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**ANOS**  
1943 - 2013  
A FAVOR DE LA SALUD

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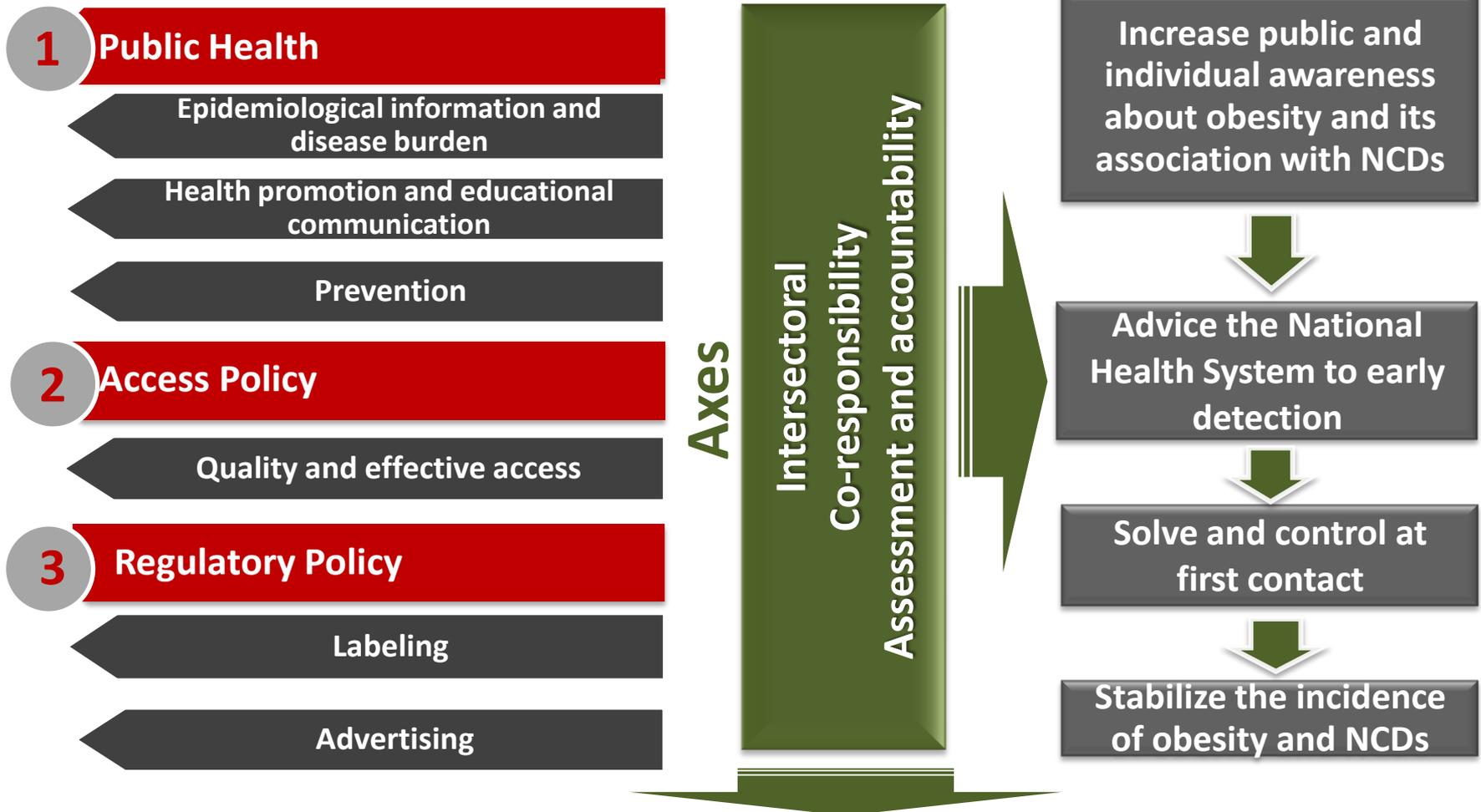


# National Strategy for the Prevention and Control of Overweight, Obesity and Diabetes

November, 2014



## Pillars of the Strategy



**Health in all policies Social determinants of health**

# Objective



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- Increase the welfare of the Mexican population and contribute to the sustainability of economic development by stabilizing and reducing the incidence of obesity in order to reverse the epidemic condition of non-communicable diseases (in particular, diabetes) through actions of public health, following an integrated medical model characterized by intersectoral public policies.



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# Public Health



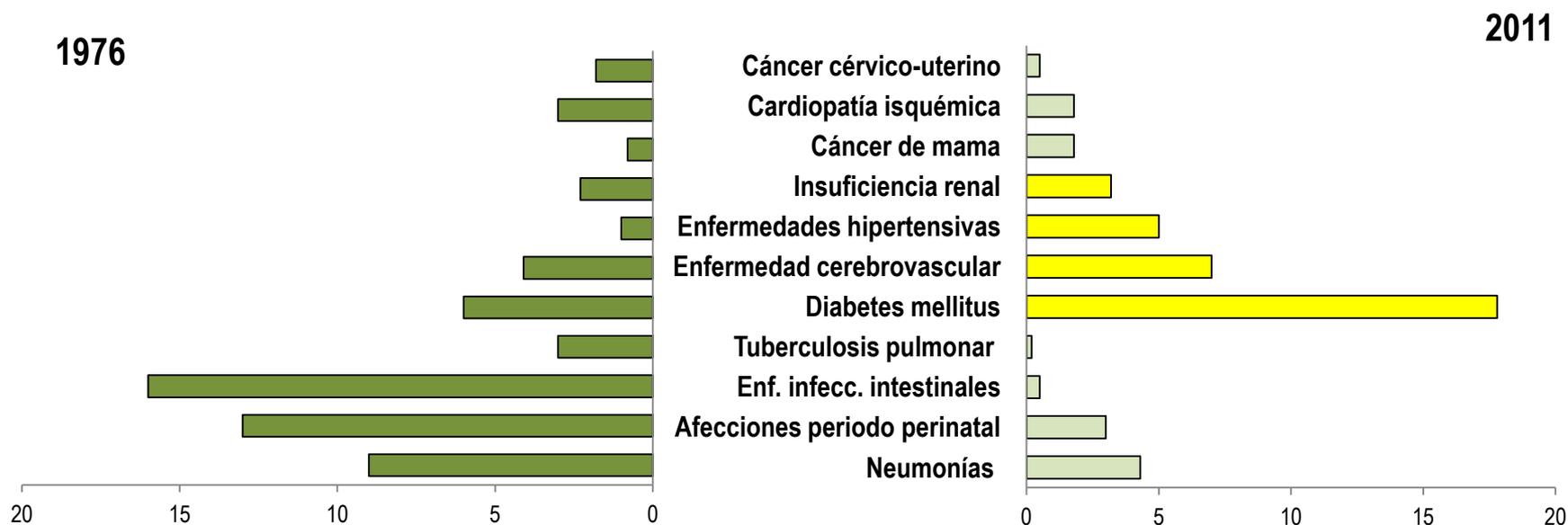
## Obesity and Diabetes

- For their magnitude, frequency and growth, Obesity and Non-Communicable Diseases (NCDs) (in particular, diabetes) represent a health emergency.
- These diseases affect labor productivity, academic performance and overall economic development in a significant manner.
- We are facing a critical situation which, if not treated in the medium term, may compromise our viability as a nation.
- For the first time ever, we envision a scenario where future generations experience a significant reduction in their life expectancy. This situation is not only counterintuitive for the future of civilization, but it is also anti evolutionary.



# Epidemiological Transition in Mexican population

- The epidemiological profile of the Mexican population shows a clear transition to chronic-degenerative diseases.
- In 2011, there was a dramatic increase in deaths associated to non communicable diseases (**Diabetes mellitus, hipertensive and cerebrovascular diseases**), as main causes of death in Mexico.

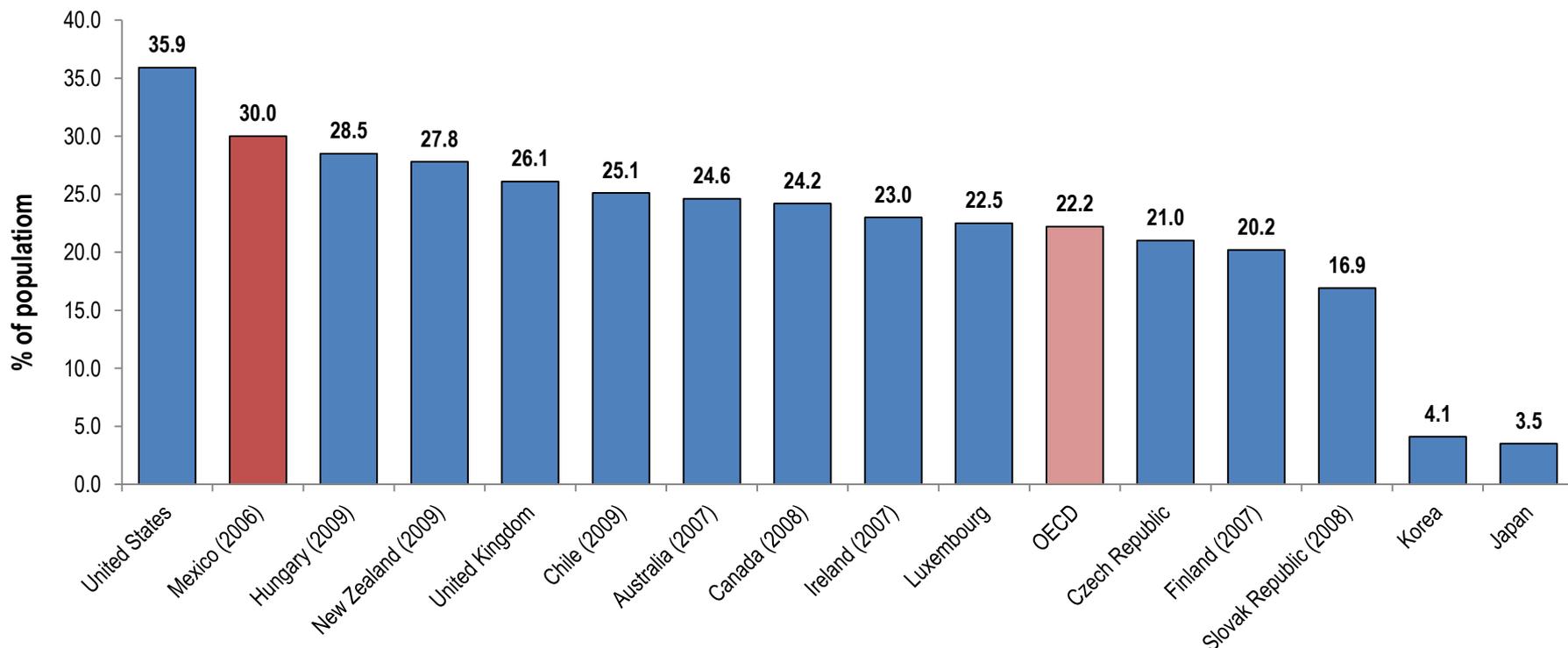




## Percentage of Adult Population with Obesity, OECD members 2010

- Mexico is the second country from the OECD with the highest percentage of obesity: **30%** of its total population. The average percentage in OECD members in this category is **22.2%**.

**Obesity in different countries, 2010**  
(% of total population)

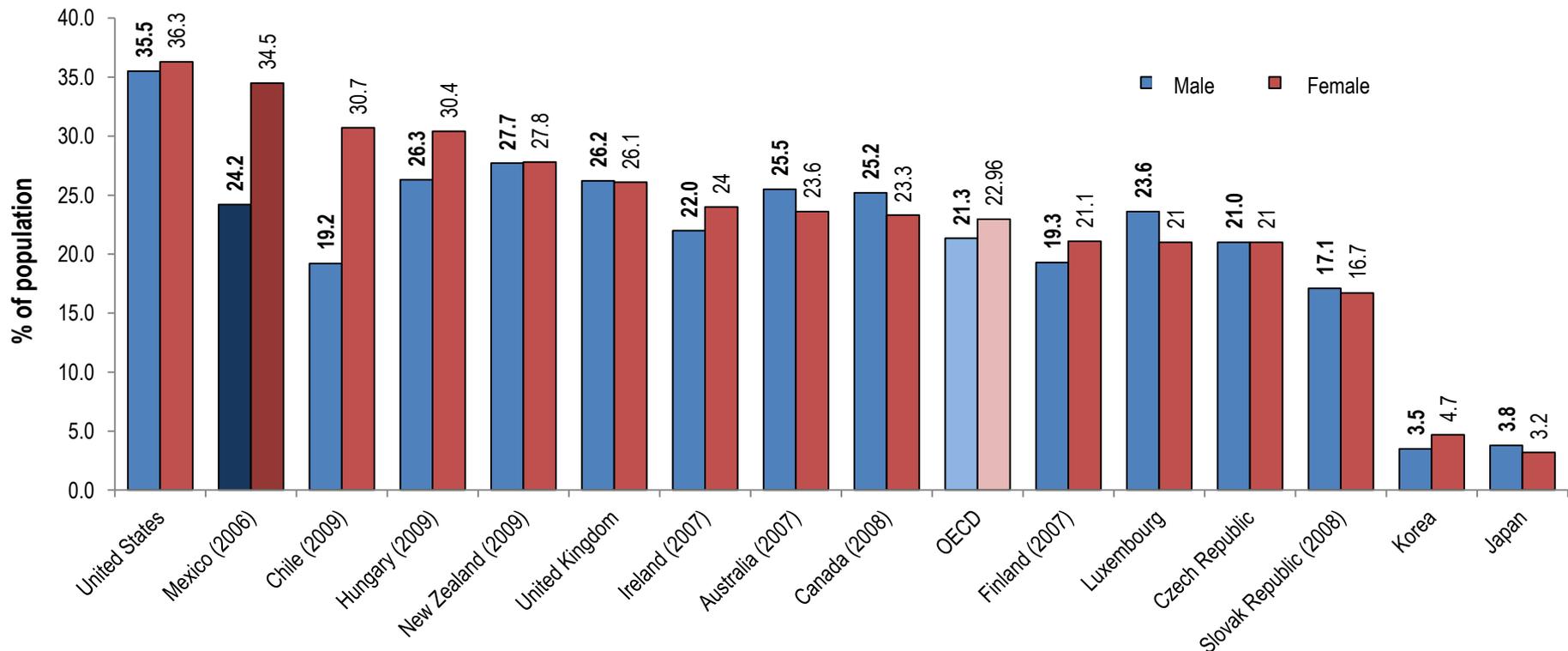




## Obesity by gender in different countries

- It is estimated that **34.5%** of the total female population suffered from diabetes, while the **24.2%** of the total male population has this condition.

### Obesity by gender in different countries, 2010 (% of total male and female population)

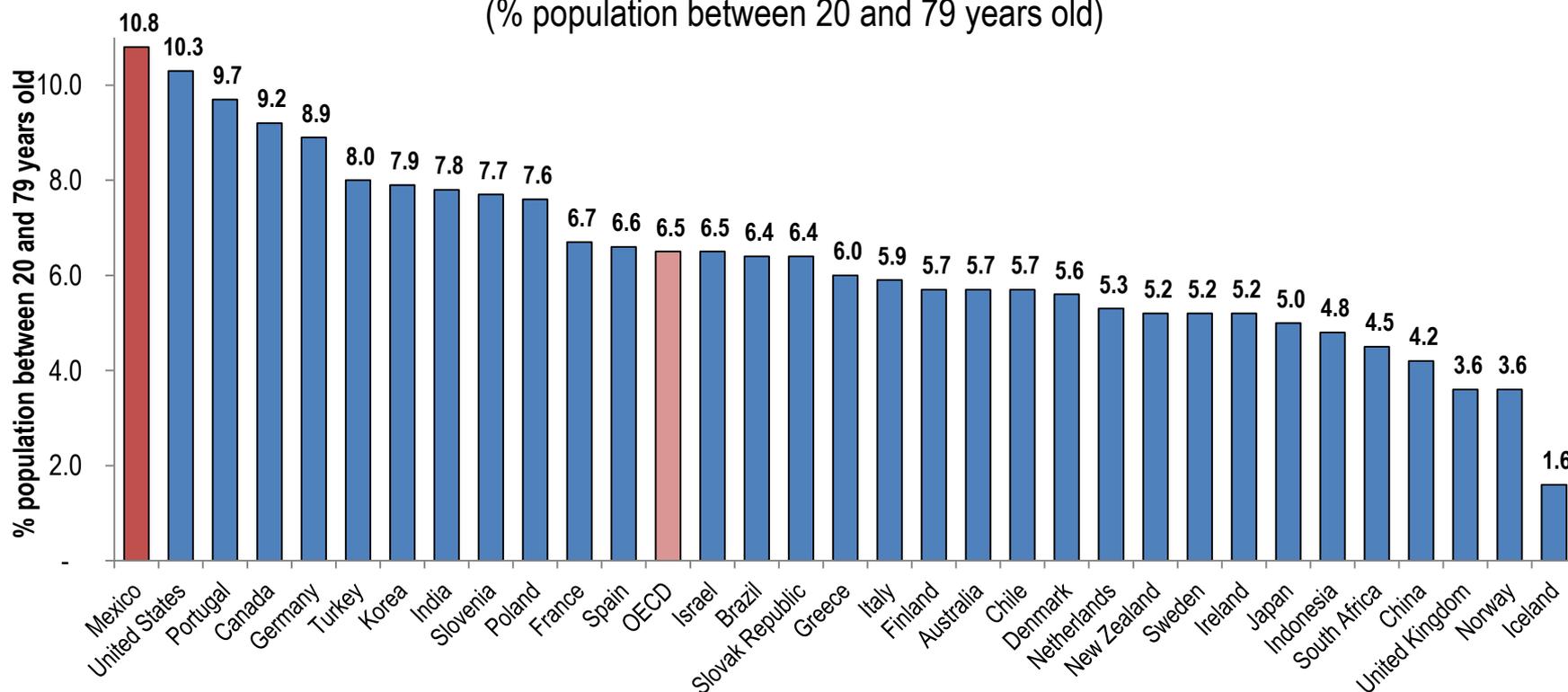




## Prevalence of Diabetes in OECD countries, 2010

- Studies have shown that in OECD countries, 83 millions people suffered from Diabetes. **10.8 million** are from Mexico, **13%** of the total amount.
- Mexico is the OECD country with the highest prevalence in the adult population.

**Prevalence of diabetes in adults, 2010**  
(% population between 20 and 79 years old)

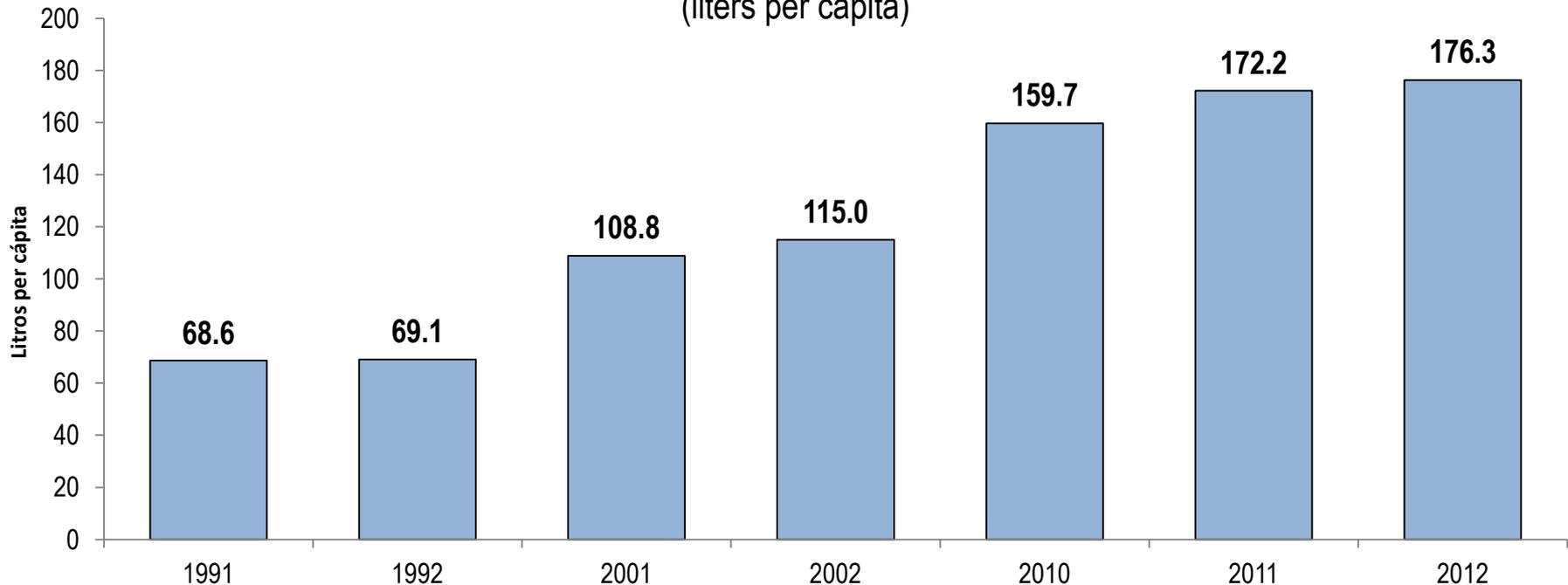




## Consumption of soft drinks and carbonated beverages

- During the period 1991-2012, the per capita consumption of soft drinks in Mexico increased by 157%, from 68.6 liters per capita in 1991 to 176.3 liters per capita in 2012.

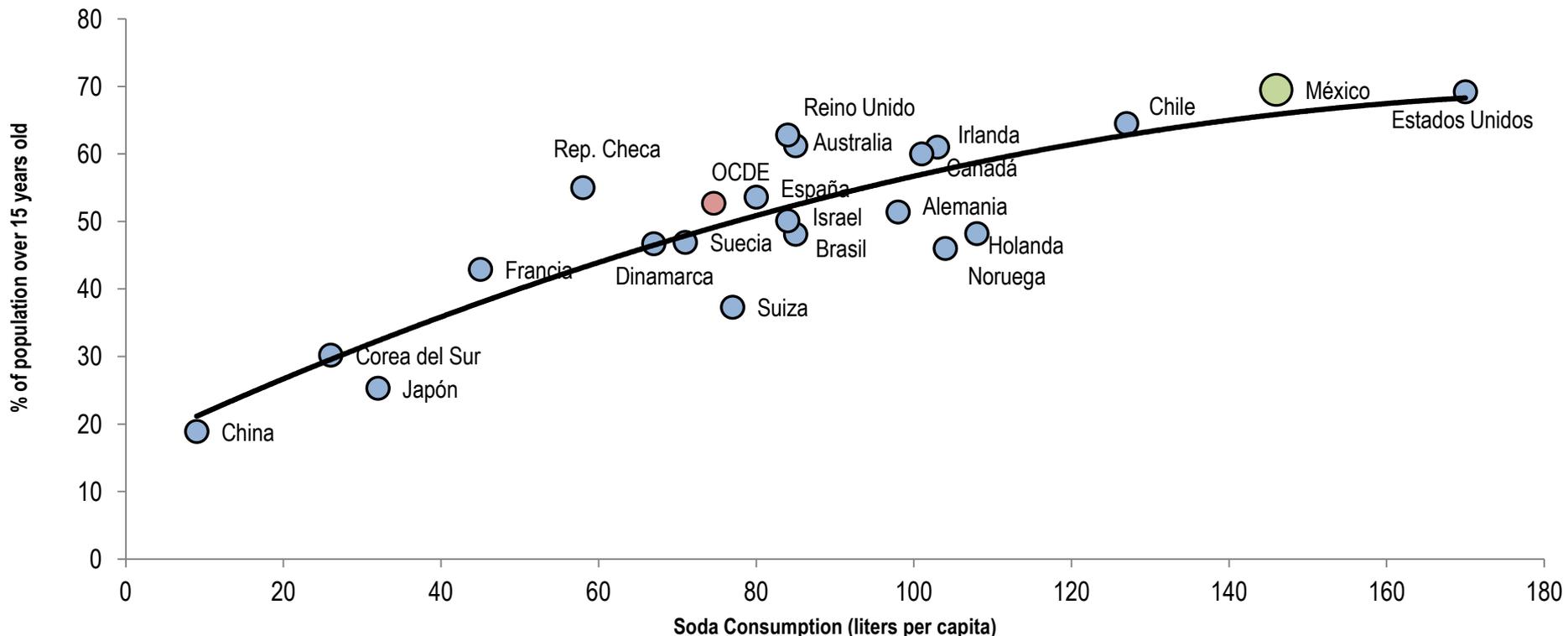
**Per capita consumption of soft drinks in Mexico , 1991-2012**  
(liters per capita)



## Overweight, obesity and soda intake

- In an international comparison, an increase in soft drink consumption is associated with a higher prevalence of overweight and obesity.
- Mexico is above the OECD average on both indicators.

### Overweight, Obesity and Soda Consumption in different countries, 2011

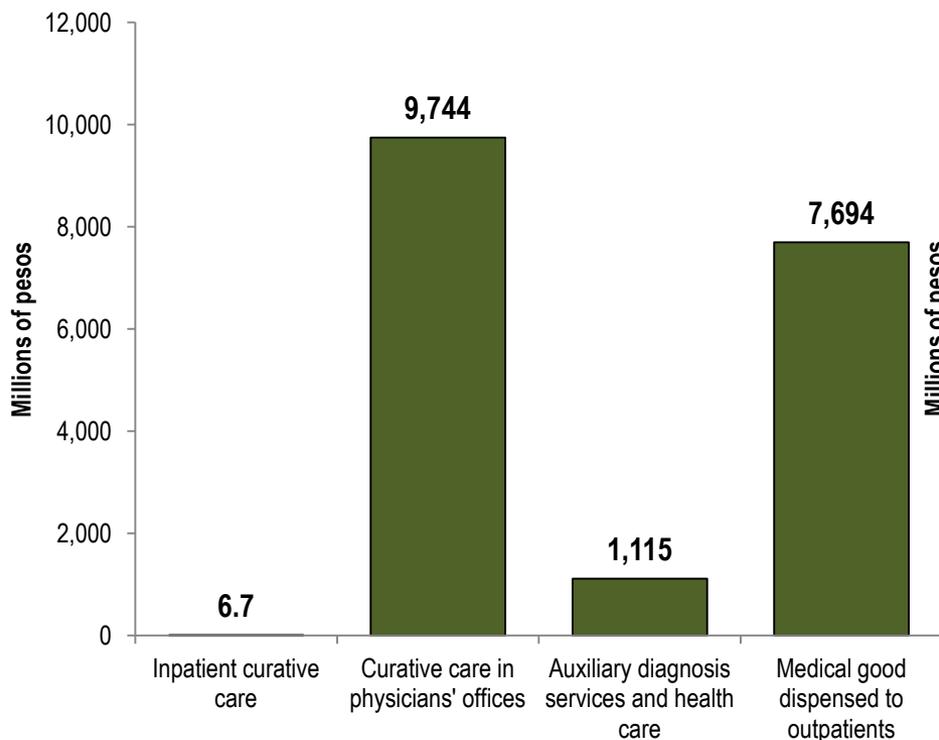




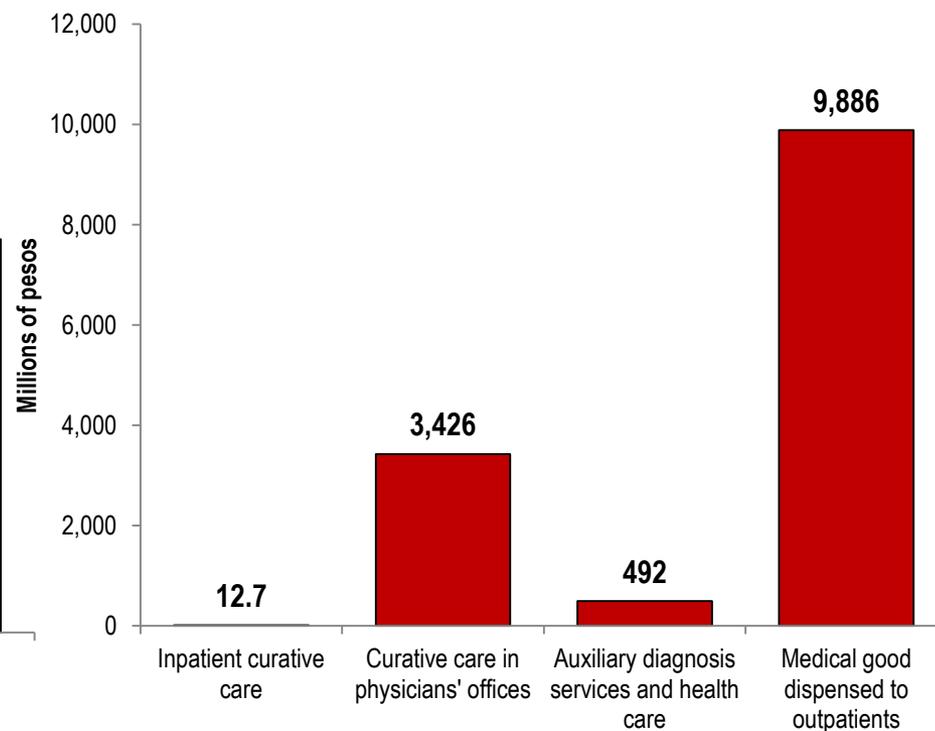
## Out-of-pocket expenditures in overweight and obesity-related diseases

- Out-of-pocket (OOP) expenditures related to treatment of diabetes mellitus is calculated in nearly 18.6 billion pesos. OOP expenditures for cardiovascular diseases is estimated in 13.8 billion pesos.

### Out-of-pocket expenditures on diabetes mellitus, Mexico (2011)\*



### Out-of-pocket expenditures on cardiovascular diseases, Mexico (2011)\*

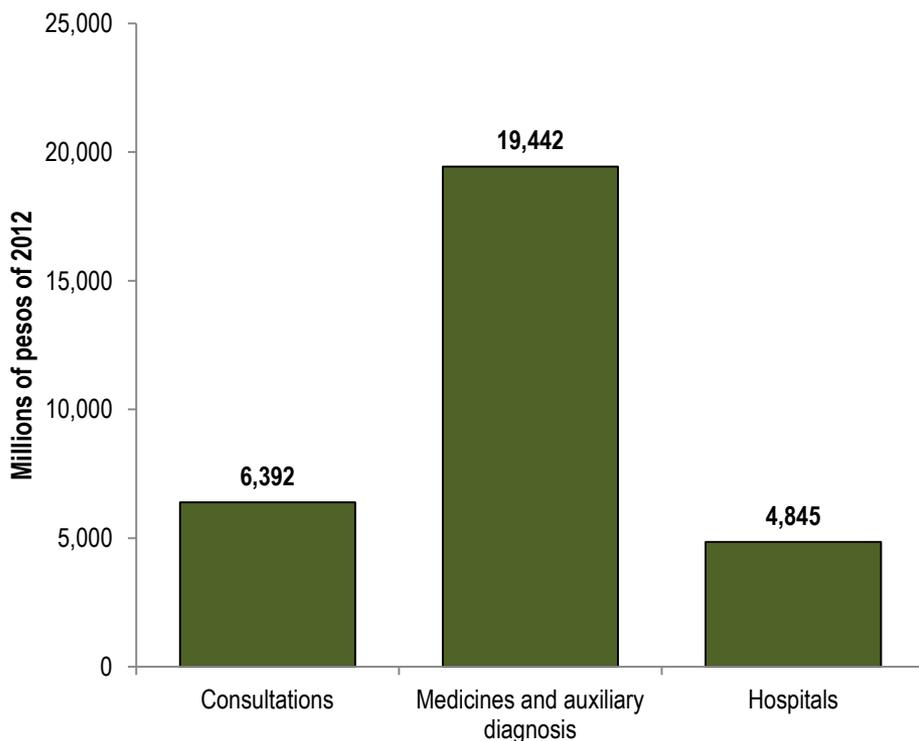




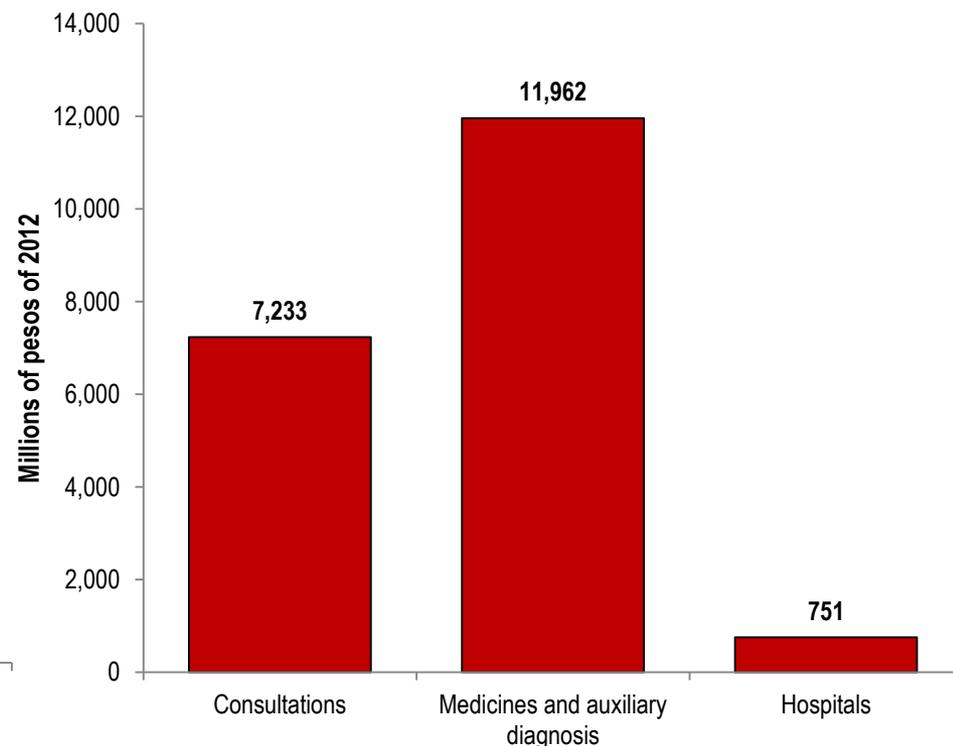
## Public expenditures in overweight and obesity-related diseases

- Medical expenses from the Mexican Institute for Social Security (IMSS) to treat diabetes mellitus amounts to roughly 31 billion pesos. Medical expenses for hypertension treatment is estimated in 20 billion pesos.

### Medical expenses on diabetes mellitus, IMSS (2011)



### Medical expenses on hypertension, IMSS (2011)





## Economic Impact

- This table shows the potential loss of welfare among individuals that increase their weight.:

<b>Diferential in the socioeconomic level between individuals with appropriate weight and individuals with overweight and obesity (Basic level of average normal BMI)</b>	
<b>Normal- Overweight</b>	28%
<b>Normal- Obesity</b>	34%
<b>Normal- Morbid Obesity</b>	73%

Source: COFEPRIS (2013), with information from the Ministry of Health and ENSANUT (2012).

- For example, one healthy individual that became overweighted, has a potential loss of 28% of his productivity.



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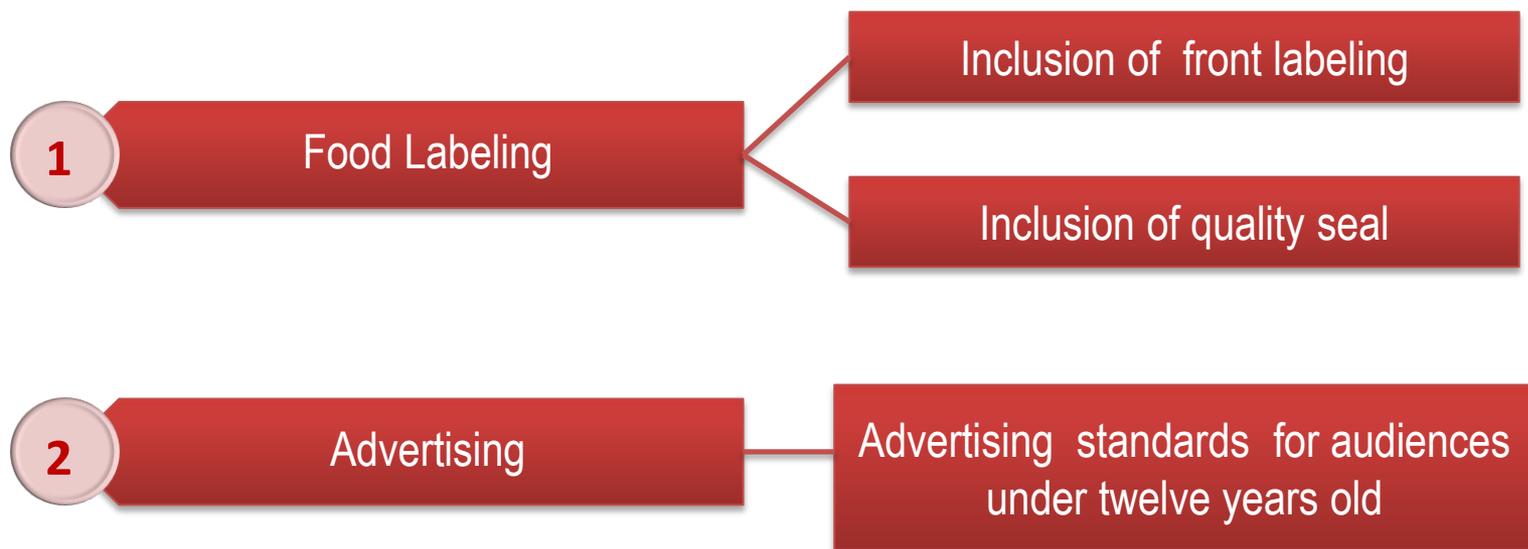
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# Regulatory Policy



# Regulatory Actions

Through the use of those mechanisms, the strategy plans to harmonize our national regulation with the best international practices.





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# Labeling



## Current Regulation

- Mexico counts with regulation, Normas Oficiales Mexicanas (NOMs), that promote best information practices for food consumption, through the inclusion of nutritional values on labels of food products.
- At present, there are two NOMs that establish labeling rules for food and beverage

NOM	Autoridades que Vigilan su Observancia	Principales Puntos Regulados
NOM 051 (Voluntary Labeling)	Ministry of Economy	Regulates the industry of food and non-alcoholic beverages to compulsorily declare the nutritional information .
NOM 086 (Nutricional board)	Ministry of Health	Sets the nutritional specifications that food and non-alcoholic drinks with changes on its composition must meet. . It is considered that a food or beverage has been modified in its composition when nutriments have been added , removed or reduced.

Source: COFEPRIS (2014) with information from Ministry of Health and Ministry of Economy.

- The Ministry of Health exercises the sanitary control of food and beverage advertising in the Bylaws of the General Health Law on Advertising .



## International Labeling Comparison

- In the developed world various mechanisms are used to ensure proper nutritional information.

Country	Nutricional panel	Frontal Labeling	Guideline Daily Amounts (GDAs)	Semáforo
USA	X		X	
UE		X	X	
Canada		X	X	
Spain		X	X	
Australia	X			X
Colombia		X		
Chile		X		
<b>Mexico</b>	<b>X</b>			

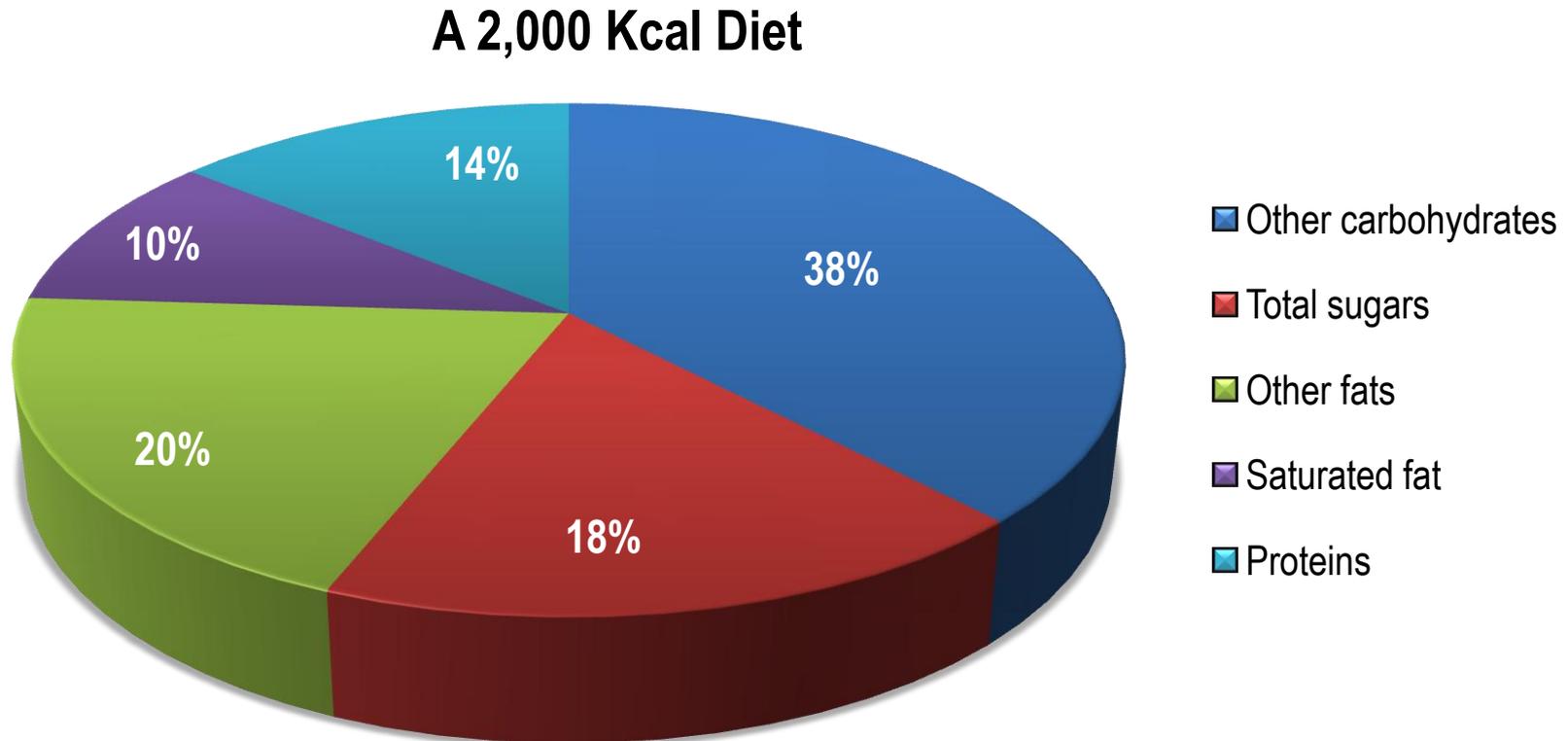
Source: National Strategy for Prevention and Control of Overweight , Obesity and Diabetes . Department of Health ( 2013).

- Only in Mexico the nutritional panel stands alone as a regulatory measure.



## Context

Calculations based on a 2,000 kcal diet **do not reflect the real impact** of the consumption of food on the ideal diet of a person, since that calculation does not distinguish between different sources of caloric intake, as shown below:





# Front Label

Therefore, the reform includes a mandatory front label that meets the following requirements:

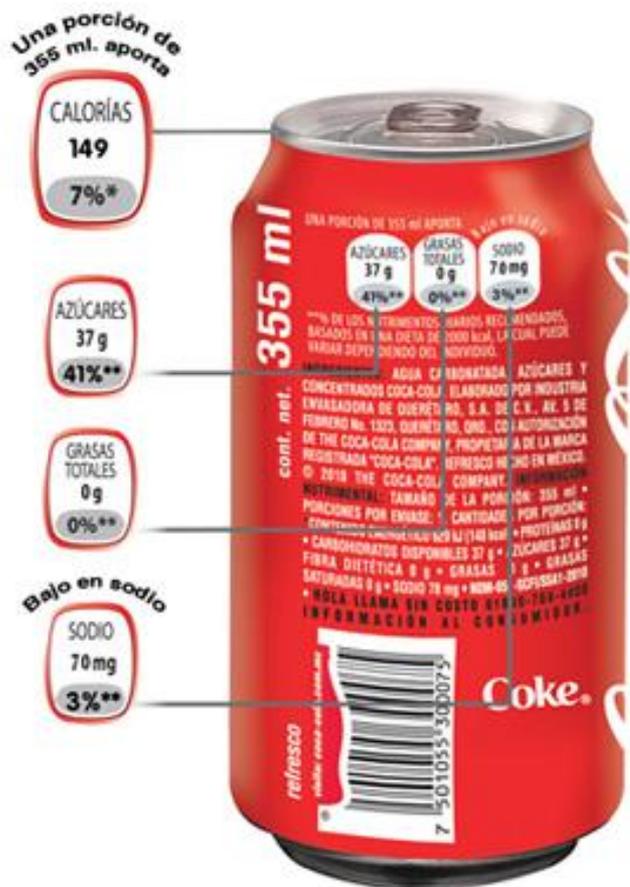
- a) Show that the calorie content of the product is according to a Dietary Allowance, distinguishing the source of the calories of the product, according to the following table:

Source of Energy Intake	Basis for the calculation
Sugars	360 Kcal
Other fat	400 Kcal
Saturated fat	200 Kcal
Sodium	2000 mg

With this, the number of Kcal in the product must be divided between the values given in the table above.

# Example 1

## Pre-packaged soft drink before the reform:



Currently, some products in the Mexican market voluntarily express Guidelines Daily Amounts (GDAs). However, it is considered that this practice can be improved by the following:

- Calculations based on a 2,000 kcal diet, do not reflect the real impact of the consumption of a food on the ideal diet of a person.
- The information provided is calculated on a serving, and not on the entire content of the package.

## Example 1

Pre-packaged soft drink after the reform:



Proposed labeling reform would be expressed as follows:

A container provides:



% of the daily recommended nutrient

By changing the basis for the calculations, the percentage goes from 7-41%, so clearer consumer information is provided.

## Example 2

### Familiar size pre-packaged soft drink before the reform:



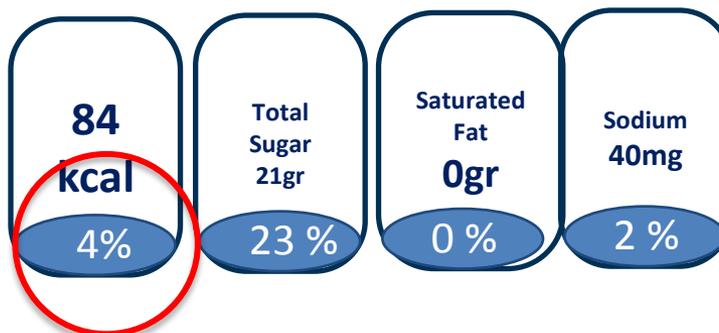
Today some products in the Mexican market do not express nutritional information on the front label. This practice has several disadvantages for the consumer, among which are:

- The caloric content of the product is unknown.
- No has a visual element that promotes improved decision making.
- The effect of nutrient to make it clear to the consumer information will be contextualized.

## Example 2

Familiar size pre-packaged soft drink before the reform:

A serving of 200 ml provides:



For the first time in Mexico, the consumer knows the total caloric content of the product and the percentage it represents of his recommended daily intake.

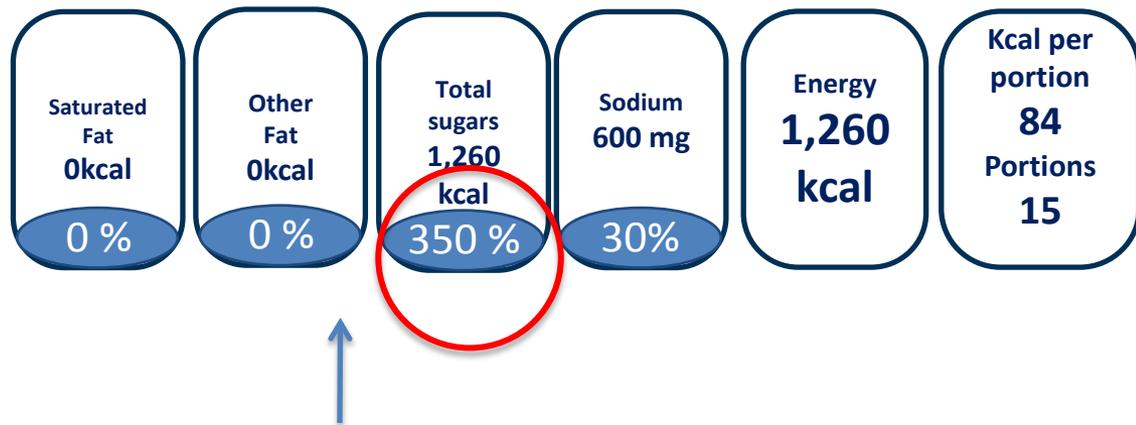


## Example 2

Familiar pre-packaged soft drink after the reform:



A package provides:



For the first time in Mexico, the consumer knows the total caloric content of the product and the percentage it represents of his recommended daily intake.



## Front Label

- b) It must express the total energy content of the product.
- c) In the case of flavored beverages, chocolates, snacks and confectionery, the family sizes should include:
  - 1. The nutritional information calculated on the total content of the package.
  - 2. The number of servings present in the container, and
  - 3. The caloric content of each serving, and the total caloric content.
- d) For other products, it provides information of family sizes, including:
  - 1. The calculated nutritional information per serving.
  - 2. The number of servings present in the container, and
  - 3. The caloric content of each serving, and the total caloric content.



# Front Label

The following table shows a comparison of the nutritional information that is expressed on the labeling of food and soft drinks, before and after the reform:

Before	After
Unclear nutritional information on the back of the product.	Total energy content of serving and the package.
	Number of servings contained in the product.
	The total caloric content per serving and container.
	Percentage representing a daily calorie intake.

In summary, consumer information for better decision-making becomes transparent.

## Nutritional Labeling

- Parallel to the mandatory front labeling, the reform will create a Nutritional Labeling, which will be given to those producers who request and meet nutritional standards to that effect issued by the Ministry of Health.
- The standards will be set by the Ministry of Health and it will be consistent with best international practices. In this regard, the criteria accepted by the US Pledge is used.



- With the inclusion of this nutritional label, product reformulation is encouraged and a visual consumer who aids him in better decision-making is provided.



## Nutritional Labeling

- The criteria that will be issued by the Ministry of Health raised split products in eight categories as shown below:

1. Animal and vegetable oils and fat source.

2. Vegetables, fruits, legumes, nuts, seeds and tubers (except for processed snacks).

3. Products with meat.

4. Fishery products.

5. Dairies.

6. Products from cereals and tubers.

7. Soups, sandwiches, seasonings and condiments.

8. Desserts.



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# Advertising

# Advertising: Previous regulation



- Before the reform there was no regulation on advertising of food and non-alcoholic drinks and there were only self-regulation practices by the industry.
- In this sense, some areas of opportunity were identified, from which measures were designed based on international best practices.

## EU Pledge / International context



- The European Union Pledge "EU Pledge " is a voluntary initiative directed to modify the parameters of advertising on TV, radio, printed and online food and beverages advertising for children under 12 years in the European Union.
- The companies pledged not to advertise food and beverages to children under 12 years old, of products that do not meet a scientific nutrition criteria.
- The Pledge was launched in 2007 by Danone, Nestle and Unilever together with the European Food Safety Authority (EFSA) - as a compromise of the action plan on Diet, Physical Activity and Health in the European Union. Currently, there are 20 members which represent 80 % of the total expense on food and beverages advertising in the European Union.
- The next chart shows the EU Pledge members with presence in Mexico:

# Children's Advertising and Regulation Schedule



- The scope of this proposal is for open and paid TV, as well as movie theaters.
- Other than the above, the proposal provides that the flavored beverages, confectionery, chocolates, chocolates similar products and snacks may not advertise in these times.
- Exceptionally, the following programming categories are excluded from the restrictions:
  - Soap operas,
  - News,
  - Movies and Series unsuitable for children, and
  - Sports.
- In addition to the above, advertisers can advertise only when is proven by audience studies, that the audience is not composed of more than 35% of people between 4 and 12 years old.



## Economic Impact

- Based on advertising records of different public and private TV media from January 2011 to February 2012, a total of **25,559 advertisements** under the new regulation were counted. This is the equivalent to **139 hours** of TV programming.
- Out of this 139 hours, **55** were actually in the child schedule, an of equivalent **40%** of the total hours restricted to the new regulations (**10,233 advertisements**).

### Advertisements susceptible to the new regulation

(Data from January 2011 to February 2012; equivalent in hours)

Category	Total Hours	Restricted Hours	%
Drinks	64	25	40%
Chocolates	17	6	37%
Confectionery	39	16	42%
Snacks	18	7	39%
<b>Total</b>	<b>139</b>	<b>55</b>	<b>40%</b>

Source: COFEPRIS (2014 ) with IBOPE (2012) and CONAR (2012 ).



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# Access Policy



## Pharmaceutical Policy

- Mexican pharmaceutical policy is committed to increase market access to a well-supplied drug market that offers innovative medicines at low prices. To comply with this commitment this policy rests on 4 fundamental pillars. These pillars are aligned with the **3 priorities of health policy** established by the Federal Government:

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



## Access Policy

- The Mexican Government is committed to increase the access of the Mexican population to a well-supplied **pharmaceutical market** with the best alternative in prices and quality.
- In this sense, the government **identified expired patents and pending records** for medicines in the period 2007-2011 in order to incorporate **new generic options to the pharmaceutical market**.
- Furthermore, generic drugs that apply for sanitary registration at COFEPRIS must comply with the criteria for **bioequivalence** and **bioavailability** in order to ensure **effectiveness, safety** and **high quality** of new medication.



## Access Policy

In this sense, COFEPRIS applied the following criteria to rank and schedule the release of **generic drugs** to **increase access of medicines** to the Mexican population:

- a. That they are **equivalent, safe, efficient** and of **high quality**.
- b. That released substances were related with the main causes of death among Mexican population.
- c. That the **patent had expired** so as to avoid violating any intellectual property rights, realizing the correspondent consult with the Mexican Institute of Industrial Property.
- d. That the amount of **public and private purchasing** represented significant savings in public and individual finance.

# Access Policy: Generic Medicines

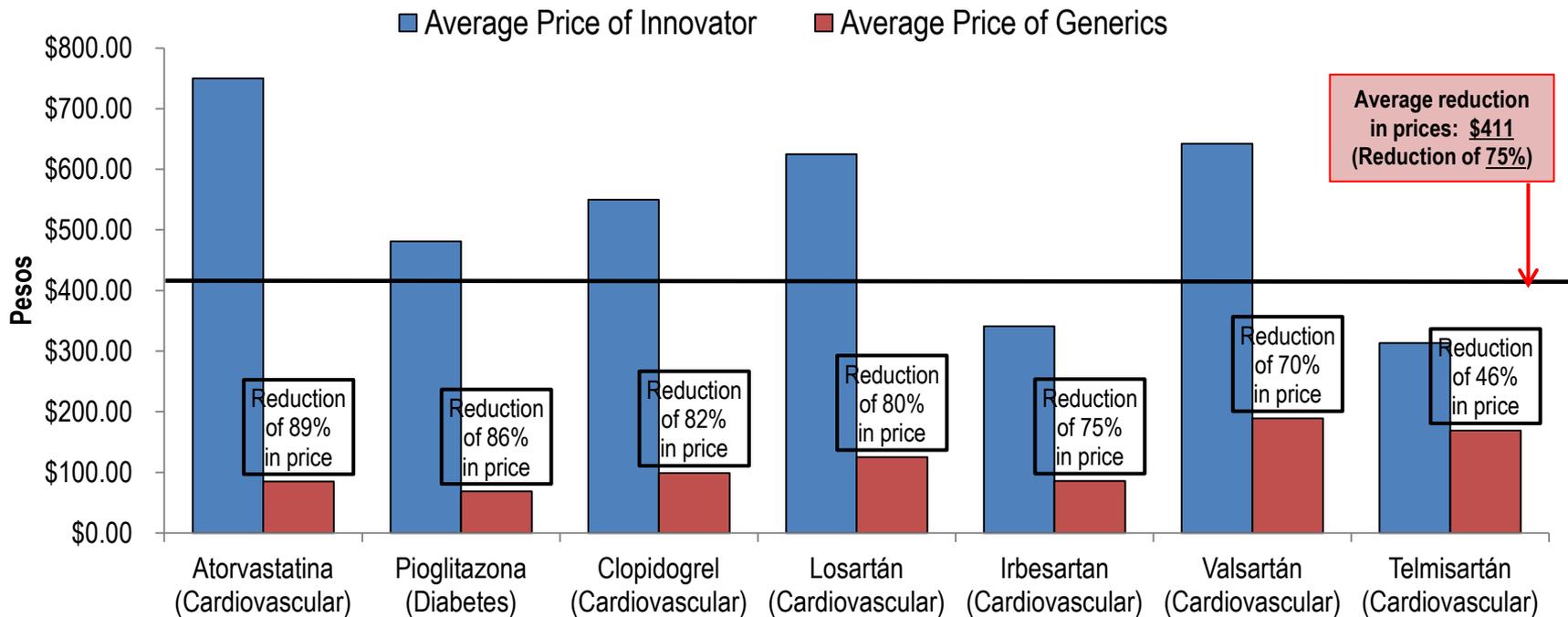
**7 active substances** authorized with **72 sanitary registrations** corresponding to **39%** of Mexican mortality.

Active Substance	Innovator's Brand	Authorization Date	Therapeutic Use	Accumulated Saving in 4 years (millions of pesos)	Registrations
Atorvastatina	Lipitor	Oct 5, 2011	Lowers blood cholesterol <b>Cardiovascular diseases.</b>	\$1,655	10
Pioglitazona	Zactos	Oct 5, 2011	Treatment for <b>diabetes mellitus</b>	\$760	15
Valsartán	Diovan	Nov 16, 2011	Treatment for <b>high blood pressure</b> and <b>heart failure</b>	\$628	8
Clopidogrel	Iscover, Plavix	Dec 13, 2011	<b>Antiplatelet to prevent blood clots</b>	\$1,692	22
Losartán	Cozaar	May, 2012	<b>Antihypertensive</b>	\$840	6
Irbersartán	Aprovel	Oct, 2012	<b>Antihypertensive</b>	\$840	4
Telmisartán	Micardis	April 4, 2013	<b>Antihypertensive</b>	\$2,675	7
<b>Total</b>	<b>7 Substances</b>	<b>7 Packages</b>	--	<b>\$9,090</b> (673 million dollars)	<b>72</b>

# Access Policy: Private Market

- In a comparison of the **private market** between innovative and generic substances, we can see that the average price decrease for the private market has been **75%**. The greatest impact in price reduction corresponds to medicines for **cardiovascular** and **diabetes**.

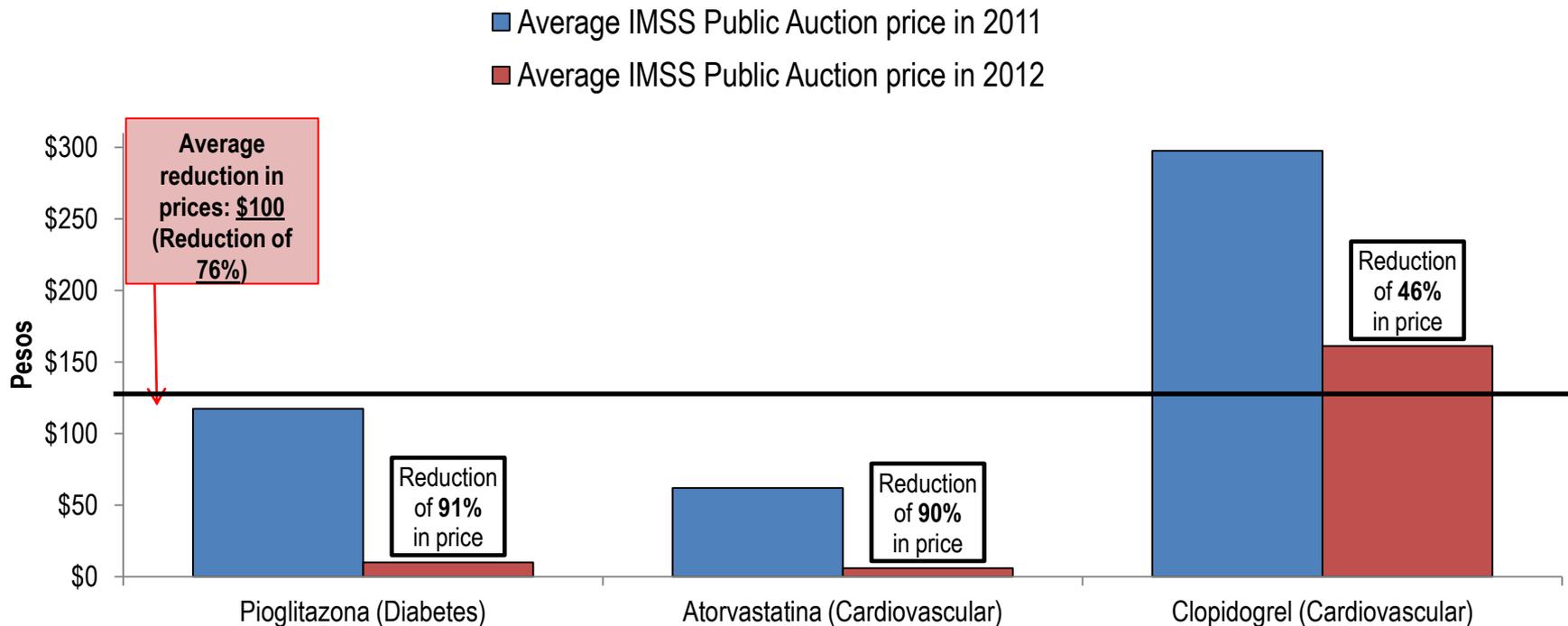
## Price Comparison: Private Market



# Access Policy: Public Purchases

- Analyzing the public auctions by the Mexican Institute of Social Security regarding the active substances used to treat obesity related diseases, we observed an **average price reduction of generics of 76%**.

## Price Comparison: Public Purchases





## Access Policy: Accumulated Savings

- Due to the release of generic drugs, accumulated savings for the **public sector** in 4 years are calculated in **299.5 million dollars (4,049.3 million of pesos)**.
- Accumulated savings for the private sector in 4 years are estimated in **373.5 million dollars (5,049.7 million of pesos)**.

Active Substance	Total Public Savings	Total Private Savings	Total Savings
Atorvastatina, Pioglitazona, Clopidogrel, Losartán, Irbersartán, Valsartán and Telmisartán,	<b>299.5 million dollars</b>  (4,049.3 million of pesos)	<b>373.5 million dollars</b>  (5,049.7 million of pesos)	<b>673 million dollars</b>  (9,099 million of pesos)



## Access Policy

### 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.



## Regulatory Actions

- The strategy of sanitary surveillance includes seizure of **tobacco, alcohol, clenbuterol, «miracle» products and health supplies.**
- From 2011 to July 2014, a total of **54 slaughterhouses** have been suspended.
- With this strategy COFEPRIS has increased its efficacy in **67,160%** during **2011 – July 2014** compared with **2010**, on average.

Sanitary surveillance: Inspections and seizure of products (2010-2014)					
Product	2010	2011-2014	Total	Growth rate	Average growth rate
<b>Tobacco</b>	40,000 cigarettes	205,590,047 cigarettes;	205,630,047 cigarettes	513,875%	<b>67,160%</b>
<b>Alcohol</b>	87,175 liters	853,567 liters	950,742 liters	891%	
<b>Clenbuterol</b>	0 suspended slaughterhouses	54 suspended slaughterhouses	54 suspended slaughterhouses	-	
<b>«Miracle» products</b>	40,000 units	1,896,990 units; 140,715.4Kg.	1,936,990 units	4,642%	
<b>Health Supplies*</b>	2.5 tons.	302.5 tons. (medicines); 1,264,013 pieces (med. devices)	305.1 toneladas de medicamentos	12,004%	

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

\* On **medicines** comparison is between **2009** and the sum of inspections from **2010** to **2014**.



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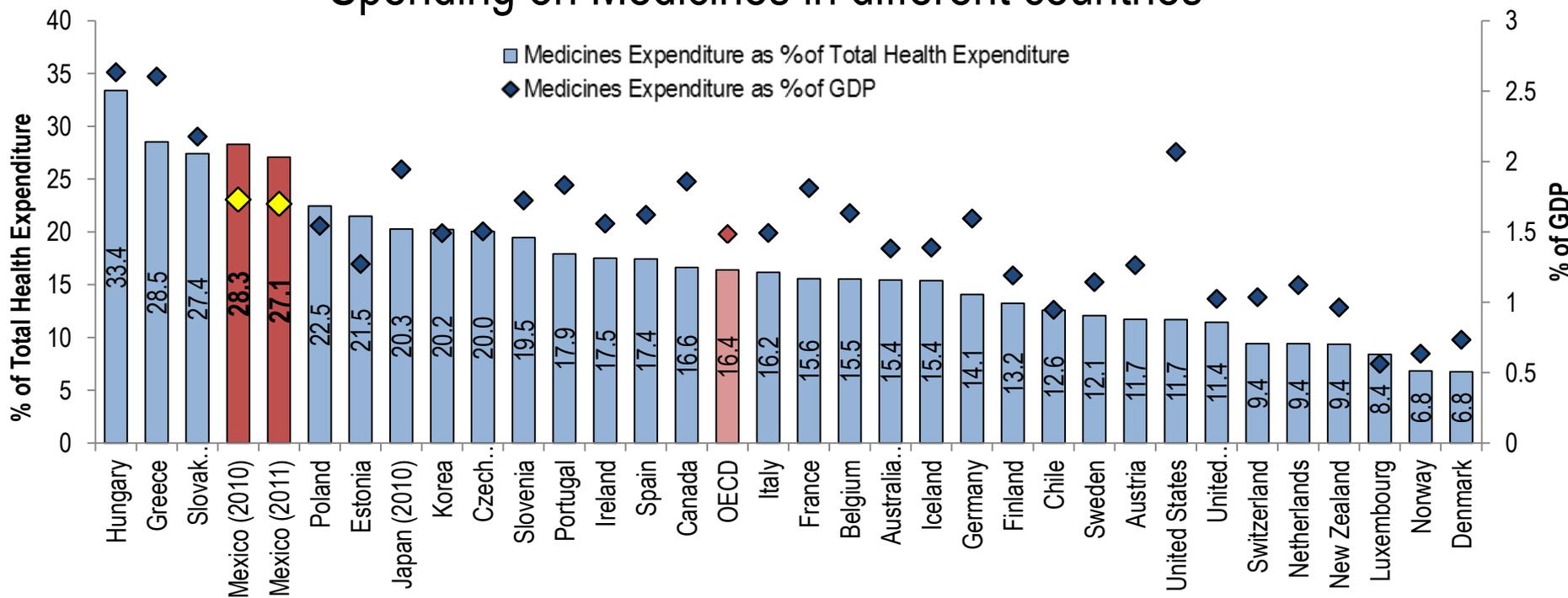
# Conclusions



# Conclusions

- These actions have helped to improve the access of the population to **safe, effective and quality medicines**.
- Mexico moved up two places among OECD countries in spending on medicines as a percentage of total health expenditure, from **28.3%** in 2010 to **27.1%** in the last measurement available of that international organization.

## Spending on Medicines in different countries

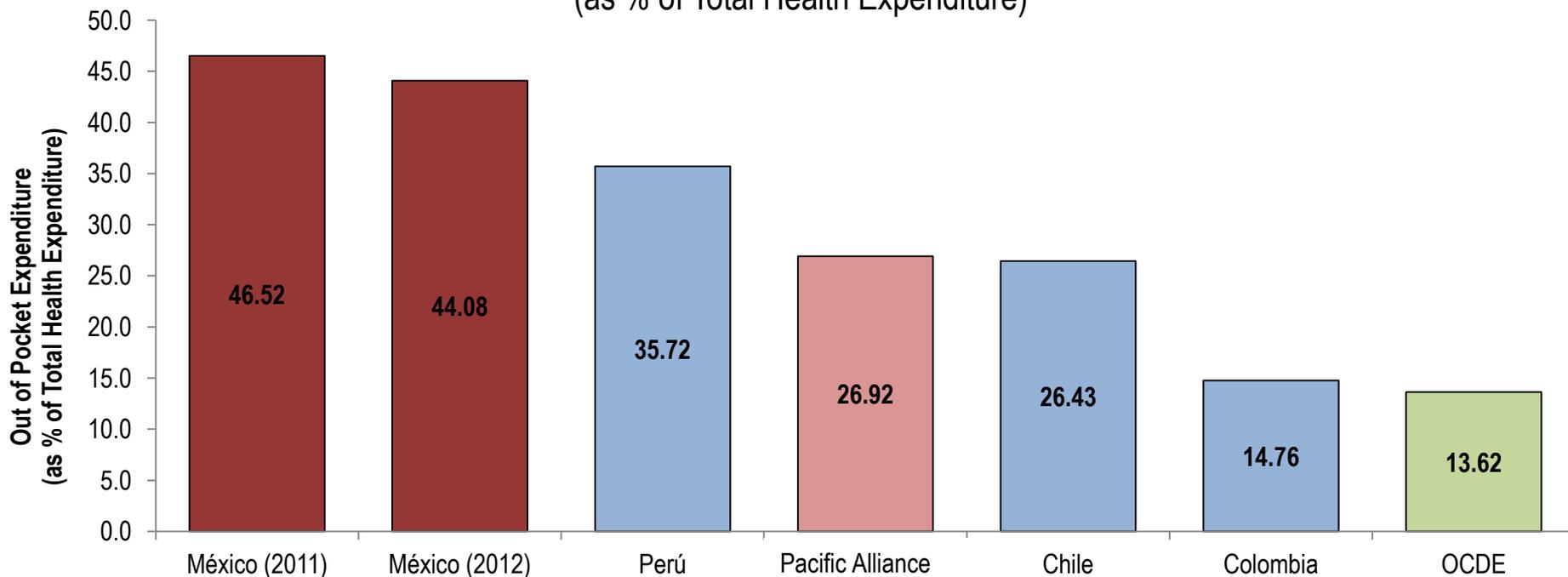




# Conclusions

- As well, the Pharmaceutical Policy implemented in Mexico and the certification as **NRA level IV** for the OPS, have contributed to reduce the Out of Pocket Expenditure in our country.
- Between 2011-2012, the Out of Pocket Expenditure in Mexico have been decreased from **46.5%** to **44%**.

### Out of Pocket Expenditure in Pacific Alliance, 2012 (as % of Total Health Expenditure)



## International Comparison



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- With the reform, Mexico becomes a pioneer in advertising and labeling, through the incorporation of best international practices in the design of regulatory mechanisms transparent to the consumer.
- Specifically, Mexico established as mandatory the following provisions:
  - a) The basis on which you must calculate the calorie content of a product.
  - b) Report the total energy content of the product in the case of flavored beverages, chocolates, snacks and confectionery.
  - c) Set fixed times in television and film to restrict advertising of food and non-alcoholic beverages that do not meet nutritional standards of quality.