

# ORGANIZATION OF AMERICAN STATES

INTER-AMERICAN DRUG ABUSE CONTROL COMMISSION

cicad

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## **CONTROL OF PSEUDOEPHEDRINE IN MEXICO**



SECRETARÍA  
DE SALUD

**SALUD**

# **CONTROL OF PSEUDOEPHEDRINE IN MEXICO**

May 2007



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# **FEDERAL COMMISSION FOR PROTECTION AGAINST SANITARY RISKS**

## **COFEPRIS**

- REGULATORY, CONTROL, AND  
PUBLIC HEALTH ACTIONS

# PROLOGUE



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- Mexico's regulatory strategy is based on three main guidelines:
  - ✓ Strengthening the law that controls the sale and use of controlled substances.
  - ✓ Enforcing public policies to protect against public health risks.
  - ✓ Close relations with the pharmaceutical industry.



## REGULATORY FRAMEWORK

- Pseudoephedrine: considered a precursor chemical and classified as a psychotropic substance; this applies both to the raw material and to pharmaceutical products that contain it. Regulated by the General Health Law, the Federal Law for the Control of Precursor Chemicals, and the Health Substance Regulations.

## GENERAL TRENDS

- The licit supply of pharmaceutical products used to respond directly to the demand for those products, NO to therapeutic needs.
- **DEMAND = LEGAL DEMAND (therapeutic use) + ILLEGAL DEMAND**



## ACTIONS

1. Request for forecasts of annual consumption of pseudoephedrine and products containing it, to be presented one year in advance. These amounts can be adjusted by the health authority in accordance with legitimate needs for the substance.
2. Suspension of pseudoephedrine imports and distribution to raw material distributors or intermediaries. The aim was to avoid, by reason of the distributors' nature, surplus raw materials in their inventories, in accordance with Art. 12 of the 1988 Vienna Convention.
3. Businesses are required to notify thefts and losses to the public health authority (COFEPRIS) and to the judicial authorities (PGR).



## ACTIONS

4. Permits to import up to a maximum of 500 kg for manufacturing laboratories only.
5. Medicines containing pseudoephedrine were reclassified, placing them in Group II (previously they were in Groups IV, V, and VI) . This means they can only be sold with a medical prescription.
6. Only three customs stations are authorized for imports and exports of pseudoephedrine, in accordance with control needs and logistics: Mexico City International Airport (AICM), Manzanillo, Colima, and Veracruz, Veracruz.



## ACTIONS

7. Use of the National Drug Control System (NDS).

Tool supplied by the United Nations Office on Drugs and Crime (UNODC).

8. Security measures are required to transport raw materials or finished products from the port of entry to the pharmaceutical laboratory.

9. Agreements signed to limit sales for medicines that are or that contain pseudoephedrine. ANAFARMEX, DIPROFAR.

10. Support for the industry in replacing pseudoephedrine with phenylephrine.

# IMPORTS OF PSEUDOEPHEDRINE INTO MEXICO

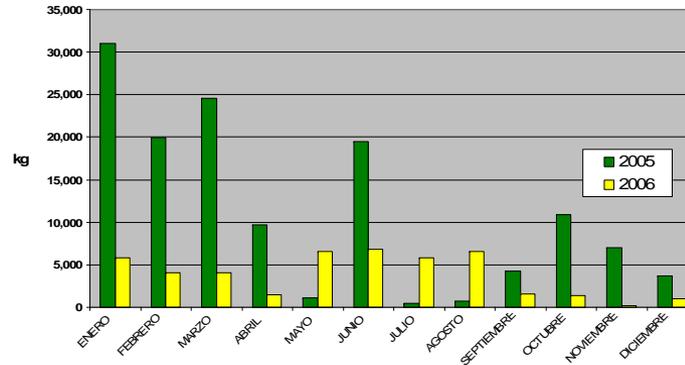


SECRETARÍA  
DE SALUD

**SALUD**

	<b>2005</b>	<b>2006</b>
<b>JANUARY</b>	<b>30,989</b>	<b>5,819.8</b>
<b>FEBRUARY</b>	<b>19,962.4</b>	<b>4,061.1</b>
<b>MARCH</b>	<b>24,552.3</b>	<b>4,093.9</b>
<b>APRIL</b>	<b>9,709</b>	<b>1,519.8</b>
<b>MAY</b>	<b>1,113.8</b>	<b>6,585.3</b>
<b>JUNE</b>	<b>19,485</b>	<b>6,820.5</b>
<b>JULY</b>	<b>475.7</b>	<b>5,826.3</b>
<b>AUGUST</b>	<b>734.8</b>	<b>6,599.2</b>
<b>SEPTEMBER</b>	<b>4,223.5</b>	<b>1,594.4</b>
<b>OCTOBER</b>	<b>10,880</b>	<b>1,412.3</b>
<b>NOVEMBER</b>	<b>7,010.6</b>	<b>150.0</b>
<b>DICEMBER</b>	<b>3,689.8</b>	<b>1042.125</b>
<b>TOTAL</b>	<b>132,826 kg</b>	<b>45,524 kg</b>

# MONTHLY PSEUDOEPHEDRINE IMPORTS, 2005 AND 2006



**TOTAL**

	<b>2005</b>	<b>2006</b>
	<b>132,826 kg</b>	<b>45,524 kg</b>



## CONCLUSIONS

- Considerable reduction in the supply of this precursor chemical in the legal market.
- Caution in imports of other raw materials.
- Importance of interinstitutional coordination — both domestic and with international agencies.
- Vital that countries that handle pseudoephedrine have similar strict regulations.