Emerging Issues in Latin America

The International Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

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Panel

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Latin America – Compliance Environment

- Diverse universe
  - Different sophistication of legal systems
  - Different approach to political, social & economic policies
- Two major political trends that impact compliance environment:
  - Nationalist Movements (Venezuela, Cuba, Bolivia)
  - Free Market Environment (Colombia, Chile, Brazil)
- Shortage of resources lead to difficult options

Latin America – Compliance Environment

- Corruption – Major issue in Latin America
  - Transparency International Corruption Perception Index
  - Reported media cases: Brazil Congress, Nicaragua President, Peru whole political system during Fujimori, Panama, Ecuador.
  - Local v Multinational company standards
  - Application of FCPA and UK Antiterrorist Act
  - Several International Treaties

Latin America – Compliance Environment

Overall Rank	Regional Rank	Country / territory	Score
14	1	Canada	8.5
20	2	Chile	7.3
		USA	7.3
24	4	Barbados	6.7
28	5	Uruguay	6.4
53	6	Dominica	4.5
55	7	Costa Rica	4.1
57	8	El Salvador	4.0
59	9	Colombia	3.9
61	10	Jamaica	3.7
66	11	Belize	3.5
		Cuba	3.5
		Grenada	3.5
70	14	Brazil	3.3
		Mexico	3.3
		Peru	3.3
79	17	Trinidad and Tobago	3.2
84	18	Panama	3.1
90	19	Suriname	3.0
93	20	Argentina	2.9
99	21	Dominican Republic	2.8

Latin America – Compliance Environment

Clinical Trials in Latin America

- Despite efforts undertaken by the Pan-American Conference on Drug Regulatory Harmonization (PANDRH) clinical trial regulation in Latin American is far from harmonized
- Different approach to key questions such as:
  - Continued supply obligations once the study is over.
  - Mandatory approvals by Competent Agency, Ethics and/or Scientific Committees
  - Insurance requirements

FCPA and Local Anti-kickback Rules

- Lack of harmonization across Latin America.
- Increase in compliance risks in some countries where:
  - The State is a major acquirer of certain drugs
    e.g. Brazil and HIV drugs.
  - HCP associations play an important role in selecting drugs for the national formularies.
- FCPA poses challenges in countries where most HCPs are considered as government officials.
- Some countries, e.g. Brazil, have implemented rules that go beyond FCPA requirements (prohibition of facilitating payments).

Promotional and Marketing Practices

- Varying degrees of activity in national associations of pharmaceutical companies
- Cultural differences
- Differences in the categorization of medicinal products as OTC, prescription medicines, or medical devices

Latin America – Compliance Environment

- Limited enforcement activity
- Product registration & approvals follow FDA/EU approvals
- Strong generics competition by local "National" pharma manufacturers
- Entry of bio-equivalents with no clinical requirements
- Extensive use of distributors for product sales
- 2006 Pharmaceutical sales
  - 12.9 % increase to $27.5 billion in LatinA
  - 4.8 % increase to $181.8 billion in Europe
- Pricing sensitivities
  - must consider high poverty levels

Latin America – Compliance Environment

Sociedad | Domingo, 01 de Octubre de 2006

DENUNCIA CONTRA LOS LABORATORIOS POR SUS ESTRATEGIAS PARA VENDER MAS MEDICAMENTOS

Peor el remedio

Los visitadores médicos denunciaron en el Congreso que las farmacéuticas "coimean" y "entregan prebendas" para que los médicos receten sus productos. Aseguran que hasta hay sorteos y "raspaditas". Y mencionan firmas y profesionales con nombre y apellido. Aquí, la presentación del gremio y la defensa de los acusados.

"Coimas, prebendas e irregularidades graves" denunció la Asociación de Agentes de Propaganda Médica "como prácticas recurrentes de la industria farmacéutica". La presentación de los visitadores médicos, efectuada ante el Congreso de la Nación, incluye nombres de laboratorios y de conocidos doctores vinculados con ellos: "Contratan médicos líderes para promocionar nuevas drogas mediante notas seudocientíficas". También para los médicos comunes habría "contribuciones" (coimas), a veces bajo pretexto de supuestos estudios científicos, y "últimamente se hacen cosas mucho más guarangas" -señaló a este diario un directivo de los agentes de propaganda médica-: las guarangadas incluirían la participación en concursos, donde cada prescripción de determinado remedio aumenta las probabilidades de ganar un auto; también "raspaditas" y entrega directa de dinero.

Latin America – Compliance Environment

Brazil Moves to Break Merck AIDS Drug Patent

By ALASTAIR STEWART, May 5, 2007; Page B6

SAO PAULO -- Brazilian President Luiz Inacio Lula da Silva Friday signed a compulsory license, breaking the patent on an anti-retroviral AIDS drug made by the U.S. pharmaceutical giant Merck

- Brazil's government issued the groundbreaking decree after rejecting a Merck offer to sell the drug at $1.10 per pill, the equivalent of a 30% discount.
- Brazil claims the price is unjust considering it can acquire the drug for 45 cents from generic manufacturers, the president said in a statement. "Between our trade and our health [interests], we chose to protect our health," said President Lula in Brasilia at a ceremony marking the signing of the decree.
- A compulsory license allows a country to manufacture or buy generic versions of patented drugs while paying the patent holder only a small royalty. Brazilian law and rules established under the World Trade Organization allow for compulsory licenses in a health emergency or if the pharmaceutical industry uses abusive pricing.

Folha de S. Paulo,Brazil

Doctors denounce favors of pharmaceutical companies (Newspaper: Folha de S. Paulo)

Journalist: CLÁUDIA COLLUCCI 29/08/2005 –

"It's promiscuous the relation between doctors and the pharmaceutical industry. Many of them were transformed in "luxury boys"- from promotional activities of the pharmaceutical companies." The statements are of the cardiologist Roberto Luiz d' Ávila, director of the CFM (Federal Advice of Medicine), an organization that has the mission of judging ethical infractions of the industry. **"They are scientific puppets**", amendment the clinician Antonio Carlos Lopes, professor of the Unifesp (Federal University of São Paulo) and president of the Brazilian Society of Medical Clinics, that unites 40 thousand professionals. **The phenomenon is not exclusive of our country, but, for the first time, renowned Brazilian doctors went public in denouncing the dark side that personal interest plays in the relation between the medical and pharmaceutical industries, that, many times, would be focused more in personal benefits than in the wellbeing of the patient**. Lopes, for example, has been invited countless times by pharmaceutical companies to do favorable presentations to support new drugs. "Never I accepted. But I know about doctors that receive R$ 5.000, on average, by presentation, air trips in first class, hotel five stars, everything including a personal guest." This is not crime in the practical sense, since the doctor informs, in the presentation, that there is a conflict of interest, and the institution interested is paying his participation, as determined by the CFM and Anvisa (National Agency of Sanitary Vigilance). "Nobody respects that. "I already interrupted at least two round-tables on scientific events on account of conflict of interest not revealed on the part of certain doctors

Latin America – Compliance Environment

- ✓ Ethical codes in Latin America since 1990, including Peru (1976).
- ✓ During 2006, 7 countries analysed (Argentina, Brazil, Colombia, Chile, Ecuador, Mexico, Peru) reviewed their national codes and changed them to align with the 2007 IFPMA Code.
- ✓ Compliance officers in each country have undertaken the challenge of promoting national and international codes among their members, healthcare professionals and authorities.
- ✓ Responding to cultural differences, the implementation of the codes has been gradual in these countries, with varying resistances from medical associations and some members and non-members of IFPMA.
- ✓ Self regulating compliance practices have been well received by authorities.

CODES OF PRACTICE 0F THE PHARMACEUTICAL INDUSTRY -

Current status in seven Latin American countries

COUNTRY	TYPE OF CODE YEAR OF PUBLICATION	LASTEST REVISION DATE/ ISSUES	BODY IN CHARGE DATE OF IMPLEMENTATION
Argentina	IFPM Code, 1994	January 2006 to December 2006 Issues: - Members and non members of IFPMA are discussing the convenience of a single National Ethics Code, congruent with IFPM 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	Ethics Committee of the Argentinean Pharmaceutical Industries Association (CAEME), Revised Code in effect January 2007
Brazil	National Code, September 2006	September 2006 - Training process to instrument IFPMA Code in industries of local IFPMA members	Considering Compliance Office or equivalent, during 2007
Colombia	National Code, 2005	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	Ethics Committee, January 2007
Chile	National Code, 1987 IFPM Code, 1994	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	Ethical Tribunal of Chilean Pharmaceutical Industries Association, November 2006

CODES OF PRACTICE 0F THE PHARMACEUTICAL INDUSTRY

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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 proffesionals. -Compliance Officers Committee, integrated by local members of IFPM 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 IFPM Code. Issues: - Promotion of Code among members - Discussing the pros and cons of constituting an Ethical Committee	Honor Committee, January 2007

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 relay 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.

Source: Health Ministry, National Health Program 2000-2006, pp. 59 – 60.

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.

Thank You

Obrigado

Gracias

Mexico - CETIFARMA

- National association of the pharmaceutical industry
- MNCs and local companies

Non profit institution that represents the interests of 170 pharmaceutical manufacturers

Integrated by two associations: ANAFAM, which affiliates national companies and AMIIF multinational companies