European Federation of Pharmaceutical Industries and Associations

IPCC - EFPIA Codes Workshop
Relationships with Patient Organisations

Agata Polinska - Cécile Gousset – Heather Simmonds – Julie Bonhomme






Presentation

Workshop Programme

Timing	Agenda Item	Introduction of topics by…
10:00	**Opening Remarks** **Consolidation of Codes** Co-existence of applicable codes and how they relate to collaborations and interactions in the healthcare sector Introduction to topical panels	Marie-Claire Pickaert, EFPIA Deputy Director General (Chief Ethics & Compliance Officer)
10:15	**Meetings & Hospitality** Events organised or sponsored by or on behalf of a Member Company must be held in an "appropriate" venue that is conducive to the main purpose of the event and may only offer hospitality when such hospitality is appropriate and otherwise complies with the provisions of any Applicable Code(s).	**Panel** Krzysztof Kaluzny (Infarma PL) **Christian-Claus Roth (IPCAA)** José Zamarriego (Codigo Spain)
10:45	**Advisory Boards** Activities relating to pre-marketing authorisation Activities following marketing authorisation Ongoing development of medicines and innovative extension of the label	**Panel** Holger Diener (FSA Germany) **Stephen Nguyen-Duc (E&CC)** Heather Simmonds (PMCPA UK)
11:15	**Relationships with Patient Organisations** All partnerships between patient organisations and the pharmaceutical industry shall be based on mutual respect, with the views and decisions of each partner having equal value.	**Panel** Julie Bonhomme (EFPIA) **Cécile Gousset (E&CC)** Agata Polińska (Alivia Foundation)
11:45	**Transparency** By the end of June 2016, EFPIA member companies will be disclosing details of collaborations with health professionals (HCPs) and healthcare organisations (HCOs) across Europe. Bringing greater transparency to this, already well-regulated and vital relationship aims to build greater understanding of industry, HCP and HCO collaboration.	**Panel** **Dominique Laymand (ETHICS)** Marie-Claire Pickaert (EFPIA) Pawel Sztwiertnia (Infarma PL)
12:15	**Concluding remarks**	
12:30	Close of the Workshop	

EFPIA PO Code – Key ethical principles

- **Independence** of POs in their political judgement, policies and activities
- **Mutual respect** and equal value of each decision
- **Non-influence** on a particular prescription-only medicine
- **Transparency** of any partnership
- **Multiple source of funding** for POs

European Directive 2001/83/EU

- Advertising prohibition
  - Prohibition of advertising for prescription-only medicines to the general public and so, to the patient organisations which are not specifically defined in the directive

- Information allowed
  - the labelling and the accompanying package leaflets
  - correspondence needed to answer a specific question about a particular medicinal product
  - factual, informative announcements and reference material
  - statements relating to human health or diseases

EMA interaction with patients and patient organisations

- This interaction exists since the EMA creation in 1995.
  - They bring a “real-life” experience as well as specific knowledge and expertise to scientific discussions on medicines and on the impact of regulatory decisions.

- Activities concerned:
  - Permanent “Patients and Consumers Working Party”
  - members of the management board, scientific committees, being consulted on disease-specific requests, taking part in discussions on the development and authorisation of medicines, etc.

CODE OF PRACTICE

for the

PHARMACEUTICAL INDUSTRY

2016

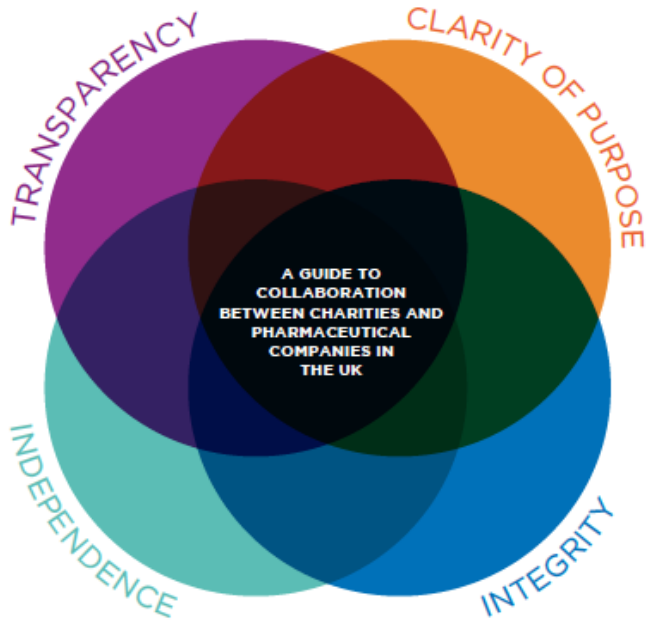
PMCPA | Prescription Medicines Code of Practice Authority

National Voices
People shaping health and social care

abpi
Bringing medicines to life

Working together, delivering for patients

A guide to collaboration between charities and pharmaceutical companies in the UK



Relations with the General Public and the Media

- Disease awareness campaigns
- Corporate advertising
- Press releases
- Sponsorship of material
- Patient leaflets/websites
- Patient organisations

CLAUSE 26 Relations with the Public and the Media

- Prescription only medicines cannot be promoted to the public (exemption for approved vaccination campaigns)
- Information made available directly or indirectly to the public must be factual and balanced etc
- Statements must not be made for the purpose of encouraging the public to ask health professionals to prescribe a specific prescription only medicine

CLAUSE 26.2 Supplementary information

Permits reference information as a library resource giving information relating to POMs which have marketing authorizations.

Includes:

- regulatory information SPC, PAR, package leaflet
- registration and other studies
- medicine guides
- disease information
- specific medicine information
- material supplied for health technology assessments (NICE, AWMSG, SMC).

Reference information must represent fairly the current evidence relating to a medicine and its benefit/risk profile.

CLAUSE 26 – Relations with the Public and the Media

Any material which relates to a medicine and which is intended for patients taking that medicine must include a statement encouraging the patient to report any side effects

When the material relates to a medicine which is subject to additional monitoring an inverted black equilateral triangle must be included together with an explanatory statement.

CLAUSE 27 Relationships with Patient Organisations

- Must respect the independence of patient organisations
- Involvement of the company and the nature of that involvement made clear

CLAUSE 27 Relationships with Patient Organisations

- Companies must make public a list of all organisations to which they provide financial support and/or significant indirect/non financial support including descriptions of that support and monetary value of invoiced costs
- For significant non-financial support that cannot be assigned a meaningful monetary value the published information must describe clearly the non monetary value that the organisation receives

CLAUSE 27 Relationships with Patient Organisations

When a company engages the services of a patient organisation, detailed requirements including:

- Written contract/agreement
- Legitimate need for the services
- Appropriate criteria for selection and payment
- Engagement must not be an inducement to recommend a particular medicine

CLAUSE 27 Relationships with Patient Organisations

When a company engages the services of a patient organisation, detailed requirements including:

- Contract to strongly require patient organisations to declare that they have provided paid services to the company when they write or speak in public
- Publish a list of patient organisations engaged to provide significant contracted services
- Declare total amount paid per patient organisation

CLAUSE 27 Relationships with Patient Organisations

A company must not:

- Require that it be the sole funder of a patient organisation or of its programmes
- Make public use of a patient organisation's logo or material without prior written permission
- Seek to influence patient organisation material in a manner favourable to its own commercial interests (factual errors can be corrected)

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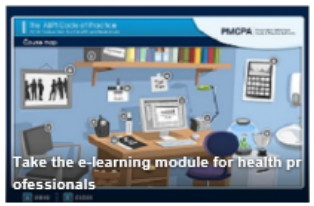

The Prescription Medicines Code of Practice Authority (PMCPA) was established by The Association of the British Pharmaceutical Industry (ABPI) to operate the ABPI Code of Practice for the Pharmaceutical Industry, independently of the ABPI.

The ABPI Code covers the promotion of medicines for prescribing to health professionals and other relevant decision makers. The Code also sets standards for information made available to the public about prescription only medicine. Advertising or promoting prescription only medicines to the public is prohibited under the ABPI Code and the UK law.

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The Prescription Medicines Code of Practice Authority (PMCPA) was established by The Association of the British Pharmaceutical Industry (ABPI) to operate the ABPI Code of Practice for the Pharmaceutical Industry independently of the ABPI. The PMCPA is a division of the ABPI which is a company limited by guarantee registered in England & Wales no 09826787, registered office 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT.

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- Download the ABPI disclosure template
- Download the Clause 3 Guidance
- Download the Digital Guidance
- Download the Guidance about Certification
- Download Guidance on Clause 18
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