

The Asia-Pacific Pharmaceutical
Compliance Congress and
Best Practices Forum

Sep. 10-12, 2013 • Kuala Lumpur, Malaysia

A Hybrid
Conference
and Internet
Event



Asia Pacific Code Roundtable

10 September 2013

3rd Asia Pacific Compliance Congress

Kuala Lumpur, Malaysia



Singapore

SAPI – Code of Marketing Practices (rev 2012)

7.1.4 Appropriate Venue

- All Events must be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the Event or meeting. Companies must avoid using renowned or extravagant venues.
- Venues associated with **activities** such as gambling, gaming and entertainment are deemed not conducive to the conduct of scientific/educational meetings/activities and would be deemed as inappropriate .

- Case 1 (2010) Outcome
- Case 2 (2012)
- Case 3 (2013)



Korea

ASIA PACIFIC PHARMACEUTICAL COMPLIANCE
CONGRESS.

CODE ROUNDTABLE

KOREA

KIM & CHANG | September 10, 2013

KRPIA/KMDIA Codes: Permitted Interactions

- Samples
- Donations
- Sponsorship for hosts of academic conferences
- Sponsorship for participants of academic conferences
- Product presentations
- Training & education (*KMDIA Code only*)
- Lecture & consulting (*KMDIA Code only*)
- Market research
- Sponsorship for clinical activities
- Advertisements and exhibitions

 ***Specific reporting requirements and monetary limits apply***

KRPIA/KMDIA Codes: Key Monetary Limits

Meals

- Product presentations: within KRW100,000/meal (*VAT and service fee excl., refreshments incl.*)
- Product presentation for single medical institution: within KRW 100,000/day, up to 4 times/month

Souvenirs, Promot'l Gifts

- Souvenirs: within KRW50,000 (*multiple medical institutions*)
- Promotional gifts: within KRW10,000 (*single medical institution*)

PMS

- KRW 50,000 or KRW 300,000/CRF

Lectures

(KMDIA Code only)

- KRW 50,000 per lecture, KRW 1,000,000 per day, KRW 2,000,000 per month

Consulting

(KMDIA Code only)

- KRW 500,000 per consultation, KRW 3,000,000 per annum

Efforts to Expand Safe Harbors

Task Force (Physicians-MoHW-Industry) examining expanding safe harbors – DPS and industry codes

Objective to Expand Permitted Activities

- Include lecture and consulting service for pharma industry (*as in KMDIA Code*)
- Lift limit on number of product presentations targeting individual medical institutions
- currently 4 times/month
- Increase PMS service fees - currently KRW 50,000 or KRW 300,000/CRF
- Expand support for HCPs participating in academic conferences
- do not limit to chairpersons, panelists and presenters
- Increase permitted number of samples - currently minimum number needed to verify features

Redefine “illegal rebates” : “promotional purposes” too broad

Aim to reach consensus by 4th Task Force session (sometime in mid-September)

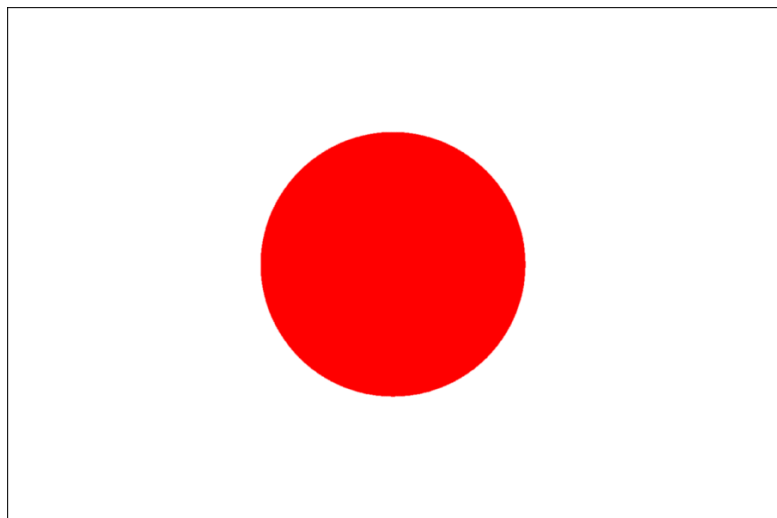
Efforts to Ensure Compliance

Transparency or “Sunshine” Act

- MOHW exploring adoption Sunshine Act-like disclosure requirements
- Reviewing disclosure/transparency systems in other jurisdictions
- Scope of disclosure being considered – e.g., voluntary vs. compulsory
- Greater transparency condition for expansion of safe harbors

“Neutral Committee” to be formed

- Would determine whether certain acts/practices constitute illegal rebates



Japan

3rd Asia Pacific Pharmaceutical Compliance Congress

JPMA Code Update

10 September, 2013

Yota Kikuchi

**Vice Chair, JPMA Code Practices Committee
Manager, Promotion Code, Public Affairs, Sanofi K.K.**

The JPMA Code of Practice

Apr. 2013

JPMA Code of Practice (COP)

Aim: Ensure ethical interactions between companies and stakeholders

Scope: All employees, Top Management, Third parties
vs. HCOs, HCPs, Researchers, Patient Organizations, Wholesalers

Transparency
Guideline (HCP)

Transparency
Guideline (PO)

Clinical Trial
Transparency

1. Studies and research activities
2. Information Dissemination Activities
3. Collaboration with Patient Groups
4. Relationship with Wholesalers

Sept. 2012

JPMA Promotion Code (PC)

Aim: Ensure ethical promotion to HCPs / HCOs.

Scope: Sales & Marketing vs. HCPs & HCO's

Fair Competition Code (FCC)

Aim: Prevent Unfair Inducements of Transactions

Scope: Sales & Marketing vs. HCPs & HCO's

JPMA Transparency Guideline

- JPMA's voluntary initiative for further transparency to gain higher trust & understanding
- Agreed by JPMA members in 2011
- Scope of Disclosure (5 categories)
 - A. R&D expenses (Annual total amount)
 - B. Academic research grants (Names of individual HCOs and amount)
 - C. Honoraria (Annual total amount, Names of individual HCPs)
 - D. Payments related to provision of information (Annual total amount)
 - E. Other Payments (Annual total amount)
- Overcoming challenges, disclosure of payments for fiscal 2012 has started this year.

Conclusion

- **Social expectations for stronger ethics and greater transparency are increasingly rising.**
- **JPMA and memberships have showed leadership in reinforcing the codes and improving transparency to maintain trust**
- **Further accountability is indispensable (beyond code compliance)**



Australia

The Antipodean View (Australia)

Asia Pacific Roundtable
10 September 2013

Deborah Monk
Director, Compliance
Medicines Australia



Recent Code Changes

- New Code (Edition 17) January 2013
- Includes new aggregated reporting of
 - Advisory Boards
 - Consulting arrangements with HCPs
 - Health Consumer Organisations (disclosure \$)
- Continue Educational Event Reports
 - Since July 2007 (12 X six monthly reports)

Key Challenges

- Competition regulator gave 2 yrs authorisation
- Introducing transparency measures
 - Similar to PPSA in US
- Transparency WG developed “A Model”
 - Now undergoing consultation
- Disparity between MA Code and “the rest”
 - Higher compliance burden and cost on Members
- Minor Political Party wants to legislate

Code Implementation

- Authorisation maintained
 - But continually pushed for “more”
- Members experiencing contraction/downsizing
 - Secretariat expected to “do more with less”
- Practical requirements of transparency model
 - Who can host/publish the reported data?
- High degree of commitment to compliance
 - What’s the tipping point where Members leave?

**Always
available to
lend a hand...**

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Thailand

ASIA PACIFIC CODE ROUNDTABLE

(Code Implementation in Thailand)

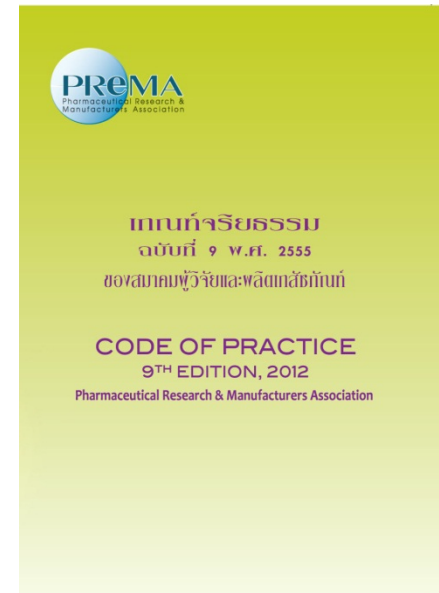
10 September 2013

Roj Rungvisai



Recent changes/additions to PReMA 9th Code of Practice (2012)

- Follow current IFPMA framework
- Address wider scope to include non-commercial activities such as:
 - Clinical trials
 - Healthcare professionals organization and
 - Patient organization
- Put more details on Fee for Service
- Have clear structure of Appeal Committee



Key challenges and developments in Thailand

No level playing field
between PReMA and
non-PReMA members
(40/130 manu & 500+
importers)

Local Cultural
Difference

Different member
implementation

Definitions:

- Extravagant/appropriate venue
- Modest hospitality

Code implementation



Success

- Proactive in code updating since the 1st Code in 1986
- Most member companies already incorporate PReMA code in their internal process
- Internal Communication (Code Day, PEP Talk, Code Contest)
- External parties outreach programme

Challenges

- Non-Members do not have Code to govern their sales and marketing practices
- Low awareness of Drugstore Code



Indonesia



IPMG
International Pharmaceutical Manufacturers Group

Marketing Ethics in Pharmaceutical Industry

Presented by:

Parulian Simanjuntak – Executive Director of IPMG

Asian Pharma Congress

Kuala Lumpur, 10 September 2013

Contentious Issues of The Code of Conduct

- Any cash payment to the healthcare professional
- Implementation and interpretation of cultural courtesy gift
- Partial sponsorship
- Sponsoring a spouse/family member
- Pre and Post conference activities/arrangements
- Extravagant events/entertainment

Challenges

- Un-level playing field with local / national pharmaceutical companies and Non-IPMG members of international generic companies.
- Market is dominated (75%) by local / national pharmaceutical companies.
- No official support yet from the relevant authorities in conducting business ethics in the biopharmaceutical industry.

Back-up Slides

About IPMG



- A non-profit organization comprising of 24 research-based pharmaceutical companies operating in Indonesia
- Established in 2002
- A member of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)

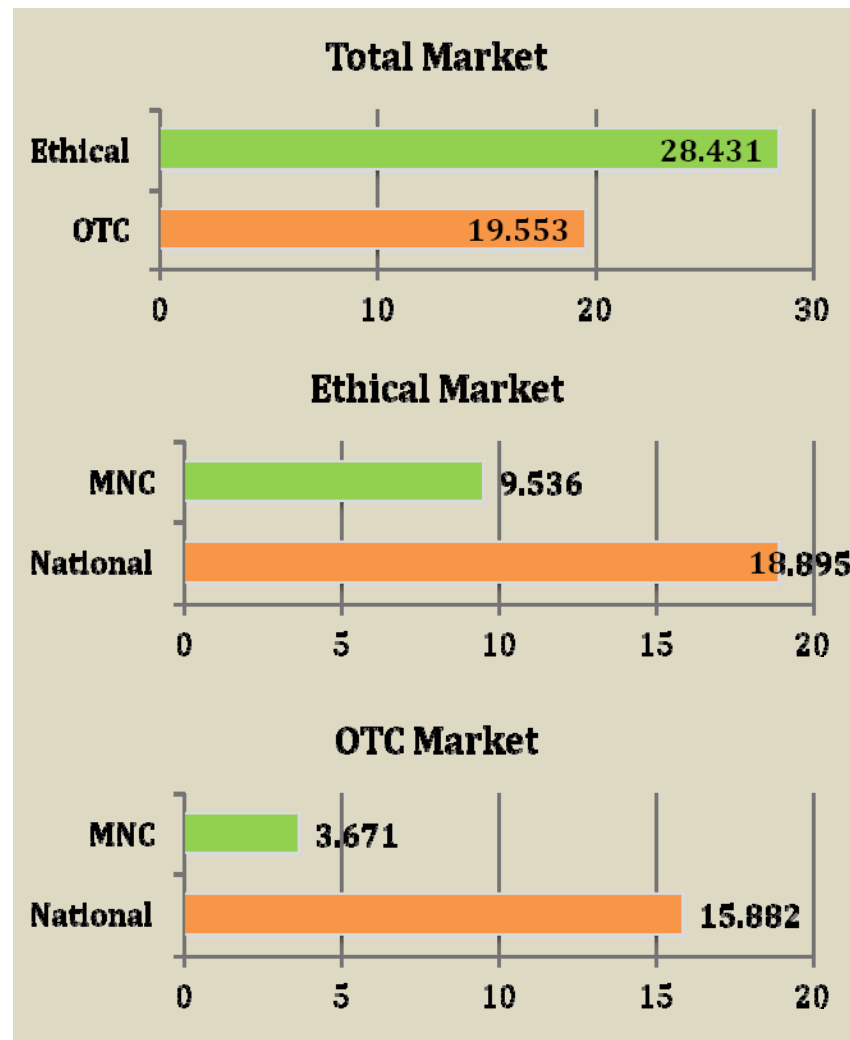
Pharmaceutical Code of Conduct in Indonesia

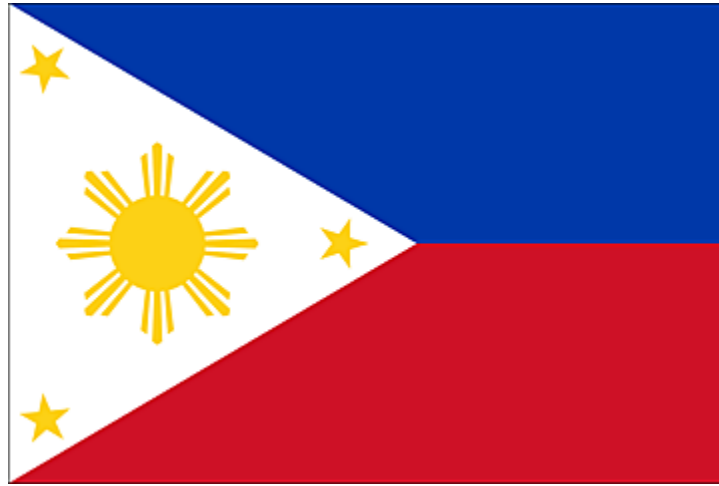


- **2001**
 - ▶ 1 January 2001 in co-existence with the Code of Conduct as issued by Gabungan Pengusaha Farmasi Indonesia (GPFI), the local pharmaceutical organization
- **2003**
 - ▶ Revised Code valid as of 1 January 2004, valid for both organization, GPFI and IPMG
- **2007**
 - ▶ Third revision in 2006 valid as of 1 January 2007 to be in line with IFPMA Code of Conduct. Valid for IPMG members only.
- **Annually revised**
 - ▶ Last revision in 2012 effective July 1, 2013

Indonesian Pharma Market

- Population estimated at 240 Million (2012)
- Market size of around USD 6.24 Billion (IMS 2012) or USD 26/capita/annum
- 58.9% Ethical and 41.1% OTC (IMS 2012)
- Market share of national companies 75% (Total)





Philippines



FRANCISCO P. TRANQUILINO, M.D., FPCP

PHAP Consultant on Ethics Matters

Chair, Ethics Committee, Philippine College of Physicians

Special Assistant to the Dean and College Secretary

University of the Philippines College of Medicine

PHAP ETHICS COMMITTEE ENFORCEMENT

- Formulate, promote and demonstrate adopted Code
- Make Code a living instrument to support ethical, promotional and monitoring activities
- Adjudicate cases and enforce Code

PHAP's Ethical Advocacy continues over the years:

The Mexico City Principles

For Voluntary Codes of Business Ethics in the Biopharmaceutical Sector

Worked with stakeholders for adoption of the MCP

- PHAP members
- Government (DOH & FDA)
- Medical and Specialty societies (PMA)
- Non-PHAP Members (PCPI & IFPMA members)



Active participant and collaborator

- Represented the industry in all IFPMA conventions
- Took measures to align the PHAP Code with the IFPMA Code and MCP
- Strongly collaborated on IFPMA Code administration in the Philippines through the PHAP Ethics Committee

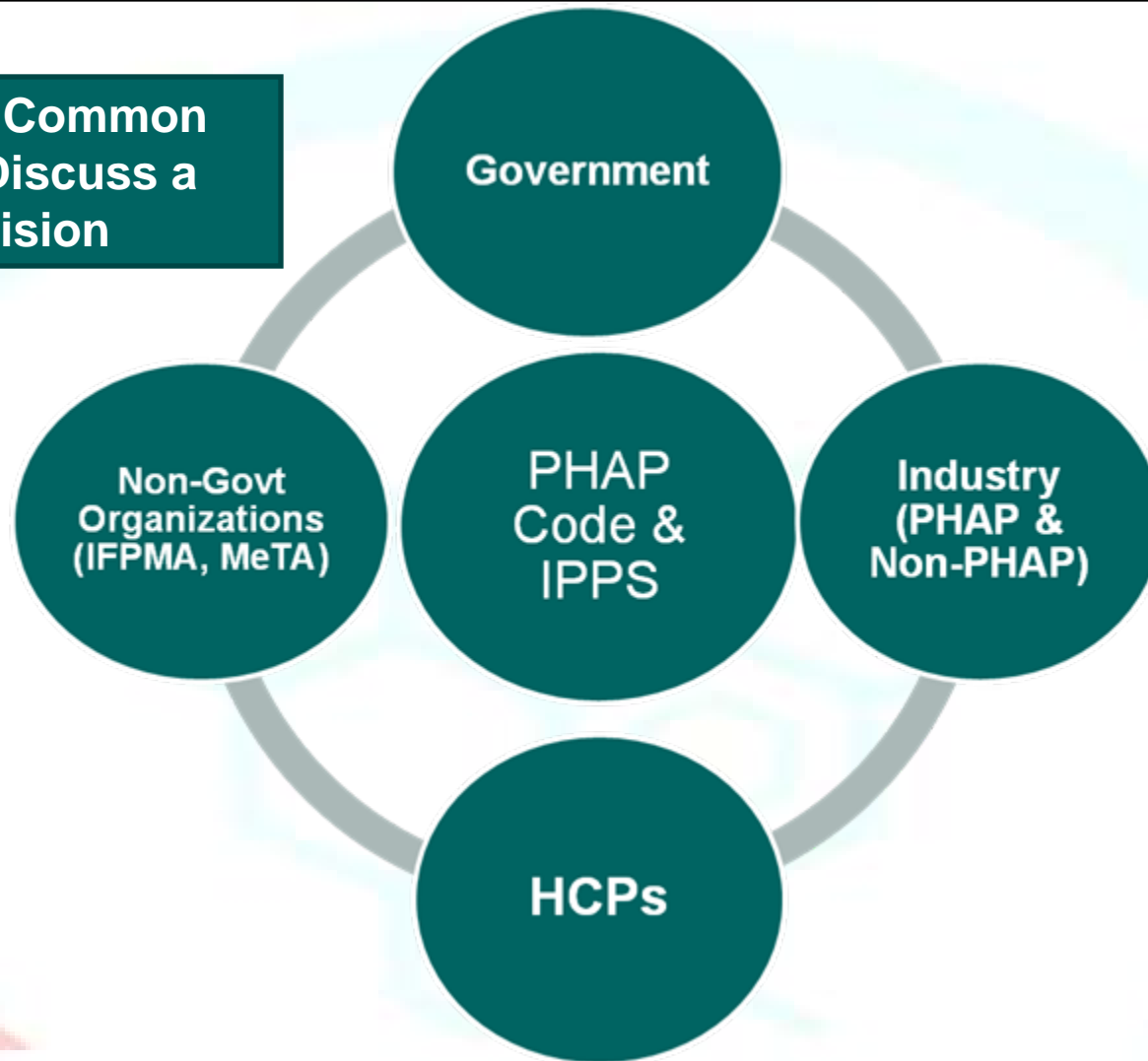


Reviewed and Strengthened the PHAP Code

- 2013 PHAP Code released. Implementation effective June 01, 2013
- Engaged more members in the review of the Code
- Ambiguous provisions clarified
- Strengthened administration of the Code

SUSTAINING THE GAINS THRU STRONGER ETHICAL COLLABORATION

Creating A Common Venue to Discuss a Common Vision



What PHAP wants to achieve:

- Further motivate members to adhere to the Codes (IFPMA, PHAP, MCP)
- Level the playing field between PHAP and non-PHAP members
- Demonstrate to stakeholders, esp. the HCPs the global trend towards regulation of the industry through ethical business practices
- Assist in the full implementation by the government of the MCP

Key Alliance with MeTA



The Philippines is one of the 7 pilot countries (along with Jordan, Peru, Kyrgystan, Ghana, Uganda and Zambia) of Medicines Transparency Alliance (MeTA) involved in developing health sector reforms. MeTA Philippines continue to look into technical issues like improving supply chain performance, fighting corruption and proliferation of fake drugs and improving purchasing practices.



Back-up Slides

WHAT IS PHAP?

- A group of pharmaceutical companies engaged in extensive R&D to discover breakthrough treatments and provide access to quality medicines that save peoples' lives.

MEMBERSHIP

- Made up of 52 member companies, both local & multinational.
- Founded in 1946, these include companies engaged in research-based companies, generic companies, pharmaceutical distribution and marketing companies, medical devices manufacturers, health research companies, over-the-counter pharmaceutical manufacturing companies and pharmaceutical retailers.

GOALS & PRINCIPLES

GOVERNING PRINCIPLES

- Good governance
- Management needs review
- Manage stakeholders' relations such as Promo Program

PHAP GOALS

- Foster good governance
- Review and update Ethics Code to adhere to international standards
(IFPMA, The Mexico City Declaration, etc.)

STRATEGIES

ADVOCACY & TRAINING

PHAP Awareness Campaign with Medical Associations/Societies

Phil. Medical Association

Philippine College of Physicians

Philippine Society of Ophthalmology

Hospital Pharmacists Association of the Philippines

Medical Doctors, Marketing & Sales people or member

Pharma Companies, NGOs, Academe

STRATEGIES

Internal Training Workshops

Conducted/Organized Code-related training sessions:

12 sessions in 2005 with 556 participants

8 in 2006 with 572 participants

6 sessions in 2007 with 302 participants

6 in 2008 with 362 participants

A Venn diagram with three overlapping circles. The top circle is labeled '2013 PHAP CODE'. The bottom-left circle is labeled 'IFPMA Code'. The bottom-right circle is labeled 'Mexico City Principles'. The circles overlap in the center and at the intersections between pairs of circles. The background features a large, faint, light blue circular graphic with a red segment on the left side.

**2013 PHAP
CODE**

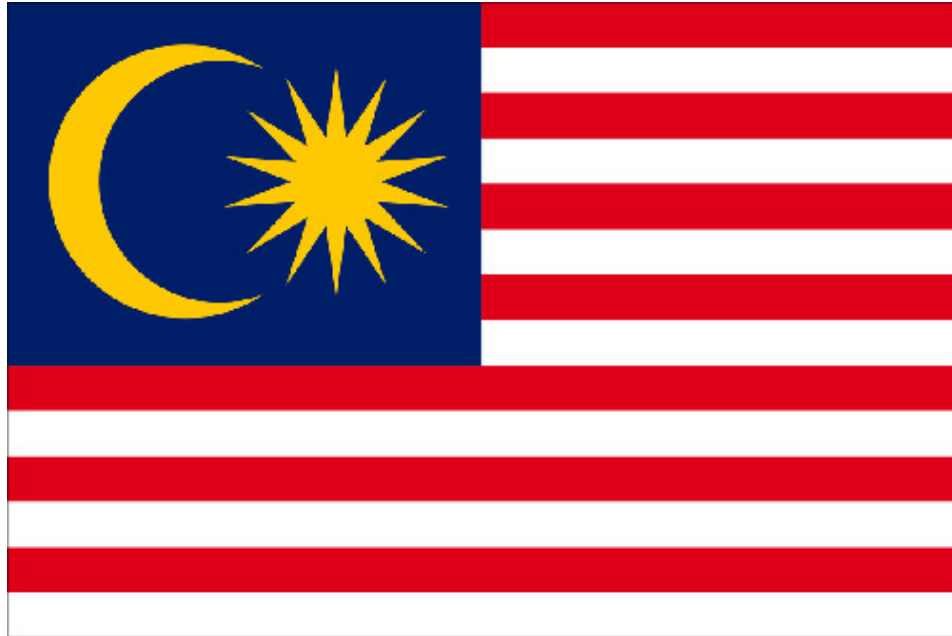
**IFPMA
Code**

**Mexico
City
Principles**

What is The PHAP Code of Practice?

- The Pharmaceutical and Healthcare Association of the Philippines (PHAP) as a member association of **the International Federation of Pharmaceutical Manufacturers Associations (IFPMA)** adopts in full and aligns with the Expanded Code of Practice of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and the **Mexico City Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector**.
- It incorporates local requirements and practices in relation to registration; labeling and scientific claims approved by the Philippine **Food and Drug Administration (FDA)**.
- PHAP and its members are committed to educational and promotional efforts that benefit patients as well as programs and collaborations that enhance the practice of medicine.





Malaysia

Recent changes/additions to the Code

- Keeping in mind - the code is a 'live' document
- The overall scope and objectives can be subject to change with the basis remaining the same
- Specifically - seeking the right venues for activities
- Fair market value for services provided by the HCP

Key challenges and developments

- Level playing field – versus non PhAMA members
- Creating a common mindset – bridging gaps between members themselves
- Stakeholder engagement – establishing relationships and/or collaborations with medical associations and ministry of health

Code implementation and potential future prospects

- Communicating the code to relevant stakeholders – to create understanding and alignment
- Highlighting the image of industry - areas of compliance and regulation – via the media – locally and internationally
- Working together to find out how best we can reach the patient – in an ethical and educational fashion

IFPMA Role

● Resource for Members

- IFPMA Code (English, French, Spanish and Japanese)
- IFPMA Website (incl. National codes and related info)
- IFPMA Sec provide support and guidance re Code related matters
- Training: Online e-learning tool and regional workshops

● Code Compliance Network (CCN)

- 100+ global experts from associations and companies
- Meet 2/year to discuss key trends, global code implementation, exchange best practices and decide on future developments

● Complaints Handling

- Process and adjudicate complaints in territories where there are no national codes or where member companies are not members of the local association
 - Adjudication Group of 3 independent experts
 - Appeal Group of 5 independent experts

For questions please contact:

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