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# Sanitary Registration Renewal for Drugs and Health Products

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# Current Situation



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Of about 125,000 current sanitary registries, it is estimated that the following will submit their renewal :

- 10,500 allopathic drugs.
  - 2,200 herbal medicines.
  - 30,000 medical devices.
- 43,00 Total

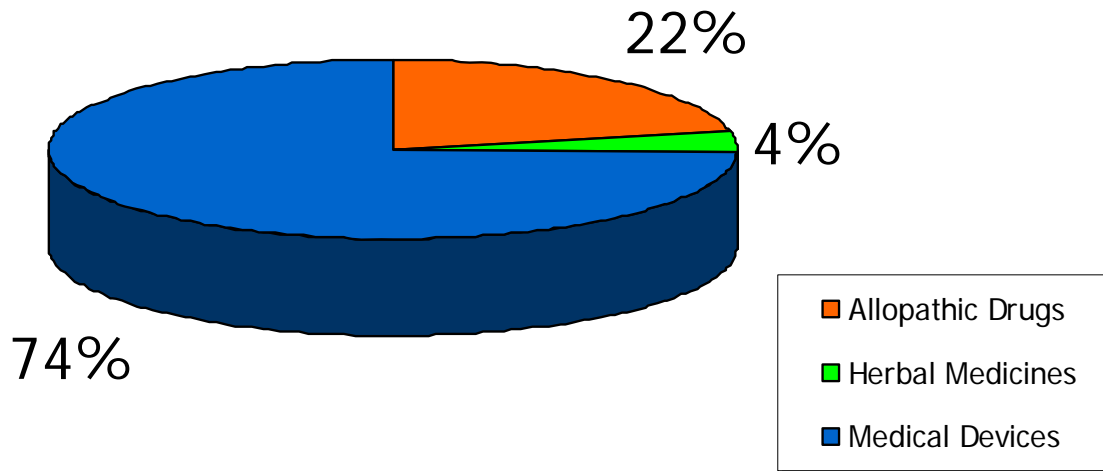
# Current Situation

## Sanitary Registries Issued from 1950 to 2006



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### Registries that can be renewed

Allopathic Drugs	Herbal Medicines	Medical Devices	Total
28,000	4,500	93,000	125,000

# Legal Framework



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On February 24th, 2005 the Article 376 of the General Health Act (GHA) was amended.

- Purpose: Warranty that every health product complies with the following:
  - ✓ Safety, Efficacy, Quality

# Legal Framework



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- The amendment establishes that the Sanitary registries for drugs and medical devices will have a validity of 5 years.
- Mexican Pharmacopoeia
- Mexican Official Standards

# Legal Framework



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- Registries issued by February 24th, 2005 should request their renewal before February 24th, 2010.

# Renewal Process



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The renewal process will begin on September 2007. In this way the first renewed registration will be issued in 2008.





# Renewal Process



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- Number of previous registration and label.
- Good manufacturing practices certificate for the Active Pharmaceutical Ingredient (API) and the dose form.
- Good manufacturing practices certificate for the medical devices.

# Renewal Process



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- Reports of pharmacosurveillance or technosurveillance.
- Bioequivalence tests for generic products

# Renewal Process



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- Promote the authorization of third parties for bioequivalence tests
  - ✓ Currently 27 units authorized.

# Relevance of the renewal for public health



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**1. Represents the opportunity to integrate an information system that allows a better surveillance of sanitary risks as well as adverse reactions and therapeutic indications.**

# Relevance of the renewal for public health



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**2. Identifies APIs producers.**

**3. Warranties the co responsibility of the services suppliers and the industry.**

# Relevance of the renewal for public health



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4. It will increase the generic variety, promoting drug availability.
5. For 2010, there will be registries only for innovators and generics.

# Relevance of the renewal for public health



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6. Updating prescription and labeling information according to the current regulation.
7. Strengthening of the competitiveness of the National Pharmaceutical Industry.



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**THANK YOU**