

APEC Business Ethics for SMEs Forum Biopharmaceutical Sector Workshop

1 & 3 September 2014 | Nanjing, China



**Asia-Pacific
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Welcome & Introductions

Ms. Lynn Costa

Project Overseer, Business Ethics for APEC SMEs Initiative

APEC Business Ethics for SMEs Forum

Biopharmaceutical Sector

1-3 September 2014 | Nanjing, China



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The Value and Responsibility of Ethics

Mr. Russell Williams

President, Rx&D (Canada)

Co-Chair, APEC Mexico City Principles Expert Working Group

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Understanding the Mexico City Principles

Mr. Neil Pratt

**Assistant General Counsel, Pharmaceutical Research
and Manufacturers of America (United States)**

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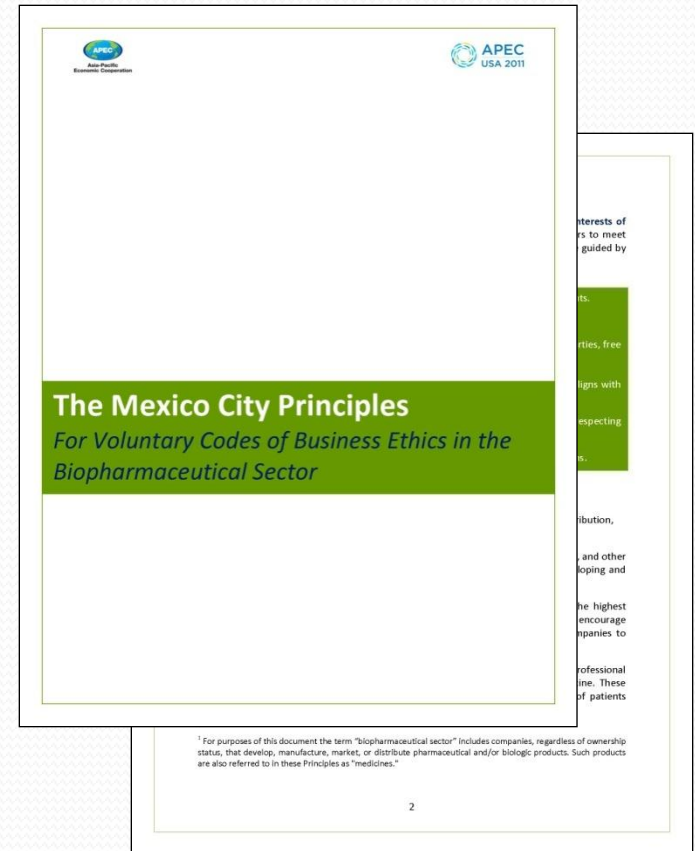


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The Mexico City Principles

for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector

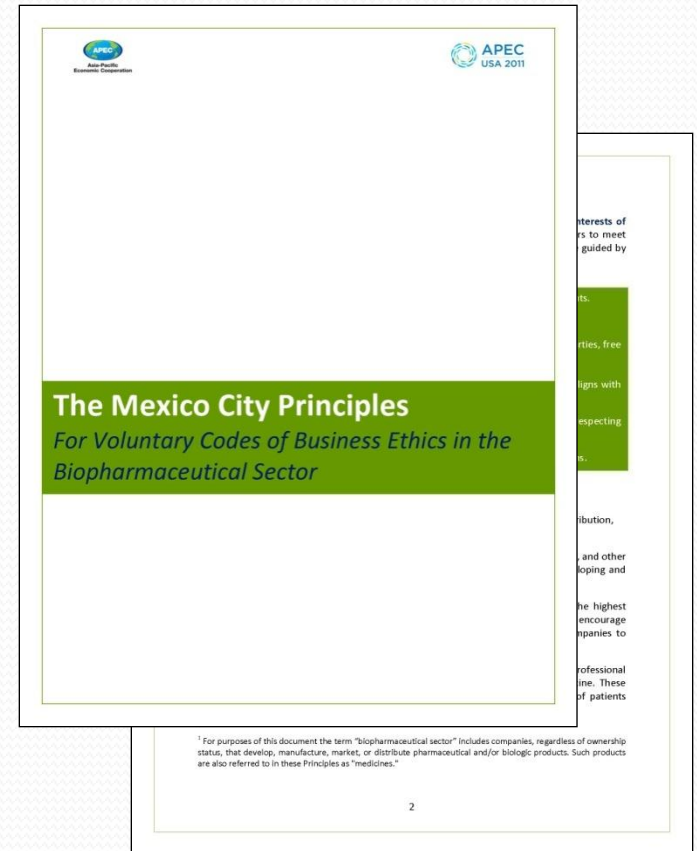
- Recognizes that appropriate and ethical interactions help ensure medical decisions are made in the **best interests of patients**
- Calls upon the entire biopharmaceutical sector and eco-system to embrace aligned standards for ethical interactions, including:
 - **Companies and industry associations**
 - **Healthcare professionals and organizations**
 - **Government regulators and anti-corruption enforcement authorities**



The Mexico City Principles

for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector

- Drafted by 36 Expert Working Group Members from industry, government, civil society and academia from 14 APEC Economies in September 2011.
- **APEC multi-year funding awarded to implement The Mexico City Principles**
- **Implementation supported by:**
 - APEC Life Sciences Innovation Forum
 - APEC Health Working Group
 - APEC Anti-Corruption & Transparency Working Group
 - APEC Business Advisory Council (ABAC)



¹ For purposes of this document the term "biopharmaceutical sector" includes companies, regardless of ownership status, that develop, manufacture, market, or distribute pharmaceutical and/or biologic products. Such products are also referred to in these Principles as "medicines."

The Mexico City Principles

Biopharmaceutical Sector Codes of Ethics

Healthcare and Patient Focus means everything we do is intended to benefit patients.

Integrity means dealing ethically, honestly, and respectfully in everything we do.

Independence means to respect the need of autonomous decision-making of all parties, free from improper influence.

Legitimate intent means everything we do is for the right reasons, is lawful, and aligns with the spirit and values of these Principles.

Transparency means a general willingness to be open about our actions while respecting legitimate commercial sensitivities and intellectual property rights.

Accountability means a willingness to be responsible for our actions and interactions.



The Mexico City Principles

for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector

The Principles cover:

1. Interactions with Healthcare Professionals
2. Promotional Information and Activities
3. Safety of Medicines
4. Symposia and Congresses
5. Informational Presentations by Company Representatives
6. Entertainment
7. Educational Items and Gifts
8. Support for Continuing Medical Education
9. Samples
10. Consultant and Speaker Arrangements
11. Compliance Procedures and Responsibilities
12. Conduct and Training of Company Representatives
13. Public Sector Relations and Procurement
14. Clinical Trials
15. Company Donations for Charitable Purposes
16. Patient Organizations
17. Adherence to Principles

Interactions with HCPS

Principle

- **The relationships between healthcare professionals and pharmaceutical companies are intended to improve patient care**

Purpose of these interactions:

- informing healthcare professionals about medicines;
- providing scientific and educational information; and
- supporting medical research and education.

Interactions

Relationship must be:

- Ethical
- With No improper influence
- To encourage the appropriate use of medicines



In connection with these interactions:

- Appropriate meals can be offered as a business necessity (not part of entertainment or recreational event)
- Always held in an appropriate venue
- No entertainment

Promotional Information and Activities

Principle

- **A company must not promote a product for use until it has received marketing approval in that economy.**
- Must follow national laws and regulations
- Promotional information should be clear, legible, accurate, balanced, fair, and objective

Symposia and Congresses

Principle:

- **The purpose and focus of all events should be to provide scientific or educational information or to inform healthcare professionals about products.**
- Events includes symposia, congresses and other promotional, scientific or professional meetings for healthcare professionals;
- All events should be held in an appropriate venue;
- Hospitality should be limited, moderate and reasonable as judged by local standards; and
- Limited to participants of the event and not the guest.

Educational Items and Gifts

Principle

- **No personal gifts**



- Payments in cash must not be provided or offered to healthcare professionals.
- Also prohibited are cash equivalents (such as gift certificates) and any gifts for the personal benefit of healthcare professionals (So no sporting or entertainment tickets, electronic items etc.).
- It is appropriate where permitted by law to offer items designed primarily for the education of patients or health care professional (must be modest in value and not to be used outside of the profession).

Samples

Principle

- **Free samples of a pharmaceutical product may be supplied to healthcare professionals authorized to prescribe that product in order to enhance patient care.**
- Companies should have adequate systems of control and accountability for samples:
 - including requirements for medical representatives in possession of samples.
- Should not be used as payment for service

Consultant and Speaker Arrangements

Principle

- **Healthcare professionals may be engaged and remunerated by companies as consultants and advisors. Their expenses (travel and accommodation, meal expenses) can also be met.**

Services they may provide include:

- speaking at and/or chairing meetings and events;
- involvement in medical/scientific studies and, clinical trials;
- providing training services;
- participation at advisory board meetings; and
- participation in market research.

The compensation for the services must be reasonable and reflect the fair market value of the services provided.

Company Procedures and Responsibilities

Principle

Companies must establish and maintain appropriate procedures to ensure compliance with relevant codes and applicable laws

Companies :

- must also have procedures to review and monitor their activities and materials. Don't forget to retain adequate records of the reviews and monitoring;
- should also ensure that relevant employees/agents receive training appropriate to their role;
- should provide updated or additional training in all of the areas needed; and
- should take appropriate action when employees fail to comply.



Clinical trials

Principle

- **Clinical trials and scientific research will be conducted with the intent to develop bona fide scientific knowledge that will benefit patients and advance science and medicine**

Clinical Trials should:

- not be used as an inappropriate inducement; and
- be undertaken in an ethical manner.



Donations for Charitable Purposes

Principle

Companies recognize their responsibility to support worthwhile activities.

Donations:

- should ensure that donations are not undertaken for product promotional reasons;
- must be documented;
- should have the appropriate acknowledgement by recipient; and
- should not be an incentive to prescribe.

Patient organizations

Principle

- **The independence of patient organizations must be respected.**
- Patient organizations are not-for-profit institutions that represent primarily the interests and needs of patients, their families and caregivers.
- All interactions with patient organizations must be ethical.

Public Sector Relationships and Procurement

Principle

- Ethical and professional public sector relationships during government procurement.

Companies

- should not attempt to exert inappropriate influence;
- must provide accurate information; and
- should ensure that all interactions comply with government rules or procedures.

Adherence to the Mexico City Principles

Principle

- All Companies should adopt procedures to assure adherence to these principles.

Principle

- Healthcare Professionals, Governments and Stakeholders should respect these principles and adopt consistent standards if applicable.

The Mexico City Principles

for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector

Beyond companies and industry associations, the Principles also cover implementation by healthcare professional organizations and governments

Implementation

In order to promote an ethical commercial environment, cooperation among multiple stakeholders is required. Therefore, it is recommended that Companies, healthcare professionals and APEC economies engage in the following activities:

Companies and industry associations should:

- Develop and implement codes of ethics consistent with the Principles set out above. Industry associations should consider publicizing those members who have signed onto the industry codes, among other steps to encourage adoption of industry codes.
- Make available training regarding industry codes of ethics to healthcare professionals and healthcare professional students in collaboration with recognized authorities.
- Contribute to and participate in capacity building, in particular for small and medium sized enterprises (SMEs).
- Work together to ensure that the above Principles and their industry codes of ethics remain relevant and effective to address new business arrangements that may emerge.

Healthcare Professional Organizations should:

- Respect these Principles and develop and implement codes of ethics consistent with the above principles.

APEC Economies should:

- Develop and make known clear, distinctive, accountable and comprehensive policies on procurement processes and procedures.
- Encourage industry regulators and/or anti-corruption enforcement authorities to endorse and support the above Principles and national and local industry codes of ethics, where appropriate.
- Encourage Companies to adhere to the above Principles and national and local industry codes of ethics.
- Formulate and promote clear laws and regulations that are objectively applied.
- Work to advance ethical collaborations consistent with the above Principles regionally, through regular communication, joint policies, joint capacity building activities, and other forms of collaboration.

- Work together to ensure that the above Principles remain relevant and effective to address new business arrangements that may emerge.

Appendix

For the purpose of these Principles, the following definitions are provided:

"Congress" means an event sponsored and organized by a society, college, university or other non-Company entity for the purpose of providing medical and/or scientific information.

"Consultant" means an external, independent healthcare professional, scientist, patient association/ patient representative, public or private payer retained individually or through an entity (e.g. university, hospital or research organization) to provide advice, information or other services.

"Healthcare Professional" means a provider of medical or health services and any other person or organization that furnishes, bills, or is paid for health care in the normal course of business, including but not limited to physicians, nurses, or pharmacists and their staff.

"Representative" means a person calling on healthcare professionals and/or their staff on behalf of a Company regarding the promotion or discussion of medicines.

Official Photograph for
Biopharmaceutical Sector Workshop

Please stand and line up on stage

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The Importance of Promoting Codes of Ethics to a Broad Range of Stakeholders

Mr. Teodoro B. Padilla

Executive Director, Pharmaceutical and Healthcare Association of the Philippines (PHAP)

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Our Challenges

- No national policy to support ethics campaign
- Discussions focused on other areas of reform
- Creating value of compliance for stakeholders



Our Response

- We initiated strategies that reinforce our commitment to support the highest standard of behavior among industry players to promote people's health
- These strategies centered on helping pave the way to establish a national policy on ethics, shaping policy discussions to make ethics a crucial part of health reform, and creating a groundswell of support for the integrity



Ethics is Everybody's Business:

Industry Alone Cannot Achieve Ethical Business Practices – Need continued engagement and partnership with all stakeholders.



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Key Strategies

No national policy

- Providing a framework for national policy



Ethics not part of health reform

- Shape policy discussions focusing on patients



Value for ethics undermined

- Create appreciation for compliance



No national Policy

Framework for National Policy

Ethics is State responsibility

Constitution

Aquino
Government's anti-
corruption drive

National laws that
promote & protect
people's/
consumers health

Ethics is an
international
commitment



Framework for national policy:

- The State has the duty to promote and protect the rights of health of the people and instill health consciousness among them (Section 15, Article II, 1987 Constitution)
- Consumer Act of the Philippines states that it is a State policy to promote the interest and general welfare of the consumers:
 - 1) protection against hazards to health and safety
 - 2) provision of information and education to empower consumers make an informed choice
 - 3) protection of the consumer from misleading advertisements and fraudulent sales promotion practices
- FDA Act of 2009 requires the adherence of all advertisements, promotions, sponsorship and other marketing activities on health products to current standards, guidelines and regulations of the FDA



Ethics is a national & international commitment

National
campaign
vs.
corruption



Regional
Code via
MCP



Formal
MCP
adoption



**INTEGRITY
INITIATIVE**



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A first of its kind, **IPPS** is a PHAP training and certification program accredited by the Government's Professional Regulation Commission.

Modules include MCP, anti-graft and corrupt laws and Code of Ethics et. al.



Shape policy discussions: Patients at the center of the campaign

Ethical interactions help ensure that medical decisions are made in the best interests of **patients**.

Providing appropriate medicines for the appropriate **patients** at the appropriate time.



No real health reform without ethics



"We take pride in standing side by side with you, realizing that no amount of health reform will be truly universal if we ignore the consequences of unethical behavior."



In 2010, the Government launched Universal Health Care as a flagship health agenda with the aim of overhauling the system to provide health for all.





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Create deeper appreciation for ethics & compliance



Code of Practice

- Workshop with Industry Members
- Forum on Ethical Business Practices in Biopharmaceutical Sector

IFPMA-CCN

- Amended to fully align with IFPMA, MCP



- Mandatory examination for all field representatives of PHAP members

IPPS





FORUM ON ETHICAL BUSINESS PRACTICES IN THE HEALTHCARE SECTOR

FOSTERING INTEGRITY AND GOOD GOVERNANCE IN THE HEALTHCARE SECTOR



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PHAP press briefing on industry support for APEC MCP



PH Pharma Industry First To Adopt FDA Code Of Ethics

The Philippines has become the first country to formally adopt a regional voluntary code of business ethics for the biopharmaceutical sector aimed at promoting ethical principles to advance patient welfare and boost the national integrity campaign.

Through the Food and Drug Administration (FDA), the Philippines is expected to fully implement the "Mexico City Principles for Voluntary Codes of Business Ethics for the Biopharmaceutical Sector" or the "Mexico City Principles (MCP)" which was endorsed during the 19th Asia Pacific Economic Cooperation (APEC) Economic Leaders Meeting in Hawaii.

"The adoption of the Mexico City Principles highlights the strong commitment of the Government to promote a whole-of-society approach to integrity that will ultimately benefit Filipino patients. Ethical relationships are crucial to our mission of developing and making quality medicines available. The implementation of the MCP is a milestone for the Philippine healthcare sector and we call on everyone to respect these Principles," said Thomas Weigold, president of the Pharmaceutical and Healthcare Association of the Philippines (PHAP), which is composed of 37 member companies.

The MCP asserts that ethical interactions help ensure that medical decisions are made in the best interests of patients and should be guided by six principles namely healthcare and patient focus, integrity, independence, legitimate intent, transparency and accountability.

"Universal ethical principles benefit Filipino patients and improve access. These principles are universal and reinforce Filipino values and ideals. PHAP strongly supports the adoption of the Mexico City Principles and envisions a pharmaceutical indus-

try complying with the highest ethical standards," said PHAP executive director Teodoro B. Padilla.

The APEC Mexico City Principles espouses the principles of healthcare and patient focus, independence, transparency and accountability.

During the 17th APEC Small and Medium Enterprises Ministerial Meeting, the Ministers issued a Joint Ministerial Statement to promote SME cooperation for innovative growth in the APEC region. The Ministers agree that corruption imposes a significant market access barrier and high costs for SMEs. To address this challenge, they endorsed principles for voluntary codes of business ethics for specific sectors, including the biopharmaceutical sector.

"In delivering the best quality healthcare to patients, it is essential that professionalism and high ethi-

cal standards are maintained between the biopharmaceutical companies, the health professionals, and the regulatory body," said the FDA in a circular that adopted the MCP (BCM)

Pharma group urges adoption of Code of Ethics for industry

By Noli A. Ermitanio

ADVOCATES OF ethical conduct in the medicine business get another strong backer, this time among the pharmaceutical industry.

The Pharmaceutical and Healthcare Association of the Philippines, an organization of research-based medicines sector in the country, is strongly backing the Food and Drugs Administration's adoption of a Code of Ethics for the pharmaceutical industry.

PHAP chair Teodoro Padilla said: "Ethical principles are universal and cut across cultures." "[Adherence to] universal, ethical principles benefits patients and improves access to healthcare." He called on everyone to respect "the principles that will benefit us all."

Sanction

In response, the FDA said it will sanction drug companies that will not comply with the guidelines of the MCP. Dr. Cynthia Diza, officer-in-charge of the FDA ethical market communications unit, said they will not hesitate to cancel the license to operate and revoke the certificate of registration of erring companies.

In a forum last April 1 with partners Medicines Transparency Alliance (MeTA), Philippine College of Physicians (PCP) and Philippine Medical Association, PHAP reiterated its call for an in-

dustry code of ethics based on "The Mexico City Principles for Voluntary Code of Business Ethics in the Biopharmaceutical Sector," or the Mexico City Principles (MCP), which is anchored on healthcare and patient focus, integrity, independence, legitimate intent, transparency and accountability, and laid out the standards for the ethical promotion of medicines.

Padilla alleges that some non-PHAP-affiliated drug companies are reluctant to adopt the MCP by reasoning that it is "only voluntary," contrasting it with PHAP member companies which since 1993 are strictly governed by an "internationally accepted code of practice."

The Philippines is reported the first country to formally adopt a regional voluntary code of business ethics for the biopharmaceutical sector, aimed at promoting ethical principles to advance patient welfare and boost the national integrity campaign.

In its circular in September 2013 which adopted the MCP, the FDA said "In delivering the best quality healthcare to patients, it is essential that professionalism and high ethical standards are maintained between the biopharmaceutical companies, the health professionals, and the regulatory body."

"Lack of consistent ethical standards increases the cost of doing business which in turn

lower sales growth, productivity and the ability to enter new markets, constriction in the access to capital, and may go as far as corruption, bribery and additional sanctions and penalties from regulatory bodies," the FDA added.

Hurting economies

PCP ethics committee chair Dr. Francisco Tranquillino, who also acts as PHAP adviser, said unethical behavior hurts economies—like reduced foreign investment and undermined health systems—and individual interests—like increased costs of doing business through bribes and penalties, lowered sales growth and productivity, constricted access to capital and undermined financial growth in the long term.

Recently, MeTA Philippines, a multistakeholder coalition of agencies and organizations in government, civil society, academe and health professional associations, said that the adoption of the MCP will address the concerns on less than favorable practices among some pharmaceutical companies, medical practitioners and government health agencies.

Speaking to reporters, MeTA Philippines chair Roberto Pagdangan said that "ensuring ethical conduct, transparency and accountability in our actions is key in the delivery of healthcare and in improving outcomes."



Calls for healthcare transparency and accountability renewed

Adherence to voluntary code of ethics pushed

By Noli A. Ermitanio
Philippine Daily Inquirer
12:30 am | Saturday, February 15th, 2014

The clamor for transparency and accountability in healthcare practices and the push for adhering to codes of ethics are becoming stronger.

Amid the growing concern of less than favorable practices among some pharmaceutical companies, medical practitioners and even the government health agencies, Medicines Transparency Alliance (MeTA) Philippines chair Roberto Pagdanganan said that "ensuring ethical conduct, transparency and accountability in our actions is key in the delivery of healthcare and in improving outcomes."

Speaking to reporters during the annual MeTA forum "Multistakeholder Collaboration in Promoting Transparency and Ethics in Healthcare" on Feb. 11 at Bayanihan Center in Pasig, Pagdanganan emphasized the need for a code of ethics grounded on the Mexico City Principles.

"The Mexico City Principles for Voluntary Code of Business Ethics in the Biopharmaceutical Sector," also known as the Mexico City Principles, is anchored on healthcare and patient focus, integrity, independence, legitimate intent, transparency and accountability. It laid down standards for the ethical promotion of medicines to ensure that medical decisions are made in the best interest of patients.

Organizer MeTA Philippines, a multistakeholder coalition of government, private sector, civil society, academe, health professional associations and international development partners, is urging for more appropriate mechanisms for the regulation and monitoring of pharmaceutical marketing activities for greater transparency in the pharmaceuticals supply chain, pricing, government procurement process and system of delivering medicines from public health facilities to patients, especially the poor.

Stricter policing

Meanwhile, the government, through its representatives in the Food and Drug Administration and the Department of Health, is pushing for the stricter policing of the pharmaceutical industry and medical practitioners among their ranks.

PHL drug firms urged to follow int'l code of business ethics

By IBARRA C. MATEO February 18, 2014 4:30pm

Philippine-based pharmaceutical companies have been urged by a coalition of health professionals and health advocates to follow a voluntary international code of business ethics in the biopharmaceutical industry seeking to ensure the best interest of patients.

The Medicines Transparency Alliance (MeTA) Philippines, a multi-stakeholder coalition composed of agencies and organizations in the government, private sector, civil society, academe, and health professional associations, together with its international development partners, said drug companies in the Philippines must adhere to "The Mexico City Principles for Voluntary Code of Business Ethics in the Biopharmaceutical Sector."

The said document spells out standards for the ethical promotion of





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A. MENARINI PHILIPPINES, INC.
 ABBOTT LABORATORIES, INC.
 ALCON LABORATORIES (PHIL.), INC.
 ASPEN PHILIPPINES INC.
 ASTELLAS PHARMA PHILIPPINES, INC.
 AZASTRAZENECA PHARMACEUTICALS (PHILS) INC
 BAYER PHILS., INC.
 BLUE SKY TRADING CO., INC.
 BOEHRINGER INGELHEIM PHILS., INC.
 CALMOSEPTINE PHIL., INC.
 ELI LILLY PHILIPPINES, INC.
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 GLAXOSMITHKLINE PHILIPPINES
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 HIZON LABORATORIES, INC.
 IMS HEALTH PHILIPPINES, INC.
 INTERPHIL LABORATORIES
 JANSSEN PHARMACEUTICA
 JOHNSON & JOHNSON MEDICAL

MERCK, INC. PHILIPPINES
 MERCK, SHARP & DOHME (MSD)
 MERCURY DRUG CORPORATION
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Research & Medicine

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BusinessMirror

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Apec Code of Conduct for Business



INNOVATION & ACCESS

By TEODORO B. PADILLA

THE Philippines will be host to the Asia Pacific Economic Cooperation (Apec) in 2015, a commitment to the region working to achieve sustainable economic growth and prosperity among member-economies.

Composed of 21 member countries, Apec pushes forward policies that promote free and open trade and investment, accelerate regional economic integration, encourage economic and technical cooperation, enhance human security, and facilitate a favorable and sustainable business environment.

Apart from the Association of Southeast Asian Nations (Asean) member-countries, Apec members include Australia, Canada, Chile, China, Japan, Korea, Mexico, New Zealand, Papua New Guinea, Peru, Russia, Chinese Taipei and the United States.

One of the recent milestones of the Apec Ministers Summit was the High Level Policy Dialogue on Open Governance and Economic Growth, where leaders recognized that transparency and open governance are a "critical element" of sustainable economic competitiveness, leading to economic growth and prosperity.

In a statement, the Apec Ministers said transparency and open governance are a critical element of long-term economic competitiveness, and welcomed the efforts of Apec members to enhance public trust by combating corruption and by committing to transparent, fair, and accountable

■ Legitimate intent means everything we do is for the right reasons, is lawful, and aligns with the spirit and the values of these Principles.

■ Transparency means a general willingness to be open about our actions while respecting legitimate commercial sensitivities and intellectual property rights.

■ Accountability means a willingness to be responsible for our actions and interactions.

The said principles apply to the biopharmaceutical sector, health-care professionals and other stakeholders.

The principles are grounded on the fact that ethical relationships are critical to the mission of the biopharmaceutical companies to help patients by developing and making medicines available.

The Apec-endorsed document recognizes that ethical interactions between the biopharmaceutical sector and health-care professionals help bolster patient care and advance the practice of medicine.

For one, it allows the manufacturers or distributors of medicines to provide health-care professionals the information about the risks and benefits of pharmaceutical products. Such exchanges are likewise beneficial as they provide an avenue for scientific and educational information and education.

During these interactions, the Mexico City Principles emphasize that biopharmaceutical companies have an obligation and

FDA, WHO, private groups underscore patient welfare in forum on ethical business practices



World Health Organization (WHO) Representative to the Philippines Dr. Julie Hall delivers a message during the PHAP Forum on Ethical Business Practices in the Healthcare sector.



Food and Drug Administration Director General Dr. Kenneth Hartigan-Go presents the agency road map to ensure patient safety.



Medicines Transparency Alliance (MeTA) Chairman Mr. Roberto Pagdanganan speaks at the PHAP Forum that calls for commitment to the "I Stand for Integrity" Campaign. With the support of the British Embassy Manila, the MeTA launched the ETHIKOS Movement, an initiative committed to undertaking a strong and sustained program for advocacy, awareness and education on standards for the ethical promotion of medicines, as well as business practices that are consistent with the APEC Mexico City Principles.



More than 160 participants from the Government, international agencies, academe, professional organizations, civil society, private groups and the pharmaceutical sector join the campaign for ethics in the healthcare sector.

A MULTI-STAKEHOLDER forum on academe and the media," Padilla said.

current circumstances. He expressed willingness to collaborate with the various groups to improve the existing Code.

Aside from Dr. Hall and Dr. Go, the other resource persons were Mr. Edgar Chua (Country President, Shell Companies in the Philippines), Mr. Carlos Conde (Trustee, Center for Media Freedom and Responsibility), Dr. Francisco Tranquilino (Assistant to the Dean, University of the Philippines College of Medicine), Mr. Roberto Pagdanganan (Chairman, Medicines Transparency Alliance), Mr. Jose Zamarrigo (Director, FarmaIndustria Spain), Ms. Chrisoula Nikidis (Regional Executive



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Moving Forward

- Framework for Ethical Collaborations
 - Philippine Medical Association
 - IAPO's local chapter
- Ethics Roadshow
 - Association of HR Practitioners
 - Philippine Association of Pharmacists in the Pharmaceutical Industry

Thank you.

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Read the PHAP column:

www.abs-cbnnews.com

www.bworldonline.com

www.businessmirror.com.ph



Promoting a Code of Ethics:
Identifying the Relevant Stakeholders

Ms. Sabrina Chan

**Executive Director, The Hong Kong Association of the
Pharmaceutical Industry (Hong Kong, China)**

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Mapping out the Relevant Stakeholders

Government

Hospitals

**Patient
Groups**



Pharmacists

**Healthcare
Professionals**

Distributors

Media



Government Stakeholders

Regulators, Enforcers, Customers, Payors, Champions

- Governments across the 21 APEC economies have endorsed the Mexico City Principles, but most of the relevant government stakeholders have probably not heard of the Principles.
- Numerous potential stakeholders at national/regional levels:
 - Food and Drug Administration
 - Ministry/Department of Health
 - Pricing and Reimbursement/Procurement Agencies
 - Anti-Corruption Authorities
 - Ministry of Industry/Trade
 - Others?

Need for continued and ongoing engagement



HCPs/Associations/Hospitals

Customers – Demand Side of Corruption

- Interactions with HCPs present the most significant corruption risks.
- Industry needs to help HCPs and their associations understand the new paradigm/rules of the road.
- To the extent that there are systemic issues that promote corruption, industry needs to partner with HCPs to seek change.
- In many of the APEC Economies, HCPs are government employees, making them foreign officials for the purpose of international corruption enforcement under the U.S. Foreign Corrupt Practices Act and the UK Bribery Act.



Pharmacists/Distributors

Intermediaries – Potential Conduits for Corruption

- Important actors in the supply chain. For over-the-counter products, pharmacists in some economies may be relied upon by patients in the same way that they would other healthcare professionals.
- Like HCPs, pharmacists and distributors need to understand Code in order to ensure new rules of road and that they do not inadvertently facilitate corrupt behaviour.
- Also like HCPs, well placed to explain if there are systemic issues that facilitate or encourage corruption.



Patient Groups

Voice for Patients

- Shared goal of ensuring that medical decisions are made in the best interests of patients.
- This principle permeates the Mexico City Principles.
- Patient groups need to understand the purpose of the Code and to see results.
- In turn, can serve as strong advocates for the Code with other stakeholders, patients and broader society.



Media

- Regardless of how successful an association is in promoting and seeking implementation of its Code, scandals will occur.
- As a result, each association should consider its communication strategy with the media.
- DO NOT WAIT until the scandal breaks. Build connections/inform media on steps industry and other stakeholders are taking to implement ethical business practices NOW, so that when the inevitable happens you are not explaining the Code for the first time.
- Scandals will always be more exciting news. However, industry is not alone – it is in the interest of ALL stakeholders to embrace ethical business practices and demonstrate that commitment to patients and broader society. To this end, media can be a key ally.
- Virtuous circle - positive media coverage can also help promote the Code to other stakeholders.



Questions?

**Interactive Session – Identifying
the Relevant Stakeholders**
20 Minutes



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Understanding Your Stakeholders: What Messages Resonate?

Moderator: Mr. Russell Williams

President, Rx&D (Canada)

Co-Chair, APEC Mexico City

Principles Expert Working Group

Dr. Pamela Milla

Head, Agencia Nacional de

Medicamentos (ANAMED)

CHILE

Dr. Maria Minerva Calimag

President,

Philippine Medical Association

THE PHILIPPINES

Mr. Kin-ping Tsang

Chairman, International Alliance of

Patient Organizations

HONG KONG, CHINA

Dr. Kit Sing Au

Director, Quality and Safety

Hong Kong Hospital Authority

HONG KONG, CHINA

Dr. Masami Ishii

Executive Board Member

Japan Medical Association

JAPAN

IAPO's Mission

Our mission is to help build patient-centred healthcare in every country by:

1. Realizing active partnerships with patients' organizations, maximizing their impact through capacity building
2. Advocating internationally with a strong patients' voice on relevant aspects of healthcare policy, with the aim of influencing international, regional and national health agendas and policies
3. Building cross-sector alliances and working collaboratively with like-minded medical and health professionals, policy makers, academics, researchers and industry representatives



What is patient-centred healthcare?


The essence of patient-centred healthcare is that the healthcare system is designed and delivered so that it can answer the needs of patients

1. Patient-Centred Healthcare Principles
2. Respect and support for the individual patient, their wants, preferences, values, needs and rights
3. Choice and empowerment
4. Patient engagement in health policy
5. Access and support
6. Information that is accurate, relevant and comprehensive



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*Principles defined in IAPO's Declaration on Patient-Centred Healthcare: www.patientsorganizations.org/declaration



International Alliance of
Patients' Organizations
A global voice for patients

Declaration on Patient-Centred Healthcare

Patient-centred healthcare is the way to a fair and cost-effective healthcare system

Health systems in all world regions are under pressure and cannot cope if they continue to focus on diseases rather than patients; they require the involvement of individual patients who adhere to their treatments, make behavioural changes and self-manage. Patient-centred healthcare may be the most cost-effective way to improve health outcomes for patients.

To us, the International Alliance of Patients' Organizations, the essence of patient-centred healthcare is that the healthcare system is designed and delivered to address the healthcare needs and preferences of patients so that healthcare is appropriate and cost-effective. By promoting greater patient responsibility and optimal usage, patient-centred healthcare leads to improved health outcomes, quality of life and optimal value for healthcare investment.

Patients', families' and carers' priorities are different in every country and in every disease area, but from this diversity we have some common priorities. To achieve patient-centred healthcare we believe that healthcare must be based on the following Five Principles:

- 1. Respect**
Patients and carers have a fundamental right to patient-centred healthcare that respects their unique needs, preferences and values, as well as their autonomy and independence.
- 2. Choice and empowerment**
Patients have a right and responsibility to participate, to their level of ability and preference, as a partner in making healthcare decisions that affect their lives. This requires a responsive health service which provides suitable choices in treatment and management options that fit in with patients' needs, and encouragement and support for patients and carers that direct and manage care to achieve the best possible quality of life. Patients' organizations must be empowered to play meaningful leadership roles in supporting patients and their families to exercise their right to make informed healthcare choices.
- 3. Patient involvement in health policy**
Patients and patients' organizations deserve to share the responsibility of healthcare policy-making through meaningful and supported engagement in all levels and at all points of decision-making, to ensure that they are designed with the patient at the centre. This should not be restricted to healthcare policy but include, for example, social policy that will ultimately impact on patients' lives. See IAPO's Policy Statement at: www.patientsorganizations.org/involvement
- 4. Access and support**
Patients must have access to the healthcare services warranted by their condition. This includes access to safe, quality and appropriate services, treatments, preventive care and health promotion activities. Provision should be made to ensure that all patients can access necessary services, regardless of their condition or socio-economic status. For patients to achieve the best possible quality of life, healthcare must support patients' emotional requirements, and consider non-health factors such as education, employment and family issues which impact on their approach to healthcare choices and management.
- 5. Information**
Accurate, relevant and comprehensive information is essential to enable patients and carers to make informed decisions about healthcare treatment and living with their condition. Information must be presented in an appropriate format according to health literacy principles considering the individual's condition, language, age, understanding, abilities and culture. See IAPO's Policy Statement at: www.patientsorganizations.org/healthliteracy

To achieve patient-centred healthcare at every level in every community, the International Alliance of Patients' Organizations is calling for the support and collaboration of policy-makers, health professionals, service providers and health-related industries to endorse the Five Principles and to make them the centre of their policies and practice. We call upon all stakeholders to provide the necessary structures, resources and training to ensure that the Principles outlined in this Declaration are upheld by all.

© 2016 IAPO. All rights reserved. This policy was adopted in February 2016 by IAPO following member consultation and agreement by the Governing Board. Further information about Patient-Centred Healthcare including evidence for its impact and lessons for its practice can be found in the IAPO position What A Patient-Centred Healthcare? A Note of Definition and Principle (IAPO, 2016) at: www.patientsorganizations.org/whatnew Contact IAPO at: info@patientsorganizations.org

Globalization and Healthcare

- Public health issues are global
- The health industry is increasingly multinational
- Healthcare policies are debated and developed internationally
- Progress in science, medicine and technology is international
- Other important stakeholders in healthcare are organized and influential internationally



Global Issues for Patients' Organizations: IAPO's Policy Priorities

1. The massive issues of access to treatment and care
2. Lack of meaningful patient involvement in health policy decision-making
3. The need for an international concerted effort to address patient safety
4. The need for quality health information and communication



Patient Group – Industry Collaborations

Benefits

- ✓ Skills/expertise sharing
- ✓ Greater understanding of respective needs
- ✓ Access to information & data
- ✓ Funding, resources & in-kind support

Challenges (and in some cases risks)

- ✓ Potential loss of independence (on both sides!)
- ✓ Differing expectations and aims
- ✓ Perceived threat to public image and credibility

Benefits and challenges are not exclusive to patient group-industry collaborations



Consensus Framework for Ethical Collaboration

- putting patients first;
- supporting ethical research and innovation;
- ensuring independence and ethical conduct; and
- promoting transparency and accountability.



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Understanding Your Stakeholders: What Messages Resonate?

Moderator: Mr. Russell Williams

President, Rx&D (Canada)

Co-Chair, APEC Mexico City

Principles Expert Working Group

Dr. Pamela Milla

Head, Agencia Nacional de

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APEC Business Ethics for SMEs Forum

Promoting Ethical Environments in the Medical Device & Biopharmaceutical Sectors

**Understanding your stakeholders:
What messages resonate?**

**September 1st, 2014
Nanjing, China**

Masami Ishii, MD

Executive Board Member, Japan Medical Association (JMA)

Vice-Chair, World Medical Association (WMA)

**Secretary General, Confederation of Medical Associations
in Asia and Oceania (CMAAO)**

WMA Statement Concerning the Relationship between Physicians and Commercial Enterprises

- **This statement was firstly adopted in 2004 and amended 2009.**
- **Commercial products and educational programs of commercial enterprises are making a significant contribution to healthcare itself, but that raises a major issue in the relationship between commercial enterprises and physicians who serve as the core of healthcare.**
- **One of the major factors that has brought advancement in medicine and healthcare is the meaningful and appropriate collaboration between commercial enterprises and physicians.**

WMA Statement Concerning the Relationship between Physicians and Commercial Enterprises

Medical Conference

- Main purpose is exchange of professional or scientific information.
- Hospitality is Secondary to the professional exchange of information.

Gifts

- Physicians may not receive payments in cash a commercial entity.
- Physicians may not receive gifts for their personal benefit.

Research

- The physician is subject only to the law.
- Physician or institution wishing to undertake research approaches more than one company to request funding for the research.

Principles

- The affiliation does not compromise the physician's integrity.
- The affiliation does not conflict with the physician's obligations.
- Affiliations are fully disclosed in all relevant situations.

Understanding Your Stakeholders: What Messages Resonate?

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JAPAN

LUNCH BREAK

13:00-14:00

*Please collect coupon vouchers
outside The Kitchen Restaurant*



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CHINA 2014**

Mini-Sessions on Effective Tools to Promote your Code of Ethics

**TOWARD STRONGER INDUSTRY SELF-REGULATION FOR THE
BIOPHARMACEUTICAL INDUSTRY IN CHINA**

Mr. Zhang Mingyu

***Vice Chairman, China
Pharmaceutical Industry
Association (CPIA)***

Dr. Xu Ming

***Vice Chairman, China Chamber of
Commerce for Import and Export of
Medicines and Health Products
(CCCMHPIE)***

Ms. Chen Jie

***Consultant, R&D Based
Pharmaceutical Association
Committee (RDPAC)***

Mr. Wang Xin

***Director, China Pharmaceutical
Industry Research & Development
Association (SINO-PhIRDA)***

Proactively Promoting Mexico City Principles and its Implementation in China – *CPIA*

- Proactively promote Mexico City Principles via multiple platforms/channels such as CPIA website, publications, Annual Summit, and Board Meetings;
- Raised awareness of Mexico City Principles among the Member Companies especially the senior executives;
- Incorporated some provisions of the Mexico City Principles into the Credit Evaluation System of CPIA and plan to raise its proportion.

Next Steps:

- Continue to promote the Mexico City Principles, organize routine training and best practice sharing;
- Advocate for endorsement from the laws and regulations to ensure implementation.



Improving Market Environment for Healthcare through Collaborative Effort – *CCCMHPIE*

- Importance of promoting and enhancing ethical practices for China's medical & biopharmaceutical Industry – a global perspective;
- Actions taken so far by CCCMHPIE in promoting ethical practices of medical & biopharmaceutical Industry;
- Establish credit-evaluation system among the member companies;
- Capacity Building for the member companies via international cooperation.

Suggestions going forward: recognition and support of Industry Code by state policies and laws; stronger leadership of trade associations; enhanced corporate governance to improve compliance by the companies; continuing international cooperation.



Commitment to Enhancing Industry Code Compliance for R&D Biopharmaceutical Industry in China – *RDPAC*

- Update the RDPAC Code in line with IFPMA Code since 2006;
 - Require mandatory compliance to the RDPAC Code of the members;
 - “Train-the-Trainer” and “Best Practice Sharing” among the Compliance Officers of the member companies;
 - Establish inter-company communication mechanism for complaints of Code violations;
 - Medical Rep Certificate program to train/test new medical reps of the member companies since 2007.
- ***Essence of Code compliance:*** commitment to “transparency” and “authenticity” of Industry’s interaction with Healthcare Professionals



Joint Efforts to Continuously Promote Ethical Business Practices of Pharmaceutical Industry in China

- Significance & importance of business ethics for China's pharmaceutical industry;
 - Related laws & regulations in China;
 - Related chapters in SINO-PhIRDA Constitution and Member Management Methods
 - Efforts made by SINO-PhIRDA in promoting ethical business practices;
 - Future actions.
- ***Joint Efforts*** by government, enterprises, NGOs and clinical agencies to continuously promote ethical business practices of pharmaceutical industry and improve related policy/ market environment in China.



Mini-Sessions on Effective Tools to Promote your Code of Ethics

PRESENTATIONS AT HCP/DISTRIBUTOR/PHARMACIST SYMPOSIA

Ms. Chrisoula Nikidis

***Code Compliance Network,
International Federation of
Pharmaceutical Manufacturers and
Associations (IFPMA)***

Ms. Claudia Perez

***La Asociación Nacional de
Fabricantes de Medicamentos
(ANAFAM), MEXICO***

Ms. Sabrina Chan

***The Hong Kong Association of the
Pharmaceutical Industry (HKAPI)***

Mr. Parulian Simanjuntak

***The International Pharmaceutical
Manufacturers Group (IPMG),
INDONESIA***



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Mini-Sessions on Effective Tools to Promote your Code of Ethics

GOVERNMENT ENDORSEMENT OF THE CODE OF ETHICS

Ms. Zhou Yan

***Secretary General,
China Pharmaceutical
Industry Association (CPIA)***

Mr. Leonard Ariff

***Immediate Past President,
Malaysian Organization of the
Pharmaceutical Industry (MOPI)***

Mr. Teodoro Padilla

***Executive Director,
The Pharmaceutical and Healthcare
Association of the Philippines (PHAP)***



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Engage Relevant Government Agencies in Gaining their Support of the Mexico City Principles

Ms. ZHOU Yan
Secretary General, CPIA

APEC Business Ethics for SMEs Forum
Biopharmaceutical Sector
1-3 September 2014 | Nanjing, China



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Enhance Communication with Relevant Government Agencies in Gaining their Support of the Mexico City Principles

- 1、Invited key government officials to attend the promoting ceremony of the Mexico City Principles;
- 2、Introduced the background and content of the Mexico City Principles as well as the progress of Industry effort of promoting the same when attending government meetings;
- 3、Actively promoted the implementation of the principles as part of the Establishment of the Credit System initiative spearheaded by the government.



Mini-Sessions on Effective Tools to Promote your Code of Ethics

GOVERNMENT ENDORSEMENT OF THE CODE OF ETHICS

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***Executive Director,
The Pharmaceutical and Healthcare
Association of the Philippines (PHAP)***



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Mini-Sessions on Effective Tools to Promote your Code of Ethics

CODE ENFORCEMENT AND ANNUAL CERTIFICATION PROCESS

Mr. Neil Pratt

***Assistant General Counsel,
Pharmaceutical Research and
Manufacturers of America (PhRMA)***

Ms. Chrisoula Nikidis

***Executive Director of Industry
Practices, Rx&D (Canada)***

Mr. Glen Argyle

***Code Practices Committee
Japan Pharmaceutical Manufacturers Association (JPMA)***



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Enforcement of the PhRMA Code

Mr. Neil Pratt

**Assistant General Counsel,
Pharmaceutical Research and
Manufacturers of America (PhRMA)**

**APEC Business Ethics for SMEs Forum
Biopharmaceutical Sector
1-3 September 2014 | Nanjing, China**



Website

The screenshot shows a web browser window displaying the PhRMA website. The browser's address bar shows the URL www.phrma.org/principles-guidelines/code-on-interactions-with-health-care-professionals. The PhRMA logo is prominently displayed at the top left, with the tagline 'RESEARCH • PROGRESS • HOPE'. A navigation menu is located below the logo, featuring links for 'ABOUT PhRMA', 'ACCESS', 'INNOVATION', 'VALUE', 'SAFETY', 'PhRMApedia', and 'THE CATALYST'. A secondary navigation bar includes 'PRESS ROOM', 'PRINCIPLES & GUIDELINES', 'PUBLICATIONS', 'EVENTS', and 'CONVERSATIONS'. The main content area is titled 'CODE ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS' and features a large heading: 'Ethical relationships with health care professionals are critical to our mission'. Below this heading, there is a list of two bullet points. To the right of the text, there are three buttons: 'SHARE', 'EMAIL', and 'PRINT'. Below these are two more buttons: 'Sign-up for Updates' and 'Subscribe to RSS'. A section titled 'THIS SECTION' lists several topics: 'Interactions With HCPs', 'Responsible Clinical Trial Data', 'Sharing', 'Conduct Of Clinical Trials', 'DTC Advertising', and 'Office Of Accountability'. At the bottom of the page, there is a section titled 'Partners for Healthy Dialogues' with a sub-heading 'Collaborations between physicians and biopharmaceutical professionals are essential to medical progress. > LEARN MORE'. The Windows taskbar is visible at the bottom of the screenshot, showing the time as 3:38 PM on 8/24/2014.

Code on Interactions With Health Care Professionals

www.phrma.org/principles-guidelines/code-on-interactions-with-health-care-professionals

PhRMA
RESEARCH • PROGRESS • HOPE

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Search...

ABOUT PhRMA ACCESS INNOVATION VALUE SAFETY PhRMApedia THE CATALYST

PRESS ROOM PRINCIPLES & GUIDELINES PUBLICATIONS EVENTS CONVERSATIONS

CODE ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

Ethical relationships with health care professionals are critical to our mission

- The Pharmaceutical Research and Manufacturers of America (PhRMA) represents research-based pharmaceutical and biotechnology companies. Our members develop and market new medicines to enable patients to live longer and healthier lives.
- Ethical relationships with healthcare professionals are critical to our mission of helping patients by developing and marketing new medicines. An important part of achieving this mission is ensuring that healthcare professionals have the latest, most accurate information available regarding prescription medicines, which play an ever-increasing role in patient health care. This document focuses on our interactions with health care professionals that relate to the marketing of our products.

SHARE EMAIL PRINT

Sign-up for Updates

Subscribe to RSS

THIS SECTION

- Interactions With HCPs
- Responsible Clinical Trial Data
- Sharing
- Conduct Of Clinical Trials
- DTC Advertising
- Office Of Accountability

Partners for Healthy Dialogues

Collaborations between physicians and biopharmaceutical professionals are essential to medical progress. > LEARN MORE

Appropriate marketing of medicines ensures that patients have access to the products they need and that the products are used correctly for maximum patient benefit. Our relationships with healthcare professionals are critical to achieving these goals because they enable us to -

- inform healthcare professionals about the benefits and risks of our products to help advance appropriate patient use,
- provide scientific and educational information

Windows taskbar: 3:38 PM 8/24/2014

Annual Certification

PhRMA identifies on its website all companies that have announced their commitment to abide by the Code and completed an annual certification, thereby demonstrating that they have policies and procedures in place to foster compliance with the Code.

See: <http://www.phrma.org/sites/default/files/pdf/2014-Master-Certifications-PhRMA-Code-042214.pdf>

PhRMA Code on Interactions with Healthcare Professionals – Certifications

In June 2008, the PhRMA Board of Directors unanimously adopted measures to enhance the PhRMA Code on Interactions with Healthcare Professionals. The revised Code took effect January 1, 2009.

Among its changes, the revised, voluntary Code provides that all companies (PhRMA members and non-members) that interact with healthcare professionals about pharmaceuticals should adopt procedures to assure adherence to the Code.

It also states that PhRMA will identify on its website all companies that have announced their commitment to abide by the Code and completed an annual certification, that they have policies and procedures in place to foster compliance with the Code.

The following chart identifies the companies that have provided an annual certification (*last updated 7/28/14*):

Company	2014 Certification	Company	2014 Certification
AbbVie	3/17/14	Merck & Co., Inc.	2/5/14
Amgen Inc.	2/4/14	Millennium Pharmaceuticals, Inc.	3/20/14
Anacor Pharmaceuticals, Inc.	6/24/14		
Astellas US, Inc.	2/5/14	Novartis Pharmaceuticals Corporation	3/18/14
AstraZeneca LP	2/10/14	Novo Nordisk, Inc.	3/27/13
Bayer HealthCare Pharmaceuticals	4/18/13	Otsuka America Pharmaceutical, Inc. (OAPI)	1/30/14
Biogen Idec	3/15/13	Otsuka Maryland Medicinal Laboratories, Inc.	1/30/14
Boehringer Ingelheim Pharmaceuticals, Inc.	3/31/14	Otsuka Pharmaceutical Development & Commercialization, Inc.	1/30/14
Bristol-Myers Squibb Company	4/8/14	Pfizer Inc	3/18/14
Celgene Corporation	2/4/14	Purdue Pharma L.P.	2/4/14
Cell Therapeutics, Inc.	2/13/13	Regeneron Pharmaceuticals, Inc.	2/16/14
Corcept Therapeutics	2/20/14	Sanofi US	10/24/13
Cumberland Pharmaceuticals Inc.	4/19/13	Shire Pharmaceuticals, Inc.	1/28/14
Daiichi Sankyo, Inc.	2/7/14	Sigma-Tau Pharmaceuticals, Inc.	3/29/13
Eisai Inc.	3/4/14	Sunovion Pharmaceuticals Inc.	3/19/13
EMD Serono	1/30/14	Takeda Pharmaceuticals North America, Inc.	1/31/14
Endo Pharmaceuticals, Inc.	3/11/13	Theravance, Inc.	1/28/14
Exelixis, Inc.	1/17/13	UCB, Inc.	2/6/14
Forest Laboratories, Inc.	2/21/13	Xenoport, Inc.	1/6/14
Genentech, Inc.	3/28/14	Zogenix, Inc.	2/1/14
Genzyme Corporation, A Sanofi Company	11/14/13		
GlaxoSmithKline	12/16/13		
GRIFOLS	3/25/13		
Ikaria, Inc.	2/6/14		
Johnson & Johnson (Pharmaceutical Cos)	3/6/14		
LEO Pharma Inc.	1/31/14		
Eli Lilly and Company	2/7/14		
Lundbeck Inc.	3/25/13		
Mallinckrodt Pharmaceuticals	9/10/13		
Marathon Pharmaceuticals, LLC	4/11/14		

External Verifications (1)

- The PhRMA Code on Interactions with Healthcare Professionals states that companies are encouraged to seek external verification periodically (ideally, at least once every three years) that company has policies and procedures in place to foster compliance with the Code.
- External verifications of compliance evaluate whether the company has policies, procedures or guidelines in place to foster compliance with the PhRMA Code.
- PhRMA identifies on its web site if a company has sought and obtained verification of its compliance policies and procedures from an external source. (As of May 6, 2013, 16 member companies had conducted an external verification.)

External Verifications (2)

Specifically, the external verification should be performed by an entity with sufficient expertise, objectivity and independence from the company, and that entity should confirm:

1. the company has policies, procedures, or guidelines in place that address the topics covered in the PhRMA Code;
2. the company has made any necessary revisions to relevant policies, procedures or guidelines to reflect the PhRMA Code and periodically evaluates the need for additional updates or revisions;
3. relevant company employees have received information/training on the PhRMA Code and the company periodically evaluates and addresses the need to provide additional training;
4. the company has considered, planned and implemented the steps it will take to monitor compliance with the PhRMA Code on an ongoing basis; and
5. the company has considered, planned and implemented the steps it will take to address reported incidents of non-compliance with the PhRMA Code.

State Law

- A number of States **REQUIRE** pharmaceutical companies to implement the PhRMA Code as part of their “sunshine” laws:
 - See, e.g., Sec. 94(a) of P. Law 10-117 (An Act Concerning Revisions to Public Health Related Statutes and the Establishment of the Health Information Technology Exchange of Connecticut): “On or before January 1, 2011, each pharmaceutical or medical device manufacturing company shall adopt and implement a code that is consistent with, and minimally contains all of the requirements prescribed in, the Pharmaceutical Research and Manufacturers of America’s ‘Code on Interaction with Healthcare Professionals’”

Mini-Sessions on Effective Tools to Promote your Code of Ethics

CODE ENFORCEMENT AND ANNUAL CERTIFICATION PROCESS

Mr. Neil Pratt

***Assistant General Counsel,
Pharmaceutical Research and
Manufacturers of America (PhRMA)***

Ms. Chrisoula Nikidis

***Executive Director of Ethics &
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Mr. Glen Argyle

***Code Practices Committee
Japan Pharmaceutical Manufacturers Association (JPMA)***



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Enforcement and Annual Certification of the Rx&D Code of Ethical Practices

Chrisoula Nikidis
Executive Director, Ethics and Compliance

APEC Business Ethics for SMEs Forum
Biopharmaceutical Sector

1-3 September 2014 | Nanjing, China



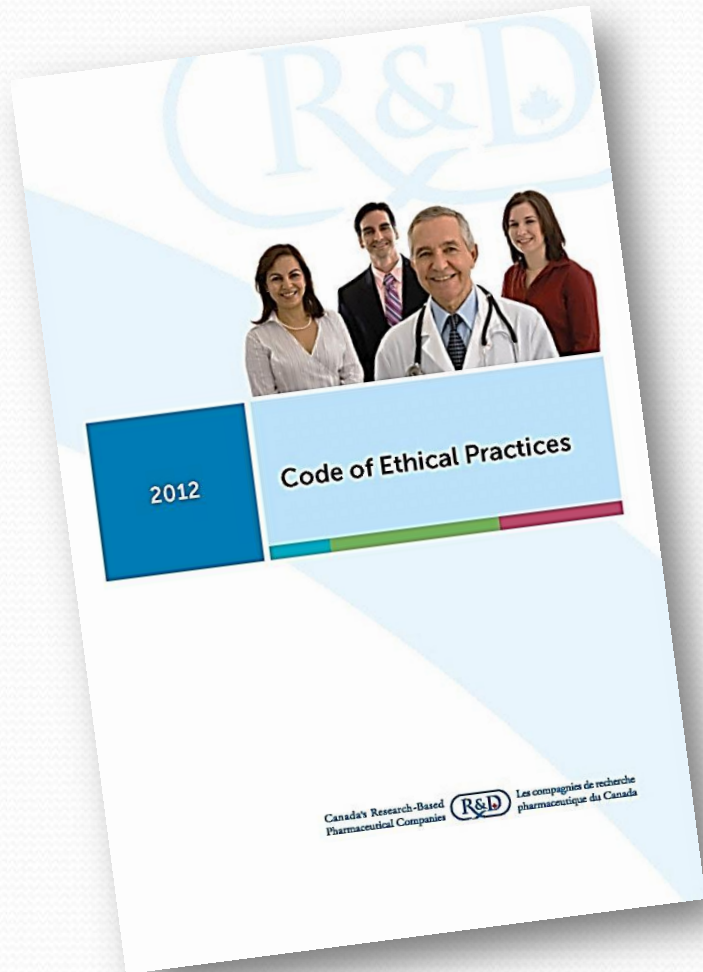
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Embracing Ethics & Transparency

- Developed in 1988
- Governs interaction with ALL stakeholders
- Promotes Reputation and Trust
- Guides us to live by the high standards we set for ourselves as an industry
- Code available at www.canadapharma.org



Annual Certification

Code of Ethical Practices Annual Compliance Confirmation

As a part of the annual confirmation process established by Section 19.1.2 of the Code of Ethical Practices, an authorized representative of the Member Company must confirm to Canada's Research-Based Pharmaceutical Companies (Rx&D) in writing that they have policies and procedures in place to facilitate ongoing compliance with the Code. Please review, sign and return the attached form to Rx&D, Nicole Lauzon (nlauzon@canadapharma.org), by March 29th, 2013.

I confirm that **(Company name)** has policies and procedures in place to facilitate ongoing compliance with the Code.

Authorized representative's Signature

I am authorized to sign this statement on behalf of **Company name**

Authorized representative's printed name

Signed on _____ day of _____, 2013

- Section 19 of the Rx&D Code requires that all Members monitor its compliance with the Code on an annual basis



Code Industry Practices Review Committee (IPRC)

IPRC Members – Balancing Industry and External Perspectives:

- Current Members:

- 2 Member company representative
- 2 External representatives (health care professionals)
- 1 individual appointed by Rx&D President
- Rx&D Chief of Staff and Vice-President, Legal Affairs*
- Rx&D Executive Director, Ethics and Compliance*



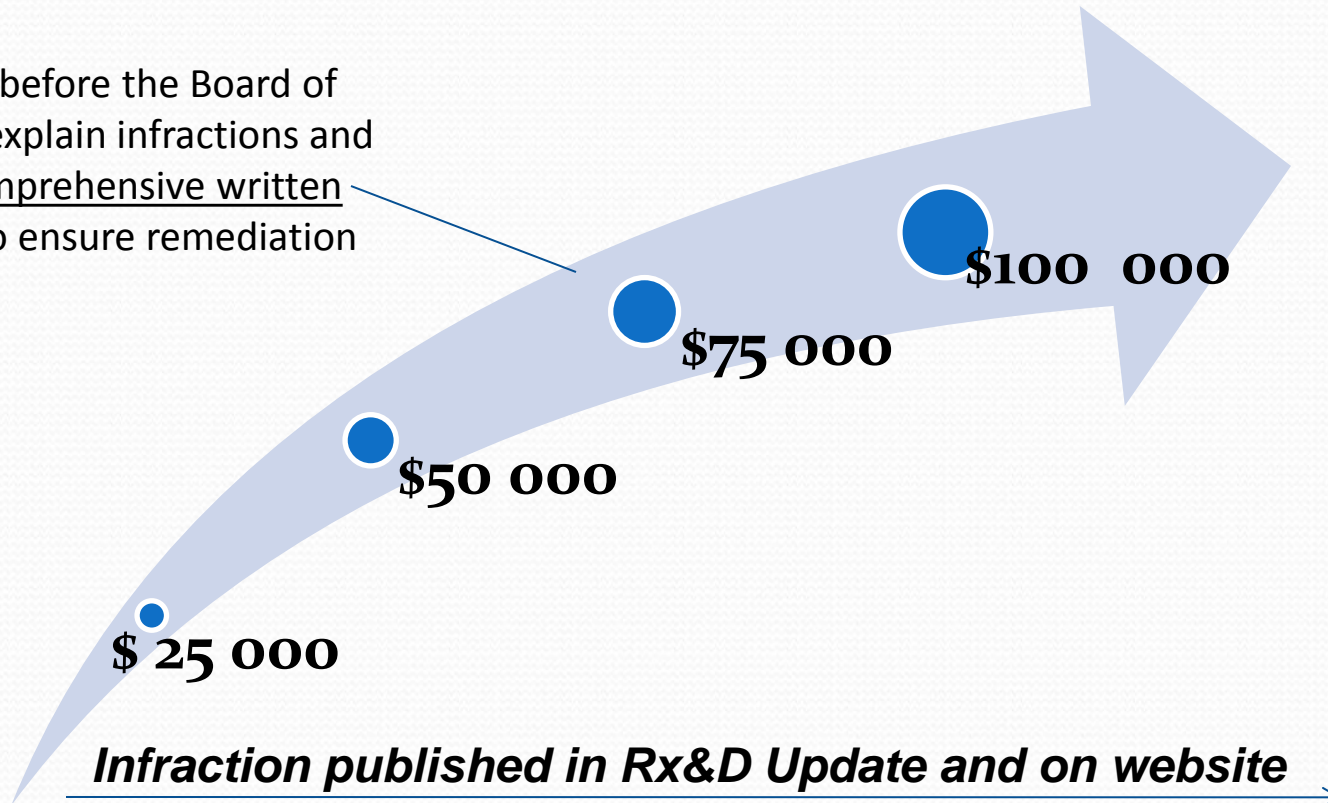
- Additional Members could include:

- 1 representative from Pharmaceutical Advertising Advisory Board (PAAB) - (infractions of PAAB Code may lead to infractions of Rx&D Code) and/or
- 1 external representative from the scientific community, as required

*** NB: Staff support the IPRC but do not vote in IPRC decisions**

Code Enforcement

CEO appears before the Board of Directors to explain infractions and provide a comprehensive written action plan to ensure remediation



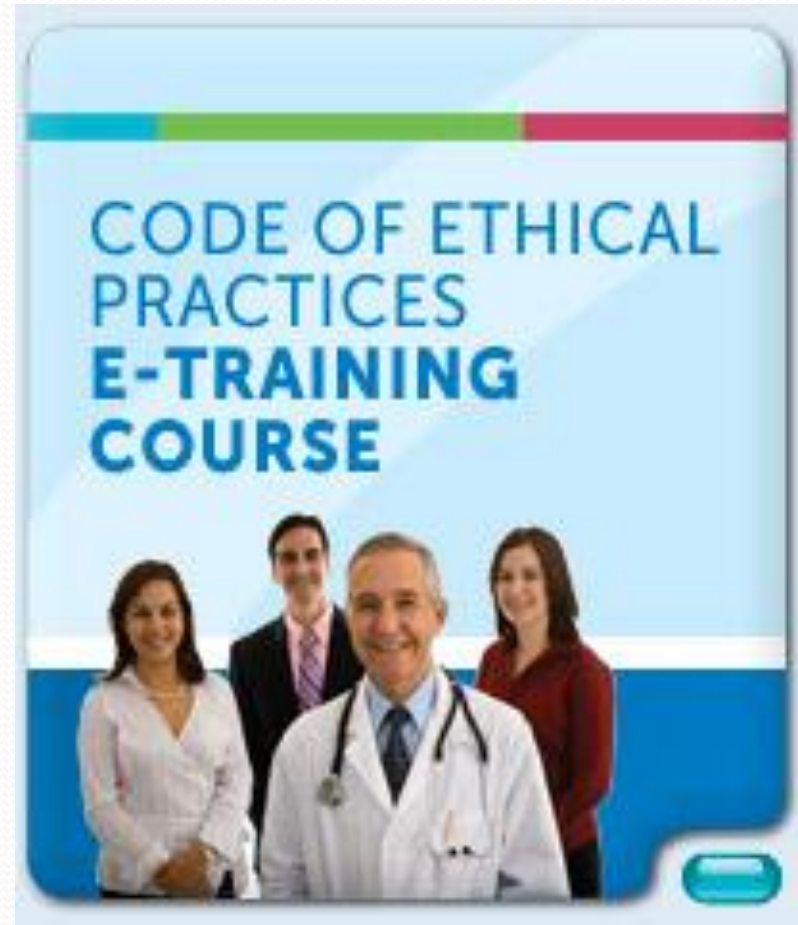
- *Member is placed on a 12 - month probationary period for 5 or more infractions / year or 3 or more / year for 2 years*
- *Infractions during probation period may result in expulsion*



Rx&D - Code of Ethical Practices

eLearning:

- Rx&D is proud to issue an integrated learning module to aid in the dissemination and training of employees and stakeholders on the revised Code
- Companies, stakeholders and individuals interested in taking this e-learning Course can contact Rx&D directly for more information



Mini-Sessions on Effective Tools to Promote your Code of Ethics

CODE ENFORCEMENT AND ANNUAL CERTIFICATION PROCESS

Mr. Neil Pratt

***Assistant General Counsel,
Pharmaceutical Research and
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Ms. Chrisoula Nikidis

***Executive Director of Ethics &
Compliance, Rx&D (Canada)***

Mr. Glen Argyle

***Code Practices Committee
Japan Pharmaceutical Manufacturers Association (JPMA)***



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APEC Business Ethics for SMEs Forum

Code Enforcement at the JPMA

September 1, 2014



Glen Argyle, MBA
International Code Subcommittee, Code Practices Committee
Japan Pharmaceutical Manufacturers Association
(Director, AMD PA, Takeda Pharmaceutical Co., Ltd.)

Trust through Transparency

Goal:

To build and maintain society's trust in our actions

Commitment



Accountability



Commitment

Laws and Regulations (Japanese examples)

- Pharmaceutical Affairs Law
- Education and Training Guidelines for MRs
- Fair Competition Code
- Guidelines for Specifying Product Information Summaries for Prescription Drugs



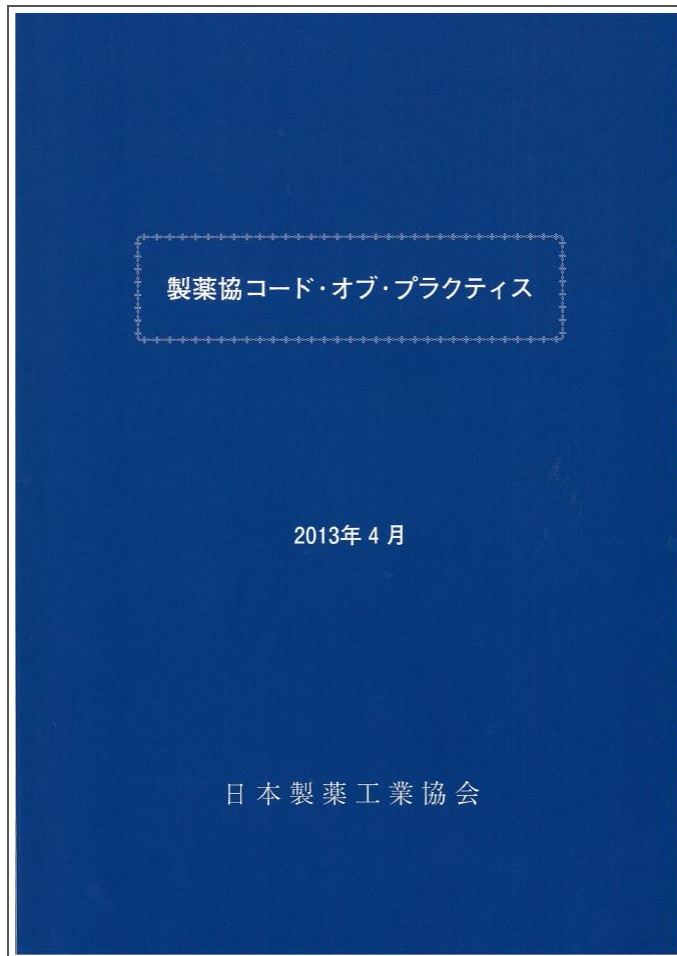
Ethical Code (examples)

- Patient health is always our first priority (non-conditional)
- Providing balanced drug information to stakeholders

JPMA's Code of Practice



- 211 pages
- Applies to 72 research-oriented pharmaceutical companies (as of April, 2014)
- **Includes procedures for dealing with complaints** (also includes JPMA notices to member company and various guidelines, such as the Transparency GL, IFPMA Code, Mexico City Principles, etc.)
- Available for purchase



The Code (or Blue) Book

Realizing Accountability

The Code Book establishes

- code committee
- code practices committee (complaints review)
- printed health information and promotional materials review subcommittee, and
- complaints procedure
- remedial measures
- requirement for each member company to establish an internal code compliance function



NB: JPMA also has Compliance Committee chaired by JPMA Chairman

Training on the Code

Annual Training Programs

-> Training to member companies

- Code of Practice (3x)
- Transparency (3-4x)
- Promotion materials (1x)
- Code Awareness Month (November)

-> Training to external stakeholders

- Promotion materials (1x)



Complaints Review Procedure

Prior to
complaint

- Encourage contacting company regarding possible breach to resolve issue directly



Complaint
submission

- Complaints possible by any stakeholder including doctors, industry, etc.

Receipt of
complaint

- Acknowledgement of receipt
- Request details from stakeholders

Complaint
Review

- Examine and review evidence
- Determine outcome

Announce /
Enforce

- Feedback outcome to stakeholders
- Public announcement for serious breaches

Trust through Transparency

Goal:

To build and maintain society's trust in our actions

Commitment

Code



Accountability

Enforcement



Mini-Sessions on Effective Tools to Promote your Code of Ethics

CODE ENFORCEMENT AND ANNUAL CERTIFICATION PROCESS

Mr. Neil Pratt

***Assistant General Counsel,
Pharmaceutical Research and
Manufacturers of America (PhRMA)***

Ms. Chrisoula Nikidis

***Executive Director of Ethics &
Compliance, Rx&D (Canada)***

Mr. Glen Argyle

***Code Practices Committee
Japan Pharmaceutical Manufacturers Association (JPMA)***



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BREAKOUT SESSIONS

16:00-17:00

*Mentors and Associations to Develop
Roadmap for Promoting Codes of Ethics to
Relevant Stakeholders in Local Economy*



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Closing Reports from Breakout Sessions & Wrap-Up Remarks

Facilitated by: Mr. Russell Williams

President, Rx&D (Canada)

Co-Chair, APEC Mexico City Principles Expert Working Group

APEC Business Ethics for SMEs Forum

Biopharmaceutical Sector

1-3 September 2014 | Nanjing, China



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APEC Business Ethics for SMEs Forum Biopharmaceutical Sector Workshop

1 & 3 September 2014 | Nanjing, China



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Welcome & Reflections on
Day One Training & Plenary Session

Mr. Russell Williams

President, Rx&D (Canada)

Co-Chair, EWG for APEC Mexico City Principles

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Setting the Scene: Future of Marketing, Compliance and Ethics in the Pharmaceutical Market

Karen Eryou, UCB (China)

Millette Asuncion-Arnedo, Pfizer (Philippines)

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Overview

Perception of the healthcare industry

What is Changing & Why Change?

Industry Stakeholders – *why they matter?*

HCPs: industry' most significant interface

Compliance vs. Ethics



Perception of the healthcare industry

guardian
 News | US | World | Sports | Comment | Culture | Business | Mon
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GlaxoSmithKline China scandal: another 18 people arrested
 No details given of the identities of those detained as scandal over bribery allegations intensifies
 Doctors in Beijing
 guardian.com, Friday 26 July 2013 23:07 EDT



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U.S. doctors steeped in financial ties with Big Pharma
 World politics | Business & finance | Economics | Science & technology
 November 01, 2011 by S. D. Wells

Pick your pill out of a hat
 The drug industry
 September 29th 2012 | From the print edition

Big Pharma. By Ben Goldacre. Fourth state, 430 pages; £13.99. To be published in America in January by Faber and Faber; \$28. Buy from Amazon.com: Amazon.co.uk

DOCTORS like to project an air of authority when making their clinical decisions. Patients like it too, for it is reassuring to think that one's health is in the hands of an expert. It would be unsettling if, upon prescribing you a drug, your doctor admitted that the scientific research about what exactly the drug did, and how effective it was at doing it, was patchy and distorted, sometimes to the



MORE DRINKS. MORE LAUGHS. MORE PLAY.
 FRAMES

Pfizer Settles a Drug Marketing Case for \$491 Million
 Science & technology
 2013

Manufacturer **Pfizer** agreed to pay \$491 million to settle criminal charges over the illegal marketing of the kidney-transplant immune, the Justice Department **announced on Tuesday.**

The settlement is the latest in a string of big-money cases involving the sales practices of major pharmaceutical companies; four years ago, **Pfizer paid \$2.3 billion** for improperly marketing several drugs. The recent case centers on the practices of Wyeth Pharmaceuticals, which Pfizer acquired in 2009.

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Full Disclosure Needed for Clinical Drug Data
 THE EDITORIAL BOARD
 Published July 4, 2013

Pharmaceutical companies are under increasing pressure to release previously hidden data on how well their drugs work. The primary push for much greater transparency has come from the **Cochrane Collaboration**, an international network of experts based in Oxford, England; **The British Medical Journal**; and the **European Medicines Agency**, which recently proposed that, starting next year, **clinical trial data** be released once a drug is approved for marketing.

The saga of **Tamiflu**, an anti-flu drug produced by Roche, a multinational company based in Switzerland, exemplifies the difficulties of extracting information vital to public

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The truth about medical journals, and how drug companies exert heavy influence over published scientific articles
 Monday, October 03, 2005 by Ben Kage

The great direct-to-consumer prescription drug advertising con: how patients and doctors alike are easily influenced to demand dangerous drugs

Sunday, July 31, 2005 by Dani Veracity



Asia-Pacific Economic Cooperation

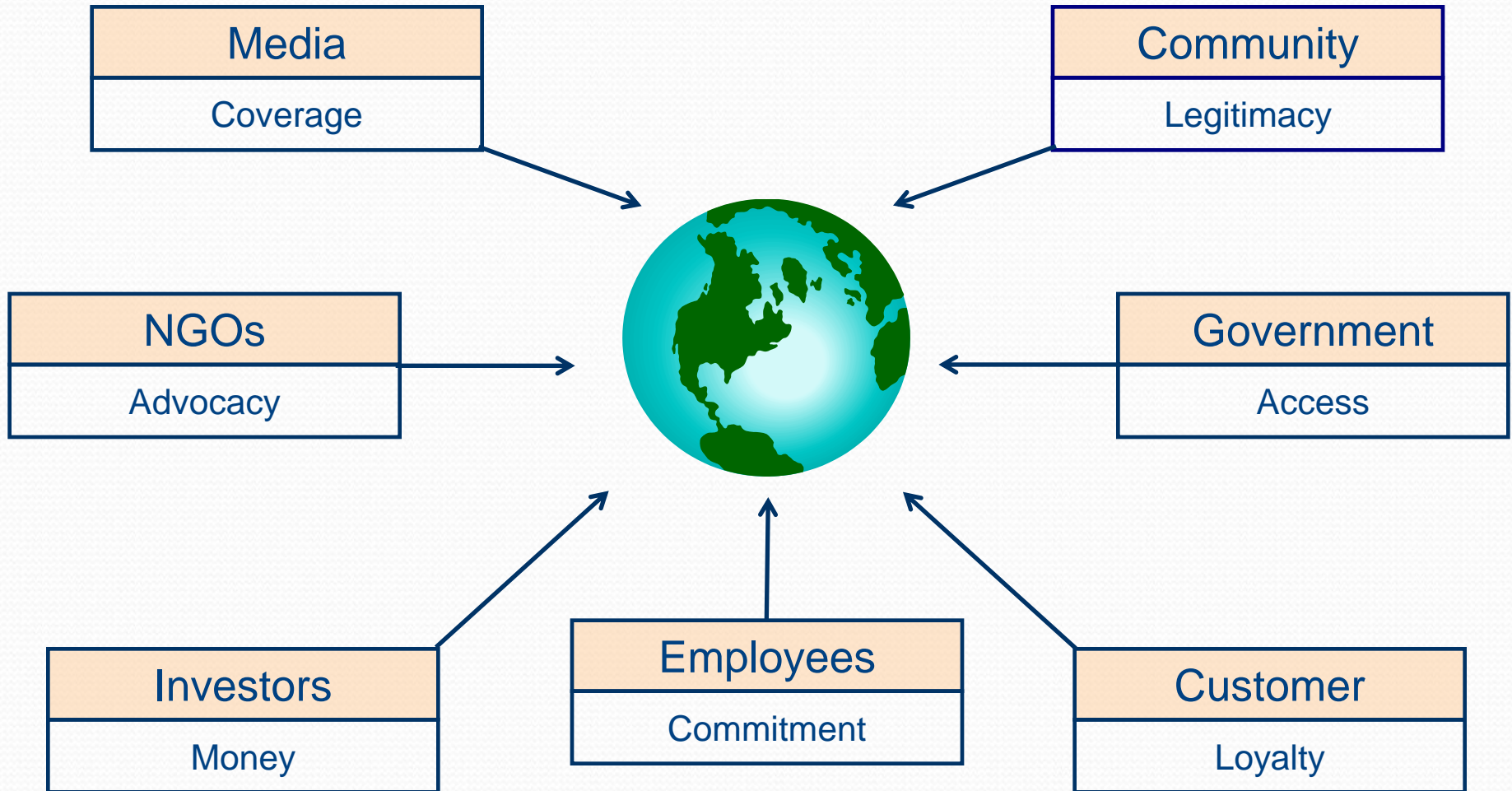
What is changing & why change?

- Public and Government expectations
 - Demand for healthcare
 - Affordability & accessibility
 - Transparency (payments / relationships / data)
- New and reinforced regulations
 - US FCPA & UK Bribery Act
 - Country laws
- Competition
 - Local vs. international companies
 - Generics vs. branded / patented

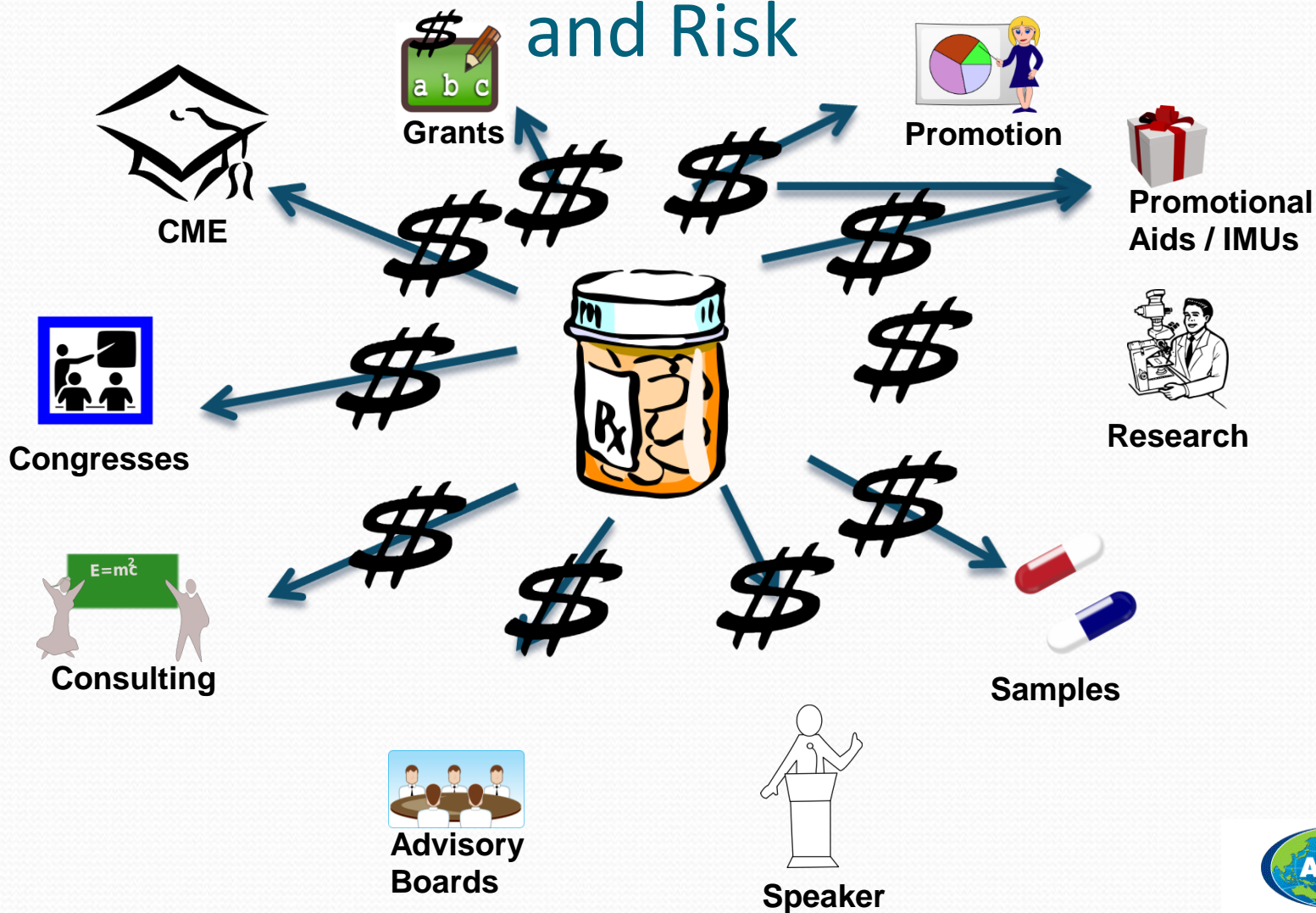


Industry Stakeholders

World of Opportunity



HCPs Represent Most Significant Interface and Risk



Compliance versus Ethics



COMPLIANCE

- In accordance with the agreed rules and standards



ETHICS

- Moral principles that govern a person's or group's behaviour

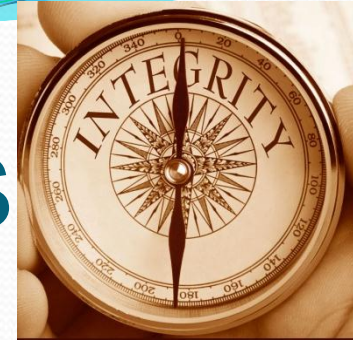


Key Responsibilities of 'Corporate Compliance'

- **Strengthen ethical decision-making and behaviour in the company**
- **Identify and oversee the management of compliance risks**
 - Assist with **development** of policy
 - **Communicate** and **train** policy
 - **Guide, investigate** and **enforce** policy compliance



Use the Ethical Compass



- Is it consistent with our mission, values and spirit?
- Is it legal and ethical?
- Is it consistent with policy and Code of Conduct?
- Can I explain it to my family and friends?
- Would I be comfortable if it appeared in the newspaper?

The Key Components of a Compliance Programme

- 1. Written Policies & Procedures**
- 2. Designated Compliance Officer and Committee**
- 3. Effective Training and Education**
- 4. Clear lines of Communication**
- 5. Auditing and Monitoring**
- 6. Enforcement and Disciplinary Actions**
- 7. Response to Detected Problems & Corrective Actions**



Setting the Scene: Future of Marketing, Compliance and Ethics in the Pharmaceutical Market

Karen Eryou, UCB (China)

Millette Asuncion-Arnedo, Pfizer (Philippines)

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Thermometer Game: How hot is this issue?

Facilitated by:
Ms. Chrisoula Nikidis
Rx&D (Canada)

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Interactions with Healthcare Professionals: Meetings and Sponsorship

Ms. Sabrina Chan

**The Hong Kong Association of the Pharmaceutical
Industry (Hong Kong, China)**

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Interactions with Healthcare Professionals: Gifts & Other Items

Ms. Genevieve Wan, GlaxoSmithKline (Singapore)
Mr. Jeffrey Liu, Pfizer (China)

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Interactions with Healthcare Professionals: Fees for Services

Mr. Howard Lin

Eli Lilly and Company (Hong Kong, China)

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Working with Patient Organization: Gifts & Other Items

Mr. YS Kwon, Johnson & Johnson (Korea)

Mr. Bruce Ellsworth, Johnson & Johnson (Japan)

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Congress Organization – How to Interact and Practical Cases

Ms. Maija Burtmanis
Abbvie (Singapore)

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Effective Training Resources for Industry Associations & Member Companies

Chrisoula Nikidis

Executive Director, Ethics and Compliance
Canada's Research-Based Pharmaceutical Companies
Member of the Code Compliance Network (CCN), IFPMA

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IFPMA Code Resources & Training Overview

- 1. Regular communication and meetings**
- 2. Interactive Workshops**
- 3. Online Training Tool**
- 4. Tools & Resources**

Meetings and communications



Regular meetings & communications

- Regular face-to-face meetings to exchange info and discuss latest developments & best practices
- Webinars to discuss Code requirements and provide a platform for members to ask questions related to code provisions and their application.

Creating a network of experts is invaluable – our people are our greatest resource!

Interactive Workshops



«Hands-on» Compliance Training

Interactive workshops format

- Groups (6-10 people) assembled into roundtables with at least one expert leader per group
- Mix of plenary sessions, case studies and simulation «game»
- Case studies discussed in small groups and feedback given in plenary
- Q&A session at the end to provide opportunity for additional questions and/or clarification on topics of interest

Workshop – focused on key topics

IFPMA Code Workshop
Hands on Compliance Training

IFPMA Code Workshop
Hands on Compliance Training

Interactions with HCPs
Part 1: Meetings, Sponsorship
Services

Interactions with HCPs
Part 2: Gifts and Other Items

Working with

IFPMA Code Workshop
Hands on Compliance Training

IFPMA Code Workshop
Hands on Compliance Training

The Spirit of the Code:
Our values & principles



IFPMA: Sales and marketing
How hot is this issue?

IFPMA Code Workshop
Hands on Compliance Training



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IFPMA Code e-learning Tool

IFPMA Code of Practice
2012



Welcome to this e-learning module about the 2012 IFPMA Code

You can go straight to any of the signposted sections but we suggest that you work through each in turn to get full benefit.

This learning programme is not the definitive word on what is acceptable practice for any particular company in any particular country because additional, stricter company and/or national code rules may apply.

The rules set out here do however provide a basis onto which you can add national or individual company requirements.



1. Welcome And Introduction



2. Overview of the IFPMA Code



3. Key Topics



4. Case Scenarios



5. Test Your Knowledge

- Quiz at the end of the training
- Certification of completion available for scores over **80%**

<http://www.ifpma.org/ethics/ifpma-code-of-practice/ifpma-online-code-training.html>

Various training methods

Webinars

WORKSHOPS

Case studies

Q&A SESSIONS

Online
modules

Interactive group
discussions

Quizzes

Use humor and make learning fun!

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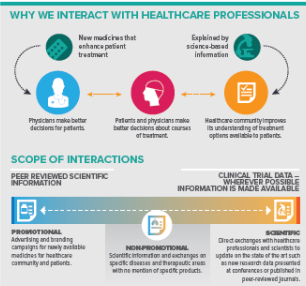
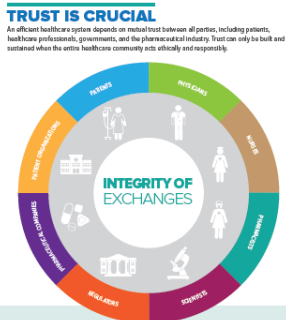
Tools & Resources



Toolbox

- Maximize use of existing resources by sharing and collating materials and best practices
- Encourage training and awareness raising at the local level
- Easily accessible to members





PHARMACEUTICAL INDUSTRY CODES: PREVENTION AND ENFORCEMENT

FOCUS ON PREVENTION OF INAPPROPRIATE BEHAVIOR. IN MOST CASES THEY INCLUDE TRANSPARENT COMPLAINT HANDLING MECHANISMS

CODE IN NUMBERS:

The IFPMA Code applies to nearly 90 members, including over 50 National Associations and nearly 70 global research-based Pharmaceutical Companies, which operate in over 100 countries.

IFPMA CODE COMPLIANCE NETWORK:	TRAINING:
<p>COMPLIANCE NETWORK:</p> <p>100+ experts representing member associations and companies to supervise Code implementation</p> <p>COMPLIANCE COACHES:</p> <p>100s of staff work to pharmaceutical company compliance programs overseen by Chief Compliance Officers</p>	<p>Association training sessions and online courses: http://www.ifpma.org/ethics</p> <p>Compliance are required to regularly train employees</p>

THE IFPMA CODE IS A SELF-REGULATORY MECHANISM WITH A MULTIPLIER EFFECT

DIRECT MEMBERS:

IFPMA members, companies and national associations, are required to adopt the code.

30 pharmaceutical companies operating all around the world	50 associations operating in 50 different countries
--	---

DIRECT MEMBERS: Any company that is a member of at least one IFPMA national association is covered by the IFPMA Code, wherever that operates. The relevant pharmaceutical companies, and some global medical device, generic, and animal product.

THE IFPMA CODE COMPLEMENTS LAWS, REGULATION, AND GUIDELINES WORLDWIDE

BUILDING AND MAINTAINING TRUST

PHARMACEUTICAL INDUSTRY CODES & SELF-REGULATION	LAWS & REGULATIONS	COMPLIANCE/ENFORCEMENT
<ul style="list-style-type: none"> IFPMA CODE NATIONAL ASSOCIATION CODES CODE COMPLIANCE NETWORK 	<ul style="list-style-type: none"> NATIONAL LAWS WITH GLOBAL EFFECT IS REGULATORY COMPLIANCE IN AN ARBITRARY ACT 	<ul style="list-style-type: none"> WHICH ETHICAL CRITERIA HEALTHCARE PROFESSIONALS CODES INTERNAL ORGANIZATION CODES HOW TO REPORT TO OTC REGULATORS

IFPMA Infographic: Health, Trust, and Code

- Snapshot on the role and value of industry self-regulatory codes
- Valuable tool to raise awareness of global standards among industry members and external stakeholders

Francis et al. *Philosophy, Ethics, and Humanities in Medicine* 2014, 9:7
<http://www.pehm-med.com/content/9/1/7>



REVIEW **Open Access**

Ethical pharmaceutical promotion and communications worldwide: codes and regulations

Jeffrey Francis*, Jose Zamariego Izquierdo², Tamara Music³, Kirti Narasi⁴, Chrisoua Nikkidi⁵, Heather Simmonds⁶ and Paul Woods⁷

Abstract

The international pharmaceutical industry has made significant efforts towards ensuring compliant and ethical communication and interaction with physicians and patients. This article presents the current status of the worldwide governance of communication practices by pharmaceutical companies, concentrating on prescription-only medicines. It analyzes legislative, regulatory, and code-based compliance control mechanisms and highlights significant developments, including the 2006 and 2012 revisions of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code of Practice. Developments in international controls, largely built upon long-established rules relating to the quality of advertising material, have contributed to clarifying the scope of acceptable company interactions with healthcare professionals. This article aims to provide policy makers, particularly in developing countries, with an overview of the evolution of mechanisms governing the communication practices, such as the distribution of promotional or scientific material and interactions with healthcare stakeholders, relating to prescription-only medicines.

Keywords: Pharmaceutical industry, Self-regulation, Code compliance, Promotion of medicines

Introduction

Recent prescribing decisions should be enhanced by the quality of interactions between healthcare providers and the companies that research and develop medicines. The medicines that research-based companies produce and the scientific information they provide to physicians are important components of quality healthcare for patients. With the ever increasing number of treatment options available to patients, healthcare providers need to be kept up to date with the scientific advancements of new medicines. Likewise, providing patients with information relating to medicines may encourage healthcare providers to explore various treatment options in order to best match patient needs. It is important therefore that the information provided by companies is scientifically accurate and fair. Interactions between pharmaceutical companies and healthcare professionals should always be appropriate and support good patient care. With the aim of further supporting these important goals, the global pharmaceutical industry has made significant changes in

recent years in the worldwide controls on companies' interactions with healthcare professionals. This review explores the mechanisms for ensuring the quality of material supplied by international pharmaceutical manufacturers, including product advertising and educational communications. Information is often categorized as "promotional," "non-promotional," or "scientific"; although the distinction between what is "promotional" and "non-promotional" may not always be clear. Promotional information, as some regulators and codes have defined, encompasses advertising and sales material related to particular products, and may be distributed to patients through advertising campaigns or to healthcare professionals by pharmaceutical representatives. Non-promotional material usually focuses on the current state of understanding of certain diseases and is not related to specific products. Scientific information broadly includes the contributions of research and development (R&D) firms to the exchange of scientific information. For example, scientists from pharmaceutical companies may present research data at scientific conferences or publish works in trade- and peer-reviewed journals. It is important to emphasize, however, that the

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²Paul Woods Compliance Ltd, Macfield, UK
 Full list of author information is available at the end of the article

IFPMA Peer-reviewed publication:

- Documents progress and impact of self-regulation and industry codes as well as external and regulatory developments.



IFPMA Code Website

***Ongoing maintenance and update of IFPMA website and web-based resources.**



IFPMA
International Federation of Pharmaceutical Manufacturers & Associations

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- The IFPMA Code of Practice 2012 (English)
- The IFPMA Code of Practice 2012 (Spanish)
- The IFPMA Code of Practice 2012 (French)
- The IFPMA Code of Practice 2012 (Japanese)
- IFPMA Code of Pharmaceutical Marketing Practices 2006 (EN)
- IFPMA Code of Pharmaceutical Marketing Practices 2006 (FR)
- IFPMA Code of Pharmaceutical Marketing Practices 2006 (ES)

<http://www.ifpma.org/ethics/ifpma-code-of-practice/about-ifpma-code-of-practice.html>



Thank you!

For inquiries please contact:
Tamara Music
t.music@ifpma.org

Visit us at: www.ifpma.org/ethics

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BREAKOUT SESSIONS

16:00-17:00

*Mentors and Associations to Develop
Roadmap of Training Opportunities
for Member Companies*



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Closing Remarks & Presentation of Certificates

Ms. Lynn Costa

Project Overseer, Business Ethics for APEC SMEs Initiative

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