

# Emerging Issues in Latin America

## *The Compliance of Pharmaceutical Industry in Mexico*

Juan F Millán Soberanes  
CETIFARMA, México  
Brussels, June 2007.

# LATIN AMERICAN ENVIRONMENT

- ✓ Ethics codes have existed in Latin America since 1990, with the exception of Peru (1976).
- ✓ During 2006, the countries analyzed (Argentina, Brazil, Colombia, Chile, Ecuador, Mexico, Peru, Venezuela) reviewed their national codes and adjusted them to the guidelines of the IFPMA Code.
- ✓ Compliance officers in each country have undertaken the challenge of promoting national and international codes among their members, healthcare professionals and authorities.
- ✓ Due to cultural differences, the implementation of codes of ethics has been gradual in these countries, with varying degrees of resistance from medical associations and some members and non members of IFPMA.
- ✓ Self regulating compliance practices have been well received by sanitary authorities.

# **- CODES OF GOOD PRACTICES FOR THE PHARMACEUTICAL INDUSTRY -**

Current status in eight Latin American countries\*

<b>COUNTRY</b>	<b>TYPE OF CODE YEAR OF PUBLICATION</b>	<b>LASTEST REVISION DATE/ISSUES</b>	<b>BODY IN CHARGE DATE OF IMPLEMENTATION</b>
<b>Argentina</b>	<b>IFPM Code, 1994</b>	January 2006 to December 2006 Issues: - Members and non members of IFPMA are discussing the convenience of a single National Ethics Code, congruent with IFPMA guidelines - Formal adherence of local IFPMA members to IFPMA Code - Events with Medical Associations to provided information about IFPMA Code - Revision of the Ethics Committee structure	<b>Ethics Committee of the Argentinean Pharmaceutical Industries Association (CAEME), Revised Code in effect January 2007</b>
<b>Brazil</b>	<b>National Code, September 2006</b>	September 2006 - Training process to instrument IFPMA Code in industries of local IFPMA members	<b>Considering Compliance Office or equivalent, during 2007</b>
<b>Colombia</b>	<b>National Code, 2005</b>	May –December 2006, with a special working group to synchronize AFIDRO- IFPMA codes. Issues: - Promotion of codes among members and associates - Administration of complaints - Limits in the cost of gifts - Provision of medical samples	<b>Ethics Committee, January 2007</b>
<b>Chile</b>	<b>National Code, 1987 IFPM Code, 1994</b>	During 2006 Issues: - Formal adherence of members to local Code - Mass media promotion of the Code - Detailed information provided to Medical Associations, Schools and Sanitary Authority	<b>Ethical Tribunal of Chilean Pharmaceutical Industries Association, November 2006</b>

Source: Local Compliance Officers. Nov. 2006, May 2007

# CODES OF GOOD PRACTICES FOR THE PHARMACEUTICAL INDUSTRY -

Current status in eight Latin American countries

COUNTRY	TYPE OF CODE YEAR OF PUBLICATION	LASTEST REVISION DATE/ISSUES	BODY IN CHARGE DATE OF IMPLEMENTATION
Ecuador	National Code, 1994	January – December 2006. Issues: - Members' formal adherence to the National and IFPMA codes. - Follow-up of possible breaches of the Code by the Ethics Commission - Publication and promotion of codes among: medical authority, physicians, congress, judiciary, media and general public	Ethics Commission, January 2007
México	National Code of Ethics, December 2004  Code of Better Practices in the Promotion of Medicines, January 2006	September 2006 - February 2007 Issues: - Promotion of codes among: members, sanitary authority, medical and academic associations, other health care professionals. - Compliance Officers Committee, integrated by local members of IFPMA and shortly by representatives of the local pharmaceutical industry (G's)	Council of Ethics and Transparency, Code of Ethics, revised March 2007
Perú	1976	2007, to synchronize the National Code to guidelines of IFPMA Code. Issues: - Promotion of Code among members - Discussing the pros and cons of constituting an Ethical Committee	Honor Committee, January 2007
Venezuela	National Code of Conduct	2007, in accordance to the IFPMA Code.	Ethics and Disciplinary Committee.

Source: Local Compliance Officers. Nov. 2006, May 2007

# **NATIONAL CHAMBER OF PHARMACEUTICAL INDUSTRIES ESTABLISHED IN MEXICO (CANIFARMA)**

- ✓ **Non profit organization that represents the interests of 170 pharmaceutical manufacturers.**
- ✓ **Integrated by national and multinational companies.**

# **Ethics and Transparency Council of the Pharmaceutical Industry in Mexico (CETIFARMA)**

## **Responsibilities**

- **Promote an ethical culture between its members.**
- **Act as an advisor in the application of the Ethics Code, verifying its compliance.**
- **Cooperation with regulatory authorities when required.**

## **Self-regulatory Instruments**

- **Code of Ethics and Transparency of the Pharmaceutical Industry Established in Mexico (March 2005)**
- **Code of Good Practices for the Promotion of Medicines. (November 2005)**

# MEXICAN CONTEXT

- ✓ **Population: 106 million inhabitants, with a rapidly aging population.**
- ✓ **National Health System's coverage: 85-90%.**
  - **Public Health subsystem: Social Security 60%, Medical welfare 20%.**
  - **Private subsystem covers 10%. However it is estimated that 21% of social security beneficiaries and 28% of the rest of the population rely on this subsystem\*.**
- ✓ **Physicians: 180,000**
- ✓ **80% of the medicine units provided by the public health subsystem are supplied by National Companies.**
- ✓ **85% of medicine units dispensed by private sector are supplied by Multinational Companies.**

# MEXICAN COMPLIANCE CONTEXT

- ✓ Since the eighties, the pharmaceutical industry has had an increasing role in the provision and finance of continuous medical education for healthcare professionals. This activity was once a responsibility of health authorities.
- ✓ Local subsidiaries of multinational companies are faced with a false dilemma regarding their compliance with the IFPMA and national codes, which had not been an issue for their headquarters and counterparts elsewhere. This issue is being resolved by the Mexican Compliance Group.
- ✓ Resistance to new rules by some pharmaceutical companies and healthcare professionals.
- ✓ Some regulatory functions of the Sanitary Authority have been gradually assumed by self-regulating practices of the pharmaceutical industry, opening a gap in terms of enforcement.



# CURRENT FACTS

- ✓ Constitution of a Mexican Compliance Group.
- ✓ Explicit adherence of CANIFARMA members to the codes and agreement to follow CETIFARMA resolutions.
- ✓ CETIFARMA is participating in an *ad hoc* group with Sanitary Authorities, National Medical Associations, National Academies of Medicine, National Bioethics Commission and Medical Schools, whose objective is to promote a culture of compliance.