



FROM SANITARY REGULATION TO RISK PROTECTION

*Federal Commission for Protection
from Sanitary Risks*

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June 20th, 2006 Albany NY

Overview

- **National Drug Policy**
 - Epidemiological environment
 - Economical issues
 - Quality, Safety and efficacy in medicines
 - Accessibility
- **Conclusions**



History

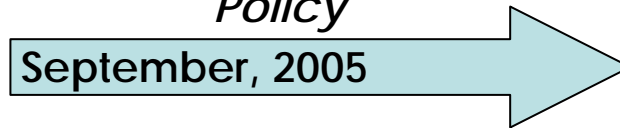
*Presidential
decree*
July, 2001



Cofepris
January, 2002



*National Drug
Policy*
September, 2005



Society expectations on drugs

- ✓ Safety and efficacy.
- ✓ Continuous quality control.
- ✓ Availability and accessibility.
- ✓ Enough information.
- ✓ Reliable publicity.



Main objectives of National Drug Policy (NDP)

- To have medicine with:
 - Safety, efficacy, quality, and
 - Accessibility.

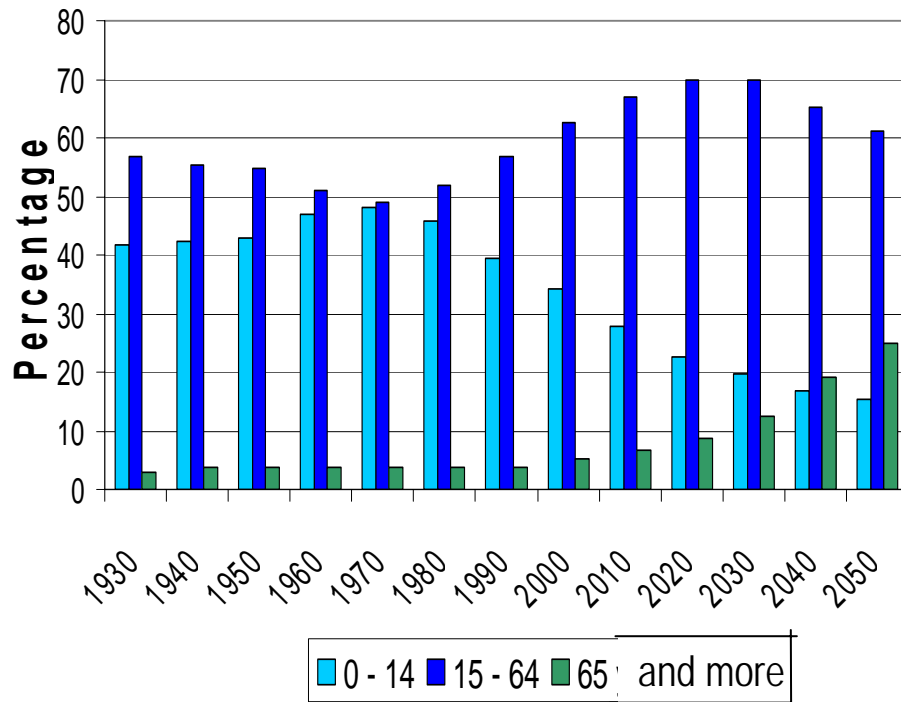
Few changes were implemented while NDP was formulated.

Most are still in process.

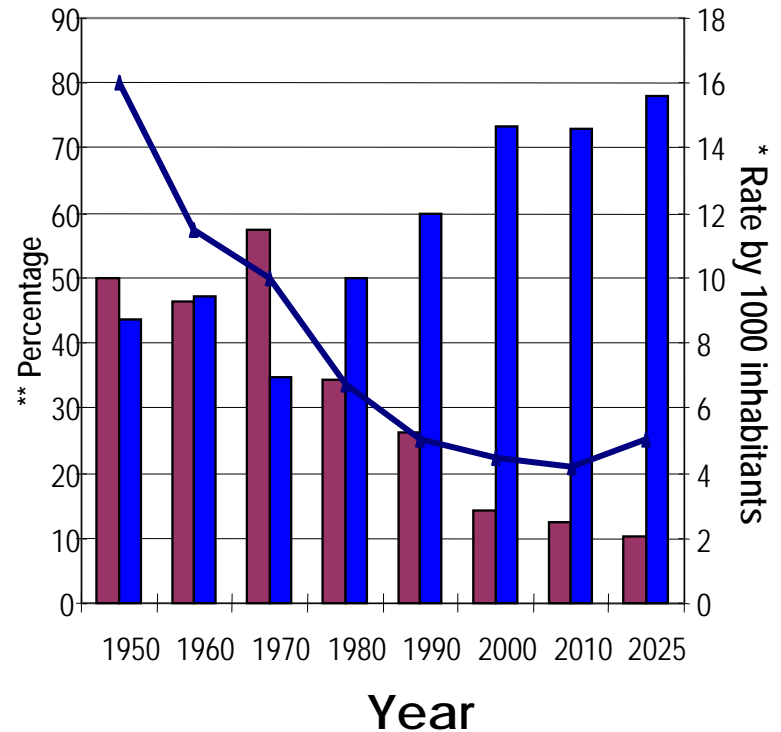


Epidemiologic environment

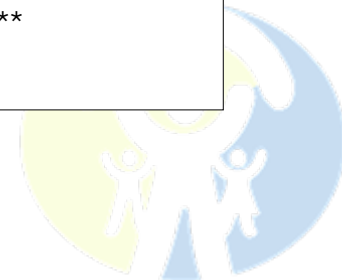
Changes of the age profile of Mexican population from 1930 to 2050



Mortality in Mexico from 1950 to 2025

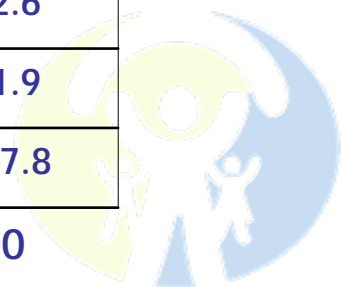


- Transmissible disease of nutrition and reproductives **
- Non-transmissible diseases**
- ▲ Mortality all causes *



Main causes of mortality in Mexico, 2004

	Causes	%
1	Heart diseases	16.3
2	Diabetes mellitus	13.1
3	Malignant tumors	12.9
4	Accidents	7.3
5	Liver diseases	6.2
6	Cerebrovascular diseases	5.7
7	Perinatal diseases	3.2
8	Obstructive chronic pulmonary diseases	2.9
9	Influenza and pneumonia	2.6
10	Renal failure	1.9
	Other causes	27.8
Total		100



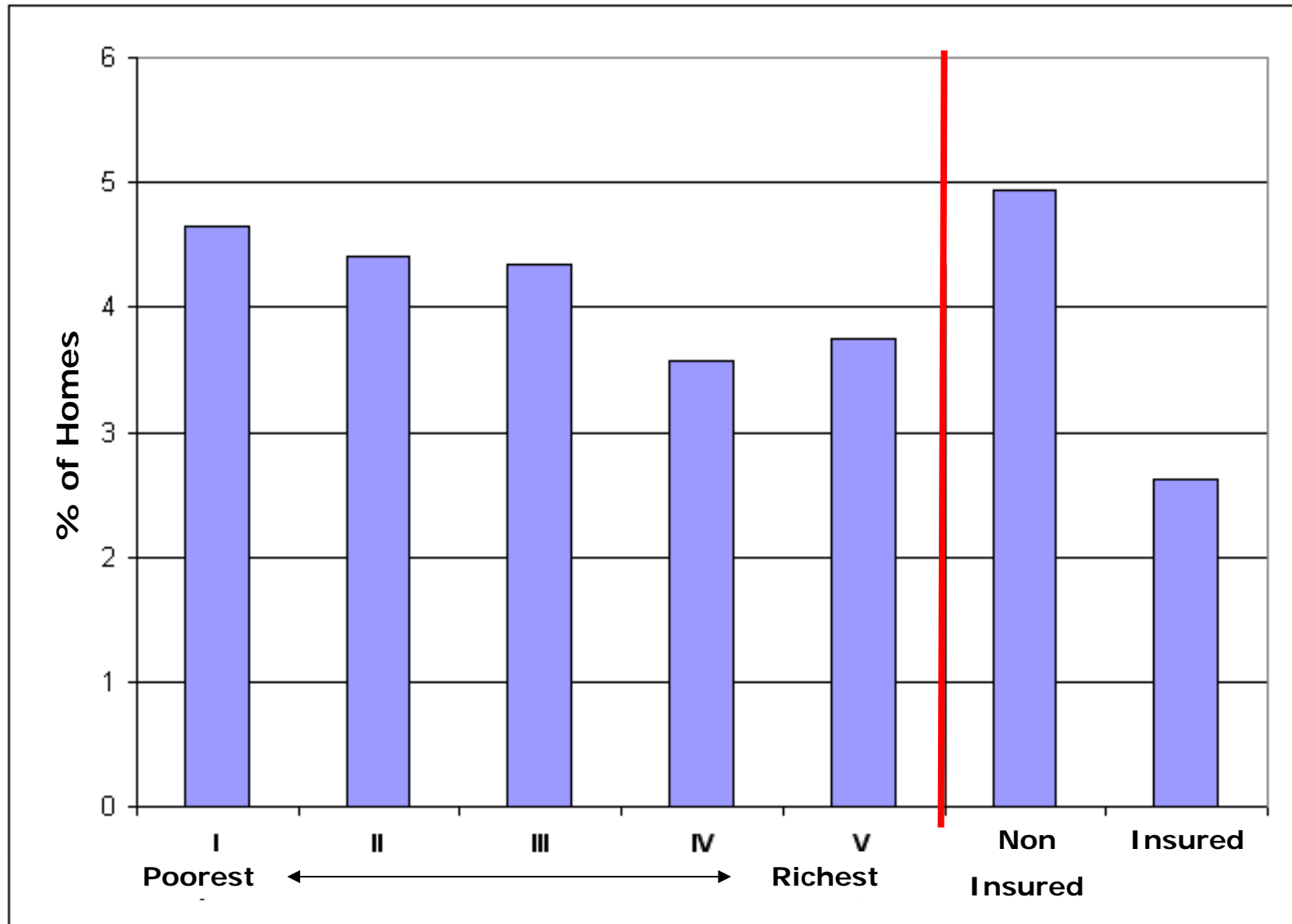
Epidemiologic environment

Causes of increased costs of medical attention

- ✓ Demographic growth
- ✓ Older population
- ✓ Increase in the prevalence and duration of chronic diseases
- ✓ Frequent complications of chronic diseases
- ✓ Drug combinations to obtain the therapeutic effect
- ✓ Patients with simultaneous diseases
- ✓ Increased costs of treatments



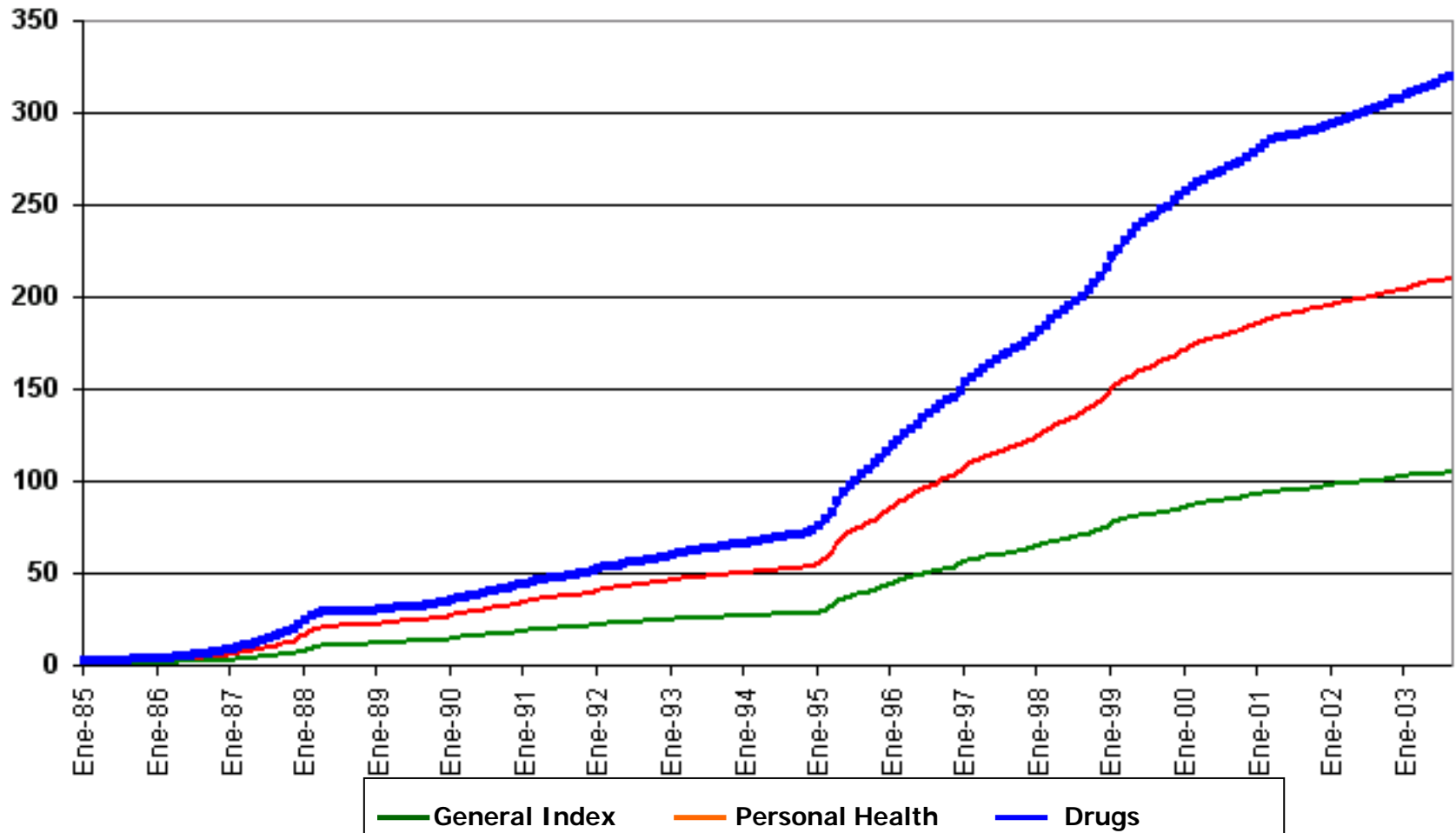
Catastrophic expenses*



* > 30% of pay capacity per year

Health, Mexico, 2002.

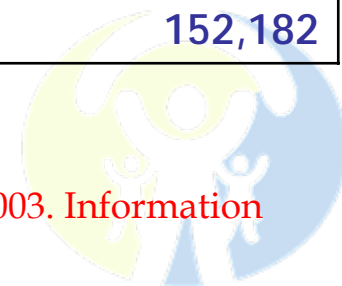
National Index of Prices



Comparative drug sales in NAFTA countries (private market)

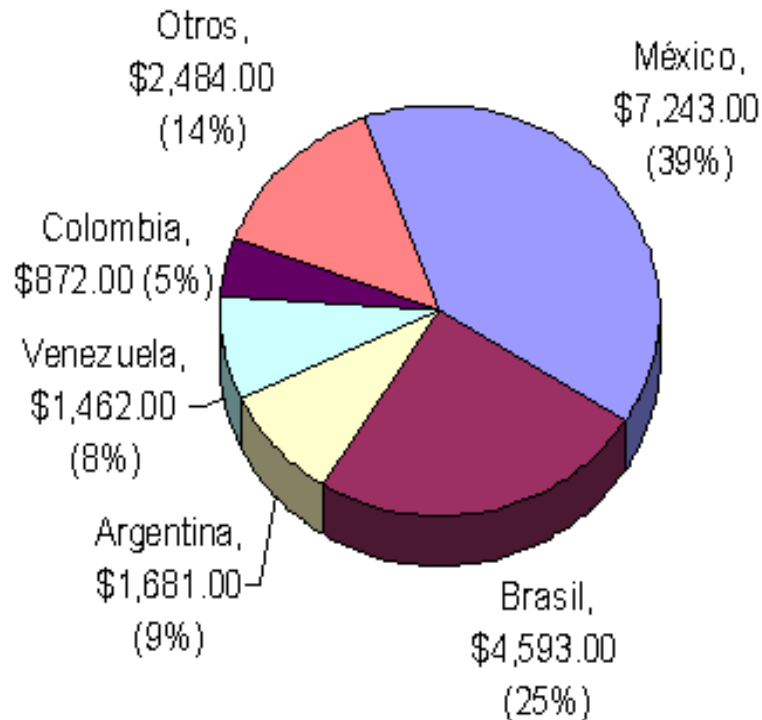
	MEXICO	CANADA	UNITED STATES
Therapeutic classification	USD Millions	USD Millions	USD Millions
Gastrointestinal Tract and metabolism	1,124	1,124	22,202
Systemic antiinfectious	951	404	12,784
Central nervous system	727	1,482	33,485
Respiratory tract	689	558	15,176
Cardiovascular system	518	1,920	26,792
Muscle-skeletal system	514	514	9,207
Genital-urinary system	434	397	9,981
Dermal	364	274	4,356
Others	733	976	18,199
Total:	6,054	7,649	152,182

Source: IMS HEALTH May 2003. Information of 12 months until May 2003.

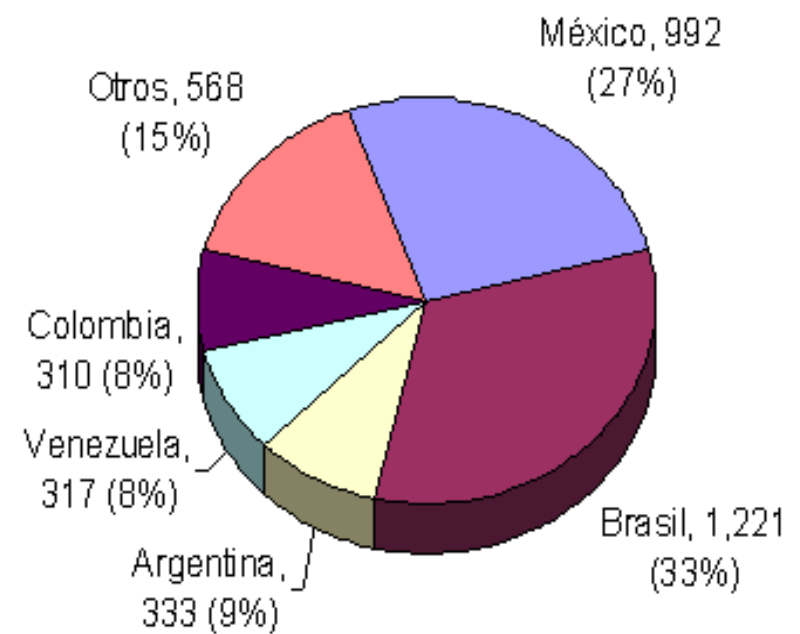


Participation in sales on several countries in the private market in Latin America on 2003

USD (Millions)



Units* (Millions)



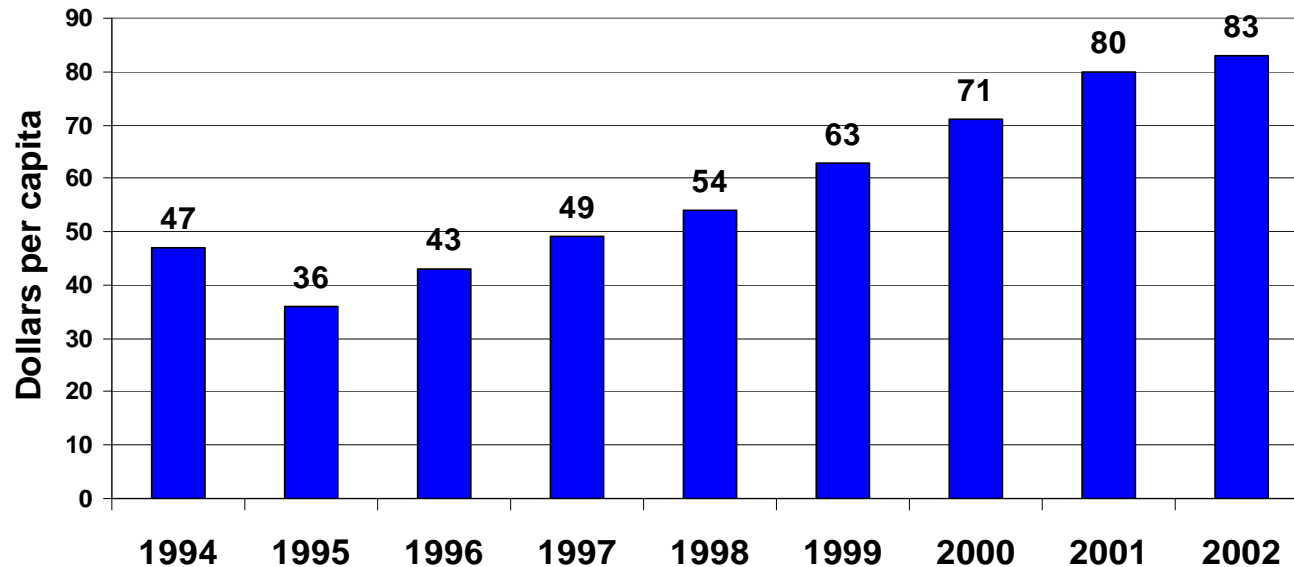
* Units: Boxes of drugs

Fifarma wiht data from IMS, 2003.



Pharmaceutical Industry in Mexico

National apparent per capita consumption of pharmaceutical products 1994-2002

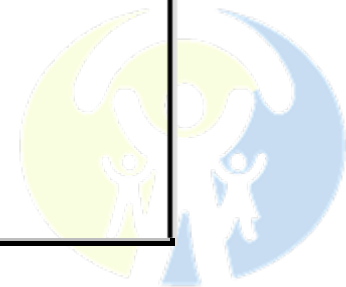
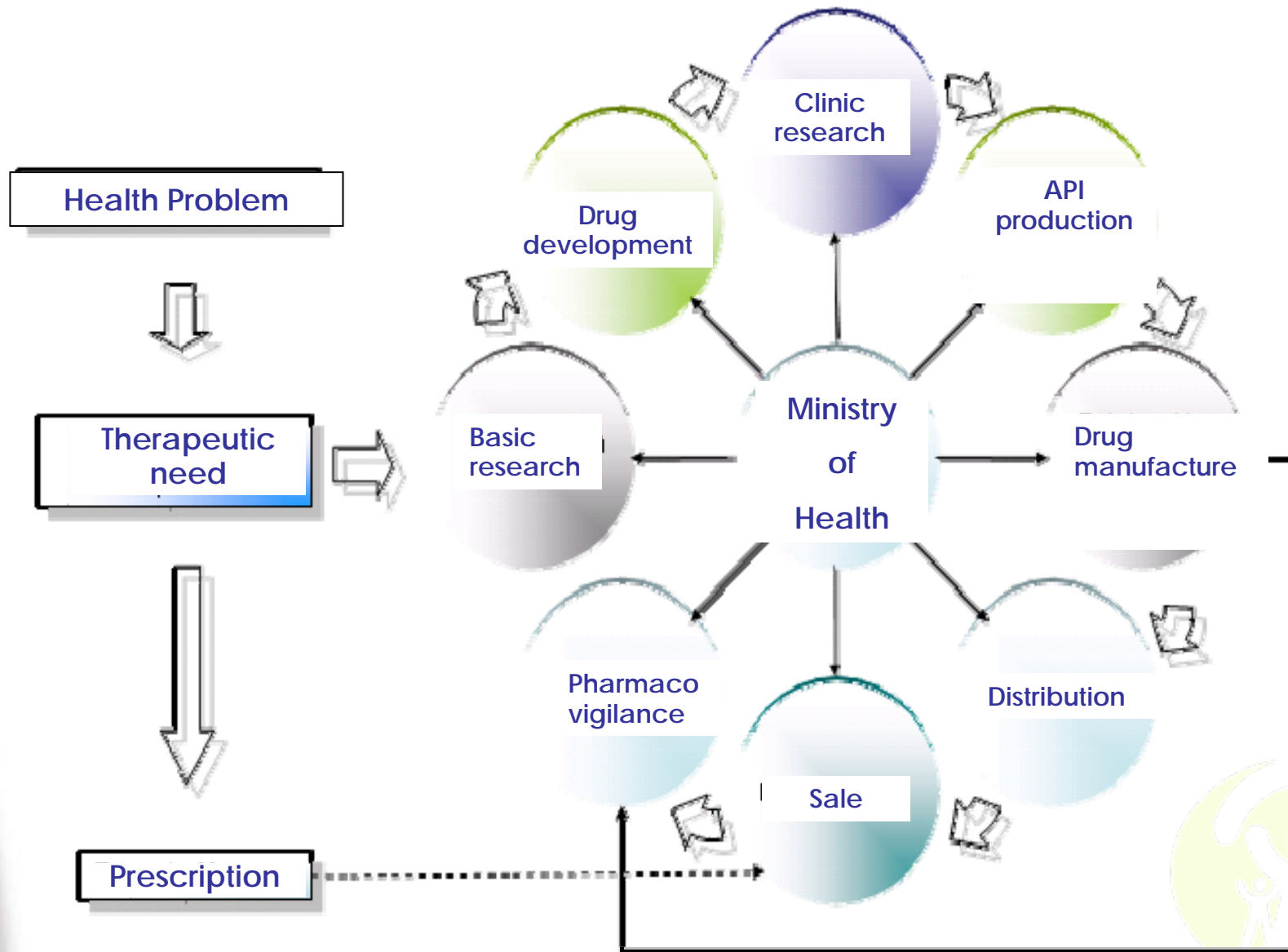


Promote the development of the pharmaceutical industry :

- ✓ Homologate the regulation with other countries.
- ✓ Surveillance of regulation compliance.



Evaluated processes



Aspects related to the sanitary registration

- ✓ Quality active pharmaceutical ingredient.
 - Validation of supplier GMP (FDA, Health Canada, Mexico).
- ✓ Compliance of medicines GMP
 - (Mexican Official Standard 059).
- ✓ Analytical proof of identity and purity.
- ✓ Stability confirmation (Mexican Official Standard 073).
- ✓ Efficacy and safety demonstration, including herbal medicines.
- ✓ Interchangeability tests for all new generics.
- ✓ Renewal of sanitary registration every 5 years.
Interchangeability tests for “old” generic drugs.



Drug Classification according to prescription

At present time there are six types of medicines:

- I. Prescription with bar code;
- II. Prescription is retained in the pharmacy;
- III. Prescription is retained at the third presentation in the pharmacy;
- IV. Prescription is not retained;
- V. OTC in pharmacy;
- VI. OTC outside the pharmacy.

Drug classification will be reduced to four types:

- I. Prescription with bar code (narcotics);
- II. Prescription is retained (psychotropics);
- III. Prescription is needed but not retained;
- IV. OTC.



Insert

- ✓ Name of the drug brand and generic.
- ✓ Dietary and life style indications when appropriate (i.e. obesity, hypertension, diabetes)
- ✓ Instructions of use (i.e. before or after the meals, at night, subcutaneous injection)
- ✓ Indicate the higher dose allowed, in order to prevent adverse reactions.
- ✓ Precautions (including pregnancy and breast feeding).
- ✓ Frequent and serious adverse reactions.
- ✓ Interactions with food and drinks, when appropriate.
- ✓ Interactions with other drugs.
- ✓ Warnings:
 - *"In case of doubt consult your physician".*
 - *"This drug was prescribed to only you, do not share it".*



ADVERTISING OF OTC DRUGS



AFAMELA

COFEPRIS

*Medicine
Labelling
Group*

INFORMATION REALLY USEFUL

*AFAMELA: Free Access Medicines Producers Association

*COFEPRIS: Federal Commission for Protection from Sanitary Risks



INFORMATION USEFUL IN LABEL

- ✓ *Guidance to patient*
- ✓ *Self recognition*
- ✓ *Real usefulness*
- ✓ *Contraindications: Minimize adverse effects*
- ✓ *Additional recommendations*
- ✓ *Language*
- ✓ *Drug store personnel*

*Self regulation
(industry
participation)*



Expected Outcomes

- Rational use and responsible self medication
- Consumer “Empowerment”, active participation in their health protection
- Co-responsibility between the industry and the authority
- Extent the experience to other products such as dietary supplements
- Share experiences in international cooperation fora.



ACCESSIBILITY



Price control

- Currently there is no effective mechanism for drug price control
- Increasing the availability of generic drugs will result on an indirect price control.

Price of innovators 100% *

Price of interchangeable generics ~57% *

Price of non interchangeable generics ~40% *

*Private market

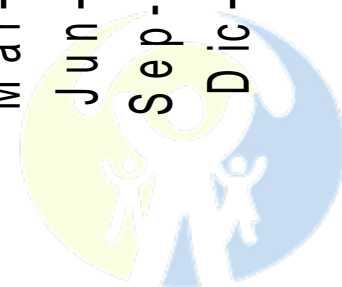
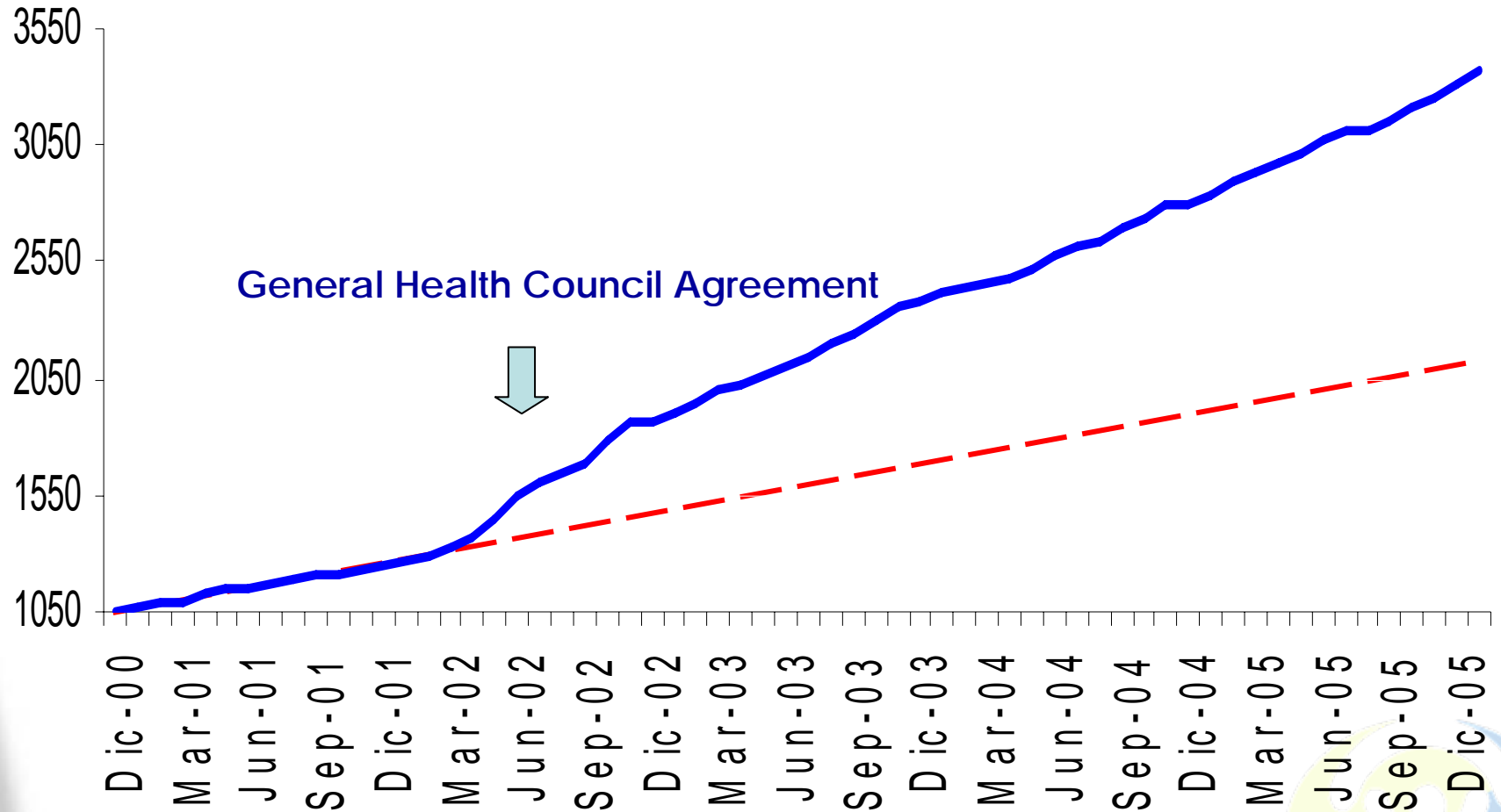


Availability of Generic Drugs

- General Health Council Agreement: Public Health Institutions should acquire interchangeable generics or innovators.
- Interchangeability tests must be approved for every new generic drug.
- Sanitary registration of medicines should be renewed every 5 years
- All non-interchangeable generics that are presently in the Mexican market should perform interchangeability tests in the next 5 years



Number of interchangeable generics registered



CONCLUSIONS



Conclusions

- **Diagnosis:**
 - Increased older population
 - More than 50% of total mortality is due to chronic diseases.
 - Long term, expensive treatments
 - Increase of medicine prices
- **Strategy: More medicines with lower prices assuring their quality**
 - Roadmap outlined towards:
 - All medicines in market with quality, safety and efficacy according to international standards
 - Need to Improve the accessibility
 - Amendments to the regulatory framework
- **Next Steps**
 - Promote implementation and consolidate our Policy
 - As in every continuous mechanism, periodic evaluation of outcomes and new proposals as needed.





Thank You

