The Role and Limits of Ethics Codes for the Pharmaceutical Industry

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Objectives

By the end of this session, you should be able to

• Explain the different sources of ethics codes in the pharmaceutical industry, the general content of these codes, and the consequences of violating them

• Distinguish between values and conduct codes

• Assess the advantages and limitations of ethics codes as a means of combatting corruption
What Is an Ethics Code?

A set of principles, standards, and/or rules designed to promote ethically acceptable decisions and actions by individuals and entities subject to the code.
Sources of Pharmaceutical Ethics Codes

- International organizations (e.g., WHO)
- Global industry associations (e.g., IFPMA, APEC)
- Regional industry associations (e.g., EFPIA)
- National industry associations (e.g., PhRMA)
- Individual companies
WHO ‘Ethical Criteria for Medicinal Drug Promotion’ (1988)
Exerts influence over company, health care professional and government codes, regulations and laws

International

IFPMA Code of Practice (first established in 1981; latest revision in 2012)

Global Company Codes of Conduct

US FCPA
UK Bribery Act
(global reach to some extent)

Regional

EFPIA Code of Practice

European Directives

National

Federación Centroamericana de Laboratorios Farmacéuticos FEDEFARMA

National Code of Practice of IFPMA Affiliated Associations

National Company Codes of Conduct

National Laws & Regulations
Issues Covered in Pharmaceutical Ethics Codes

- Overarching ethical principles
- Interactions with HCPs
- Interactions with patient organizations
- Providing medical information to prescribers
- Sponsorship for HCPs’ attendance at CME events
- Acceptability of venues and locations for meetings
- Hospitality limitations
- Fees for consulting services
- Providing promotional aids and samples
- Advertising
- Prohibition on promoting unlicensed products
- Prohibition on off-label promotion
- Transparency obligations
- Complaints mechanisms
Values vs. Conduct Codes

Values Codes

- Formal articulation of **broad ethical principles** to which those subject to the code are expected to adhere
- The most common ethical values found in corporate ethics codes include **integrity, fairness, honesty, trustworthiness, respect, openness**

Conduct Codes

- Specifies **particular behaviors** that are permitted or prohibited
- **Example:** “No colleague nor anyone acting on Pfizer’s behalf may ever offer, authorize or provide a payment or benefit that is intended to improperly influence—or even appears to improperly influence—a government official, or to gain any unfair business advantage.”
Consequences for Violations

- Requirement to cease non-compliant activity
- Publication of the outcome or public reprimand
- Requirement to issue a corrective communication
- Monetary penalties
- Additional pre-screening requirements
- Requirement for a formal audit of company procedures
- Suspension or expulsion from membership of the local trade association

*Some codes contain no formal consequences for violations*
Examples
WHO Ethical Criteria for Medicinal Drug Promotion

“The interpretation of what is ethical varies in different parts of the world and in different societies.”
WHO Ethical Criteria Examples

• The fact of sponsorship by a pharmaceutical manufacturer or distributor should clearly be stated in advance, at any symposium or scientific meeting.

• Any support to individual health practitioners to participate in any domestic or international symposia should not be conditional upon any obligation to promote any medicinal product.

• Medical representatives should make available to prescribers and dispensers complete and unbiased information for each product discussed, such as an approved scientific data sheet or other source of information with similar content.
IFPMA Code

• Updated 2006, 2012
• Condition of membership for IFPMA members (national associations and individual companies)
  • Companies that are not IFPMA members become bound to the IFPMA code through their membership in national associations
**Requirements of the Code**

The IFPMA Code is guided by 8 high-level principles and requires that:

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

STOP NOT ALLOWED
- 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)

© IFPMA 2013
APEC Code ("Mexico City Principles")

Adopted by APEC members in 2011

Based on the IFPMA Code

In 2014, the Philippines FDA announced that it would impose sanctions on companies that violate the APEC code.
APEC Code Principles

- **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 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.
# EFPIA Code

## EFPIA HCP Code

**EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals**

Adopted by EFPIA Board on 5 July 2007, and ratified by the EFPIA Statutory General Assembly of 19 June 2008

as amended by
the Statutory General Assembly on 14 June 2011 – amending Article 17 on Medical Samples (previously Article 16), and requiring implementation in national codes by 31 December 2011

as amended by
the Statutory General Assembly on 24 June 2013 – amending Article 10 (previously Article 9) on Events & Hospitality, Article 17 (previously Article 10) on Gifts, and introducing a new Article 9 on Informational & Educational Materials, and Items of Medical Utility, and requiring implementation in national codes by 31 December 2013

as amended by
the Statutory General Assembly on 6 June 2014 – amending para. 3 of the Section “Applicability of Codes” (p. 7), Section 9.03 (scope of materials and items considered) (p. 11), Section 10.5 (monetary thresholds) (p. 12) and Article 17 (clarification) (p. 16-17)

**Final Consolidated Version 2013**

Approved by the General Assembly of 6 June 2014

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EFPIA Code Coverage

Member Associations

- MUST adopt in their national codes provisions no less rigorous than the provisions contained in the EFPIA Code
- are ENCOURAGED TO tailor their national codes to adapt to national conditions and to adopt additional provisions that extend further than EFPIA’s minimum standards
- MUST establish appropriate complaint procedures and sanctions for breaches of their codes

Member Companies

- MUST EITHER be a member of the member association in each country where it conducts activities covered by the EFPIA Code OR agree in writing with each such member association that it is bound by such code
- MUST appoint at least one senior employee who shall be responsible for supervising the company and its subsidiaries to ensure that the standards of all applicable codes are met
Section 10.02. No company may organize or sponsor an event that takes place outside its home country unless:

a. most of the invitees are from outside of its home country and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the event in another country; or

b. given the location of the relevant resource or expertise that is the object or subject matter of the event, it makes greater logistical sense to hold the event in another country (an “international event”).
EFPIA Conference Vetting System

Through e4ethics, EFPIA pre-assesses meetings and events to ensure that they comply with the EFPIA Code. Pre-assessments focus on:

- **Scientific program schedule/structure** – the program should show that the event has a true scientific purpose;

- **Venue and exhibition area** – the venue must be conducive to the main purpose of the event (i.e., no venues known for their entertainment facilities);

- **Hospitality provided** (directly or indirectly) – hospitality shall be limited to travel, accommodation, registration fees and meal, and may not be extended beyond the duration of the event.

- **Other activities** – hospitality shall not include sponsoring or organizing any entertainment, sporting, or leisure events

- **Accompanying persons** – hospitality shall only include those who qualify as participants in their own right.
e4ethics Conference Assessment: 17th World Congress of Psychiatry

Name: 17th World Congress of Psychiatry (WPA BERLIN 2017)
Organised by: World Psychiatric Association (WPA)
Venue: Messe Berlin
City: Berlin
Country: GERMANY
Starting Date (dd/mm/yy): 09/10/2017
Ending Date (dd/mm/yy): 12/10/2017
App. Nr. of HCP: 1000
Speciality: Psychiatry
Website: http://www.wpaberlin2017.com

The pre-assessment of events provided on e4Ethics cannot, under any circumstance, be interpreted as a judgement on the quality or content of the scientific programme, or on the quality of the speakers.

It is the company’s individual decision to decide to sponsor / participate in the event. Companies belonging to the EFPIA membership should be mindful of the rules and provisions that apply when deciding to sponsor, participate or collaborate in an event.

EFPIA pre-assessment: (Date (dd/mm/yy): 03/07/2017)

- Scientific Programme Schedule / Structure
  It is recommended to check the rules prevailing under applicable national codes.

- Location and Venue
  It is recommended to check the rules prevailing under applicable national codes.

- Hospitality Provided (Directly or Indirectly) to HCP
  Concern may arise with regard to EFPIA HCP Code provisions, for the following reasons:
  Hospitality may not be reasonable.
  Accommodation is (directly or indirectly) provided beyond the duration of the scientific programme.

- Other Activities
  Concern may arise with regard to EFPIA HCP Code provisions, for the following reasons:
  Pre-congress and/or post-congress sightseeing tours are organised in connection with the event.
  Sightseeing tours are organised in connection with the event.
  Leisure activities are organised in connection with the event.

- Accompanying Persons
  Concern may arise with regard to EFPIA HCP Code provisions, for the following reasons:
  Accompanying persons shall not be invited to the event or activities organised in connection with it.
  An alternative programme is proposed for accompanying persons.

It is always recommended to check the rules prevailing under applicable national codes.

EXHIBITIONS – please read carefully the provisions of the EFPIA HCP Code and the additional guidance.
Code on Interactions with Healthcare Professionals

2016
National Industry Association Codes

- More detailed than international or regional codes
- Frequently updated
- Enforcement mechanisms
  - Reporting systems
  - Complaint handling procedures
  - Pre-approval requirements
Prescription Medicine Code of Practice Authority (UK) Complaint Process

- **Complaint to Prescription Medicine Code of Practice Authority**
  - Code of Practice Panel
    - Can report companies to appeal board
      - Complainant advised of ruling
        - Accepted
        - Appealed
      - Respondent advised of ruling
        - Accepted
        - Appealed
      - Code Practice Appeal Board
        - Can report companies to ABPI Board
          - ABPI Board of Management
PMCPA Sanctions

- Company must give an **undertaking** that the practice in question has ceased and that all possible steps have been taken to avoid a similar breach in the future.

- Additional sanctions can include:
  - **audits**, possibly followed by requirement that promotional material be submitted for pre-vetting for a specified period.
  - requiring the company to take steps to **recover items** from those to whom they have been given.
  - requiring the company to issue a **corrective statement**.
  - **public reprimand**.
  - **suspension or expulsion** from membership of the ABPI.

- The PMCPA **advertises** in the medical and pharmaceutical press brief details of all cases where companies are ruled in breach of Clause 2 of the Code, are required to issue a corrective statement or are the subject of a public reprimand.
AUTH/2917/12/16 - Anonymous, non-contactable v Janssen

Case number: AUTH/2917/12/16
Case ref: Anonymous, non-contactable v Janssen

Description:
Conduct of a representative
No breach: No Breach Clauses 2 and 9.1
Breaches: Breach Clause 15.2

Appeal: No appeal
Review: Published in the February 2017 Review
Received: 21/12/2016
Completed: 31/01/2017

Click here to suggest your own keywords for this case (cases/pages/suggestkeyword.aspx?cn=AUTH/2917/12/16)

Case Summary:
An anonymous, non-contactable complainant, who stated he/she was a general practitioner submitted a complaint about a named Janssen representative.

The complainant alleged that the representative was appointed based on the roles of his/her family members in primary care. The representative’s parent was the local clinical commissioning group (CCG) clinical lead and diabetic lead and the representative was married to a local general practitioner (GP) and the in-law of another.

The complainant stated that the representative and Janssen manager recently saw a colleague and the representative had since bragged about how this manager informed the complainant’s colleague that the representative’s previous companies were foolish to let the representative go when the representative’s parent was the clinical diabetic lead and could influence prescribing of the product promoted by his/her child.

The detailed response from Janssen is given below.

The Panel noted that there would be occasions when representatives had links with health professionals and other relevant decision makers which would be of potential concern. In such cases it might be prudent for companies to consider changing a representative’s territory so they did not call upon such people. The external perception of the arrangements was important.

It appeared in this case that the representative had a number of close relatives in the territory who were either health professionals or relevant decision makers. That the representative’s parent was a locum GP was disclosed to the hiring manager during initial conversations about the employment opportunity with Janssen. It appeared that the hiring manager had not probed for more detail in that regard. The parent’s position as chair of the local diabetes network only came to light in an email from the representative late in 2016. Given that the representative’s parent had an interest in diabetes (as noted on the CCG website), the Panel queried why Janssen did not previously know about this before engaging the representative. The Panel noted that Janssen appeared to have only recently discovered that other GPs called upon by their representative with the same surname, were related.

The Panel noted that Janssen had a policy to ensure that staff disclosed interest or relationships which conflicted with the interests of the company. The policy included examples of conflicts or the appearance of a conflict and specifically referred to family members. It was stated that any activity which even appeared (emphasis added) to present a conflict must be avoided or terminate unless an appropriate level of management deemed otherwise. The representative had not informed the company of the close links he/she had with health professionals in one surgery and the role the representative’s parent had as diabetes lead with the local CCG. In the Panel’s view these close interests were a concern. There was no evidence that the representative had influenced the relatives but the company should have been informed so that it could take appropriate action to ensure there were no conflicts of
Company Codes

Our Code of Conduct
Living our values

The Blue Book
Summary of Pfizer Policies on Business Conduct

Committed to COMPLIANCE
Conducting ourselves with integrity helps us earn the trust and respect of the people we serve.

OUR VALUES AND STANDARDS
THE BASIS OF OUR SUCCESS

Code of Conduct | Edition II
Examples from Company Codes

• “Employees shall not treat customers or suppliers in an unfair and unprofessional manner.”

• “Offers and proposals must be evaluated objectively on the merits of price and performance.”

• “We must not offer or give money or other anything else of value either as an inducement to make, or as a reward for making, any decision favorable to the interests of [the company].”
Impact of Codes

Advantages

- The process of developing and adopting a code can lead to greater understanding and acceptance of what is expected
- Codes can have an expressive function that reinforces a culture of compliance
- Active self-regulation can leverage limited resources of government enforcers

Uncertainties

- Gaps in coverage
- Strong language may not reflect how codes are communicated/understood in practice
- Penalties for violation may not be significant for all actors
- Can we trust self-regulation?
Conclusions

- Ethics codes can play an important role in combatting corruption by establishing and reinforcing expectations for appropriate conduct and creating standards and procedures for self-regulation.

- Ethics codes are unlikely to be effective in the absence of a strong regulatory environment and a culture of compliance.

I'm just slipping into something more ethical.