

Council of Ethics and Transparency of the Pharmaceutical Industry in Mexico

**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

COUNTRY	TYPE OF CODE	RELEVANT ISSUES	BODY IN CHARGE
Argentina	National Ethics Code, in progress 2010	<ul style="list-style-type: none"> Members and non members of IFPMA agreed on the convenience of a single Ethics Code, aligned to IFPMA guidelines. Events with Medical Associations to provide information about IFPMA Code. 	Ethics Committee of the Argentinean Pharmaceutical Industries Association (CAEME)
Brazil	National Code of Conduct 2010	<ul style="list-style-type: none"> Although more specific, INTERFAMA's Code is aligned to IFPMA guidelines. Gifts: related to the medical practice from US \$100.00 to 500.00; non-related up to US \$60.00. Sanctions: Notice, Suspension and Exclusion, Fines (US \$1,200.00 - 916,000.00). 	Ethics Commission, with representatives of members of all associated companies.
Colombia	National Code 2007	<ul style="list-style-type: none"> AFIDRO- IFPMA codes are aligned Promotion of code among members and associates Administration of complaints on: Cost of gifts Medical samples 	Ethics Commission
Chile	National Code 1987	<ul style="list-style-type: none"> Formal adherence of members to IFPMA Code Detailed information provided to Medical Associations, Schools and Sanitary Authorities The medical profession has established its own Ethics Tribunal, in case of complaints it operates with the Ethical Tribunal of Chilean Pharmaceutical Industries 	Ethical Tribunal of Chilean Pharmaceutical Industries Association

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Source: Local Compliance Officers. May 2008 and presentations 2009, 2010.

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MEXICO = CULTURAL DIVERSITY

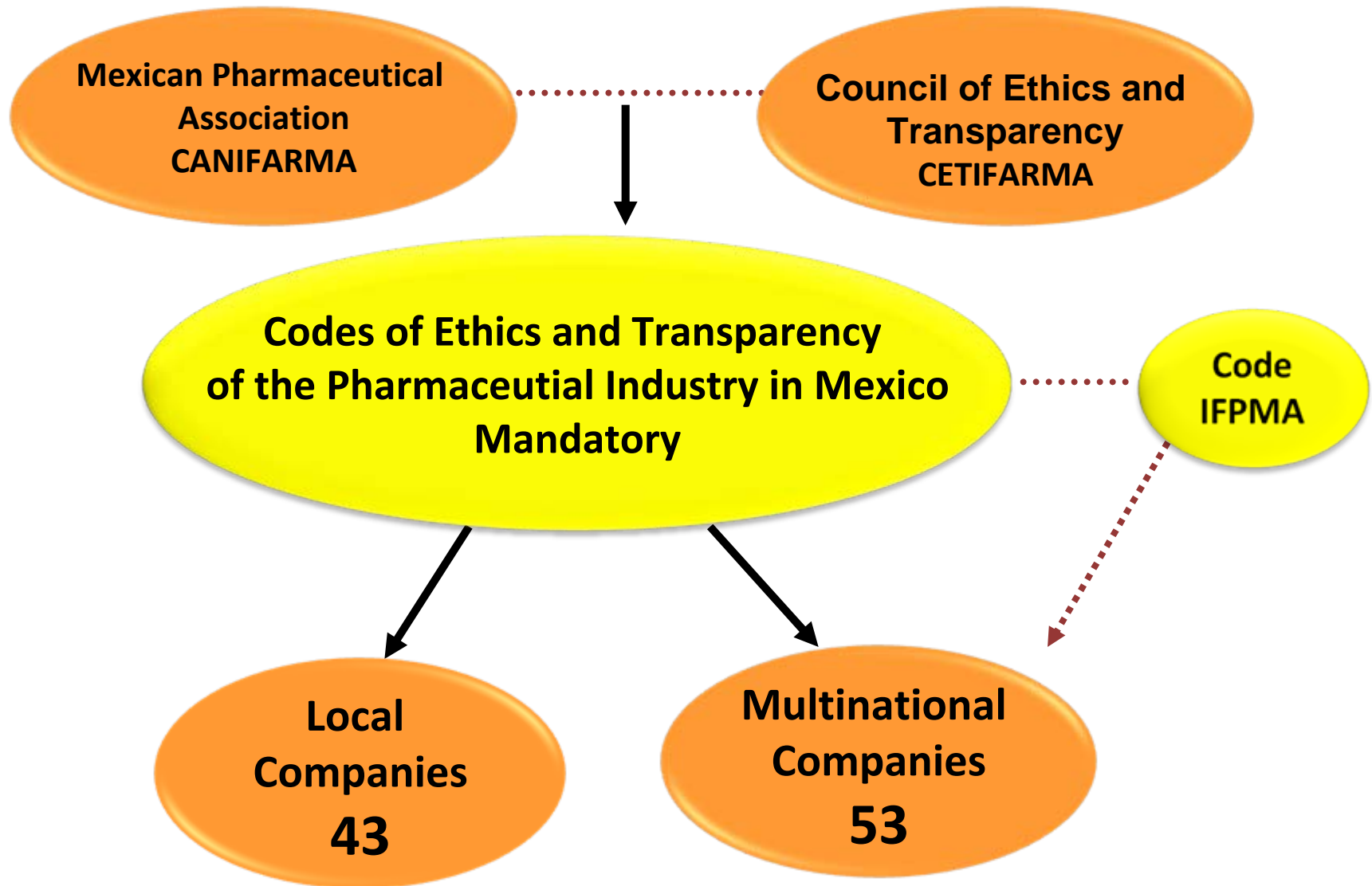
Population **107.5 million**



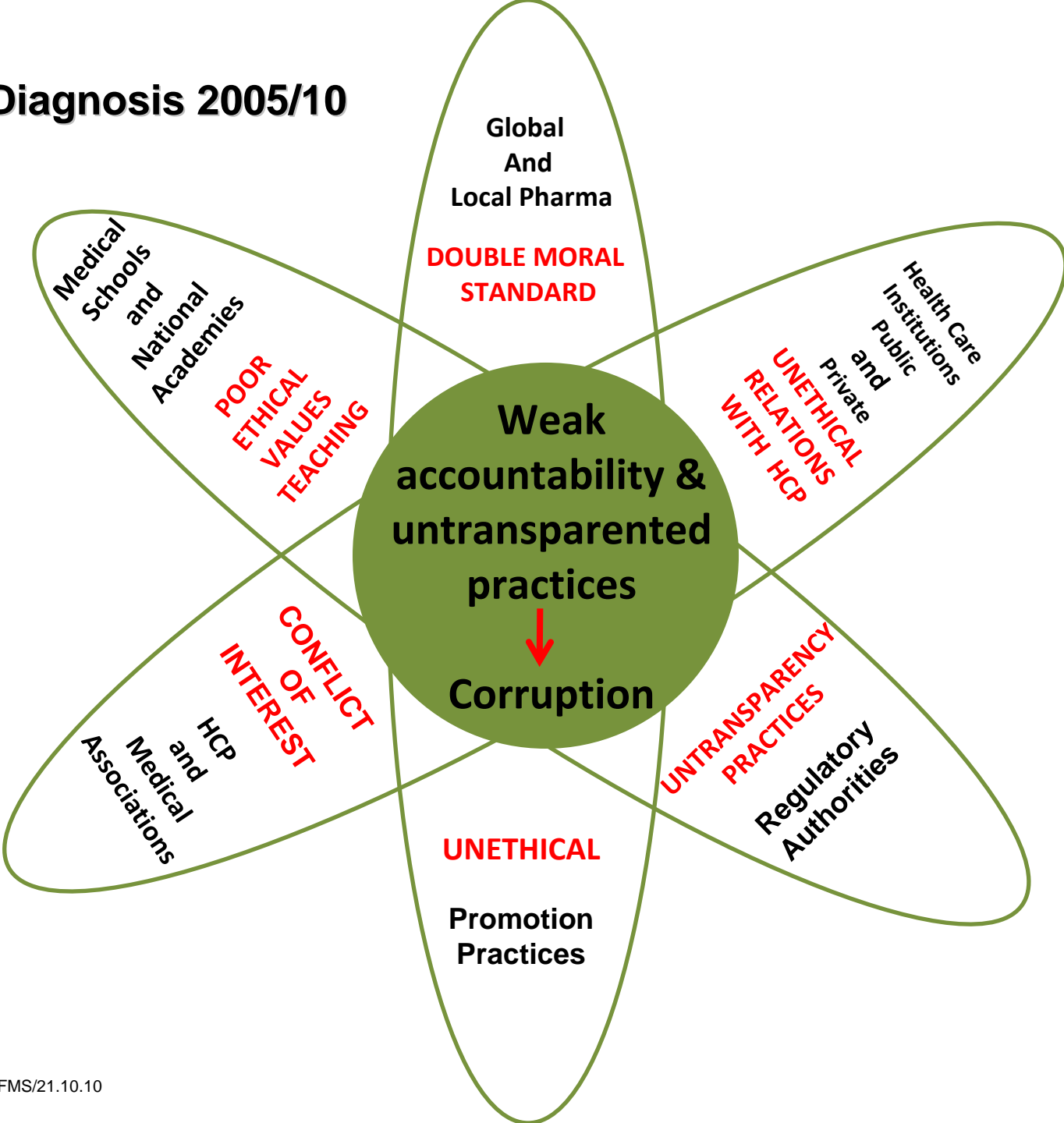
	Public Sector	Private Sector	Total
Physicians	142,453	55,173	197,626
Nurses	196,675	37,697	234,372
Reps.			30,000
Drug units sold	1.2	1.0	2.2 billion

Source: Mexican Health Ministry, 2005
CANIFARMA, 2009

INSTITUTIONAL FRAMEWORK



Context: Diagnosis 2005/10



Council of Ethics and Transparency of the Pharmaceutical Industry in Mexico

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

- **Code of Ethics and Transparency of the Pharmaceutical Industry (March 2005).**
- **Rules of the Council of Ethics (March 2005).**
- **Code of Good Practices of Promotion of Drugs. (November 2005).**
- **National Agreement for Transparency (October 2007).**
- **Code of Interactions with Patient Organizations (2010).**

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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- Participants: stakeholders involved in healthcare services, R&D, production and provision of medicines to consumers
- 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

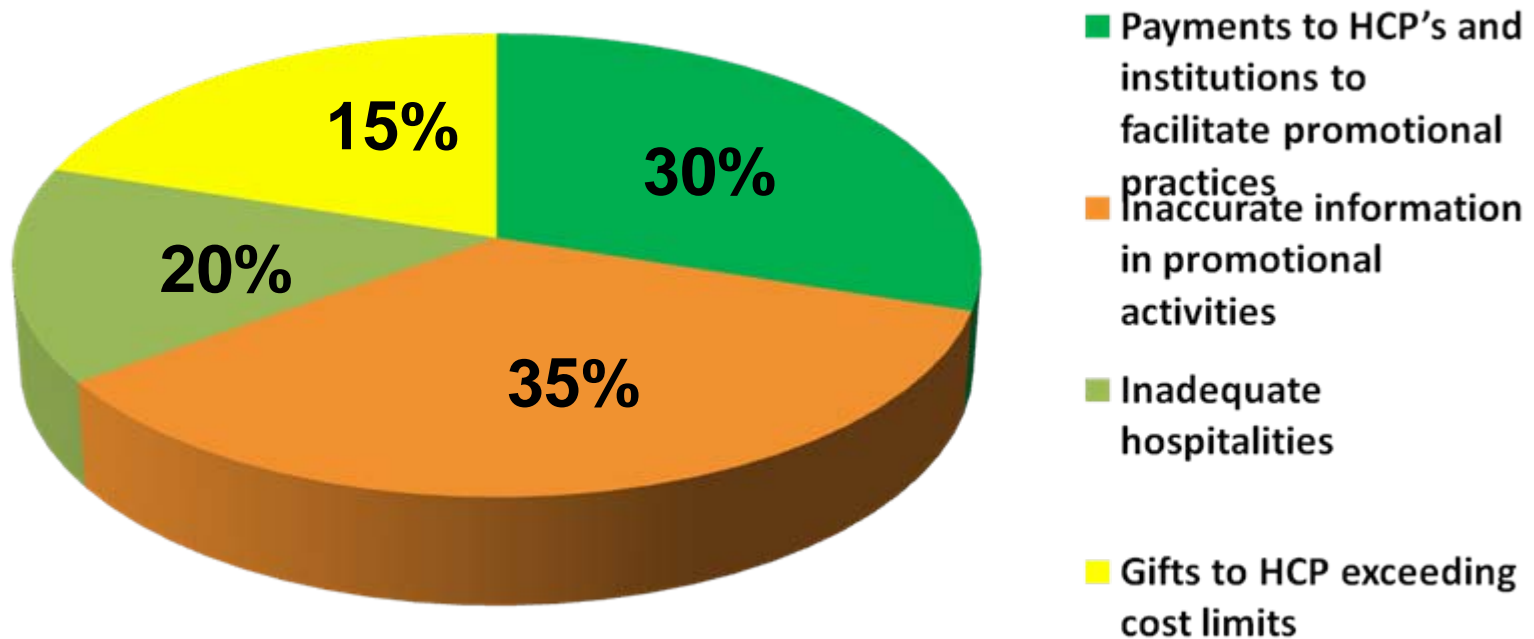
Instrument a regulation and co-regulation paradigm.

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



Accreditation of Transparent Practices



El Consejo de Ética y Transparencia de la Industria Farmacéutica en México, con base en la evaluación realizada por Gestión Social y Cooperación, A. C., afiliado a Global Reporting Initiative, acordó acreditar a

como empresa con prácticas de transparencia apegadas a los códigos en

- Control de muestras médicas
- Apoyos a eventos educativos
- Desarrollo de actividades promocionales

con fecha de agosto de 2009.

DR. Carlos Campillo Serrano
PRESIDENTE CETIFARMA



MTRO. Alejandro González Arreola
DIRECTOR GENERAL GESOC



Challenges

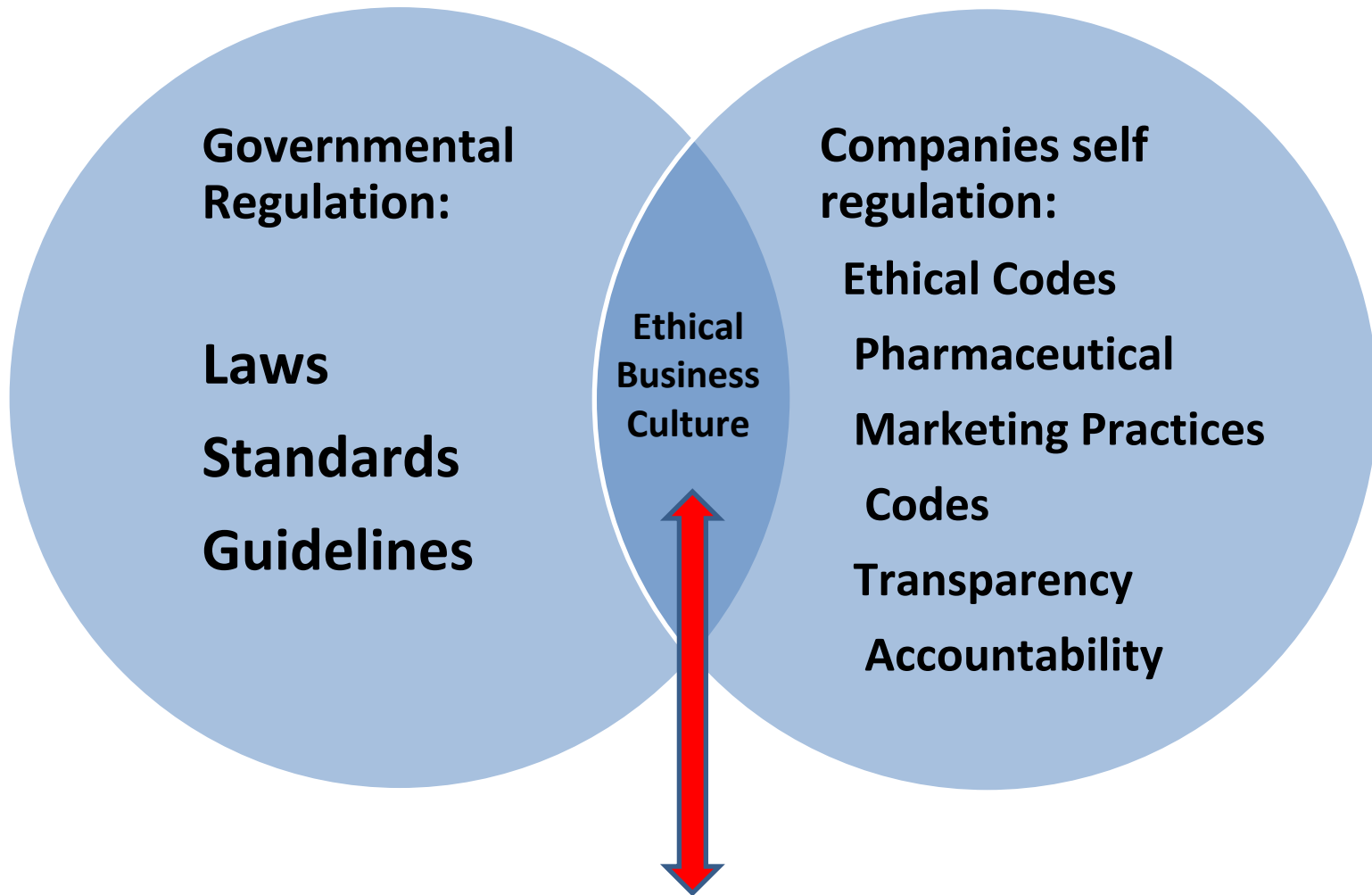
- **Strengthen transparent activities and interactions with HCP's.**
- **Promote antibribery practices to block corruption.**
- **Strengthen the monitoring and evaluation systems.**
- **Enhance consumers, authorities and HCP'S trust in the pharma industry.**

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.



CO –REGULATION = NEW GOVERNANCE ?

Old word, New world

Transparency

Responsibility

Accountability

Deontology

Ethics

TRADE

THANK YOU

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