APEC & The Biopharmaceutical Sector

Andrew Blasi

Senior Consultant, C&M International

Business Ethics for APEC SMEs Initiative

APEC Train-the-Trainer Workshop for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector

26-30 August 2013 | Kuala Lumpur, Malaysia

Asia-Pacific Economic Cooperation

A Long History

- Asia-Pacific Economic Cooperation Forum (APEC) was founded in 1989 as an inter-governmental and multi-stakeholder organization to advance free trade and economic cooperation.

- APEC Life Sciences Innovation Forum (LSIF) was launched in the 1990s as a permanent, tripartite sub-fora to support the life sciences sector in the region.

- The Life Sciences Innovation Forum also oversees the APEC Regulatory Harmonization Steering Committee

Asia-Pacific Economic Cooperation

Economic Significance

Asia-Pacific Economic Cooperation

Economic Significance

- APEC's 21 member economies account for more than 40% of the world's population, 57% of global GDP, and a near majority of worldwide trade.

- Four of the top ten biopharmaceutical markets are APEC member economies (United States, Japan, China and Canada) and many of the fastest growing.

- APEC's member economies are home to thousands of biopharmaceutical researchers, manufacturers, distributors, and importers/exporters.

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So what about business ethics?

- In 2010, APEC Small and Medium Enterprise Minister's endorsed efforts by the region's medical device sector and government officials to pursue APEC Principles for Voluntary Codes of Business Ethics in the Medical Device Sector (what were to become The KL Principles in 2011).

- APEC SME Ministers also called upon other sectors of crucial importance to the region's economic growth and the well being of its member economies citizens to also pursue APEC Principles for Voluntary Codes of Business Ethics.

- The biopharmaceutical sector closely followed and efforts to assemble an Expert Working Group commenced in early 2011.

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The Mexico City Principles

- Expert Working Group of public, private and civil society representatives from a majority of APEC economies convene in Mexico City to draft APEC Principles reflecting the highest global standard at the time.

- Why did APEC hold the expert working group in Mexico?

- The Mexico City Principles is not a code of ethics. It is a standard industry associations can reflect through their code of ethics and also calls for specific action by governments, HCPs and other stakeholders.

- The Mexico City Principles were swiftly endorsed by APEC Foreign and Trade Ministers in 2011 and APEC Leaders in 2012.

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Transforming Words into Action

- With these endorsements, the APEC Secretariat, member governments and other stakeholders formed a multi-year initiative (the Business Ethics for APEC SMEs Initiative) with near $1.3 million over two years to bring the APEC Principles to life.

- July 2012: Code Drafting Workshop (Chinese Taipei)
- 2012-2013: Monitoring & Support Program
- August 2013: APEC Train-the-Trainer Workshop (Malaysia)
- September 2013: APEC Healthcare Stakeholders Meeting (Indonesia)

- Codes have recently been adopted, or are in the process of being adopted, by industry associations in at least 6 APEC economies, joining with dozens of industry associations across 19 APEC economies.

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APEC Train-the-Trainer Workshop

- Continued drive toward alignment with The APEC Principles:
  - Understanding the benefits and sharing your challenges

- Code implementation and best practices in sustainable compliance for your associations and companies

- Forming the largest network of ethics practitioners in the biopharmaceutical sector for the Asia-Pacific region

Asia-Pacific Economic Cooperation

Key Trends in Biopharmaceutical Sector Compliance

Abdul Luheshi

VP Health Care Compliance, Janssen, Asia Pacific

APEC Train-the-Trainer Workshop for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector

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Disclaimer

The comments, thoughts and views presented here are my own and should not be interpreted as representing the position, interpretation or recommendation of Johnson & Johnson.

Asia-Pacific Economic Cooperation

Overview

The Environment

- Regulatory focus
- Transparency
- Industry competition

Internal Factors

- Nature and type of interactions
- Risks

Industry Response

- Code of ethics / conduct
- Compliance functions

Asia-Pacific Economic Cooperation

Overview

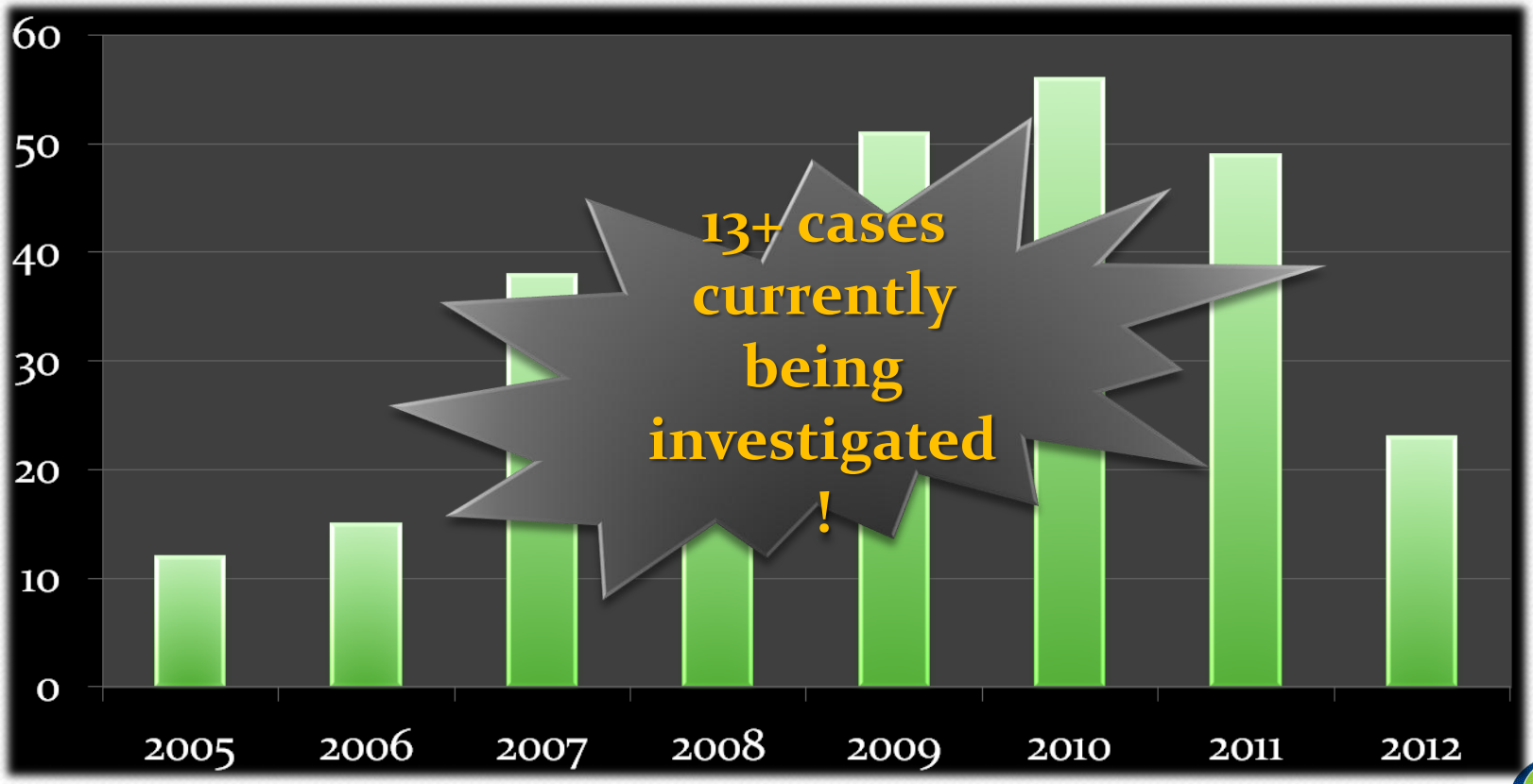
The Environment

- Regulatory focus
- Transparency
- Industry competition

Asia-Pacific Economic Cooperation

Governments and Regulators Continue to Focus on Anti-corruption …

Number of enforcement actions brought by DOJ/SEC



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… and there is Increasing Attention to Enforcement of International and Local Laws on Anti-corruption

Country	Law(s)	Applies to Foreign Officials	Applies to Private Sector
US	FCPA	✓	×
UK	Bribery Act	✓	✓
China	Criminal law Anti-unfair Competition law	✓	✓
Japan	Criminal code Unfair Competition Prevention Act	✓	×
S Korea	Criminal Code Specific Economic Crimes Act	✓	✓
Australia	Criminal code	✓	✓
Malaysia	Malaysia Anti-corruption Commission Act	✓	✓

The Requirement for Public Transparency is Expanding across the Globe

Sunshine Act

Name, specialty, address, value, date, form, category

Medicines Australia

Name, location, value, date, form, category

JPMA

Name, address, form, category, value & frequency (annual)

France Decree 2013-414

Name, address, value (>€10), date, category

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Growth Markets in Emerging Economies Present Competitive Pressures

- Quest for talent
- Aggressive business expectations
- Developing experiences on customer and supplier sides
- Varied marketing practices
- Pricing, reimbursement and affordability
- Third parties and supply chains
- Need for clinical trials

Overview

The Environment

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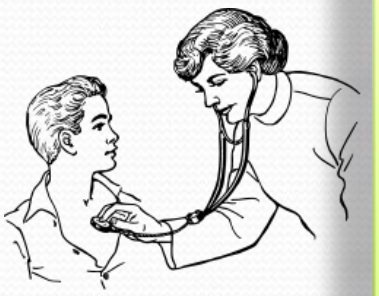
Internal Factors

- Nature and type of interactions
- Risks

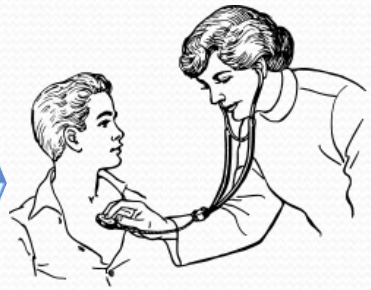
Asia-Pacific Economic Cooperation

Why does Industry Need to Interact with HCPs?



- Professional input / advice / consulting
- Clinical studies / research

- Product information / promotion
- CME
- Product training



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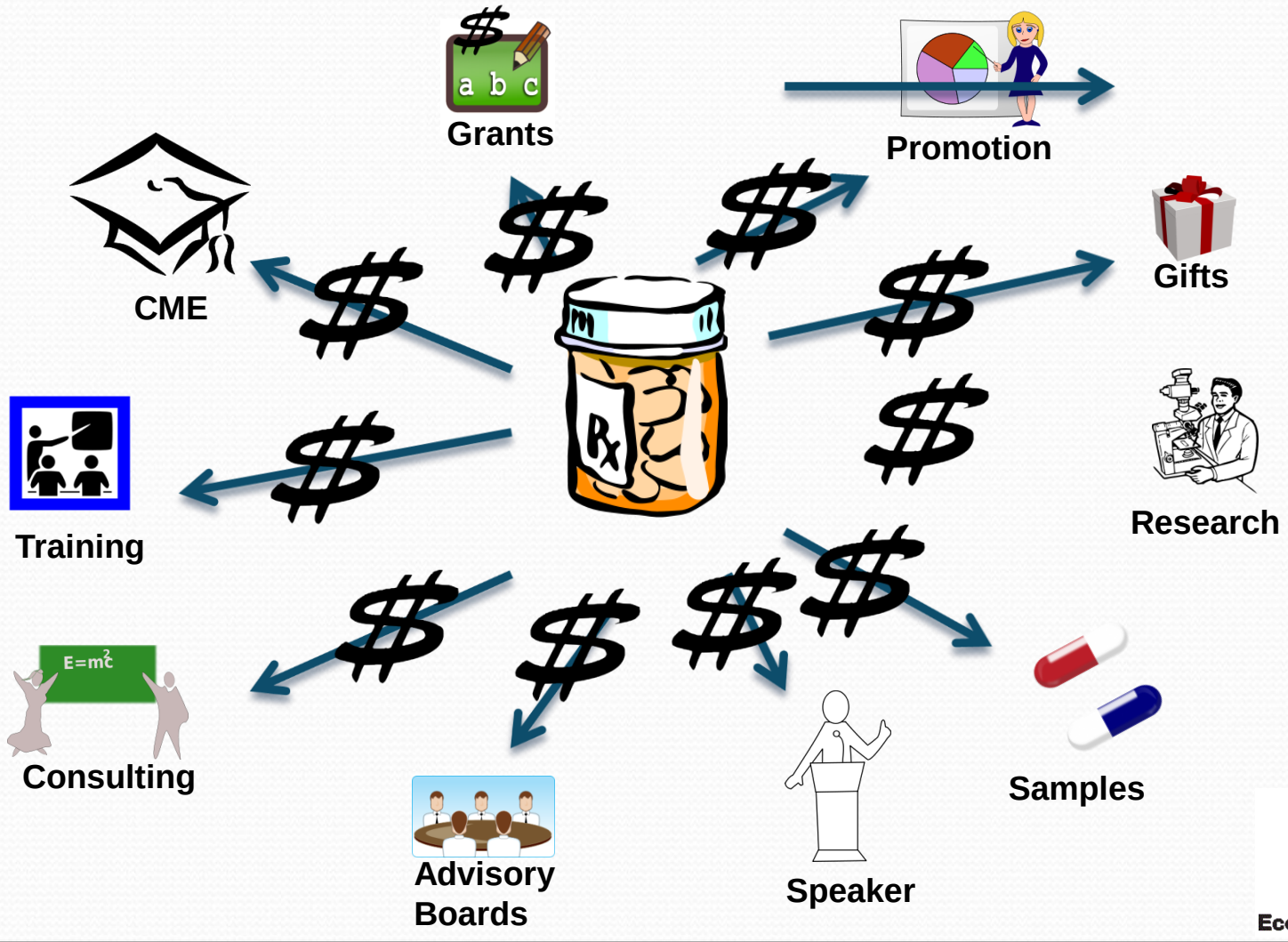
These Interactions Raise Potential Risks …



Intermediaries Present an Additional Layer of Risk

Sales Intermediary

- Reduced transparency and control
- Potential for diverting profit margins

Travel Agencies & Event Managers

- Falsification of charges / activities

Clinical Research Organisations

- Quality control

Asia-Pacific Economic Cooperation

Overview

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- Code of ethics / conduct
- Compliance functions

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Industry has been Deploying/Reinforcing Codes of Ethics & Conduct

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Supported by the Development of In-house Compliance Functions

- Policy setting and investigations
- Processes and controls
- Due diligence
- Systems

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In Summary …

- Governments and the public will continue to demand more transparency of industry/HCP interactions

- Industry is already responding through
  - International Codes (e.g. IFPMA, ADVAMED)
  - Company Codes
  - Compliance organisations
  - Systems and processes

- Opportunity is to strengthen country codes and improve self-regulation

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THANK YOU

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Economic Cooperation

BUSINESS ETHICS FOR APEC SMES TRAIN THE TRAINER WORKSHOP FOR CODES OF ETHICS

IN THE MEDICAL DEVICE, BIOPHARMACEUTICAL, CONSTRUCTION & ENGINEERING SECTORS

By Mr. Reiner W. Gloor, Adviser to PHAP

MACA & IIM, Kuala Lumpur, Malaysia

26-30 August 2013

Value of Ethics & Compliance in Today's Biopharmaceutical Sector

Value of Ethics & Compliance….

PHAP established the Code in 1993 and has become a requirement for membership

Some of the challenges:

PHAP covers about 40 % of companies in the Philippines

- Members felt particularly MedReps, that they are at competitive disadvantage due to these prohibitions:
  - No gifts
  - Restriction on number of HCPs that can be sponsored to CMEs abroad
  - No “extra services” to HCPs and their families

Value of Ethics & Compliance…

Ethics Committee composition THEN: GMs of member companies

Ethics Committee composition NOW : Independent and credible professionals from various fields were invited to form the Ethics Committee.

As a result, PHAP and its member companies were able to **strengthen relationship** and **credibility** with various industry players including the government. PHAP **earned the respect** of the stakeholders.

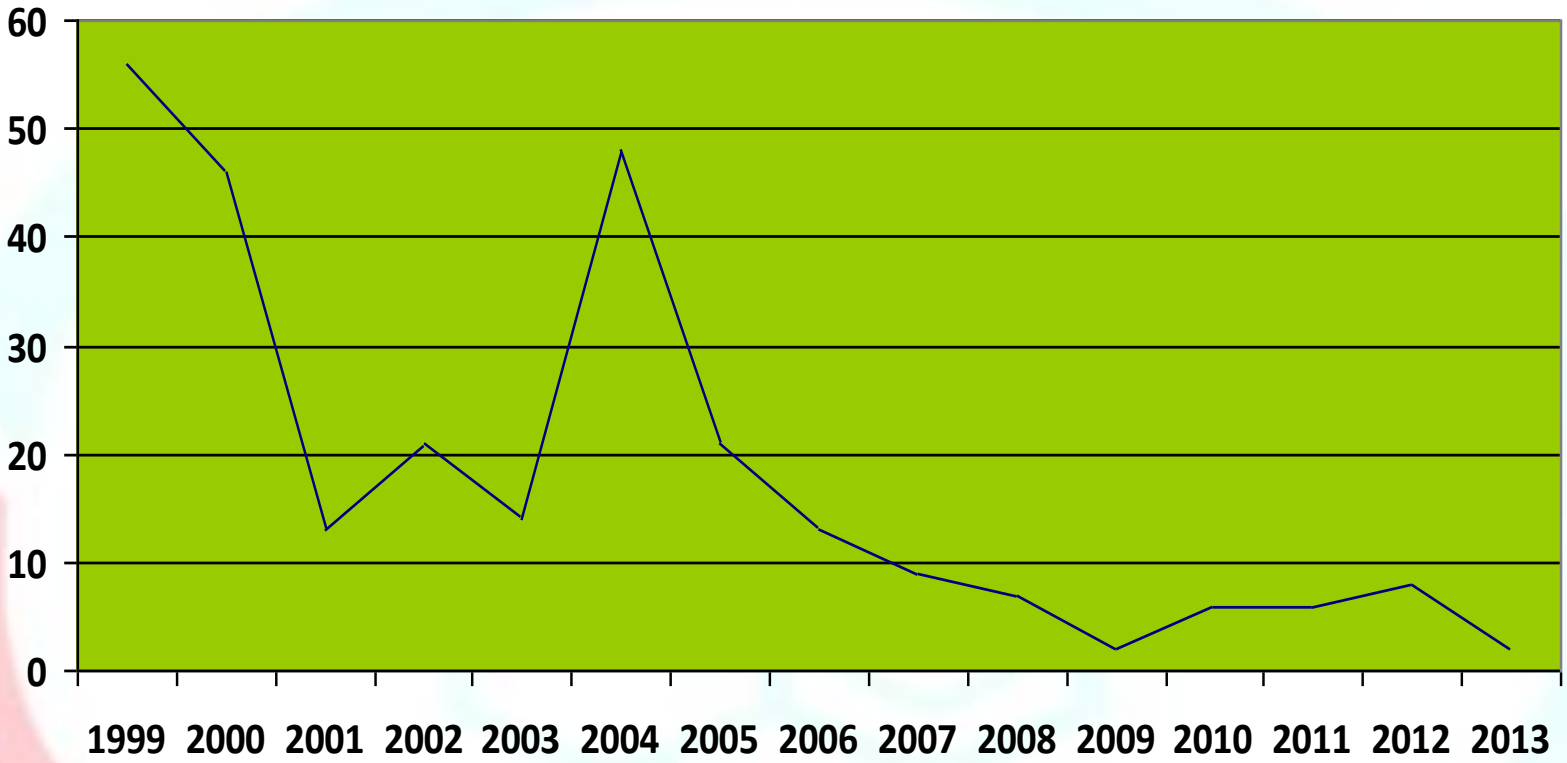
Value of Ethics & Compliance

PHAP distinction :

Only industry organization in the Philippines with internationally-aligned Code.

One of the few organizations in the world with an independent Ethics Committee

Cases Deliberated and Decided By the Ethics Committee
(1999 to 2013)



As a result:

- **Perception change**
  - Credibility
  - Transparency
  - Independence
  - Scientific evidence
- **Paradigm Shift**
  - Relationship based on trust and patient needs

Key Challenges in the Biopharmaceutical Sector Compliance

Tom Zerull

Regional Compliance Director, AbbVie

APEC Train-the-Trainer Workshop for Voluntary Codes of Business Ethics in the Medical Device Sector

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Asia-Pacific Economic Cooperation

Agenda

- Demonstrating the value of compliance to employees & management
- Achieving business & CEO buy-in
- Overcoming cultural & customary items: Hospitality, Gifts & Entertainment

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Demonstrating Value

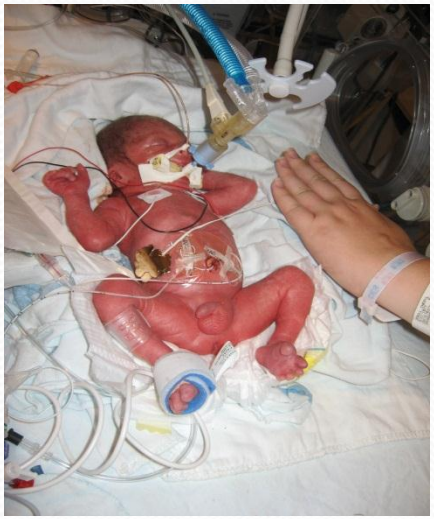
"We would like to drive enhancements to our compliance program; we just don't have the resources right now to do so as our financial performance is struggling"

- **The aim of this section is to make the business case for robust compliance programs**
  - **Our industry is heavily regulated across the globe, we believe compliance programs and promoting an ethical approach to business to our external stakeholders will lead to measurable financial returns.**

Reputation = Value

Who depends on each of our organizations reputation?

Employees	Retirees	Small Businesses	Shareholders



But most importantly

OUR PATIENTS

Our industry makes products that save lives or improve lives of patients all around the world

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Demonstrating Value

- What led to the downfall of this company?

- What led to the downfall of these companies?

ENRON

ARTHUR ANDERSEN

APEC
Asia-Pacific Economic Cooperation

Achieving CEO & Business Buy-In

Key Attributes of selling benefits of compliance programs (1/4)

- **(1) Localize Compliance Program**
  - Embed global expectations in local compliance program policies
    - FCPA, UK Anti-Bribery Act, IFPMA Code
  - Embed additional local expectations in local policies
  - Ensure compliance program is in local language
  - Devise training strategies based on what is most effective in each individual country
    - Live Instructor
    - Computer based
    - Awareness messages

Achieving CEO & Business Buy-In

Key Attributes of selling benefits of compliance programs (2/4)

- **(2) Compliance Team**
  - Areas of Expertise
    - Comprehensive understanding of external requirements and its applicability to the organizations business practices and business model
  - Strong communication skill sets (educate / influence / persuade)
  - Pro-active compliance support team designed to ***help / guide*** employees to make the correct decisions
  - Manage effective compliance steering committees with management focused on continuously enhancing the compliance program based on risk
- **(3) Compliance Policies**
  - Provide ***clear expectations*** on what the requirements are for all relevant business activities
    - Can be understood by all employees
    - Can be accessed by all employees

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Achieving CEO & Business Buy-In

Key Attributes of selling benefits of compliance programs (3/4)

- **(4) Compliance Training & Awareness**
  - Communicate to employees ***WHY*** it is important that your organization is committed to following all relevant laws, ***WHAT*** those laws are, and ***HOW*** to comply with those laws when engaging in relevant business activities
    - Design Thinking
      - Know audiences needs
    - Fun Theory
      - Engaging session that holds audience attention
- **(5) Monitoring**
  - Robust risk-based program that identifies problems early to provide a process for correcting them before they become systemic & prevent further transgressions
    - Will provide management with confidence in the system

Achieving CEO & Business Buy-In

Key Attributes of selling benefits of compliance programs (4/4)

- **(6) Compliance Tools (Efficient Compliance Program)**
  - Provide efficient tools / guidance to support well-intentioned employees understand the expectations under the compliance program
    - Cross Border Guidance
      - Application to provide efficient compliance guidance for cross border activites (e.g., advisory board meeting with HCPs from multiple countries)
    - Policy Algorithms
      - Quick access to policy requirements based on specific needs
    - Local Compliance Program platform
      - Go to application that provides an employee with access to local compliance program (e.g., policies, training, reporting channels)

Overcoming Culture

- Building robust compliance programs
  - Protecting Company / Industry Reputation
- Implementation of anti corruption & transparency laws
  - Protecting HCPs
- Maintaining heritage while driving progress
- Focus on what is best for our patients (HCPs also want what is best for their patients)
  - Our expenses should be focused on only programs leading to enhancements in the level of patient care

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Questions

Asia-Pacific
Economic Cooperation

2013 APEC Train-the- Trainer Workshop
for Voluntary Codes of Ethics
26-30 August 2013, Kuala Lumpur, Malaysia

The Pharmaceutical Enterprise Ethical Practices in China

China Pharmaceutical Industry Association

Aug.26, 2013

Outline

- 1. The Current Situation and Development Trend of Chinese Pharmaceutical Enterprises
- 2. Tasks of Pharmaceutical Industry Associations of China
- 3. The Pharmaceutical Enterprise Ethical Practices in China

1.The Current Situation and Development Trend of Chinese Pharmaceutical Enterprises

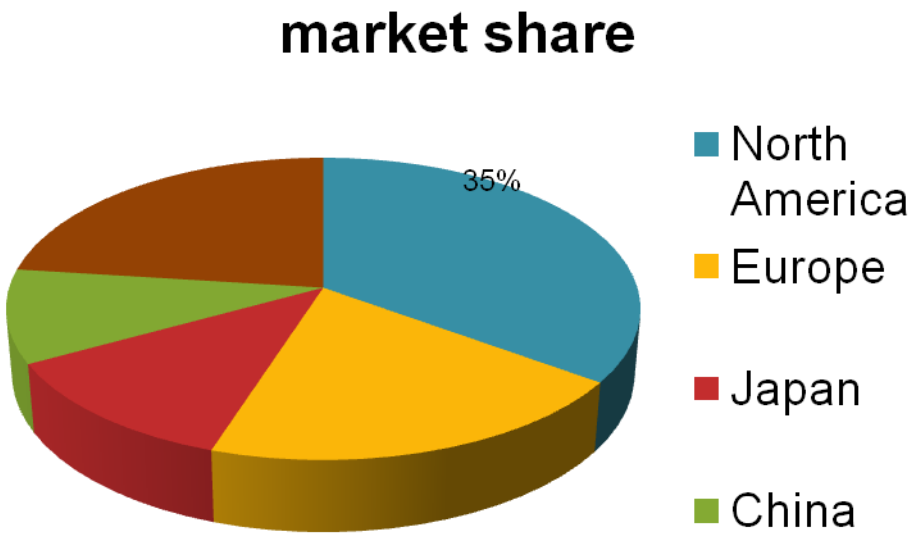
The Current Situation

- 200,000 drugstores
- 120,000 drug retail companies
- 8,000 drug wholesale companies
- 6,154 pharmaceutical enterprises

- Pharmaceutical industry output value（1.83 trillion RMB）
- Sales value（1.11 trillion RMB）
- Average growth rate of 16.6%

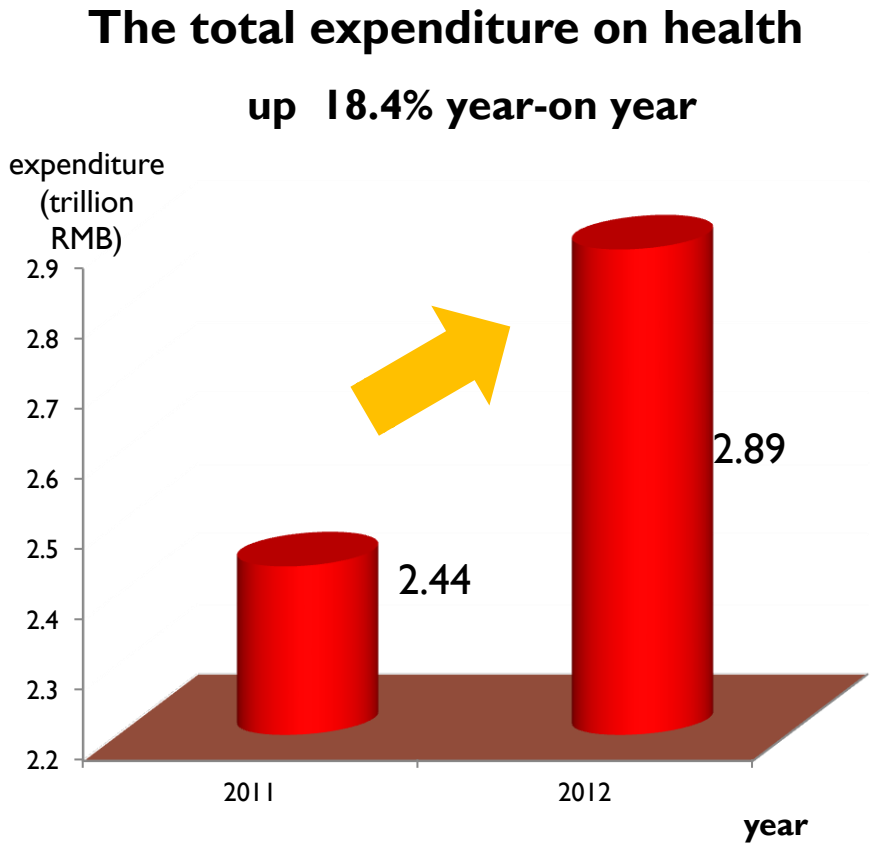
The Role China Pharmaceuticals play in the world pharmaceutical market

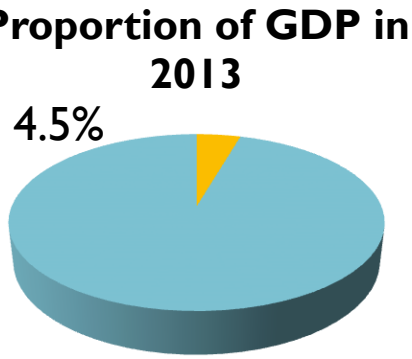
- **the world's third largest pharmaceutical market by country.**
- **the largest materials producer and exporter in the world**

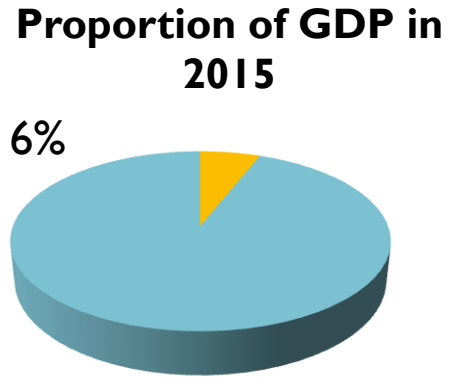


The Development Trend of Chinese Pharmaceutical market

- **The total expenditure on health is rising steadily.**







The Development Trend of Chinese Pharmaceutical market

- **The Payment ability of health insurance is improving steadily.**
  - **Unification of the basic medical insurance, the urban resident insurance and the rural cooperative medical insurance**
  - **95% of Chinese people**
  - **A fund of 150 billion RMB**

- **The aging of population in China is increasingly obvious, following by an increase of demands for health care.**

The Development Trend of Chinese Pharmaceutical market

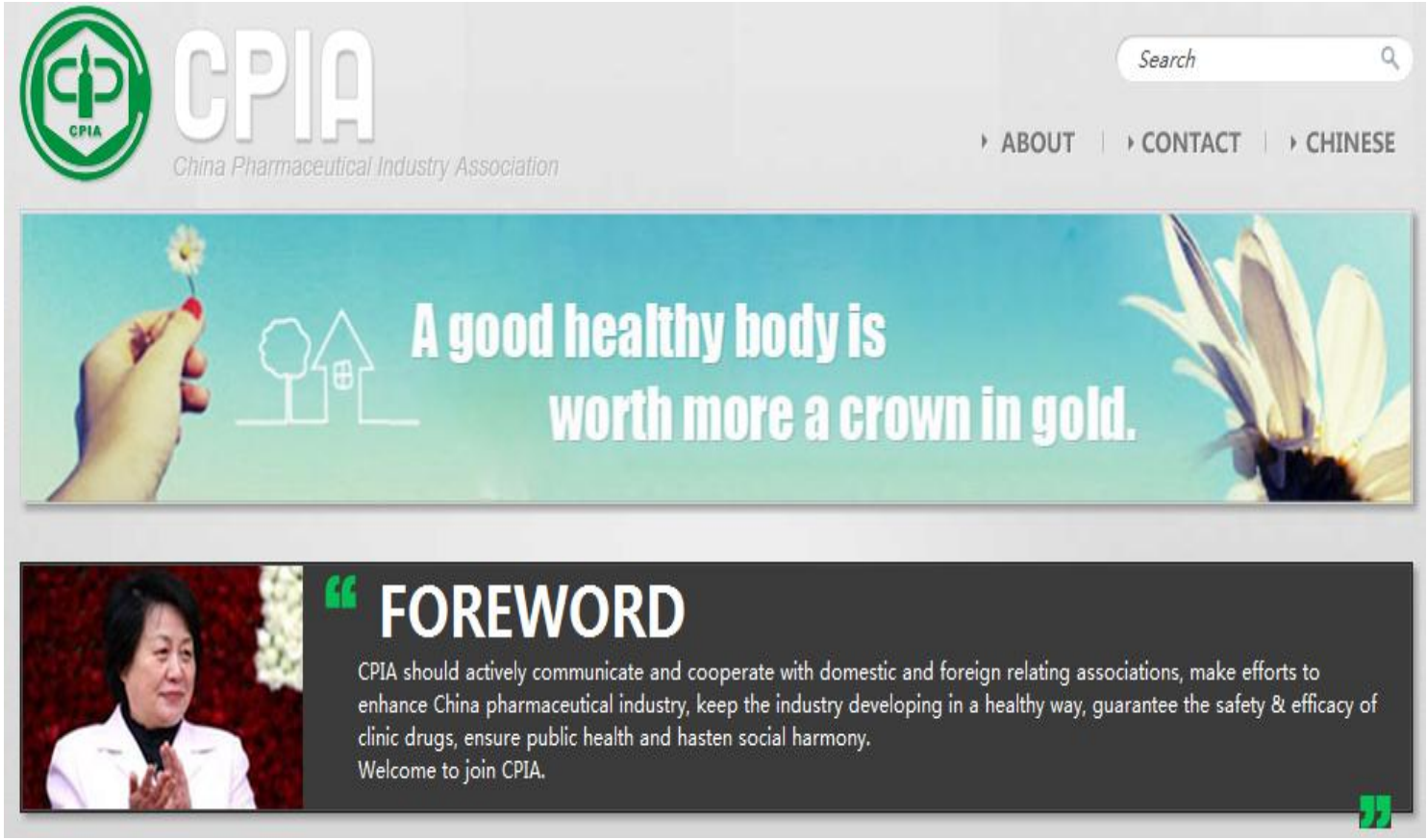
- The population of patients with chronic diseases is growing fast, followed by sharp increase of demands for drugs of noninfectious chronic diseases
- With the improvement of the material and cultural life and the growth of the middle class, the demands for health care present a trend of diversified development

- Chinese pharmaceutical market would
- **reach 1 trillion dollars by 2020**
- **become the second largest in the world** in the future

2. Tasks of Pharmaceutical Industry Associations of China

- Overview of
  China Pharmaceutical Industry Association(CPIA)

China Pharmaceutical Industry Association(CPIA)



- **Functions:**

  Rights protection, Services, Self-discipline and Coordination.

- **Aims:**

  To serve the enterprises, the industry, the government and the society.

- **members: a unit membership basis,302 members**

- 270 large and medium-sized pharmaceutical enterprises,
- Chinese associations from some provinces and cities,
- medical research institutes, colleges,
- organization of investment and financing, etc.

- The core business revenue and the profits of the member enterprises accounts to 65% and over 60% of the chemical pharmaceutical industry respectively.

Stress on the establishment of communication channels with related government departments

- Ministry of Labour and Social Security
- National Health and Family Planning Commission
- National Development and Reform Commission
- China Food and Drug Administration
- Ministry of Commerce
- Chinese Ministry of Industry and Information Technology
- Ministry of Environmental Protection……

China Pharmaceutical Industry Association (CPIA)

Key emphasis in work

- to provide suggestions for related government policies
- to launch information services
- to promote the development of science and technology
- to work for drug safety
- to provide training for the pharmaceutical industry
- to promote the brands
- to work actively in the international cooperation
- to culture the members
- to self-decipline the pharmaceutical industry
- to expand the market

3.The Pharmaceutical Enterprise Ethical Practices in China
Actions by CPIA

- The Chinese government's stance on anticorruption
- The determination of the new Chinese government to anticorruption
- The support from international pharmaceutical associations and the cooperation with them
- The joint action by Chinese Pharmaceutical Industry Associations

Actions by CPIA

- In 10~11 July 2012, attended the APEC workshop on business ethics in Taiwan.
- In the middle of Aug.2012, presented a subjects reporting on the origin and contents of the Mexico City Principles during the eighth second president meeting.
- In late Aug.2012, invited China Chamber of Commerce for Import & Export of Medicine & Health Products (CCCMHPIE) and China Pharmaceutical Industry Research and Development Association (PhIRDA) to have a discussion on implementing the Mexico City Principles in China.

After that, PhIRDA officially launched the Chinese version after carefully checking and proofreading the translation text of the principles from Taiwan, which is called "the Pharmaceutical Enterprise Ethical Practices".

Actions by CPIA

- In Oct. 2012, CPIA and Canadian R&D held a meeting on the business ethics. Canadian R&D introduced their experience on the work in the meeting.

- From Sept. to Nov. in 2012, presented the subjects reporting on the business ethics to the NBCP,CMIIT, CFDA for the policy support from the government. These departments voiced full support to the promotion of the ethics and viewed this work as reflecting the positive energy and as a part of the government function.

- In early 2013, made the promotion of the ethical practices as one of CPIA's key work of the year, and assigned the relevant departments to take charge of this work.

Actions by CPIA

- On 20 March 2013,
- **CPIA, some of its member enterprises**, China Pharmaceutical Industry Research and Development Association (**PhIRDA**), China Association of Pharmaceutical Commerce (**CAPC**), China Nonprescription Medicines Association (**CNMA**), China Chamber of Commerce for Import& Export of Medicine & Health Products (**CCCMHPIE**)
- convened a conference on the necessity and feasibility of implementing the Mexico City Principles among the pharmaceutical enterprises. And a consensus was reached.

Actions by CPIA

- On July18, 2013,
- responsible officials from China Pharmaceutical Industry Association (**CPIA**), China Association of Enterprises with Foreign Investment R&D-based Pharmaceutical Association Committee（**RDPAC**）, China Chamber of Commerce for Import& Export of Medicine & Health Products (**CCCMHPIE**), China Association of Traditional Chinese Medicine (**CATCM**), China Association of Pharmaceutical Commerce(**CAPC**), China Nonprescription Medicines Association(**CNMA**) and China Pharmaceutical Enterprises Development Promote Association (**CPEP**)
- convened a meeting in Beijing, discussing the establishment of a specific working group for conference on the release of "the Pharmaceutical Enterprise Ethics".

The joint action by Chinese Pharmaceutical Industry Associations

CPIA actively promote the implementation of the principles in China

- 6 Nov.2012, released the translation draft of the principles in the Xiamen Summit
- 20 March 2013, convened a meeting with relevant industry associations and domestic pharmaceutical enterprises to reach a consensus.
- 18 July 2013, eight associations convened a meeting to establish a specific working group for conference on the release of "the Pharmaceutical Enterprise Ethical Practices" and to discuss the work plan.

The joint action by Chinese Pharmaceutical Industry Associations

The decisions were made as follows:

1. To establish a specific working group for conference on the release of "the Ethical Practices". The eight units confirmed a list of contacts (as presented in attachment).

2. To release the Chinese version of APEC "The Mexico City Principles" (translated by PhIRDA) as the release text of the Ethical Practices.

3. To hold the program of "Biopharmaceutical associations taking the oath of jointly promoting the Ethical Practices" in Beijing.

- **It was agreed that**

- (1) the Ethical Practices have great value for regulating the behavior of whole industrial chain in pharmaceutical industry, while meeting the requirements of the trend of regulating the development of domestic and global medical market

- (2)Considering the serious situation of drug safety and its scientific promotion, it is quite necessary to implement the Ethical Practices

- (3)With the rapid development of pharmaceuticals industry and the speeding up in the pace of implementing the "Going out" strategy, the implementation of the ethical practices is of positive significance to improve the international image of Chinese enterprises.

- **Title**:
- Conference on the release of "the Pharmaceutical Enterprise Ethical Practices"

- **Organizers:**
- co-organized by the above-mentioned eight units(China Pharmaceutical Industry Association (CPIA), China Association of Enterprises with Foreign Investment R&D-based Pharmaceutical Association Committee（RDPAC）, China Chamber of Commerce for Import& Export of Medicine & Health Products(CCCMHPIE), China Association of Traditional Chinese Medicine (CATCM), China Association of Pharmaceutical Commerce(CAPC), China Nonprescription Medicines Association(CNMA) ,China Pharmaceutical Enterprises Development Promote Association (CPEP) and China Pharmaceutical Industry Research and Development Association (PhIRDA))

- **Time:**
- 29 Oct.2013

- **Venue:**
- Landmark Tower Building, Beijing China

Acknowledgements

- PhRMA
- Canada Rx&D
- EFPMA
- IFPMA

- Special Thank to RDIPIC

Acknowledgements

CPIA and PhRMA

Acknowledgements

CPIA and Canada Rx&D

Acknowledgements

CPIA and EFPIA

Acknowledgements

CPIA and IFPMA

Wish this APEC workshop success!

Thank you!

Ethical Business Practices Code in Biopharmaceutical Sector

— *A View from SINO-PhIRDA*

Wang Xin

China Pharmaceutical Industry Research and Development Association

26-30 August 2013 | Kuala Lumpur, Malaysia

APEC Asia-Pacific Economic Cooperation

APEC INDONESIA 2013

Ethical Business Practices Code in Biopharmaceutical Sector

- I. Overview of business ethics worldwide
- II. Status of business ethics in China
- III. Brief introduction about SINO-PhIRDA

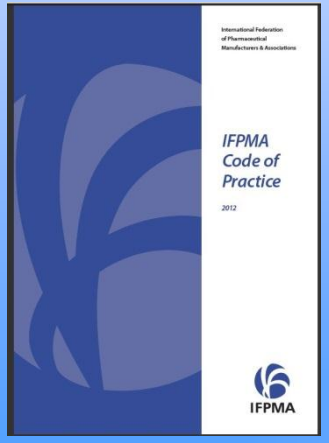
I. Overview of business ethics worldwide

Why code of business ethics?

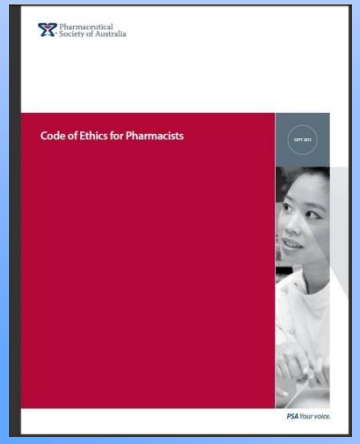
- Biopharmaceutical industry is a highly competitive business and its success is dependent on the sales and marketing of drugs.
- It is important that fraud / bribery cases are prohibited to ensure people's healthcare.

I. Overview of business ethics worldwide

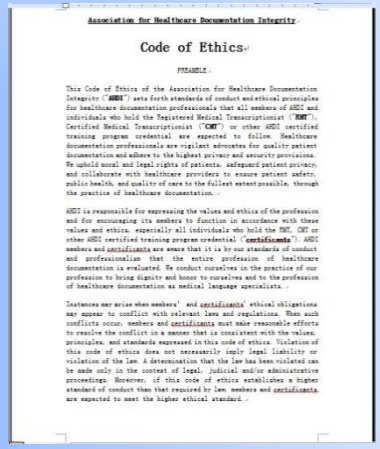
- Ethical interactions help ensure that medical decisions are made in the best interests of patients.
- Companies in biopharmaceutical sector should be guided by 6 principles: Healthcare and Patient Focus, Integrity, Independence, Legal intent, Transparency and Accountability.
- Many APEC Economies especially parties in developed countries, already implemented code of business ethics in biopharmaceutical industry.



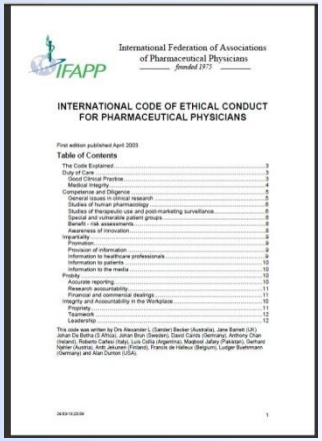
IFPMA



Pharmaceutical Society of Australia



Association for Healthcare Integrity

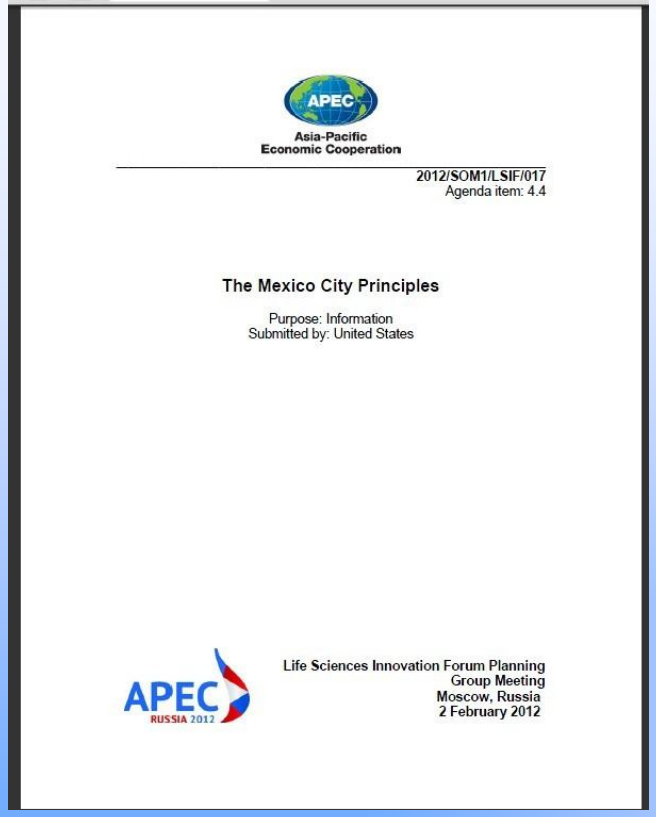


International Federation of Associations of Pharmaceutical Physicians

PhRMA
RESEARCH • PROGRESS • HOPE

efpia
European Federation of Pharmaceutical Industries and Associations

I. Overview of business ethics worldwide



APEC
Asia-Pacific
Economic Cooperation

2012/SOM1/LSIF/017
Agenda item: 4.4

The Mexico City Principles

Purpose: Information
Submitted by: United States

APEC RUSSIA 2012

Life Sciences Innovation Forum Planning
Group Meeting
Moscow, Russia
2 February 2012

The Mexico City Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector

- Ethical relationships with healthcare professionals, government officials, patients, and other stakeholders are critical to the mission of companies to help patients by developing and making medicines available.
- Companies undertake to adhere to relevant local, national, and regional industry ethics codes in both the spirit and the letter.
- Companies will ensure that all personnel and third parties working on their behalf comply with these Principles and all related laws and regulations.
- …

II. Status of business ethics in China

According to predictions by IMS Health and ChinaBio, China is to surpass US and become the world's #1 Economy with largest pharmaceutical market by 2020, due to robust economic growth and healthcare reforms.

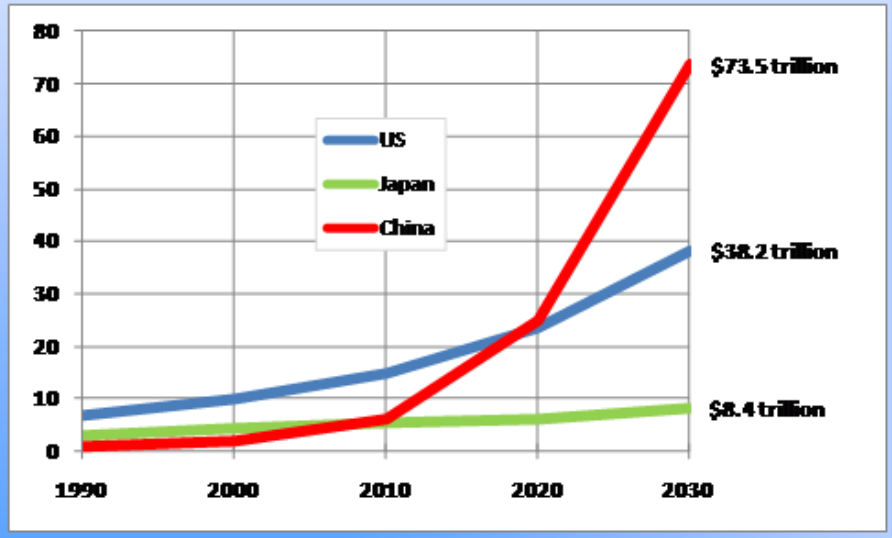


Figure 1. *China to become #1 Economy by 2020 (Source: IMF, Xinhua, Standard Charter & Time)*

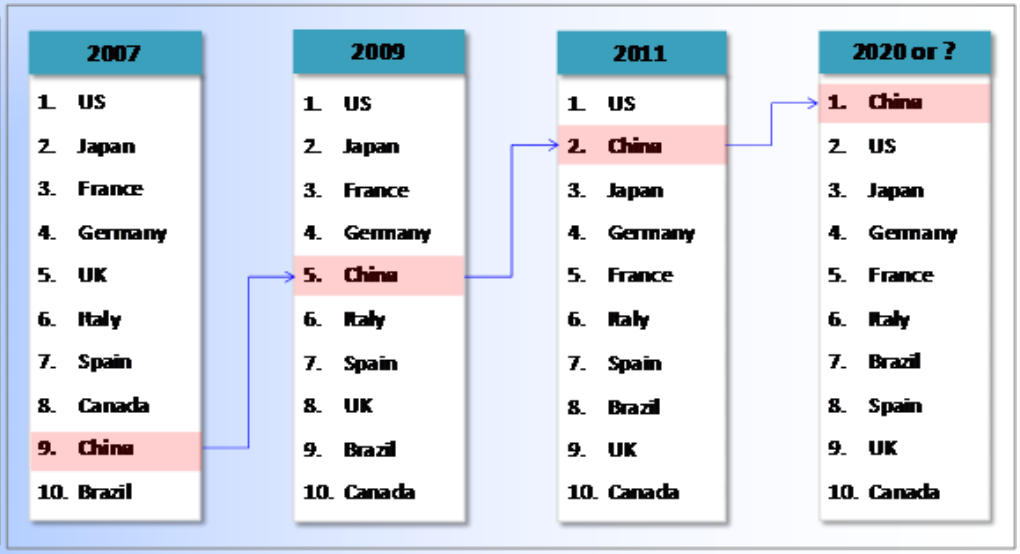


Figure 2. *China to Become #1 Pharmaceutical Market by 2020 (Source: IMS Health & ChinaBio)*

II. Status of business ethics in China

Associated with China's fast development and growth, there are ethical issues in biopharmaceutical industry…

The recent pharmaceutical bribery case

Recently, investigations on suspect for commercial bribery with doctors and officials continues to make headlines.

People's Daily

"These bribery case shows the complex nature of the struggle against commercial corruption. Striking hard against the commercial bribery of multinational companies has important significance for safeguarding the market's economic order and maintaining a fair environment."

China Central Television

"China is not a hotbed of bribery for multinational firms and they should regulate their own behavior as soon as possible."

WHAT SHOULD CHINA DO?

II. Status of business ethics in China

Our opinion

- Ethical issues commonly exist around the world, no matter in developed countries or developing countries, no matter with big-size multinational companies or small/ medium-size domestic companies.
- These issues are highly related with regulations and policies, such as healthcare reimbursement system, hospital management regulations.
- Companies should promote, sell and distribute their medicines in a manner that is ethical, balanced, accountable, and in compliance with relevant laws and regulations.

"SINO-PhIRDA forbids commercial bribery in all means, so as to create healthy market environment for the development of pharmaceutical industry."

---- *Section 6, Constitution of SINO-PhIRDA*

II. Status of business ethics in China

Laws and Regulations – Government

- Chinese Criminal Law - corruption/ bribery section
- Law Against Unfair Competition
- Interim Provisions on Prohibition of Commercial Bribery

Actions – Social Society (NGOs, enterprises…)

- Develop a suitable code of business ethics
- Sign onto the code
- Monitor and evaluate its implementation
- Assist the government to further improve related policies and regulations

II. Status of business ethics in China

Recent actions taken by NGOs in China

- November 2012: "Mexico City Principles" translated and reviewed (CPIA, SINO-PhIRDA)
- March 2013: 1st working group meeting by 5 associations in China (CPIA, CCCMHIE, CAPC, CNMA, SINO-PhIRDA)
- July 2013: 2nd working group meetings by 8 associations in China (CPIA, RDPAC, CCCMHPIE, CATCM, CAPC, CNMA, CPEP, SINO-PhIRDA)
- August 2013, APEC workshop in Malaysia (CPIA, RDPAC, SINO-PhIRDA)

Future Plan

- October 29, 2013: Joint Press-conference on Code of Business Ethics
- …

II. Status of business ethics in China

Questions and Concerns

- The best timeline/ plan for future actions?
- How to encourage companies to voluntarily sign onto the code?
- Who will monitor and evaluate the implementation?
- How to evaluate the implementation?
- What actions need to be taken when a company signs onto the code, but does not really follow it?
- Do we need the involvement of government? What role should it be?
- …

III. Brief introduction about SINO-PhIRDA

Introduction

SINO-PhIRDA, founded in 1988, is registered as a non-profit organization at the first national level in China.

Purpose

To promote Innovation, Industrialization, Internationalization of China’s domestic pharmaceutical industry, and improve people’s healthcare standard.

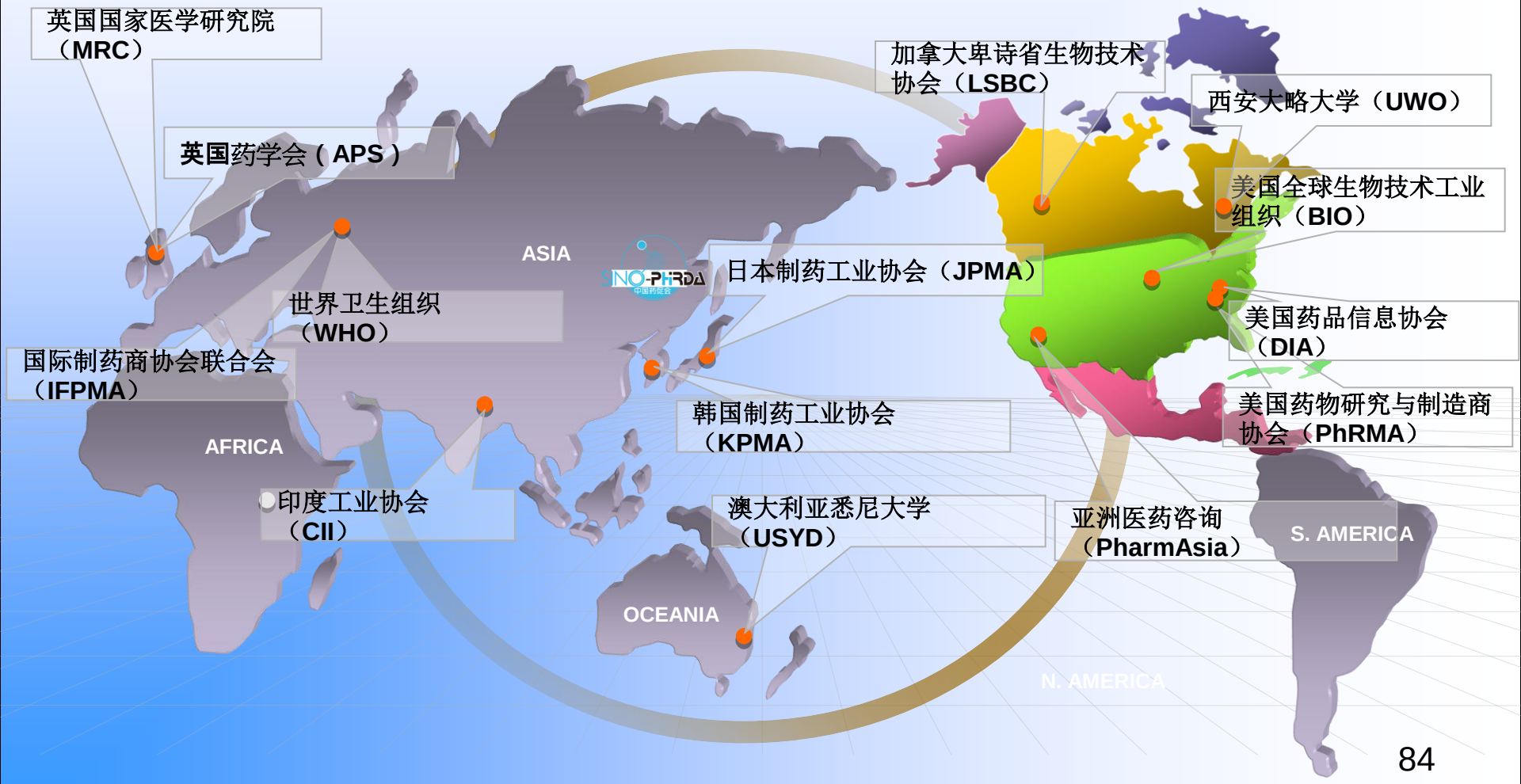
III. Brief introduction about SINO-PhIRDA

64 members
- mainly consists of 3 categories

- China's leading domestic pharmaceutical companies in new drug innovation
- Universities and research institutions conducting pharmaceutical R&D
- Clinical institutions featuring high skills in clinical trial research of new drugs, such as hospitals

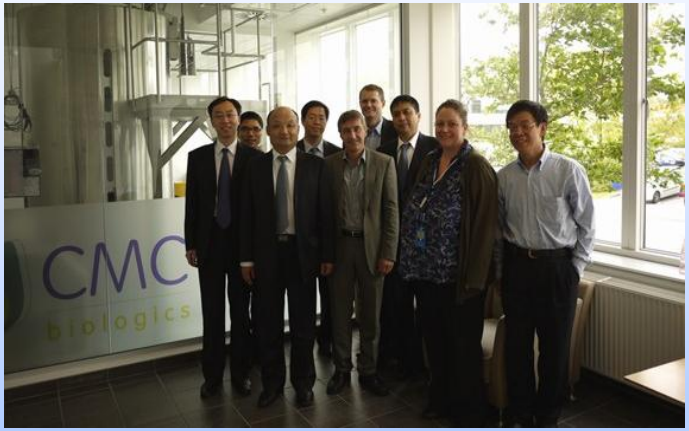
III. Brief introduction about SINO-PhIRDA

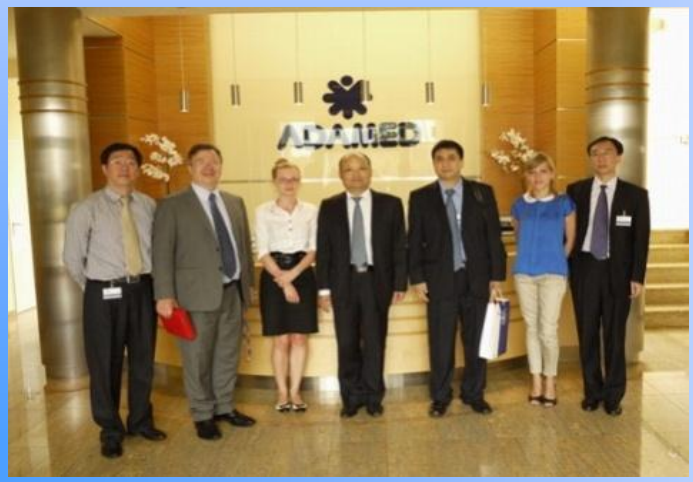
Over the past two years, SINO-PhIRDA has established collaborative partnership with 32 embassies in China and more than 20 organizations worldwide.



III. Brief introduction about SINO-PhIRDA

2012: Delegation visits to Denmark, Switzerland, Poland and Australia





III. Brief introduction about SINO-PhIRDA

2013: Delegation visits to U.S. and Canada

United States

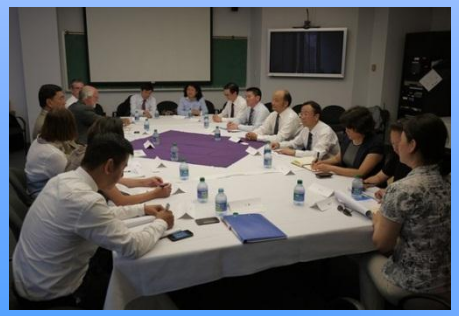
Columbia University

PhRMA & FBD

USPTO

DOC

Canada



Univ. of Western Ontario

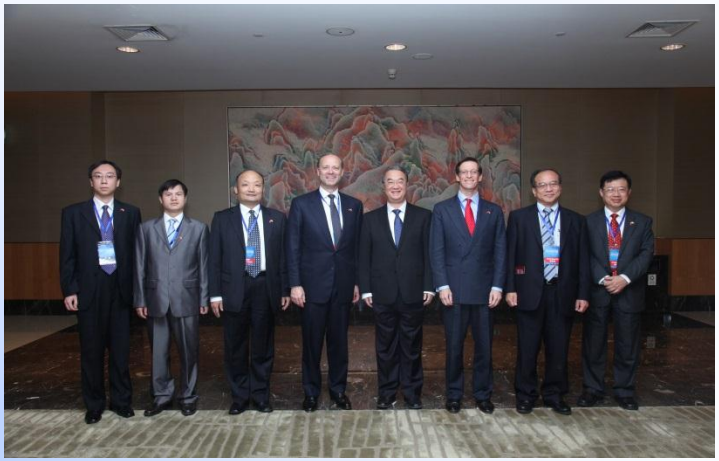
WORLDiscoveries

Ontario

British Columbia

III. Brief introduction about SINO-PhIRDA

International Pharmaceutical Innovation Forums / Summits



2014: *Biopharmaceutical social responsibility & business ethics*

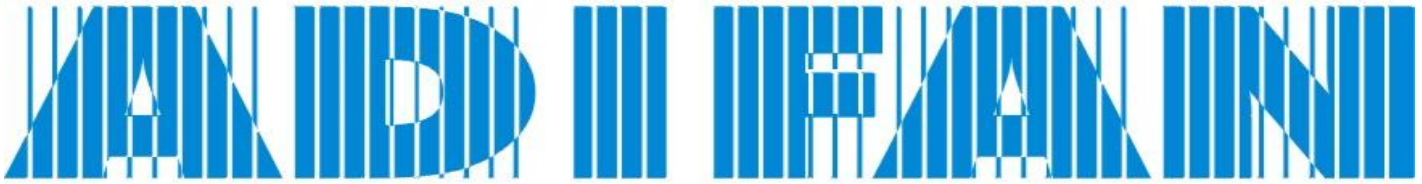
Conclusion

- In order to promote ethical commercial environment, cooperation among multiple stakeholders is required. These includes joint efforts from companies, healthcare professionals, NGOs and APEC economies.

- The Mexico City Principles is just our first step towards the ethical environment, there is still a long way to go. SINO-PhIRDA would like to work together with worldwide colleagues and we are confident on the brighter future in biopharmaceutical industry.

Thanks for your attention!

Wang Xin
Deputy Senior Director – International Affairs, SINO-PhIRDA
Email: wang@alumni.uwo.ca



National Pharmaceutical Industries Association

Peru

Berenice Pinto Vizcardo
General Manager

What is ADIFAN?

- National Pharmaceutical Industries Association.
- Represents the most important drug manufacturing companies in Peru.
- National pharmaceutical industry supplies 70% drug units to the Peruvian State.
- Its main goal is to produce first quality drugs and compete to facilitate Peruvian population's access to first quality drugs.

Adifan and Ethics Code

- After July 2012 meeting in Taipei, Adifan's BoD evaluated installing an ethics code.
- This code is based on The Mexico City Principles.
- Adifan considered these principles to be in the same line of those of ADIFAN's companies.

Integrity and Ethics Principles

- ADIFAN agreed to form a Consulting Council in which high-experienced leaders within the pharmaceutical sector would, among other tasks, care to make the integrity and ethics code principles be followed.

ADIFAN suggests ethics code to ALIFAR

- During meeting in Cartagena on May 2013, ALIFAR was suggested to install an ethics code.
- ALIFAR's BoD approved the suggestion to install an ethics code.
- ADIFAN has built an ethics code for ALIFAR based on The Mexico City Principles, which shall be submitted to ALIFAR during next meeting scheduled in November 2013 (date TBA).

What is ALIFAR?

- Latin America and The Caribbean Pharmaceutical Laboratories Association.
- Formed by those manufacturing pharmaceutical laboratories in Latin-American and Caribbean countries .
- ALIFAR member countries do not have a current ethics code.
- ADIFAN considered necessary to suggest ALIFAR installing an ethics code.

Importance

- We consider important and necessary that pharmaceutical laboratories members of ALIFAR shall care to follow the same line of ethics applied to all laboratories in Latin America and the Caribbean.
- We thank APEC for promoting embracement of an ethics code by sharing its importance and experiences; which shall be shared with ALIFAR.

Thank You!

MALAYSIAN ORGANISATION OF PHARMACEUTICAL INDUSTRIES

EXPERIENCE IMPLEMENTING A CODE OF ETHICS

BUSINESS ETHICS – TRAIN THE TRAINER PROGRAMME
KUALA LUMPUR – 26-30 AUGUST 2013

MALAYSIAN ORGANISATION OF PHARMACEUTICAL INDUSTRIES

mopi

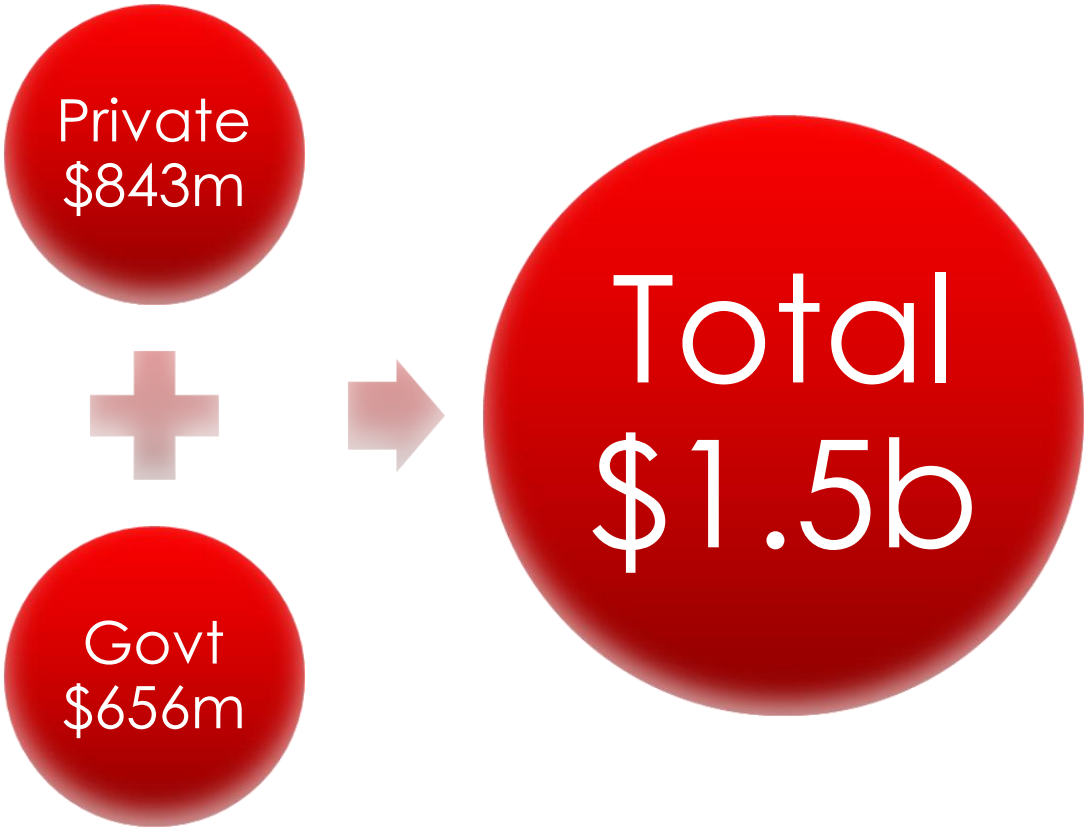
Introduction to MOPI

- Incorporated in Malaysia on 6th March 1981
- Company limited by guarantee
- Represents 35 domestic pharmaceutical manufacturers (≈7000 jobs)
- All members are cGMP registered with NPCB
- Produces approximately 35% of Malaysia's medicine requirement by value
- Capability of producing 80% of Malaysia's National Essential Drugs List

MALAYSIAN ORGANISATION OF PHARMACEUTICAL INDUSTRIES

mopi

Domestic Pharmaceutical Industry - USD



Generics:
65% by volume
35% by value

MALAYSIAN ORGANISATION OF PHARMACEUTICAL INDUSTRIES

mopi

Strategic to Malaysia

- Part of Healthcare Economic Transformation Program (ETP)
- Entry Point Project (EPP) 3: Generics Export
- 2020 GNI: RM$4,300m
- 2020 Jobs: 12,500
- Investments: RM$3,200m

ECONOMIC TRANSFORMATION PROGRAMME

MALAYSIAN ORGANISATION OF PHARMACEUTICAL INDUSTRIES

mopi

START OF JOURNEY

- 2009 – MOPI EXCO decided to develop voluntary Code of Ethics for members
- Mr. Alex Tan, Advisor to MOPI tasked to produce first draft
- 2010 – Draft Code established based on Code adopted by Pharmaceutical Association of Malaysia (PhAMA)
- 2010 – First circulation to members but issues arose due to lack of International Best Practices

MALAYSIAN ORGANISATION OF PHARMACEUTICAL INDUSTRIES

mopi

APEC ASSISTANCE

- 2012 – MOPI invited to participate in APEC Workshop to Align Voluntary Codes of Business Ethics for the Biopharmaceutical Sector in Chinese Taipei on July 10-11, 2013
- Attended by President, MOPI
- Platform to look at best practices bringing together WHO guidelines and APEC Mexico City Principles
- Allocated Ms Millette Asuncion to assist with development of Code

APEC
Asia-Pacific Economic Cooperation

MALAYSIAN ORGANISATION OF PHARMACEUTICAL INDUSTRIES

mopi

MACC ASSISTANCE

- At APEC Workshop, met representative from Malaysian Anti-Corruption Commission, Mr. Shaharuddin Khalid, Director – Inspection & Consultancy Division
- MOPI draft Code was reviewed by MACC to ensure compliance to Mexico City Principles

MALAYSIAN ORGANISATION OF PHARMACEUTICAL INDUSTRIES

mopi

TIMELINES

- 2009 – Decided to develop Code of Conduct
- 2010 – Developed first Draft
- 2012 – Assistance from APEC & MACC
- Apr 2013 – Original Planned Launch
- July 2013 – Final Approval by MOPI EXCO

MALAYSIAN ORGANISATION OF PHARMACEUTICAL INDUSTRIES

mopi

LEARNINGS

- Consensus building among Members took a long time due to entrenched practices.
- Designed Code to be Voluntary in order to get 100% consensus among members
- Requires assistance in order to develop best practices

MALAYSIAN ORGANISATION OF PHARMACEUTICAL INDUSTRIES

mopi

GOING FORWARD

- Participation in Train the Trainer Training - August 2013 Kuala Lumpur
- Design training of members in short blocks at the beginning of each GMP training to ensure effective dissemination
- Production of Code in booklet form to be distributed to all members

MALAYSIAN ORGANISATION OF PHARMACEUTICAL INDUSTRIES

mopi

Thank you

Contact:

Y S Tong, Executive Director

Malaysian Organisation of Pharmaceutical Industries (MOPI)

email: admin@mopi.org.my

website: www.mopi.org.my

Implementing a Cost Efficient Compliance Program

Cost to Association

Minimal out of pocket cost. It is manned by Secretariat & the Board

EC members, mostly experts from academe and HC industry, receive honorarium once a month

PHAP
PHARMACEUTICAL & HEALTHCARE ASSOCIATION OF THE PHILIPPINES

Code of Practice

Printing and revision of the PHAP Code of Practice.

Code is online.

Stakeholders' engagement thru fora

As seen from the PHAP's point of view: More of the cost in time than financial

Compliance Programs of Distributors

Genevieve Wan

Compliance Director Pharmaceuticals, Asia Pacific

David Brandt

Sourcing Group Director Freight and Distribution, Asia Pacific

APEC Train-the-Trainer Workshop for Voluntary Codes of Business Ethics in the Medical Device Sector

26-30 August 2013 | Kuala Lumpur, Malaysia

Asia-Pacific Economic Cooperation

Why Should We Care?

- **Asia Pacific Growth**
  - CAGR from 8% → 13% by 2015 ($242 B → $333 B)
- **Shifting Pharma Trends**
  - Impacts on distributors
- **Changing Regulations**
  - Raising the bar on Supply Chain safety
- **Recent cases**
  - Biomet - $22MM
  - Smith & Nephew - $22MM

APEC
Asia-Pacific Economic Cooperation

Distributors and Subdistributors

Distributors: Entities that purchase products from Pharma companies, taking title to and possession of goods and selling them from their own account to end customers, including dealers and resellers.

Range of Services:

Asia-Pacific Economic Cooperation

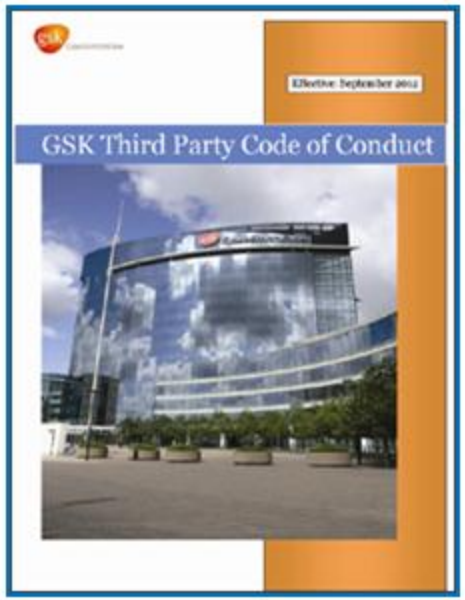
Third Party Risk and Compliance Considerations

Current regulatory environment expects, and regulators are increasingly demanding that companies know who is conducting business on their behalf and the risks associated with doing business with these vendors.

Third Party Framework

- Due Diligence
- Contracting
- Monitoring and Oversight

GSK Third Party Code of Conduct



Asia-Pacific Economic Cooperation

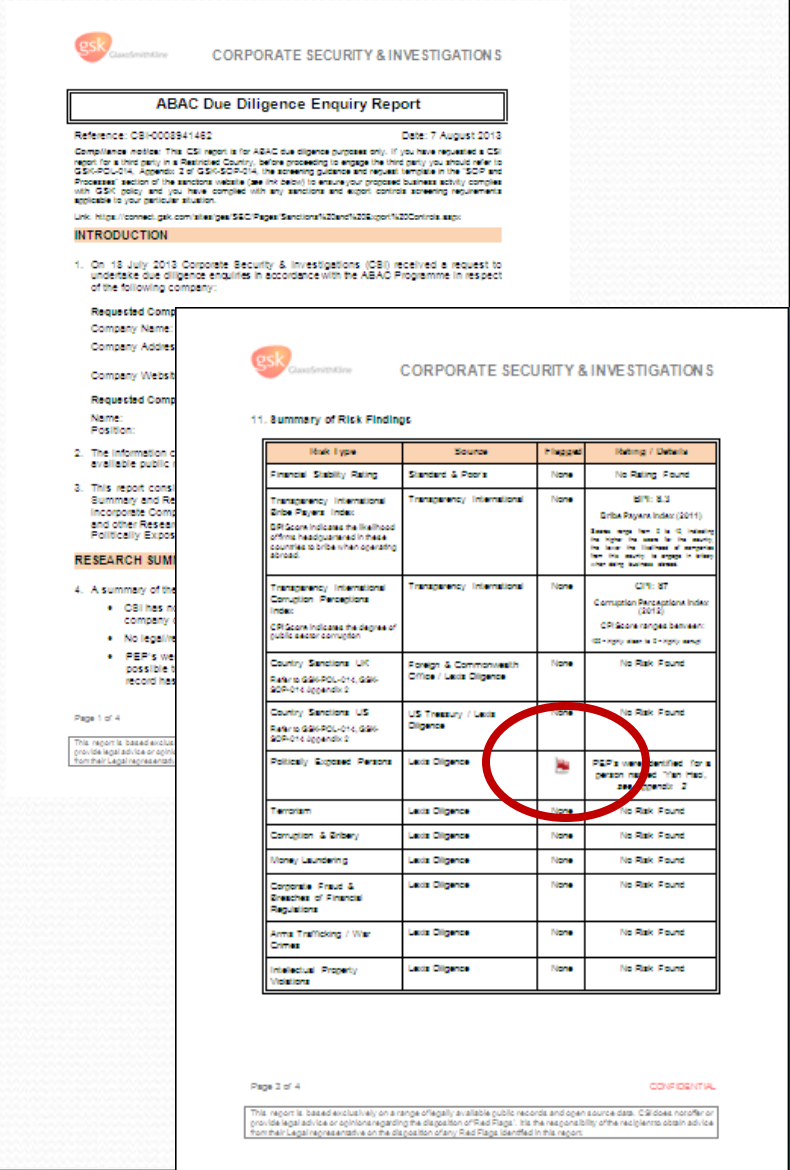
Due Diligence

Criteria for Selection and Service

Anti-Bribery Due Diligence

Background Checks on Key Individuals

Red Flags and Risk Mitigations



CORPORATE SECURITY & INVESTIGATIONS

ABAC Due Diligence Enquiry Report

Reference: CSI-I0008941462 Date: 7 August 2013

INTRODUCTION

1. On 18 July 2013 Corporate Security & Investigations (CSI) received a request to undertake due diligence enquiries in accordance with the ABAC Programme in respect of the following company:

RESEARCH SUMM

4. A summary of the

Page 1 of 4

CORPORATE SECURITY & INVESTIGATIONS

11. Summary of Risk Findings

Risk Type	Source	Flagged	Rating / Details
Financial Stability Rating	Standard & Poors	None	No Rating Found
Transparency International Bribe Payers Index	Transparency International	None	BPI: 8.3 Bribe Payers Index (2011)
Transparency International Corruption Perceptions Index	Transparency International	None	CPI: 37 Corruption Perceptions Index (2012)
Country Sanctions UK	Foreign & Commonwealth Office / Lexis Diligence	None	No Risk Found
Country Sanctions US	US Treasury / Lexis Diligence	None	No Risk Found
Politically Exposed Persons	Lexis Diligence		PEPs were identified for a person named Yan Hao; see Appendix 2
Terrorism	Lexis Diligence	None	No Risk Found
Corruption & Bribery	Lexis Diligence	None	No Risk Found
Money Laundering	Lexis Diligence	None	No Risk Found
Corporate Fraud & Breaches of Financial Regulations	Lexis Diligence	None	No Risk Found
Arms Trafficking / War Crimes	Lexis Diligence	None	No Risk Found
Intellectual Property Violations	Lexis Diligence	None	No Risk Found

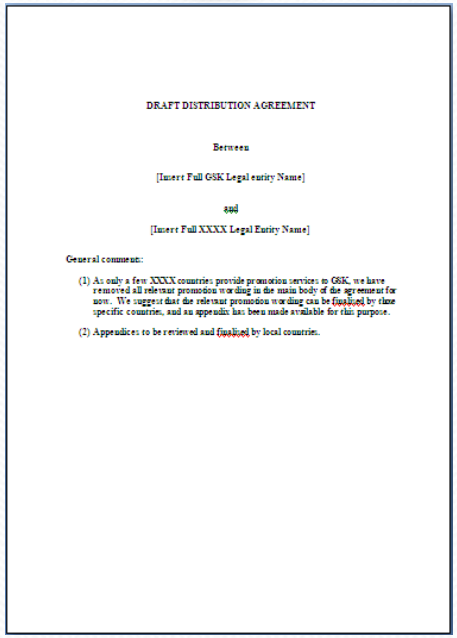
Page 3 of 4

CONFIDENTIAL

- **Financial Due Diligence**
- **Capability Screening**
- **Data Privacy**
- **Legal Questionnaire**
- **Etc.**

Contracting

- Product Complaints/ Adverse Event Reporting
- Promotion and Customer Interactions
- Robust Anti-Bribery Clauses
- Document Retention Policies
- Quality Audit & Inspection Rights
- Compliance Certification Requirements
- 3rd Party Code of Conduct Comparisons
- Data Security/ Data Privacy
- Pre-Employment Screening
- Discounting Policies



DRAFT DISTRIBUTION AGREEMENT

Between

[Insert Full GSK Legal entity Name]

and

[Insert Full XXXX Legal Entity Name]

General comment:

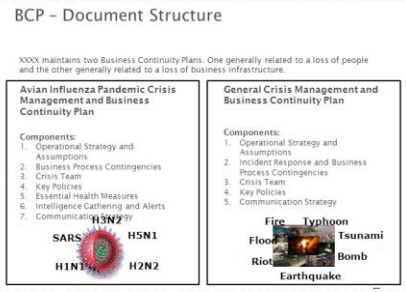
(1) As only a few XXXX countries provide promotion services to GSK, we have removed all relevant promotion wording in the main body of the agreement for now. We suggest that the relevant promotion wording can be finalized by those specific countries, and an appendix has been made available for this purpose.

(2) Appendices to be reviewed and finalized by local countries.

Asia-Pacific Economic Cooperation

Monitoring & Oversight

Business Continuity Plans


BCP – Document Structure

XXXX maintains two Business Continuity Plans. One generally related to a loss of people and the other generally related to a loss of business infrastructure.

Avian Influenza Pandemic Crisis Management and Business Continuity Plan

Components:
1. Operational Strategy and Assumptions
2. Business Process Contingencies
3. Crisis Team
4. Key Policies
5. Essential Health Measures
6. Intelligence Gathering and Alerts
7. Communication Strategy

H5N2 SARS H5N1 H1N1 H2N2

General Crisis Management and Business Continuity Plan

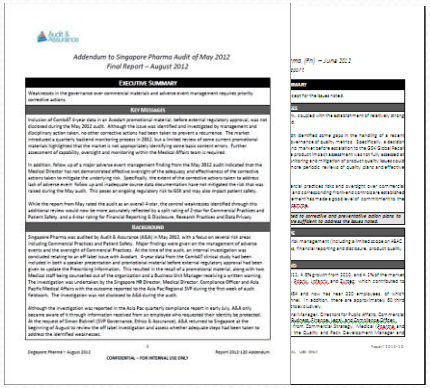
Components:
1. Operational Strategy and Assumptions
2. Incident Response and Business Process Contingencies
3. Crisis Team
4. Key Policies
5. Communication Strategy

Fire Typhoon Flood Tsunami Riot Bomb Earthquake

Pricing Tables

Sampling

Commercial & Quality Audits


Addendum to Singapore Pharma Audit of May 2012
Final Report – August 2012

EXECUTIVE SUMMARY

Financial Controls

Sales Incentives/Customer Interactions

APEC
Asia-Pacific Economic Cooperation

Monitoring & Oversight

Storage & Temperature & Access Controls

Delivery Management

Data Privacy

Compliance & Training


Certificate of Compliance

awarded to

Your Company Name Here
Technology City, USA

ISO 6 Cleanroom and Gown

MEETS OR EXCEEDS THE REQUIREMENTS OF ISO 14644-1:1999 CLASS 6
(FEDERAL STANDARD 209E CLASS 1,000)
AT 0.5 MICRON IN THE OPERATIONAL MODE

presented by

Gerbig Engineering Company

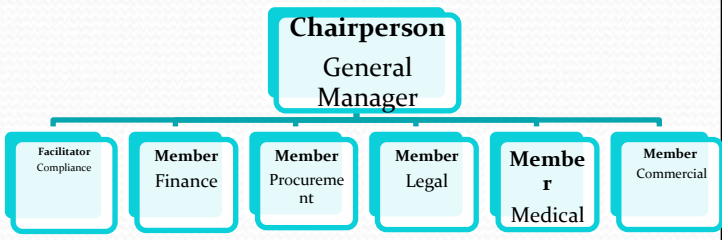
August 30, 2007

Recommended Recertification Date: August 30, 2008

Mike Turnure, Validation Director — Fred Gerbig, President

Customer Maintenance

3rd Party Oversight Council



APEC
Asia-Pacific Economic Cooperation

Challenges

- Limited Enforcement
  - Disciplinary Actions
  - Breaches
  - Investigations
- External Investigations
- Complacency
- Termination of Contract

Asia-Pacific Economic Cooperation

Relationship,

Relationship,

Relationship!

Asia-Pacific
Economic Cooperation

Thank You!

Asia-Pacific
Economic Cooperation

Compliance Programs & Physicians

How to work with physicians/physician associations to engage them on the industry's compliance code

Kitima Yuthavong, CEO

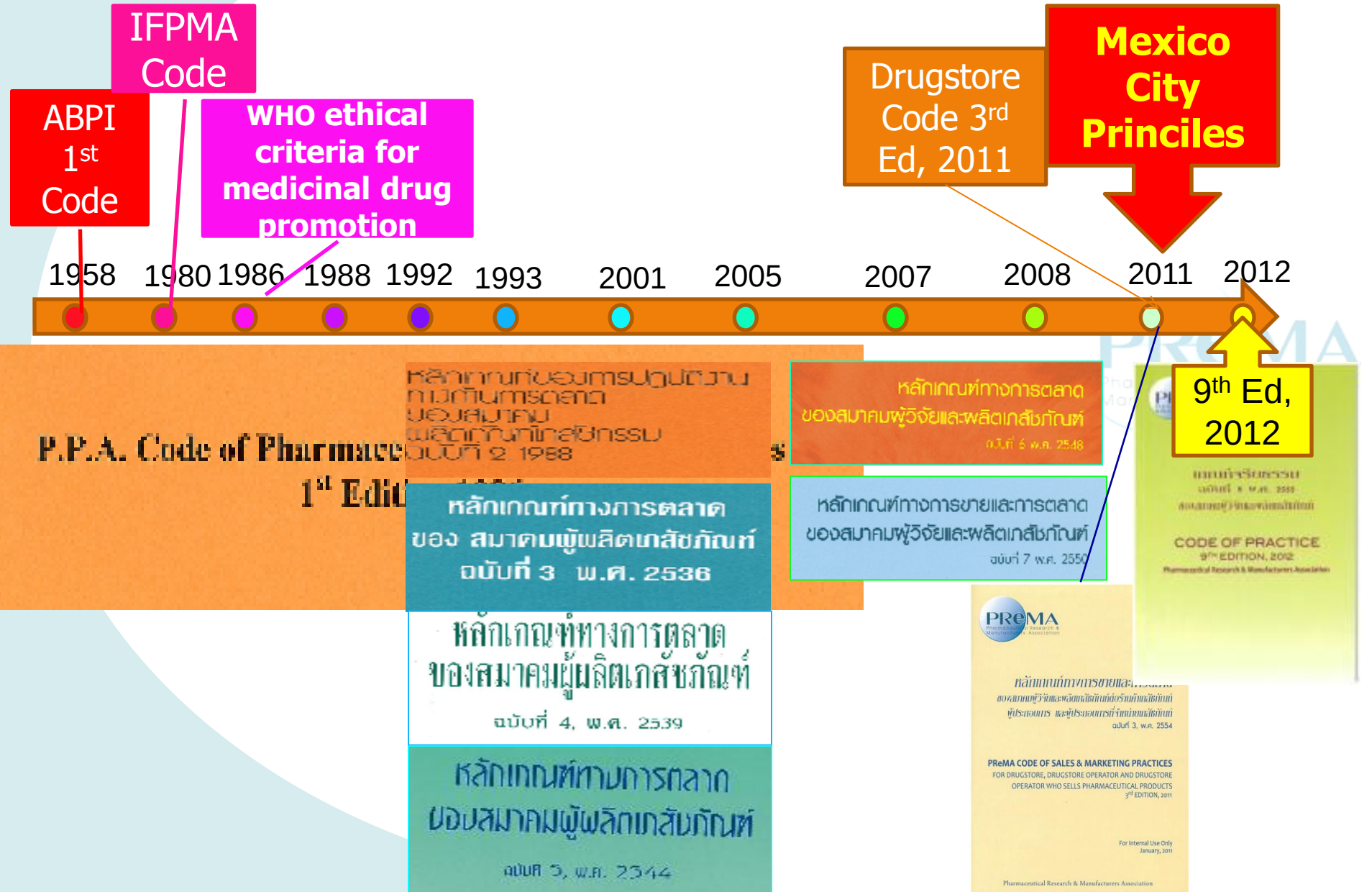
Pharmaceutical Research & Manufacturers Association (PReMA)

August 2013

Outline

- PReMA Code Development
- Reaching out to physicians
  - Code Adjudicating Committee
  - Booth exhibition
  - Forum on Ethics with Medical Council and Medical Association of Thailand
- Code Awareness Week
- Presentation at Symposium & Universities
- Physicians' awareness flash survey (9-17 August 2013)

PReMA Code Development



Code Adjudicating Committee

Code of Conduct Committee

1986 — 2007 — 2013

2008

P.P.A. Code of Pharmaceutical Marketing Practices
1st Edition 1986

Code of Conduct Committee

Booth exhibition at Royal College of Physicians meetings

1986

2007

2009

P.P.A. Code of Pharmaceutical Marketing Practices
1st Edition 1986

Engagement of Medical Council &and Medical Association of Thailand

Booth Exhibition (2008-2010) at the Royal College of Physicians annual meeting

Senior doctors' testimonials on importance of ethics of med rep as part of display

2009

At the PReMA 39th Anniversary

- Seminar on "**Image of Sales Promotion (in Pharma): Public Reflection**"
- Panelists
  - Prof. Emeritus Dr. Somsri Paosawad,

Medical Association of Thailand

  - Dr. Ittaporn Kanacharoen,

Deputy Secretary General, Medical Council

  - Dr. Chumsak Prueksapong,

Senior Advisor, **Central Institute of**

Forensic Science & Chairman of PReMA Code of Conduct Committee

2010

Part of **PReMA's 40th Anniversary**

Roundtable **"Ethical Practices in Today's Dynamic Healthcare"**

Moderated by Dr. Chumsak P.

- Richard Bergstorm, **IFPMA CCN Chairman**
- Peter Jager, **KRPIA President**
- Dr. Wittaya S., **Medical Council**
- Dr. Noppadol W., **Royal College of Surgeons**
- Dr. Kidapol W., **Royal College of Family Physicians**
- Etc.

Code of Conduct Committee

Booth exhibition at Royal College of Physicians meetings

1986 2007 2009 2010 2011 2013

P.P.A. Code of Pharmaceutical Marketing Practices
1st Edition 1986

Code Awareness Week

Code Awareness Week
5-9 July 2010

Objectives:

- Communicate key ethical business practice issues to doctors via the med rep.

Key messages:

- Both HCP and " WE" (research-based pharma) perform duty with highest ethical and scientific standard.

Campaign :

- All med rep. from PReMA members wear the badge " SO DO WE" all week at public places.
- Med Rep discussed with doctors about message in the "leave piece"

Tool Kit: Leave Piece

Page 1

You hold yourself to the highest standard. So do we.

This year Pharmaceutical Research & Manufacturers Association (PReMA) are celebrating our 40th anniversary.

Since 1967, The Code of Sales and Marketing has been a tangible demonstration of PReMA's commitment to relationships based on trust, openness and transparency with healthcare providers.

The main objectives in developing the Code are to:

- Ensure that the information provided to the healthcare professionals is factual
- Ensure that there be no inappropriate benefit used to induce healthcare professionals' decision
- Ensure that medical representatives have appropriate conduct and perform their duty professionally

PReMA is a non-profit organization representing research based pharmaceutical companies who brings value of quality innovative medicines to support better medical treatment through ethical sales and marketing practices.

Delivering Value and Quality Ethically to the Thai Medical Society

Page 2

CODE of CONDUCT

The Guiding Principles of PReMA Code of Sales & Marketing Practices

As a responsible partner in providing healthcare, PReMA members conduct themselves with integrity and maintain consistently high ethical standards coupled with constant product innovation and excellence in sales and marketing.

1. All members must adhere to the Code and its intent as a condition for membership.
2. All product information provided to healthcare professionals must be accurate, fair and balanced.
3. PReMA members shall ensure that their personnel are adequately trained and possess sufficient medical and technical knowledge to present information in an accurate, responsible and ethical manner.
4. No financial inducement or other consideration is to be given to healthcare professionals for the purpose of gaining access or influence.
5. Market research and post-marketing scientific studies shall not be used as a disguised form of promotion.
6. Only modest meal and refreshment would be an acceptable form of hospitality.
7. With the primary focus on scientific/medical knowledge dissemination, at least 75% of the total time when organizing symposia, congresses and the like shall be dedicated to scientific program or therapeutic focuses.
8. Sponsorship for attending medical or scientific meetings shall limit to the payment of travel, meals, accommodation and registration fees and must only be given to healthcare professionals.

For more information, please contact Pharmaceutical Research & Manufacturers Association (PReMA) Tel: (+662) 619 0252-5 / Fax: (+662) 619 0237
Website: www.prema.or.th

Leave pieces: Contents on page 1

- You (doctors) hold yourself to the highest standard. "So Do We"
- PReMA celebrate 40th Anniversary in 2010. Our code is in place for the 24th year (since 1987)
- Main Objectives of the Code:
  - Information provided is factual
  - No inappropriate benefit done to induce HCP's decision
  - PReMA MR appropriately perform duty professionally
- PReMA members bring value of innovative treatment to the society, we ensure that our products have good quality and we are doing our business ethically.

Leave pieces: Contents on page 2 - Principles

1. All members must adhere to the Code
2. All product information must be accurate, fair and balanced.
3. Members' personnel are adequately trained and possess sufficient medical and technical knowledge to present information in an accurate, responsible and ethical manner.
4. No financial inducement or other consideration is to be given to healthcare professional for the purpose of gaining access or influence.
5. Market research and Post-Marketing scientific studies shall not be used as disguised form of promotion.
6. Only modest meal and refreshment would be acceptable form of hospitality.
7. At least 75% of the total time when organizing symposia, congresses and the like will be dedicated to scientific program or therapeutic focuses.
8. Sponsorship for attending medical or scientific meetings shall limit to payment of travel, meals, accommodation and registration fees and must only be given to healthcare professionals

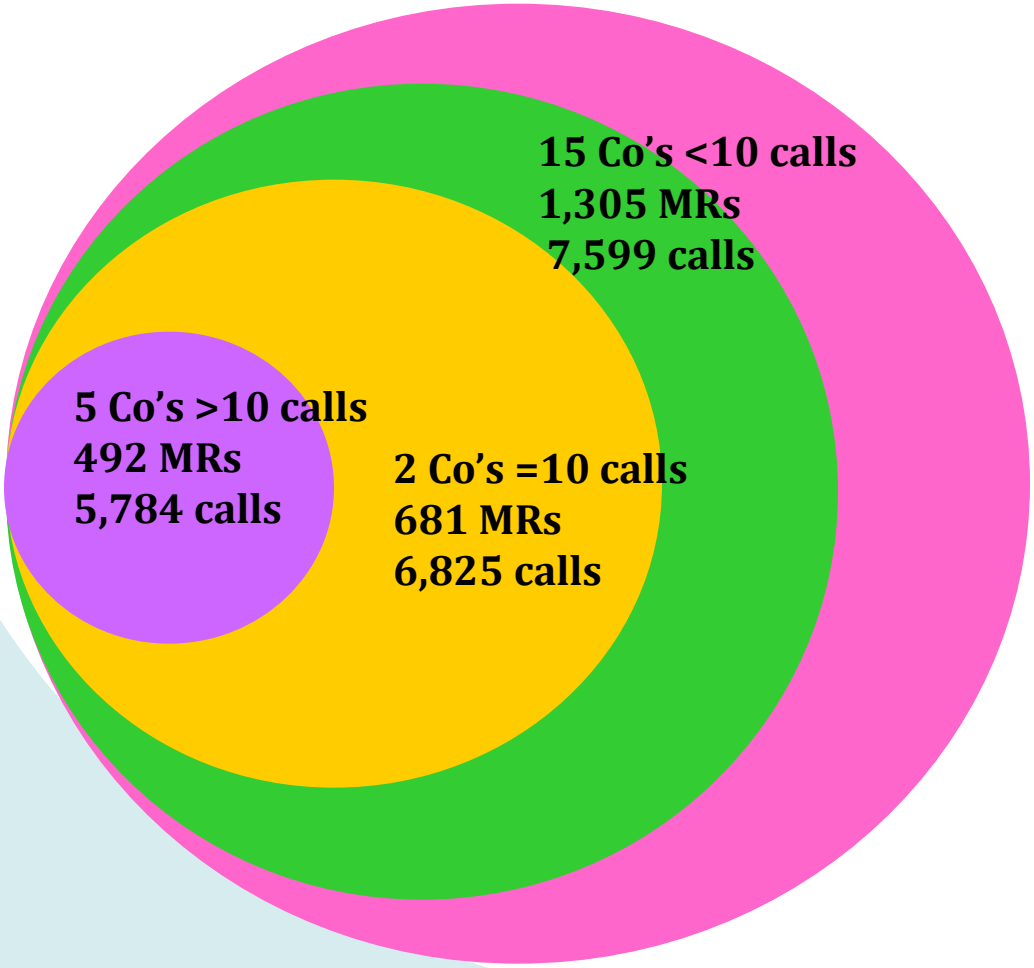
Communications:

- Get support from the GMs
- Training of key messages to training managers of all member companies
- Press Conference of the campaign
- Companies' HR managers send daily reminding SMS to Med rep

Code Awareness Week
5-9 July 2010

- Targeted 3,000 MRs
- At least 10 calls per MR
- Expected total 30,000 calls

Code Awareness Week
5-9 July 2010



Total MRs

Joining MRs

MRs/ =10 calls

MRs/ >10 calls

Total Joining
2,478 MRs
20,208 calls

Code of Conduct Committee

Booth exhibition at Royal College of Physicians meetings

PEP Talk

1986 2007 2009 2010 2011 2013

P.P.A. Code of Pharmaceutical Marketing Practices
1st Edition 1986

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PEP Talk: 2011
PReMA Ethics Partnership

Objective: Turn compliance into a positive & transparent communication through internal engagement

Tool:

- CD containing:
  - interview or quote of all GM on their emphasis about ethics
  - **Interview of KOL (HCP) how they perceive on importance of ethics in pharma industry**
- PEP Talk Poster for company to hang at their office

Methodology:

- All GMs are encouraged to either open on touch on ethics at company town hall meeting
- Company can select contents from the CD to inspire staff in office
- Encourage company to send photos of the activities to PReMA as record

PEP Talk
PReMA Ethics Partnership

Invite for HCP testimonials in addition to GM testimonials on ethics

Prof. Kammant Phanthumchinda MD.
President of Royal College of Physicians

"Nowadays the main method is evidence based. Medical representatives and industry professionals who are in contact with doctors should use evidence based material to provide information."

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PEP Talk

PReMA
Pharmaceutical Research & Manufacturers Association

PREMA
Pharmaceutical Research & Manufacturers Association

University Lectures

Objective:

To create awareness among medical and pharmacy students about PReMA Code of Practice

2013
Flash Survey

- A flash online survey of doctors' awareness and agreement on Ethical Business practice
- August 9th -17th , 2013
- Distributed via unofficial doctors communities online emails, facebook, LINE etc. by fellow doctors.

Questionaires for doctors

1) How long have you graduated with a Medical degree?

a) less than 5 years b) 6-20 years c) more than 20 years

2) Have you ever heard about business ethical code for pharmaceutical industry?

a) Yes b) No

3) Which organization does the business ethical code you have heard of belong to?

a) NHA Ethical Criteria in Drug Promotion

b) PReMA Code of Practice

c) Both

d) Never heard of both

4) Do you think ethical code of the industry is beneficial to the medical field in general?

a) Yes b) No c) No opinion

5) Do you think all companies/organizations which sells drugs in Thailand should follow business ethical code?

a) Yes b) No c) No opinion

6) Have you ever heard of Medical council's ethical code of practice re: relation with health product business operator?

a) Yes b) No

Result of the survey

- To be presented

The Adoption of Transparency Guidelines by the Pharmaceutical and Medical Device Industries in Japan

Bruce J. Ellsworth
Director, Corporate Government Affairs & Policy
Johnson & Johnson Family of Companies
Governor, American Chamber of Commerce in Japan

APEC Train-the-Trainer Workshop for Voluntary Codes of Business Ethics

26-30 August 2013 | Kuala Lumpur, Malaysia

Asia-Pacific Economic Cooperation

Agenda

1. Background
2. Increasing demand for transparency
3. Transparency guidelines
4. Building internal consensus
5. External stakeholder outreach
6. Medical device industry follows suit
7. Overcoming challenges
8. Conclusion

JPMA Promoting Ethics Since 1976

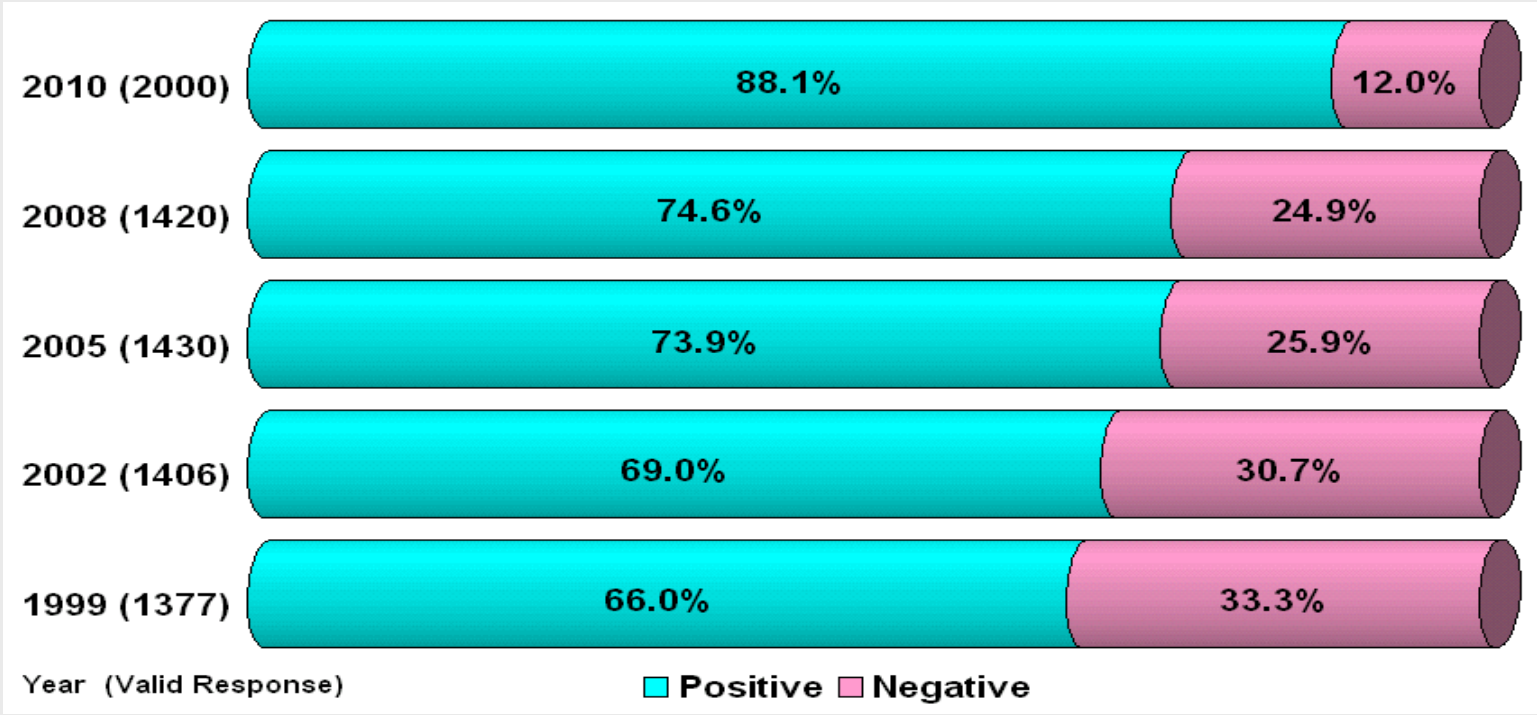
- The Japan Pharmaceutical Manufacturing Association (JPMA) has several types of self-regulation based on high ethical standards:
  1. JPMA Promotion Code for Prescription Drugs (Adopted in 1976. Revised in 1993 based on IFPMA Code)
  2. JPMA Charter of Corporate Behavior (Adopted in 1997 and revised several times).
  3. JPMA Compliance Program Guidelines (Adopted in 2001 and revised in 2011)
  4. Fair Competition Code in Ethical Pharmaceutical Drugs Marketing Industry
- These industry codes have self-enforcement mechanisms, with penalties for non-compliance
  - ✓ Exclusion from Board or committee membership
  - ✓ Expulsion & fines

Improving Reputation in Japan

Industry's reputation has been increasingly favorable.

Reliability of the Pharmaceutical Industry

88.1% replied "The pharmaceutical industry is trustworthy"



6th Survey on Public Perceptions of Medicines and the Pharmaceutical Industry (JPMA) June 25-29, 2010 survey conducted among 2,000 men & women aged 20 or older via the internet.

Growing Demand for Transparency

- Growing trend of disclosure of payments around the world (industry disclosure in UK, Canada, & Australia and legal requirement for disclosure via U.S. Sunshine Act).
- Increasing public demand for transparency in Japan. Conflict of Interest guidelines for clinical research were established by the Ministry of Health in 2008 and by the Japan Medical Society in 2011.
- Recognition that even with codes of ethics, there could be concern that payments may influence judgment.
- Recognition that as an industry closely involved in the life and health of patients, payment activities should be more transparent than in other industries.

Objectives of Transparency Guidelines

In 2011, the JPMA decided to proactively promote disclosure of payments via a set of voluntary "Transparency Guideline for the Relations between Corporate Activities and Medical Institutions."

Objectives

- Gain higher trust from society by increasing transparency of member company's activities with medical institutions
- Gain public understanding of industry's contribution to the advancement of life science.
- Gain public understanding that corporate activities are conducted with high ethical standards.

Transparency Guideline Outline

Voluntary Policy by Member Companies:

- Each member company will establish its own internal policy based on JPMA Guidelines

Disclosure method / timing:

- Member companies will disclose fiscal 2012 payments on their websites in fiscal 2013.

Scope of Disclosure (5 categories)

A. R&D expenses
B. Payments related to academic research grants
C. Honoraria
D. Payments related to provision of information
E. Other Payments

Scope of Disclosure

Category	Expenses for disclosure	Form
A. R&D expenses	Joint research	[Amt. / yr]
	Research commissioning	[Amt. / yr]
	Clinical study	[Amt. / yr]
	Post-marketing clinical study	[Amt. / yr]
	ADR / infection case reporting	[Amt. / yr]
	PMS	[Amt. / yr]
B. Academic research support expenses	Scholarships to medical schools	[Name of Inst.] [Freq] [Amt. / yr]
	Donation to academic societies	[Name of Org.] [Freq] [Amt. / yr]
	General donation	[Name of Org.] [Freq] [Amt. / yr]
	Co-sponsoring (at academic societies)	[Name of Event, Seminar] [Amt. / yr]
C. Manuscript / writing fee, etc.	Lecture	[Name of HCP & Inst.] [Freq.] [Amt. / yr]
	Manuscript writing / supervising	[Name of HCP & Inst.] [Freq.] [Amt. / yr]
	Consulting/commissioning	[Name of HCP & Inst.] [Freq.] [Amt. / yr]
D. Information provision-related expenses	Lecture meeting	[Freq.] [Amt. / yr]
	Explanation meeting	[Freq.] [Amt. / yr]
	Medical / pharmaceutical literature, etc supply	[Amt. / yr]
E. Other expenses	Hospitality, etc as social courtesy	[Amt. / yr]

Discussion Within JPMA

Apr. 2009	Basic stance on transparency determined
Jun. 2009	Disclosure Task Force (Code Committee)
Sep. 2009	JPMA Standing Board Review
Oct. 2009	Transparency Task Force (JPMA wide)
Feb. 2010	Proposal of draft Guidelines
Dec. 2010	Approval by JPMA Board
Dec. 2010	Explanation meeting for member companies
Jan. 2011	Approval at JPMA General Assembly

Member Company Explanation

APEC
Asia-Pacific Economic Cooperation

Implementation by JPMA Member Companies

2011	Companies adopt their own transparency guidelines
2011	Member companies publish their own policies on their websites
2011	Establish procedures to obtain consent from health care practitioners for disclosure for payments, including the addition of language to legal contracts
2011	Prepare necessary IT systems to record, track and aggregate all payment information
2012	Member companies start data collection
Jul. 2013	Member companies start disclosure

Enforcement

- Voluntary and non-binding
- No penalties or fines
- Approved by consensus of all member companies
- Implementation will be seen by the public

JPMA Explanation to External Stakeholders

Nov. - Dec. 2010 Pre-Announcement Consultation

- Ministry of Health, Labour & Welfare (MHLW)
- Ministry of Economy, Trade & Industry (METI)
- Japan Fair Trade Commission (JFTC)
- Japan Pharmaceutical Association (JPA)
- Japan Medical Association (JMA)
- Japanese Association of Medical Sciences (JAMS)
- Federation of Pharmaceutical Manufacturers Assoc. of Japan
- Fair Trade Council of Pharmaceutical Industry
- Japan Pharmaceutical Wholesalers Association

March 2011

- External announcement via media press conference

During 2011-2012

- Continue external stakeholder consultation

Activities to Increase Awareness

- Issue additional guidance (Q&A)
- Presentations at medical institutions
- Participation at academic symposiums
- Presentations to other industry associations
  - Federation of Pharmaceutical Manufacturers' Associations of Japan
  - Japan Kampo (Traditional) Medicine Manufacturers Association
  - Japan Association of Clinical Reagents Industries
  - The Japan Federation of Medical Devices Associations
  - The Federation of Japan Pharmaceutical Wholesalers Association
  - Japan Generic Medicines Association

Symposium on Conflict of Interest

APEC
Asia-Pacific Economic Cooperation

Medical Device Industry Follows Suit

In January 2012, the Japan Federation of Medical Device Associations adopted transparency guidelines

- **Device Companies will begin disclosure in 2014**
- **Covers 4,900 medical device and diagnostic companies in 19 medical device industry associations**
- **Asked support from 134 doctors associations, hospital groups and medical societies in Japan**

The JFMDA already had strong Codes of Ethics

- **JFMDA Code of Ethics (Est. 1993)**
- **Promotion Code of the Medical Device Industry (Est. 1997)**
- **JFMDA Charter of Corporate Behavior (Est. 2005)**
- **Fair Competition Code of the Medical Devices Industry**

The JFMDA also decided in 2013 to limit entertainment to 10,000 yen ($100) per doctor per meal.

Overcoming Challenges

Apr. 2012 Japanese Association of Medical Societies (JAMS), Council of Heads of National Medical Schools of Japan (CHNMSJ), Japan Medical Association say:

- ✓ Guidelines are "unbalanced" with more detail for individual payments than for institutions

Jan. 2013 JPMA, JAMS, CHNMSJ & JMA form a Council.

- ✓ JMA & JAMS request a 3-year delay disclosure of individual payments to increase awareness

Mar. 2013 JPMA agrees to

- ✓ Delay disclosure of individual doctor payment amounts by 1 year
- ✓ Not publish individual doctor payment amounts, but give out only when requested
- ✓ Cooperate to raise awareness further

Scope of Delay

Disclosure to start from fiscal 2013

Category	Expenses for disclosure	Form
A. R&D expenses	Joint research	[Amt. / yr]
	Research commissioning	[Amt. / yr]
	Clinical study	[Amt. / yr]
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E. Other expenses	Hospitality, etc as social courtesy	[Amt. / yr]

Delay the start of disclosure to 2014

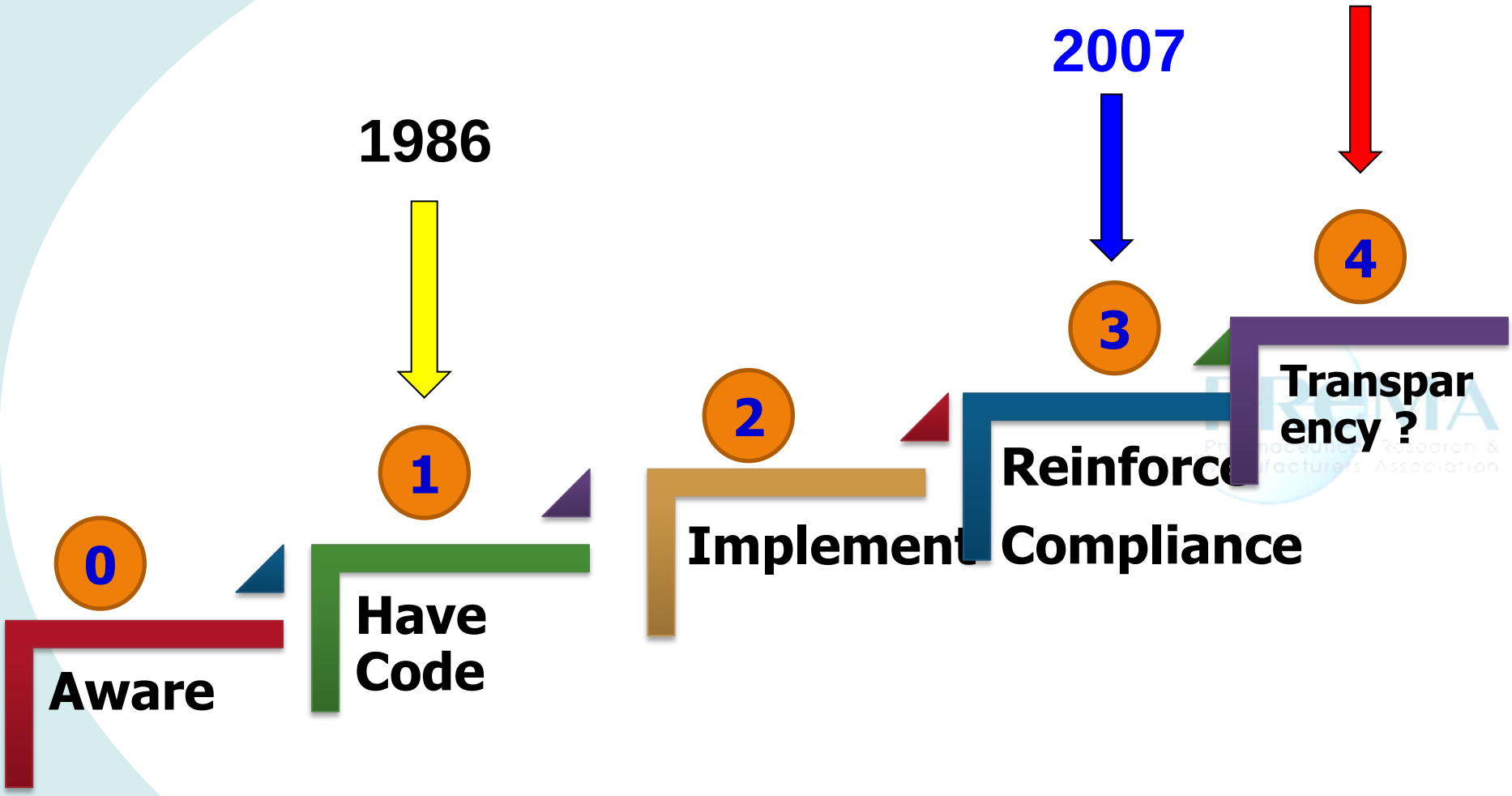
tion

Conclusion

- Social expectations for stronger ethics and greater transparency are rising.
- The JPMA and the JFMDA showed leadership to maintain the trust of health care professionals, patients, the government, the media, the public.
- By implementing “self-regulation” on a voluntary basis, the industry may avoid more complicated and burdensome requirements from the government.

Best Practices for Promoting and Implementing a Code of Ethics

Kitima Yuthavong, MD.
CEO
PReMA
29 August 2013
At APEC TRAIN-THE-TRAINER WORKSHOP
Kuala Lumpur, Malaysia


1986
2007
0
Aware
1
Have Code
2
Implement
3
Reinforce Compliance
4
Transpar ency ?

PReMA Code Promotion Cycle

Internal Engagement: Members' MoU on Code Compliance

"As a member of PReMA, we voluntarily pledge to adhere to the spirit and intent of PReMA's Code"

PReMA
Pharmaceutical Research & Manufacturers Association

Letter of Acknowledgement

October 2008

This Letter acknowledges that as a member of the Pharmaceutical Research and Manufacturers Association in Thailand (PReMA), we voluntarily pledge to adhere to the spirit and intent of PReMA's Code of Sales and Marketing Practices.

The 8th Edition PReMA Code of Sales & Marketing Practices (Code) sets out the principles and guidelines with respect to professional and ethical standards in promotional activities, sales and marketing practices.

As a member of PReMA, our company voluntarily agrees to abide with the tenets of the Code and to avoid any transgressions of the Code's underlying ethical principles; and in doing so we ensure that our established internal procedures and business operations will comport with the principles embodied in the Code

We further acknowledge that sanctions against a PReMA member company may be applied subject to the Code's Section 7 when a breach of the Code is confirmed.

As member company, we undersign this Letter as record for PReMA.

Amporn Charoensomsak · Yoshitaka Koketsu · Fredrik Andersch · Rajesh Pai · Tippawan Jitpimolmard · Uwe Dalichow · Terapon Kietsuranon · Mario Albiez

Thomas Karalis · Suthas Thongprasert · Bernd Lepper · Sompol Wutikornwipak · Sunee Sueng · Nemy Lim · Prakarn Kunothai · Thanad Ngaotepprutaram

Somgiat Mahapun · Vivek Dhawan · Heinz Landau · Douglas Cheung · Sirilak Suteekul · Teera Chakajnarodom · Cyrille Buhrman · Manu Sawangjaeng

Brett Hayes · Rolf Ammelburg · Graham Almond · Supachai Subudomkul · Dr. Jean-Yves GAL · Jean Sebastian Ricard · Busakorn Lerswatanasivalee · Masahiko Shimizu

Weerapong Bhurikap · Wichai Laocharoenpornkul · Suree Sawartsoot · Viriya Chongphaisa · Patrik Bruhlmann

Pharmaceutical Research & Manufacturers Association 408/85, 19th Floor, Phaholyothin Place Bldg., Phaholyothin Rd., Samsennai, Payathai, Bangkok 10400, Thailand. Tel. (662) 619-0232-36 Fax (662) 619-0237 E-mail: office@prema.or.th www.prema.or.th

Med Rep Accreditation Program (MRAP) 2008-present

- PReMA Code of Practice is one learning module in the program
- Members encouraged to regular train on industry code to staff for MRAP exam
- PReMA provides intensive training for companies prior to exam
- > 70% of med rep has been trained and already accredited

- All accredited med rep get certificate as personal credit in their career
- Encourage Co's to recognize accredited med rep (HR set as criteria when recruit)
- Continued educational program introduced to support career development of accredited med rep

Code Awareness Week
5-9 July 2010

Objectives:

- Communicate key ethical business practice issues to doctors via the med rep.

Key messages:

- Both HCP and " WE" (research-based pharma) perform duty with highest ethical and scientific standard.

Campaign :

- All med rep. from PReMA members wear the badge " SO DO WE" all week at public places.
- Med Rep discussed with doctors about message in the "leave piece"

Innovative Medicines
Healthier Life.

You hold yourself to the highest standard. So do we.

This year Pharmaceutical Research & Manufacturers Association (PReMA) are celebrating our 40th anniversary.

Since 1967, The Code of Sales and Marketing has been a tangible demonstration of PReMA's commitment to relationships based on trust, openness and transparency with healthcare providers.

The main objectives in developing the Code are to:

- Ensure that the information provided to the healthcare professionals is factual
- Ensure that there be no inappropriate benefit used to induce healthcare professionals' decision
- Ensure that medical representatives have appropriate conduct and perform their duty professionally

PReMA is a non-profit organization representing research based pharmaceutical companies who brings value of quality innovative medicines to support better medical treatment through ethical sales and marketing practices.

Delivering Value and Quality Ethically to the Thai Medical Society

CODE of CONDUCT

The Guiding Principles of PReMA Code of Sales & Marketing Practices

As a responsible partner in providing healthcare, PReMA members conduct themselves with integrity and maintain consistently high ethical standards coupled with constant product innovation and excellence in sales and marketing.

1. All members must adhere to the Code and its intent as a condition for membership.
2. All product information provided to healthcare professionals must be accurate, fair and balanced.
3. PReMA members shall ensure that their personnel are adequately trained and possess sufficient medical and technical knowledge to present information in an accurate, responsible and ethical manner.
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For more information, please contact Pharmaceutical Research & Manufacturers Association (PReMA) Tel. (+662) 619-0232-6 / Fax: (+662) 619-0237
Website : www.prema.or.th

PReMA
Pharmaceutical Research & Manufacturers Association

Engaging members in the “Code Week” campaign

- GM Meeting
- Training of key messages to training managers of all member companies
- Press Conference of the campaign*
- Communicate list of daily reminding messages through HR managers – tool SMS during 5-7 July

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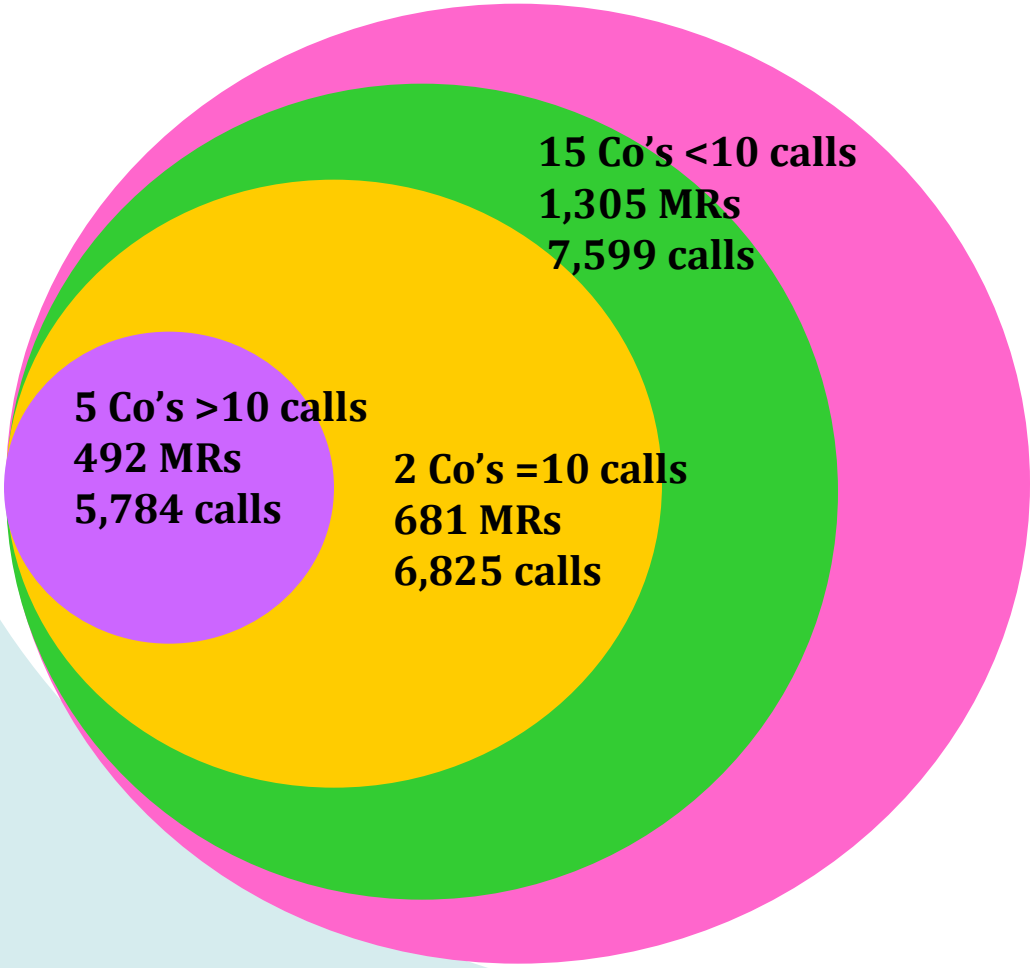

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Joining MRs

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MRs/ >10 calls

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2010
New Gen Med Rep Campaign

- Members identify obvious practice in the market that industry would like to see change
- Voluntary campaign for members to go toward such direction
  - Do what companies see they are most comfortable with first
  - Periodically repeat the message to encourage change
  - Survey in Dec. 2010, got feedback from 16 Co's & communicate back to members

New Gen Med Rep

Professional Dress

Stop Giveaway

Stop Serving Food in OPD

Stop Provide Regular Driving Service

Stop Carrying Bag with the Brand Name when Visit Customers

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Members sharing photos of their activities on PEP Talk

PREMA
Pharmaceutical Research & Manufacturers Association

Introduction of additional complaint channels:

- Through PReMA website www.prema.or.th
- Anonymous complaint
  - All complaints from above two channels can come from:
    - Doctor and Pharmacist
    - Sales Rep and Manager
    - General Public
    - No evidence
- PReMA will investigate whether there be any ground and decide further action

PReMA Code Promotion

Code of Conduct Committee

Roundtable discussion on career path and Code with PECT (pharmacy schools)

Code Outreach: Lecture at Chula Med school, Silpakorn Pharmacy School

Seminar on Sales Rep Image

1986 2007 2008 2009 2010 2011 2012 2013

P.P.A. Code of Pharmaceutical Marketing Practices
1st Edition 1986

Booth exhibitions at Royal College of Physicians Conference

Code Awareness Week & New Gen Med Rep; Roundtable discussion

Presentation on PReMA Code:
- Ortho Dep., Chulalongkorn U.
- Police Hospital
- Pediatric Nutrition Mfg Assoc.

PEP Talk (PReMA Ethics Partnership)

PReMA Members' MoU