The Eleventh Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum
Global Compliance: Reports from Mexico and LA

Washington D. C.
October 21, 2010

Dr. Juan F. Millan S.
# Codes of Good Practices for the Pharmaceutical Industry

## Current Status in Latin American Countries

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### Public vs Private Sector Healthcare Workers

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<th>Private Sector</th>
<th>Total</th>
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<tr>
<td>Physicians</td>
<td>142,453</td>
<td>55,173</td>
<td>197,626</td>
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<tr>
<td>Nurses</td>
<td>196,675</td>
<td>37,697</td>
<td>234,372</td>
</tr>
<tr>
<td>Reps.</td>
<td>196,675</td>
<td>37,697</td>
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<td><strong>Drug units sold</strong></td>
<td><strong>1.2</strong></td>
<td><strong>1.0</strong></td>
<td><strong>2.2 billion</strong></td>
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Source: Mexican Health Ministry, 2005
CANIFARMA, 2009

Population 107.5 million
INSTITUTIONAL FRAMEWORK

- Mexican Pharmaceutical Association CANIFARMA
- Council of Ethics and Transparency CETIFARMA

Codes of Ethics and Transparency of the Pharmaceutical Industry in Mexico
- Mandatory
- Local Companies 43
- Multinational Companies 53

Code IFPMA
Weak accountability & untransparented practices ➔ Corruption

Global And Local Pharma

Double Moral Standard

Medical Schools and National Academies

Poor Ethical Values Teaching

Health Care Institutions and Public Private Relations With HCP

Conflict Of Interest

HCP and Medical Associations

Unethical Promotion Practices

Untransparency Practices

Regulatory Authorities

Context: Diagnosis 2005/10

JFMS/21.10.10
Responsibilities

- Promote an ethical culture among its members.
- Act as an advisor in the application of the Code of Ethics, always verifying its compliance.
- Contribute to the development of social responsibility.
- Act as a mediator in controversies among its members.
- Active cooperation with regulatory authorities.
Mexican Self-regulatory Codes

- National Agreement for Transparency (October 2007).
AGREEMENT FOR TRANSPARENCY

BACKGROUND

- Conceived as a co-regulation instrument designed to promote transparency in the interactions between HCP, medical academies, healthcare institutions and the Mexican Pharma Manufacturers Chamber (which includes global and local companies).
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- The General Council of the Health System, Federal Board responsible of regulating and supervising healthcare provision in the country, assumed the leadership and follow-up of the Agreement in close collaboration with CETIFARMA and the Mexican Pharma Manufacturers Chamber (MPMC).
AGREEMENT FOR TRANSPARENCY

Purpose

To establish a consensual framework of ethical principles and practices in order to promote ethical and transparent relations between the MPMC, physicians, and healthcare institutions.

Scope

Instrument a regulation and co-regulation paradigm.
Participating Institutions

- National Academies of Medicine and Surgery
- Mexican Pharma Manufacturers Chamber
- National Committee of Bio-Ethics
- Mexican Medical Association
- Private Hospital Association
- National Schools
- Health Ministry
- National Social Security System
- Council of Ethics and Transparency of the Pharmaceutical Industry
Code Infringements

Nov. 2005-Sept. 2010: 76 complaints admitted/72 resolved

- 35% Gifts to HCP exceeding cost limits
- 30% Inadequate hospitalities
- 20% Inaccurate information in promotional activities
- 15% Payments to HCP’s and institutions to facilitate promotional practices
Acreditation of Transparent Practices
Challenges

- Strengthen transparent activities and interactions with HCP’s.
- Promote antibribery practices to block corruption.
- Strengthen the monitoring and evaluation systems.
- Enhance consumers, authorities and HCP’S trust in the pharma industry.
Regulation + Self regulation = Co-regulation ?

Regulation and self regulation have been operating the past century. Is co-regulation the future?

Is it a form of a new governance?

If the answer is yes, it means that we are facing a different challenge: the development and implementation of a new paradigm for the XXI Century.
Governmental Regulation:
- Laws
- Standards
- Guidelines

Companies self regulation:
- Ethical Codes
- Pharmaceutical Marketing Practices
- Codes
- Transparency
- Accountability

**CO –REGULATION = NEW GOVERNANCE?**
Old word, New world

Transparency
Responsibility
Accountability
Deontology
Ethics
THANK YOU

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