International Federation of Pharmaceutical Manufacturers & Associations





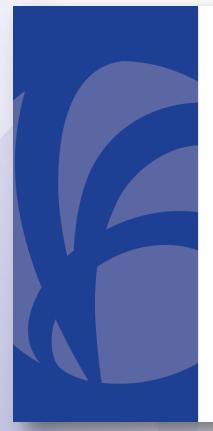
IFPMA Code of Practice 2012

Heather Simmonds
IFPMA CCN Vice-Chair and Director, ABPI/PMCPA UK

IFPMA/PhAMA Event on Ethical Collaboration 10 September 2013, Kuala Lumpur, Malaysia

Our Role and Commitment





International Federation of Pharmaceutical Manufacturers & Associations

IFPMA Code of Practice

2012



Focused on serving the best interests of patients, we have a moral obligation to communicate and participate in all relationships with integrity, accuracy and clarity. The IFPMA Code of Practice is a tangible example of the research-based pharmaceutical industry's commitment to making a strong contribution to global public health while adhering to the highest standard of practice.

Eduardo Pisani

Director General

International Federation of Pharmaceutical

Manufacturers and Associations (IFPMA)

Requirements of the Code



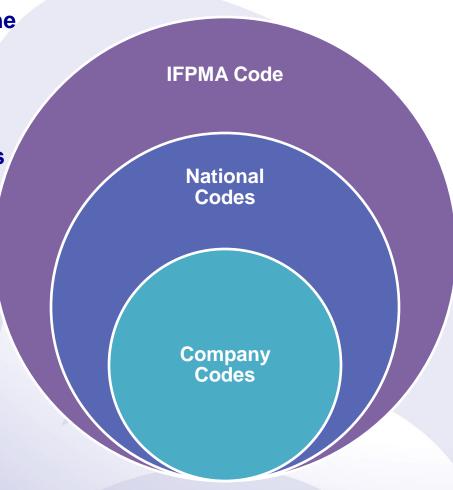
The IFPMA Code is guided by 10 high-level principles and requires that:

- patient safety and full information to health care professionals is the primary objective;
- promotional activities are carried out in a responsible, ethical and professional manner
- therapeutic choices of doctors should be based on objective information, and not swayed by nonscientific or non-transparent considerations
- a balance is sought between the needs of patients, health professionals and the general public

IFPMA Code – Global Standard



IFPMA Codes sets the global standard for research-based Multinational pharmaceutical companies' activities on pharmaceutical promotion and interactions.



IFPMA Codes applies to member companies and associations (direct members) and is a condition of membership; the Code also applies to companies belonging to national member associations (indirect members).

IFPMA Code Coverage



- The IFPMA Code <u>DOES</u> regulate:
 - Standards of promotional information incl.
 promotional material
 - Pre-approval
 Communications & Offlabel Use
 - Interactions with key stakeholders incl sponsorship to scientific congresses
 - Samples
 - Etc.

- The IFPMA Code <u>DOES NOT</u> regulate:
 - Pricing and Terms of Trade
 - Communication with the Public
 - Disclosure of Payments to HCPs, Patient Organizations and Medical Institutions

2012 Revision: Key changes

IFPMA

Scope – extended to cover interactions with healthcare professionals (HCPs), medical institutions and patient organizations

Principles – highlevel guiding principles developed that speak to the spirit of the code



Interactions with

HCPs – more clarity on provisions relating to hospitality, entertainment, gifts and samples Code Operating
Procedure – more
detail regarding
complaint processing
and breach remedies

2012 Revision: New Provisions





Fee for Services

Covers
 consultancy,
 market research,
 advisory boards,
 etc.

Clinical Research &
Transparency – all
human subject research
should be scientific and
educational in nature and
must not be disguised
promotion; Companies will
disclose clinical trial
information as set out in
the joint statement*



(CME) – General statement on the value of CME and requirement that CME must be education in nature, fair and balanced Interactions with
Patient
Organizations —
Includes scope,
definition, declaration
of involvement and
restrictions on events

10 Sept 2013

Company
Procedures and
ResponsibilitiesIncludes scope,
definition, declaration
of involvement and
restrictions on events

*IFPMA/EFPIA/PhRMA/JPMA Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases (2009) & IFPMA/EFPIA/PhRMA/JPMA Joint Position on Publication of Clinical Trial Results in the Scientific Literature (2010)

DOs & DON'Ts



GO ALLOWED

- Promotional Aids (strict provision)
- Items of Medical Utility (strict provision)
- Hosting of scientific promotional meetings
- Limited sponsorship to genuine scientific event
- Cultural Courtesy Gifts (i.e. inexpensive gifts not related to medical utility, and only if allowed by local law)
- Meals/Dinners if in connection to an event and secondary
- Etc....

NOT

- Monetary Gifts
- Personal Gifts (i.e. flowers, jewelry, cars, etc.)
- Recreational Activities (i.e. golf, tickets to sporting events, concert, vacations, etc.)
- Sponsoring of family events or paying for a guest/companion
- Meals/Dinners if not in connection to an event
- Any form of entertainment (i.e. company paid for musical performance during dinner)
- Etc.....

What does it mean in practice?



Global implementation: 1st September 2012



- Increased global standard on how research-based pharmaceutical companies conduct business and interact with key stakeholders
- Direct applicability of the IFPMA Code and the operating procedure of the IFPMA Code are in countries where there are no national codes or where a member company may not be a member of the local association
- Requires national and company codes to be revised as necessary to align with new provisions of the IFPMA Code

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IFPMA Code Compliance Network (CCN) & Resources

Tamara Music Manager, Code Compliance, IFPMA



IFPMA/PhAMA Event on Ethical Collaboration 10 September 2013, Kuala Lumpur, Malaysia

Code Compliance Network (CCN)



- Established in 2006
- Gathers worldwide experts to discuss latest developments and issues in the field of ethical promotion of medicines
- Composed of at least one representative from each IFPMA member association & member company
- Currently the network has over 100 members

IFPMA CCN – Key Activities



- Consultation on future code revisions
- Webinars on Code changes
- Training through Workshops
- Roll-out events in key regions
- Survey

IFPMA Code Changes & Implementation

Communication & Outreach

- Presentations at external events
- IFPMA organized events
- CEO Engagement
- Press Release
- Publications

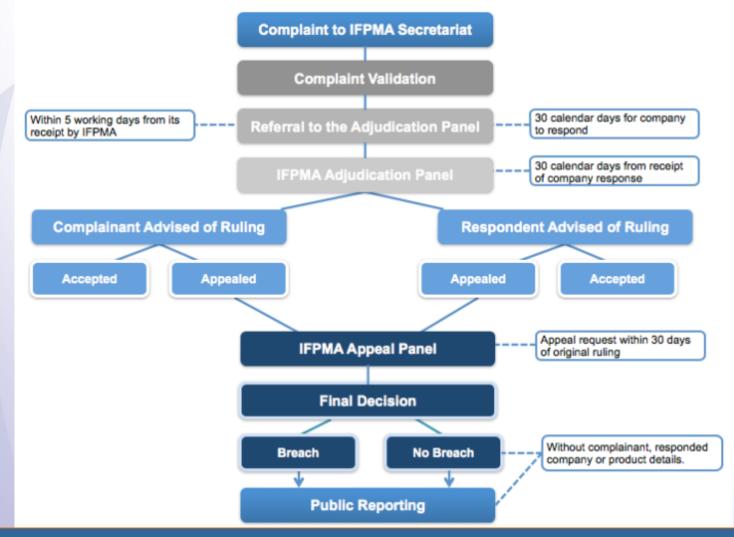
- Stakeholders Roundtable (2/year)
- Bilateral interactions
- Inviting stakeholders to IFPMA meetings
- Information exchange

Engagement with Stakeholders

(WMA, WHO, FIP, IAPO, ICN, etc.)

Code Operating Procedure

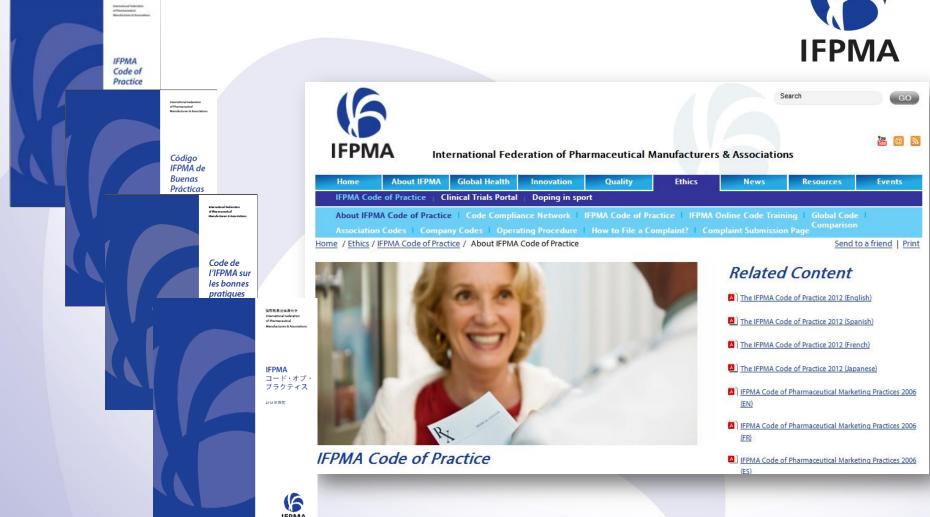




http://www.ifpma.org/ethics/ifpma-code-of-practice/operating-procedure.html

IFPMA Code Website





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

IFPMA Code e-learning Tool

IFPMA Code of Practice



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

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

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