

# Value and potential economic savings in the health budget of Mexico due to OTC self-care

APRIL 2018





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# Value and potential economic savings in the health budget of Mexico due to OTC self-care

## Objective

Provide evidence that allows the Asociación de Fabricantes de Medicamentos de Libre Acceso, AC (AFAMELA) to demonstrate the value and real importance of the use of OTC\* medicines in Mexico, to its main audiences (patient, family, society in general, regulatory authority, National Public Health System), by means of the benefits and savings that are generated through that usage, in two specific situations:

- **self-care in acute non-severe conditions and,**
- **as a complement in the management of chronic conditions with high potential consumption of health and social resources.**

\*Over The Counter\* (medicines sold without prescription)

## Methodology

A **Comparative Healthcare Attention Costing Model**, and a **Budget Impact Model** were developed in order to estimate the cost of clinical event per capita, costs of medical attention per capita/year, and institutional/year healthcare costs.

**Benefits and economic savings** were estimated with use of OTC medicines in four common acute and non-severe illness, and fracture complementary preventive regime with OTC medicines in women of 50 years and older with osteoporosis as well.

### ◀ Studied clinical conditions

#### **Non-severe acute common clinical conditions.**

A cost of illness model, was developed in some of the main causes of non-severe acute diseases in Mexico, to compare: the use of OTC medicines vs the conventional management of these cases in the Public Health System (IMSS, ISSSTE and SSA).

The considered clinical conditions were:

- **Common cold/Flu**
- **Acute Diarrhoea**
- **Vulvovaginal Candidiasis**
- **Mycosis: Tinea/Onychomycosis**

The selected target population was:

- Patients who use OTC medicines for their clinical condition.
- Patients who receive medical attention according to the Clinical Practice Guideline (CPG) at IMSS, ISSSTE and SSA for their clinical conditions events.

A Comparative Healthcare Attention Costing Model, and a Budget Impact Model were developed.

In four common acute and non-severe illness, and in a fracture complementary preventive regime with OTC medicines.

Direct medical costs at the institutions and OTC medicines were considered, as well as social costs generated by the loss of productivity for not attending to work.

### **Chronic clinical condition: Complementary preventive regime of fractures with OTC supplements in ≥50 years old women with Osteoporosis.**

A cost of illness analysis of osteoporosis was developed in non-treated women ≥50 years, with high risk of osteoporosis and affiliated to IMSS, ISSSTE or SSA for medical attention; complications such as pathological fractures<sup>1</sup> were included as well. A comparison between the usage of a complementary preventive regime with OTC medicines (calcium drugs + D vitamin) vs conventional management was done.

#### **The selected target population was:**

- Women aged 50 and over diagnosed with osteoporosis, affiliated to IMSS, ISSSTE and SSA clinics who receive medical attention at these institutions.
- Women aged 50 and over with probable osteoporosis (due to the prevalence of this disease in Mexico), affiliated to IMSS, ISSSTE and SSA institutions or general population, which are assumed as not attended at these institutions.

#### **The assumption used in this part of the study was as follows:**

In women aged 50 and over with osteoporosis, a potential savings in costs and use of health resources are generated by using the combination of calcium and vitamin D in their authorized sale presentations for OTC, as complementary preventive management. This condition is chosen in this group of patients because scientifically it is possible to demonstrate the benefit proposed (reduction of the relative risk for pathological fractures in 19.7% with the systematic consumption of calcium supplements + D-vitamin), and because it represents for the institutions of the Public Health System, a population at risk that might generate high costs and consumption of resources. This risk occurs in those who are not being treated at the Public healthcare System, in the general population, and those who are in specific treatment as well (relative risk of pathological fractures).

For both economic analyses (common acute non-severe conditions, and the use of a complementary preventive regime for fractures in women with osteoporosis), direct medical costs at the institutions and OTC medicines were considered, as well as social costs generated by the loss of productivity for not attending to work.

#### **◀ Healthcare resource usage.**

##### **Private Sector (OTC).**

To measure the use of resources in the self-managed group with OTC medicines, interviews were applied to patients who had any of the selected clinical conditions (recently or not) themselves or their close relatives (especially in the case of young children), and properly medicated (until the symptoms were resolved, that is, not requiring complementary medical management). The sample consisted of 75 urban individual (housewives, workers, students and retirees) from Mexico City, from socioeconomic levels A-B, C, and D-E, proportionally represented by both genders, in a range of 18 to 75 years old.

<sup>1</sup> A pathological fracture is the fracture which occurs without adequate trauma and is caused by pre-existent pathological bone lesion. (Mukhopadhyay S. 2016)

## Public Sector

The healthcare process at the Public Sector, was based on specific and official Clinical Practice Guidelines of the Public Health System of Mexico and was validated by a panel of local treating physicians (from the three institutions: IMSS, ISSSTE and SSA), using the conventional Delphi methodology<sup>2</sup>. The sample consisted of 45 general practitioners, and 12 specialists (orthopedists and obstetrician gynecologists). Mean values were estimated and the results are presented with a 95% confidence interval [95% CI].

### ◀ Sources of costs.

The unitary costs of medication, medical care (general and specialty consultation, hospitalization, emergency care room, diagnostic tests, surgery, etc.) and “working-days lost” (due some of these clinical conditions) were obtained by the following sources:

#### Public Sector

**IMSS:** portal IMSS® purchase for drugs, and from the document Unitary Costs per Level of Medical Care for 2016 ACDO.SA3.HCT.040414/73.PDF for the costs of medical care.

**SSA:** web Compranet® 5.0 for drugs and from the costs tabulator of medical care for the SSA 2016.

**ISSSTE:** control panel of medical supplies of the ISSSTE 2016 (for drugs as well as elements of medical care).

#### Private Sector (OTC)

For the OTC medication, the consumer price (at June 2016) was considered using an average price of independent pharmacy, self-service pharmacy and chain pharmacy.

#### Social Cost

The cost of productivity lost was estimated, represented in this specific case by the “working-day lost” due to the clinical conditions analysed. It was calculated based on the average income/day in Mexico determined by ENIGH<sup>3</sup> 2014 (updated to 2016) and INEGI, and the frequency of lost days were determined by the Delphi panel, correspondingly.

### ◀ Definition of the attended cases in the Public Health System.

#### Sources of attended cases in the Public Health System

To determine the number of cases treated for each of the clinical conditions analysed in the Public Health Sector (IMSS, ISSSTE, SSA), the number of events attended specifically in each institution was obtained during a full year period (2015)<sup>4</sup>. All these data came from the institutional information itself (reports and statistical yearbooks, direct consultations Infomex-INAI, and from the General Direction of Health Information at the Ministry of Health).

The specific information of each clinical condition was obtained from the databases through the corresponding ICD-10 code (acute conditions, osteoporosis, and related pathological fractures.<sup>5</sup>

The study was carried out both in the private (OTC) sector and in the public sector.

<sup>2</sup> It is a widely used process in both health research and health economics. The aim is to achieve the truth by consensus, generating a statistical response from the group or panel. It is an anonymous process, iterative and with feedback.

<sup>3</sup> Encuesta Nacional de Ingresos y Gastos de los Hogares; INEGI. (National Survey of Incomes and Households Expenses; INEGI).

<sup>4</sup> Last year available of information of official sources of the Public Health System in Mexico at the time of the study performing.

<sup>5</sup> The CIE-10 code corresponds to the International Classification of Disease, tenth edition. It is a specific nomenclature generated by the World Health Organization (WHO), and it is widely used internationally.

◀ Prevalence estimation of Osteoporosis, incidence of related fractures, and reduction of the relative risk with a complementary preventive regime.

A focused review of the national and international literature with meta-analysis was conducted to determine the prevalence rate of osteoporosis, the incidence of related pathological fractures, as well as the reduction of the relative risk (RR) of presenting fractures as an effect of the consumption of calcium supplements + vitamin D in OTC presentations.

Additionally, CONAPO population pyramid for 2016 was used to obtain the segment of women aged 50 and over. The distribution of the affiliated population to the different institutions (IMSS, ISSSTE and SSA), was obtained from the information of the mid period Survey 2015 of INEGI, and of the ENSANUT MC 2016.<sup>6</sup>

<sup>6</sup> Encuesta Nacional de Salud y Nutrición de Medio Camino (National Interview of Health and Nutrition of Half Journey), 2016. Instituto Nacional de Salud Pública (National Institute of Public Health). México.

# Results

**Influenza or common cold (CC)** is a very frequent clinical condition. It represents one of the main causes of consultations at the first level of care at the Public Health System. During the analysed year (2015) about 7.5 million patients sought medical attention at the Public Health System. Mexican families presented three episodes per year<sup>7</sup> on average. This generated a significant burden for the institutions.

The average cost of care for a CC event in the Public Health System is \$1025 MXP, while with OTC self-care is \$32 MXP, that is, with a total cost difference of \$993 MXP per event.

This implies potential savings of 993 million MXP/year for each million of events managed with self-care with OTC medicines compared to receiving medical care in the Public Sector.

The average cost of care for a Common Cold event in the Public Health System is \$1025 MXP, while with OTC self-care is \$32 MXP.

## Common flu in México

<b>Annual cases (thousands)</b>	<b>7,493</b>
IMSS	2,091
SSA	4,405
ISSSTE	997
<b>Average Costs per Event in the Public Sector</b>	
Medical care	\$ 996. <sup>81</sup>
Treatment	\$ 28. <sup>61</sup>
<b>Cost per event</b>	<b>\$ 1,025.<sup>43</sup></b>
OTC cost per event	\$ 32. <sup>00</sup>
Loss of Productivity due to work absenteeism by family / year	\$ 481. <sup>55</sup>
Savings per case handled with OTC	\$ 993. <sup>43</sup>
<b>Savings per million events attended with OTC</b>	<b>993 Million Pesos</b>

This implies potential savings of 993 million MXP/year for each million of events managed with self-care with OTC medicines compared to receiving medical care in the Public Sector.

<sup>7</sup> Data determined from the analysis of institutional databases, Panel Delphi of treating physician, and from the patient interviews.

The average cost for an Acute Diarrhoea event in the Public Health System is \$664 MXP, while with OTC self-care medication is \$71 MXP.

**Acute Diarrhoea (AD)** is a very frequent clinical condition. It occurs in all age groups and in both genders and its eventual severity is concentrated in the extreme ages of life: young children and older adults, essentially due to the greater frequency and risk of complications.

It is also one of the first causes of consultation at general or family medicine in the Public Health System.

During the analysed year about 3 million of patients sought attention to the Public Health System at primary medical care level. 2.5 episodes per year occurred in Mexican families on average. The burden for public institutions was substantial.

**The average cost for an AD event in the Public Health System is \$664 MXP**, while with OTC self-care medication **is \$71 MXP**; that is, with a total cost difference of \$592 MXP per event.

**It means potential savings of 592 million pesos/year for each million of events managed with self-care with OTC medication vs receiving care in the Public Sector.**

## Acute diarrhoea in México

It means potential savings of 592 million pesos/year for each million of events managed with self-care with OTC medication vs receiving care in the Public Sector.

<b>Annual cases (thousands)</b>	<b>2,818</b>
IMSS	1,098
SSA	1,333
ISSSTE	386
<b>Average Costs per Event in the Public Sector</b>	
Medical care	\$ 628. <sup>64</sup>
Treatment	\$ 34. <sup>87</sup>
<b>Cost per event</b>	<b>\$ 663.<sup>51</sup></b>
OTC cost per event	\$ 71. <sup>19</sup>
Loss of Productivity due to work absenteeism by family / year	\$ 127. <sup>80</sup>
Savings per case handled with OTC	\$ 592. <sup>32</sup>
<b>Savings per million events attended with OTC</b>	<b>592 Million Pesos</b>



**Vulvovaginal Candidiasis (VVC)** is a frequent clinical condition in the female population. It occurs in all age groups, being more relevant in adolescence and adulthood. It is also a significant cause of consultation for primary health care in the Public Health System in this group. There are 1.4 events/year per family in our environment on average. During 2015 around half million cases were registered in the Public Sector.

The average cost of attending a VVC event in Public Health System is \$1078 MXP; while with OTC self-care medication is \$79 MXP; that is, with a total cost difference of approximately \$1000 MXP per event.

This represents potential savings of 100 million pesos/year for every hundred thousand events managed with self-care with OTC medication, compared to receiving care in the Public Health System.

The average cost of attending a Vulvovaginal Candidiasis event in Public Health System is \$1078 MXP; while with OTC self-care medication is \$79 MXP.

## Vulvovaginal Candidiasis in México

Annual cases (thousands)	482
IMSS	134
SSA	283
ISSSTE	64
Average Costs per Event in the Public Sector	
Medical care	\$ 1,057. <sup>91</sup>
Treatment	\$ 20. <sup>39</sup>
Cost per event	<b>\$ 1,078.<sup>30</sup></b>
OTC cost per event	\$ 78. <sup>53</sup>
Loss of Productivity due to work absenteeism by family / year	\$ 240. <sup>16</sup>
Savings per case handled with OTC	\$ 999. <sup>77</sup>
Savings per million events attended with OTC	<b>100</b> Million Pesos

This represents potential savings of 100 million pesos/year for every hundred thousand events managed with self-care with OTC medication, compared to receiving care in the Public Health System.

The average cost of care for a Tinea and Onychomycosis event in the Public Health System is \$1049 MXP, while with OTC self-care medication is \$616 MXP.

**Mycosis** of the **Tinea** and **Onychomycosis (TOM)** type are also frequent clinical conditions in the general population, being more frequent in adolescence and adulthood.

It is a relatively important reason for first-contact medical care in the Public Health System. One event/year is estimated in Mexican families on average.

During the year of the analysis about one and half million cases were attended in the Public Sector.

**The average cost of care for a TOM event in the Public Health System is \$1049 MXP, while with OTC self-care medication is \$616 MXP; that is, with a total cost difference of approximately \$434 MXP per event.**

**This implies potential savings of 43 million MXP/year for every hundred thousand events managed with self-care with OTC medication compared to receiving care in the Public Sector.**

This implies potential savings of 43 million MXP/year for every hundred thousand events managed with self-care with OTC medication compared to receiving care in the Public Sector.

## Superficial Mycosis In México

<b>Annual cases (thousands)</b>	<b>1,483</b>
IMSS	414
SSA	872
ISSSTE	197
<b>Average Costs per Event in the Public Sector</b>	
Medical care	\$ 650. <sup>93</sup>
Treatment	\$ 398. <sup>28</sup>
<b>Cost per event</b>	<b>\$ 1,049.<sup>21</sup></b>
OTC cost per event	\$ 615. <sup>50</sup>
Loss of Productivity due to work absenteeism by family / year	\$ 160. <sup>52</sup>
Savings per case handled with OTC	\$ 433. <sup>70</sup>
<b>Savings per million events attended with OTC</b>	<b>43 Million Pesos</b>

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## Complementary preventive regime for fractures with OTC supplements in women aged 50 and over with Osteoporosis.

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**Osteoporosis (OP)** is a chronic and progressive health condition, particularly in women, and specially from 50 years of age. **It represents a relevant public health problem.** According to the data from Mexican studies, interviews with experts and local treating physicians, the **average prevalence of this clinical condition in Mexico is 20.5%.** Similarly, the average international **incidence of pathological fractures as a complication,** according to the specialized literature, is 17.7% (Clark, 2010, 2013). This means that, in the year of the study, the prevalence in this population group **was 2 million women with osteoporosis and about 349 thousand related fractures** with significant implications to the Mexican society, both in loss of productivity and quality of life.

The strategy with the use of OTC medicines corresponds to **a complementary preventive regime based on calcium + vitamin D supplements,** with the aim of preventing pathological fractures by reducing the relative risk (RR) of suffering an event of this type. According to the published international literature **the relative risk (RR) is reduced 19.7%.**

During the year analysed for this study (2015), 791,174 women aged 50 and over in the Public Health Sector were treated with this diagnosis. Registering 140,271 related pathological fractures.

**The average cost of care for a fracture event in the Public Health System is \$9,394 MXP, while the average annual cost of the preventive regime with OTC supplements is \$4675 MXP.**

Based on the above, in 2015 the use of the complementary preventive regime with OTC products, would have represented around 69,000 fractures of this type avoided, equivalent to approximate savings of 648 million MXP of direct medical costs.

In Mexico there are approximately 2 million women (50 years and over) with Osteoporosis, and around of 349 thousand related fractures.

The average cost of care for a fracture event in the Public Health System is \$9,394 MXP, while the average annual cost of the preventive regime with OTC supplements is \$4675 MXP. Based on the above, in 2015 the use of the complementary preventive regime with OTC products, would have represented around 69,000 fractures of this type avoided, equivalent to approximate savings of 648 million MXP of direct medical costs.

# Osteoporosis and related fractures In México

Osteoporosis in women $\geq 50$ years (millions)	<b>2</b>
Annual pathological fractures (thousands)	<b>349</b>
IMSS	65
SSA	61
ISSSTE	14
Average cost per fracture in the Public sector	
Medical care	\$ 5,915. <sup>45</sup>
Treatment	\$ 3,478. <sup>09</sup>
Cost per fracture	<b>\$ 9,393.<sup>54</sup></b>
OTC cost preventive regime/year	\$ 4,675. <sup>04</sup>
Reduction of relative Risk of Fractures con a preventive regime	<b>19.70%</b>
Fractures avoided with OTC (thousands)	<b>69</b>
Potential savings of avoided fractures associated to the preventive regime with OTC	<b>648</b> Million Pesos

## Budget impact in the public health care system in México

A proportion of the health budget<sup>8</sup> of the main institutions of the Public Health Sector (IMSS, SSA, ISSSTE) is dedicated to addressing the acute non-serious common conditions analysed here. This is something to highlight, because those health incidents could have been managed easily and effectively with OTC medication. **The budget dedicated in the institutional level is the following:**

- ◀ **5.06% in IMSS**
- ◀ **13.88% in SSA**
- ◀ **9.81% in ISSSTE**

If we consider exclusively the budget proportion related with the **care for Osteoporosis and secondary fractures in women of 50 years and over**, results are:

- ◀ **2.87% in IMSS**
- ◀ **6.61% in SSA**
- ◀ **1.54% in ISSSTE**

<sup>8</sup>It corresponds to the sub functions of health service provision to the person, and of social protection in health, of the health function. Programmable expenditure on health. Budget of Expenditures of the Federation 2017.

# Key results and conclusions

This study shows that the **Public Health Care System in Mexico faces a significant cost burden for the care of common acute non-serious health problems, which can be easily and effectively treated with OTC medicines.**

The annual per capita cost paid by Mexican families for **self-care with OTC** medication of non-serious common health conditions was **\$199 MXP**, compared to **\$954 MXP** for those **patients treated in the Public Health Sector.**

**OTC products contribute to maintain an active workforce in the Mexican society, offering \$195 million MXP/year as a potential benefit for every million of cases of this type of diseases treated with OTC medicines vs being treated in the Public Health Sector according to the reduction in working-days lost.**

**Every \$1 MXP spent among the four categories of OTC medicines for acute non-serious clinical conditions analysed allows the optimization of approximately \$5 MXP, by the Public Health Sector.**

**Also every \$1 MXP spent in the complementary preventive regime with calcium + vitamin D supplements with OTC medicines allows the optimization of \$3.7 MXP in relation to pathological fractures avoided in women aged 50 and over with Osteoporosis, treated in public health care institutions.**

OTC products contribute to maintain an active workforce in the Mexican society, offering \$195 million MXP/year as a potential benefit for every million of cases of this type of diseases treated with OTC medicines vs being treated in the Public Health Sector according to the reduction in working-days lost.

**Considering the foregoing, the need to increase the participation and social responsibility of the OTC medication is clear.**

**The results of the present economic analysis are very clear. The practice of self-care using OTC medicines by Mexican families is economically affordable and easily accessible to consumers, who can thus contribute to the Public Health System in the care of their own health, as a personal, family and social asset.**

## The number and variety of treatments for self-care should be increased in order to:

- ◀ **Optimize the operating costs of the Public Health Sector**, by exchanging costly treatment at the institutional level, for a very accessible management with OTC medicines at the pharmacy level.
- ◀ Improve social **productivity** by reducing working-day lost, favouring a better quality of life.
- ◀ **Encourage the timely and expeditious management of chronic and progressive health conditions**, which today generate the greatest burden on the Public Health System, when time and space are freed in the outpatient clinic of the first level of care.
- ◀ **Help reduce the risk of serious, costly and eventually disabling complications**, of chronic conditions such as osteoporosis (associated pathological fractures) in vulnerable groups of society (women aged 50 and over), favouring the use of accessible preventive regimes (calcium + vitamin D supplements).
- ◀ The above can be fulfilled through a **coordinated and joint effort**, between **AFAMELA, COFEPRIS**, and the National Healthcare System through a common agenda, oriented to the improvement and optimization of the regulatory framework, communication and education in the responsible employment of OTC medicines, as well as greater and better access to more product categories progressively.

\* Se asume el SNS integrado por: las instituciones públicas de salud, los proveedores privados, las academias nacionales de medicina, los consejos de las especialidades y las escuelas médicas de México.

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