DEVELOPMENTS IN EMERGING MARKETS
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MEXICO
**MEXICO; An Emerging Economy**

- **$1.261 TRILLION**
  - GDP
  - #14 Worldwide
  - #2 Latin America
  - 2.5% annual growth rate

- **127.01 million people**
  - 45.5% below poverty line

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**The Need for Updated Regulations**

**MEXICO**

epidemiological transition

- New challenges for evaluation and regulation

- **INFECTIOUS DISEASES**

- **CHRONIC DEGENERATIVE DISEASES**
  - Cancer
  - Diabetes
  - Rheumatoid

- biotech drug products
Table: Vital Statistics / Population Piramide 5-2030

<table>
<thead>
<tr>
<th></th>
<th>2005 F</th>
<th>2010 F</th>
<th>2020 F</th>
<th>2030 F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Life expectancy at birth, males (years)</td>
<td>72.4</td>
<td>73.7</td>
<td>75.8</td>
<td>77.2</td>
</tr>
<tr>
<td>Life Expectancy at birth, females (years)</td>
<td>77.4</td>
<td>78.6</td>
<td>80.6</td>
<td>81.9</td>
</tr>
</tbody>
</table>

Life expectancy estimated at 2005:

F = Forecast

Source: UNESCO
**Chronic Degenerative Ethical Consumption / % + GI Segment Endless**

**IN 2020:**
- 20% of the population over 45 years - 34.8 million
- 11.2% of the population over 60 years - 13.9 million

![Graph showing units and values for 2000 to 2020 with percentages increasing over time.]

Approx 4,500 Mill USD prices ’14

Source: MFPM

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**Ministry of Health in Mexico**

**Federal Commission for Protection against Sanitary Risks**

New Molecules Committee

- New drug substances
  (New in the world or new in Mexico)
- New combinations of drug substances
- New indications
- Other special cases (e.g. Biosimilar)

Support in evaluation quality, efficacy and safety information.
Understanding the pharmaceutical application in Mexico

- The timeline to approval varies, real anywhere for one to two years, (official 6 months ATP).
- The registration period is for 5 years, but renewal submission must be at least 6 months before registration expires.
- The regulation of biotechnology products was nonexistent until 2011.

Mexico Healthcare System

**CURRENT**
- Increase in health coverage due to “Seguro Popular” (80%-90%)
- Health expense continue low as % of GDP: 6.2% The average of OECD countries is 8.9%
- COFEPRIS prestige improvement; national and international.
- Government increased support for generics approval.
- Government focus on diseases prevention, mainly obesity and diabetes.

**FUTURE**
- Government health challenge: service quality.
- It is not expected and increase in health expense as % of GDP.
- Government budget restriction.
- Support to generics approval will continue to improve market access.
- MOH will continue to reinforce processes, looking for approval with international practices.
Mexico and the Pharma business

- Epidemiological transition.
- Strong brand loyalty.
- Alternate Market, low-cost medicines.

2/3 of the population under the Social Security System

Aim: Universal Healthcare

Mexican Pharmaceutical Market
worth around
$13.3 Billion
#2 Latin America

<table>
<thead>
<tr>
<th>PUBLIC SECTOR</th>
<th>Generic drugs-tender</th>
<th>Private sector</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Value</td>
<td>20</td>
<td>80</td>
</tr>
<tr>
<td>% Volume</td>
<td>80</td>
<td>20</td>
</tr>
</tbody>
</table>
Breakdown of Total Private Market

**PRIMARY MARKET (Audited)**
- Traditional wholesalers
- National Chains
- Regional Chains
- Self-service stores
- Independent pharmacies
- Others

**ALTERNATE MARKET**
- Farmacias Similares (≈ 5,000)
- Farmacia GI (≈ 1,100)
- Generixs Farmacia
- Wineries generics
  - (≈ 60)
  - (≈ 48)
  - (≈ 40)

Mexico Pharmaceutical Industry

**CURRENT**
- Pharmacy chains growth, mainly from new POS.
- Consolidation: Medium-large laboratories buying biological, research and generics.
- New international and national companies.
- Important increase of doctor’s offices at POS.

**FUTURE**
- Pharmacy chains will dominate segment with organic and inorganic growth.
- International laboratories will continue purchasing local companies.
- Aggressive price strategies from competitors.
- Doctor’s offices at POS, will be the main private supplier for medical consultation.
- Integrated service at POS: Clinical analyzes.
HISTORICAL DEVELOPMENT
UNITS AND VALUES

Audited Historical Market Development / Total OTC / GI's / Ethics without Mill
/12MM December 06 - 2015

Units (Mill)

OTC
GMBP
06 07 08 09 10 11 12 13 14 15

Audited Historical Market Development / Total OTC / GI's / Ethics without Mill
/12MM December 06 - 2015

Units (Mill)

OTC
GMBP
06 07 08 09 10 11 12 13 14 15

AEGI
Audited Historical Market Development / Total OTC / GI’s / Ethics without Milk
12MM December 06 - 15

Values Pesos (Bill)

Average Price / December 2015

<table>
<thead>
<tr>
<th>Category</th>
<th>Average Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patents Products</td>
<td>USD $ 38.04</td>
</tr>
<tr>
<td>Rx Products Ethical</td>
<td>USD $ 18.10</td>
</tr>
<tr>
<td>OTC Products</td>
<td>USD $ 4.33</td>
</tr>
<tr>
<td>LPBG</td>
<td>USD $ 4.29</td>
</tr>
<tr>
<td>Pure Generics</td>
<td>USD $ 2.87</td>
</tr>
<tr>
<td>Private Label Generics</td>
<td>USD $ 2.87</td>
</tr>
</tbody>
</table>
With only 14% of POS, national pharmacy chains have 44% of the audited market (Units)

POS 3,855
U 102,355

POS 15,287
U 8,145

POS 27,035
U 33,482

POS 3,097
U 3,097

POS 4,793
U 39,368

2013
38%

2013
20%

2013
22%

2013
20%

14% 44% 20%

NATIONAL PHARMACY CHAINS (3)
INDEPENDENT PHARMACIES
SUPER MARKET PHARMACIES
REGIONAL PHARMACY CHAINS

Source: CID / MFMM Acum Dic 2015

Biotech regulations: Mexico at the vanguard

- Some legal adaptations to include innovative biotech drug products.
- Modification to Health General Law – all biotech products.
- Inclusion of some concepts and guidelines in Health.
- USA - EU started discussions on regulations for SBP.
- EU: First specific guidelines.

- Some legal adaptations to include innovative biotech drug products.
- Modification to Health General Law – general principles for SBP.
- New biotech regulation.
- Regulation became effective.
Mexican Ministry of Health strategy for biosimilar applications and renewals

- New **NOM-257** for **MA** of biotechnology products.
- All products will be renewed as innovators or **biocomparable**.
- **Physical-chemical** comparability mandatory.
- **Clinical comparability** required for biocomparable candidates.

The future of the biopharmaceutical market in Mexico

- **The high cost of medicines**, including biotech, impacts the cost of health care.
- **Biocomparables** have the advantage of all the indications for which innovators have been used.
- Automatic substitution in the National Formulary.
- Barriers to register a **biocomparable drug** are much more strict than for any **allopathic drug**.
Conclusions

- With the strategy for implementing the regulation for MB and MBB in Mexico, the safety and efficacy of MBB will be confirmed and a Health goal will be achieved, ensuring access to drugs with proven quality, safety and efficacy.

- Biocomparables penetration in the Mexican market will be closely related to how the availability of such drugs is communicated.

- We must not lose sight of the impact of interchangeability or automatic substitution.

- Remember that a drug that you can not pay is the same as a non existent drug!

THANK YOU!