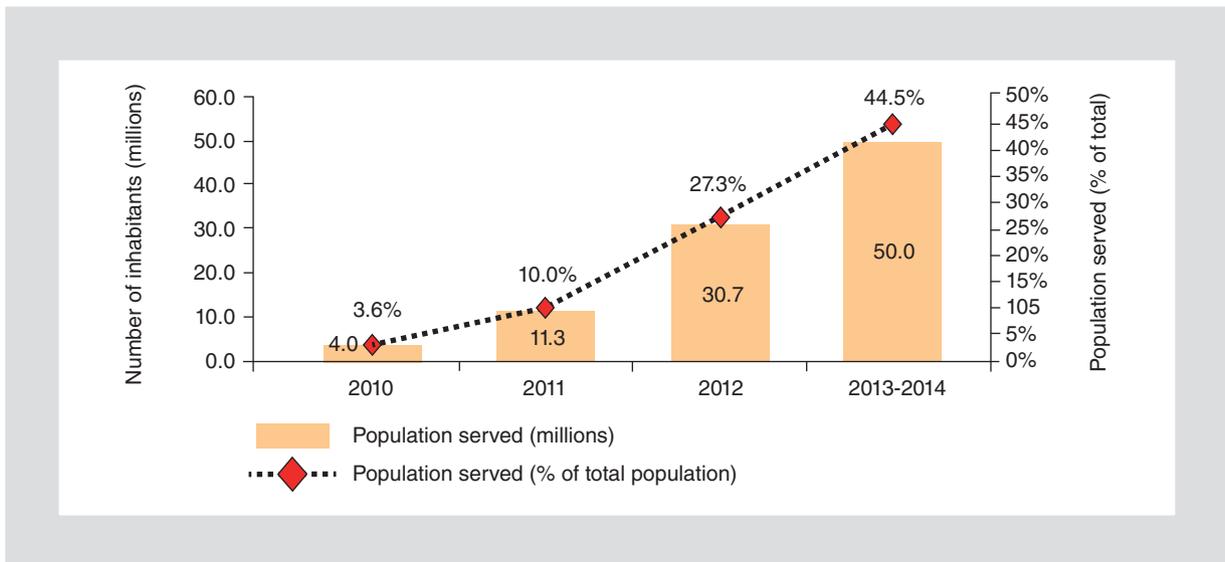


Figure 7. Population benefited by the SINGREM (2010-2012) (source: COFEPRIS, 2014).

### Health promotion campaign on shelf life of medications and adequate disposition of expired drugs

COFEPRIS continues with health promotion actions directed to the consumer in order for the consumer to exactly know the negative effect on health the ingestion of an expired drug can have.

In addition, actions are fortified in order for the consumer to know that the expiration date as determined by COFEPRIS, which results from a rigorous scientific analysis in the process of approval of a drug, is reliable. Finally, measures have been established for elimination of asymmetric information in the market.

### Advertising regulation against “miracle” products

To combat the informality represented by miracle products, the Ministry of Health proposed the following reforms to the General Statute of Health Regulations with regard to advertising, which were published in the DOF on January 19, 2012, and became effective on March 2, 2012:

- To require sanitary registry and/or advertising license to the advertiser for spots scheduling
- To require the diffusion media to cease the transmission or advertising of a product not complying with health legal regulations in a 24-hour-period.

**Table 2. Results of adopted measures**

Description	2010	2011-2014	Growth rate
Sale of antibiotics (units)	61.1 million	44.9 million	-26%
Seizure of irregular medications (tons)	2.5	302.6	12,004%
Seizure of miracle products (units)	40,000	1,893,759	4,634%
Health surveillance operatives	17	88	417.6%
Fines to pharmacies, laboratories, warehouses, distributors, subway establishments	16	119	643.7%
Time spent by drugs (within shelf life) off the shelf	9 months	1 month	-88.88%
Percentage of expired drugs returned to the distribution chain on the last month of shelf life	15%	80%	433%
Collected drug containers (kg)	75,000	285,000	280%
Containers for expired drugs	1,891	3,485	84%
Benefited population (SINGREM), millions	4	92	2,200%
Miracle products advertising schedules	3,676	0	-

- To increase to up to 400% the amount of the sanctions imposed for not obeying the regulatory requirements.

In addition, on January 18, 2012, the decree that modifies the General Statute of Health with regard to advertisement in order to agilize the suspension of deceitful or non-authorized advertising was signed. Between January 2011 and March 2012, the decrease in the advertising schedule was 87.4%; by June 2014, no advertising schedule was recorded.

In order to promote the compliance with health regulation on advertising, on February 12, 2014, COFEPRIS issued the "Attention Criteria for the Processing of Applications for Drugs Advertising Authorization". With these criteria, COFEPRIS tries to give certainty to the consumer with regard to advertising of drugs.

The suspended spots are on dictum process in order to establish the amount of the applicable fine. These amounts can range from \$403,740 to \$1,076,000, and thereby the range of fines can go from 27 million to 73 million pesos.

## Conclusions

The pharmaceutical policy enforced by the Government of the Republic has been effective. As for antibiotics supply, sales decreased by 26%, which reflects that the measures taken by COFEPRIS have reduced antibiotic self-medication, which in many cases is deleterious for health. Furthermore, this measure has achieved to reduce antibiotics deviation to the informal market.

With regard to the growing offer of pharmacies with consulting rooms, the implemented health promotion

and surveillance actions have turned out to be effective. As of today, most part of consulting rooms in pharmacies are in compliance with the regulations established in the guidelines issued by COFEPRIS.

On the other hand, the results of the strategy against the medications illegal market are encouraging, since with the 417.6% increase in health surveillance operatives for the seizure of irregular medications, 302.6 tons of drugs have been seized, which represents a growth rate of 12,004% in relation to 2010. Furthermore, nearly 1.9 million units of miracle products have been seized, i.e., 4,634% more have been seized than in 2010.

In addition, with regard to the implemented strategy to prevent the use of expired drugs, COFEPRIS' approach managed to promote adequate medication in the population and prevent the use of medications that for having reached their expiration date can be a threat for health. By means of the SINGREM, it was possible to extend medications shelf life and more than 285 tons of residues have been collected by means of more than 3,485 containers, thus preventing for these substances to cause damages to health.

Finally, in order to fight the informality represented by miracle products, the regulatory framework was strengthened. Among other measures, the regulation was reinforced to speed up the suspension of unauthorized deceitful advertising. As a result of this, between January 2011 and March 2012, the decrease in advertising schedules was 87.4%, and by June 2014, no off-regulation scheduled advertising was recorded.

The results of the described measures are shown in table 2.