PMCPA | Prescription Medicines Code of Practice Authority

BrAPP Education Day

Thursday, 14 March 2019

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Agenda

- The 2019 Code – key changes to the 2016 Code
- IFPMA Code
- Cases published in 2018
- Learnings from 2018 cases

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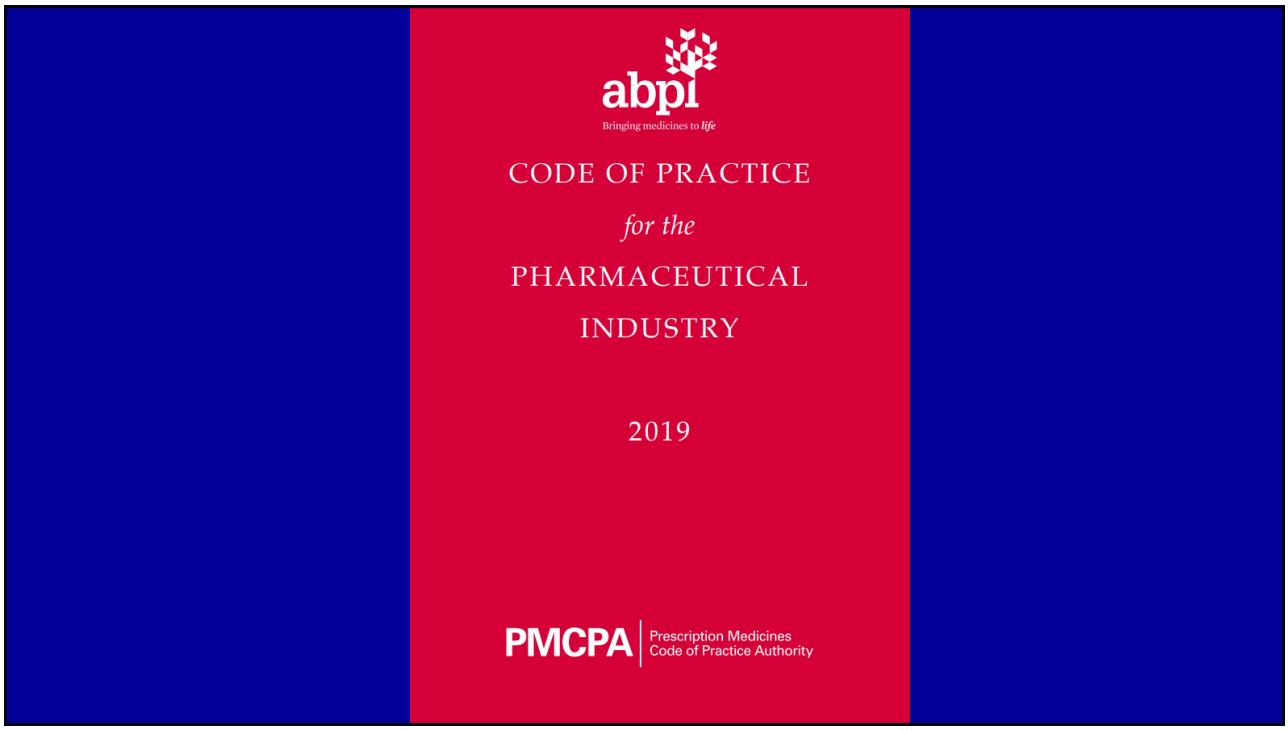


Hierarchy of regulation

- Q&A
- Supplementary information
- Code

2019 ABPI Code

- Key changes include:
  - Early Access to Medicines Schemes
  - Conditional Licensing

2019 ABPI Code

Key changes include:

- Risk minimisation plans

Clause 1.2 Supplementary Information – Definition of Promotion

Amendment

To add new supplementary information referring to risk minimisation plans and material.

New text

'Clause 1.2 Risk minimisation plans and material

As part of the marketing authorization process companies can be required to have risk minimisation plans and material approved by the MHRA as part of the company's pharmacovigilance obligations. Such approved documentation is exempt from the definition of promotion and can be delivered by a representative or included on a company website without being considered to be promotion of the medicine to which it refers.'

2019 ABPI Code

Key changes include:

– Provision of prescribing information

Clause 4.4 Supplementary Information – Use of Links for Prescribing Information

Amendment

Remove the reference to emails and the like in relation to material viewed offline and add it to material generally expected to be viewed online.

To read

When digital material provides the reader with a link to prescribing information on another website then such a link should only be included for use when the material is generally expected to be viewed online, for example, advertisements in electronic journals, emails, electronic detail aids when used remotely and the like. This is to ensure that at the time of reading the link is active and will provide readers with the necessary information. When material is more likely to be viewed offline, such as electronic detail aids to be used by representatives when visiting health professionals, then the requisite information must be provided as part of the item itself or as a link that does not require the reader to be online.

2019 ABPI Code

Key changes include:

– Clause 14 Certification

Clause 14.1 Supplementary Information – Certification

Amendment

Amend the second sentence, second paragraph to allow the printed material to be checked by an appropriately qualified person rather than a signatory.

To read

When certifying material where the final form is to be printed companies can certify the final electronic version of the item to which no subsequent amendments will be made. When such material is printed the company must ensure that the printed material cannot be used until an appropriately qualified person has checked and signed the item in its final form. In such circumstances the material will have two certificates and both must be preserved.

2019 ABPI Code

Key changes include:

– Clause 14 Certification

Clause 14.1 Supplementary Information – Certifying Digital Materials

Amendment

To amend to remove the requirement to certify all possible combinations.

To read

When certifying dynamic content for websites, care must be taken to ensure the dynamic content meets the requirements of the Code as a standalone item. As the final form of digital material might not be static, consideration needs to be given to the context in which it appears but each possible combination does not need to be certified.

2019 ABPI Code

Key changes include:

– Clause 14 Certification

Clause 14.2 Meetings Involving Travel Outside the UK

Amendment

To remove the reference to UK company funding UK delegates and to allow material to be certified by an appropriately qualified person.

To read

14.2 All meetings which involve travel outside the UK, unless the company's only involvement is to support a speaker to present at the meeting must be certified in advance by an appropriately qualified person. That person does not need to be either a registered medical practitioner or a UK registered pharmacist.

2019 ABPI Code

Key changes include:

– Clause 14 Certification

Clause 14.2 Supplementary Information – Meetings Involving Travel Outside the UK

Amendment

New supplementary information to set out what is required.

New text

Clause 14.2 Suitable Qualifications for those who Certify Meetings Involving Travel Outside the UK

In deciding whether a person is appropriately qualified to certify meetings involving travel outside the UK when this is done by someone other than a registered medical practitioner or a UK registered pharmacist, account should be taken of relevant experience both within and outwith the industry, length of service and seniority. In addition such a person must have an up-to-date and detailed knowledge of the Code.

2019 ABPI Code

Key changes include:

– Clause 18 Package deals

Clause 18.1 Supplementary Information – Package Deals

Amendment

To add a new paragraph that package deals relating to ordinary course purchases are exempt from the requirements to disclose . To similarly amend the supplementary information to Clause 1.10 excluded disclosures.

New text

The supplementary information to Clause 1.10 exempts package deals relating to ordinary course purchases and sales of medicines from the requirement to disclose. Transfers of value made in the course of other package deals would need to be disclosed in accordance with Clause 24.

2019 ABPI Code

- Key changes include:
  - Constitution and Procedure
  - Principles of self-regulation

PRINCIPLES AND OVERVIEW OF SELF REGULATION

1. The pharmaceutical industry in the United Kingdom is committed to benefiting patients by operating in a professional, ethical and transparent manner to ensure the appropriate use of medicines and support the provision of high quality healthcare.
2. Patient safety is the priority. All information relating to safety must be shared accurately and transparently.
3. The aim of the Code is to ensure that the promotion of medicines to health professionals and other relevant decision makers and other activities are carried out within a robust framework to support high quality patient care.
4. Prescription only medicines must not be promoted to the public.
5. Working with patients and patient organisations can bring significant public health benefits.
6. Information about prescription only medicines made available to the public must be factual, balanced, not misleading and must not encourage prescription of a specific prescription only medicine.
7. Whilst the industry has a legitimate right to promote medicines to health professionals, the Code recognises and seeks to balance the needs of patients, health professionals and the public, bearing in mind the environment within which the industry operates and the statutory controls governing medicines.
8. The Code supports the prescribing decisions of health professionals.
9. Transparency is an important means of building and maintaining confidence in the pharmaceutical industry.
10. Companies must ensure that their materials are appropriate, factual, fair, balanced, up-to-date, not misleading and capable of substantiation and that all other activities are appropriate and reasonable. Promotion must be within the terms of the marketing authorization and not be disguised. Material must be tailored to the audience.
11. Companies are responsible under the Code for the activities of their staff and third parties. Training must be provided.
12. It is a condition of membership of the ABPI to abide by the Code in both the spirit and the letter. In addition many non member companies agree to comply with the Code and accept the jurisdiction of the PMCPA.
13. Any complaint made against a company under the Code is regarded as a serious matter both by that company and by the industry as a whole. Sanctions are applied against a company ruled in breach of the Code.

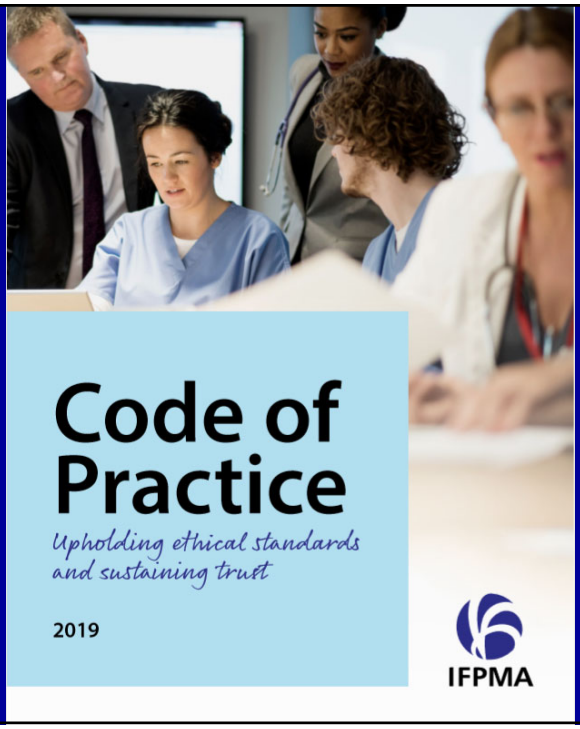
Director of Code Engagement

Purpose

- Demonstrate ABPI commitment to ethical stance and self-regulation
- Achieve reputational benefit for industry from ABPI Code
- Secure and maintain strong industry and stakeholder support for self-regulation

Areas of work

- Champion self-regulation
- Code development
- Support, training and advice



IFPMA

IFPMA Note for Guidance on Fees for Services

Preamble

The purpose of this document is to provide additional interpretation and further guidance towards the relevant provisions of the Code of Practice. This Note for Guidance is not binding by itself. It must be read with the spirit of the Code in mind and always in accordance with applicable laws and regulations and other applicable industry codes. IFPMA member companies and member associations are encouraged to take into account the considerations given in this Note for Guidance when implementing the IFPMA Code of Practice in their daily practice. The overall intention of this Note for Guidance is that the cooperation between companies, HCPs and other stakeholders is always based on high ethical standards and clearly aims to benefit patients.

Introduction

Pharmaceutical companies can compensate healthcare professionals and others for advice on subjects relevant to their products or business. Payment of fees for services are covered in Article 7.4 of the IFPMA Code of Practice including the requirement for a legitimate need for the service and that a written contract be agreed in advance. Fees for services include many activities such as speaking at and/or chairing meetings and events, involvement in medical/scientific studies, clinical trials or training services, participation in advisory board meetings, participation in market research. If a fee for service is offered it should be made clear that it is a payment for such work and advice. Fees for services must be commensurate with the time and effort involved and the professional status of the recipients. Article 7.4 of the IFPMA Code requires that compensation must be reasonable and reflect the fair market value of the services provided. Account should be taken of the country of practice of each participant.

Practical Guidance – points to consider

The IFPMA considers that the following points are helpful to ensure that fee for service arrangements meet the required standards and that the relevant information is available to those assessing proposals. The points to consider reflect what information might be required in the event that a company has to respond to a complaint.

The answers to the following questions should be 'yes':

1. Are the participants being paid no more than 'fair market value'?
2. If the product/indication is unlicensed, is the company confident that there is no promotion of that medicine/indication?
3. Are all those involved with the fee for service activity (staff, third parties, participants) clear on the need for it and expected output?
4. Are the arrangements (such as venue, refreshments, travel, and contract) appropriate?
5. Are there arrangements to manage any conflicts of interest?
6. Are the number of engagements and total compensation paid to an individual in one year reasonable?

IFPMA

IFPMA Note for Guidance on Sponsorship of Events and Meetings

Preamble

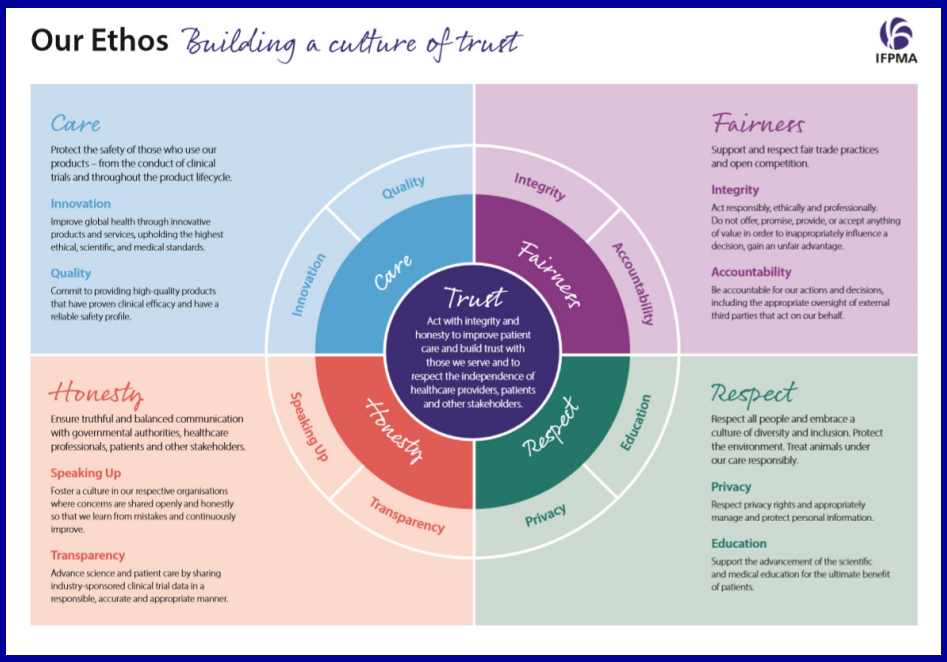
The purpose of this document is to provide additional interpretation and further guidance towards the relevant provisions of the Code of Practice. This Note for Guidance is not binding by itself. It must be read with the spirit of the Code in mind and always in accordance with applicable laws and regulations and other applicable industry codes. IFPMA member companies and member associations are encouraged to take into account the considerations given in this Note for Guidance when implementing the IFPMA Code of Practice in their daily practice. The overall intention of this Note for Guidance is that the cooperation between companies, HCPs and other stakeholders is always based on high ethical standards and clearly aims to benefit patients.

Introduction

Advancing medical knowledge and improving global public health remains a priority for the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) representing the research-based pharmaceutical industry. Collaborations between healthcare professionals and the pharmaceutical industry are essential and ensure that patients have access to the medicines they need and that healthcare professionals have up-to-date comprehensive information about the diseases they treat and the medicines they prescribe. IFPMA members remain committed to activities that provide scientific and educational content to healthcare professionals and advance their medical knowledge and expertise.
These activities may take place through various means and media.

The IFPMA Code of Practice sets global standards for industry business practices and includes guiding principles of ethical conduct and promotion as well as requirements for the promotion of medicines to health professionals and interactions with healthcare professionals and other stakeholders. The pharmaceutical industry provides various types of support for a wide range of local, national, and international meetings including funding to assist in the medical education of healthcare professionals, provision of sponsorship agreements to medical societies organizing events, hiring of exhibition space, support of speakers, etc. Pharmaceutical companies are involved in the medical education through company specific meetings, and also by supporting meetings organized by other parties. These activities are covered by Article 7 (Events and Meetings) of the IFPMA Code. The reason for attending such meetings should be the educational value and not other factors such as the location, venue, hospitality or timing of the meeting. The choice of location and venue must be appropriate, conducive to the educational objectives and modest. In determining whether to support an event consideration should be given to the educational program, overall cost, facilities offered by the venue, justification for the location, nature of the audience, hospitality and for certain situations, security arrangements. The overall impression given by all of the various arrangements should be kept in mind. Pharmaceutical companies might find it helpful to clearly document the reasons as to why they decide to support or run a meeting. Member Associations' codes and member companies' policies and procedures are often even more prescriptive than the IFPMA Code in relation to arrangements for meetings.

The purpose of this document is to provide more information in relation to relevant requirements of the IFPMA Code of Practice. In this respect, the guidance intends to:



Cases published in 2018

Highlights and lowlights

Case AUTH/3015/1/18

- Have all final signatories been notified to MHRA and PMCPA?
- Did you receive a response from us acknowledging that it was received?

Case AUTH/2979/9/17

- Complaint about a 'Meetings Highlights' document with the disclaimer
  - 'This newsletter has been funded by an unrestricted educational grant provided by PharmaMar S.A. PharmaMar S.A has not been involved in the production, review or distribution of this material'.
- The material mentioned off-label use of Yondelis.
- PharmaMar gave the money to BSG so that it could deal with the medical writer etc after the document had been drafted and the company realised the difficulties with the references in the document to the unlicensed use of Yondelis.
- The Panel was extremely concerned that the changes to the Meeting Highlights document suggested by PharmaMar showed a very poor understanding of the Code.
- The Panel was also concerned about PharmaMar's arrangements for certification.
- The Panel therefore decided, in accordance with Paragraph 8.2 of the Constitution and Procedure, to report PharmaMar to the Appeal Board.

Matters arising from 2018/2019 cases

SPC and prescribing information updates:

- Governance at international and local levels:
  - international, local and functional responsibilities
  - SOPs – consistency
- Does SPC update trigger change to prescribing information:
  - two formats of prescribing information
- Materials and activities:
  - current materials list
  - scope of review
  - third parties

Matters arising from 2018/2019 cases

- Corporate websites:
  - references to medicines compliant with Clauses 26 and 28
  - up-to-date?
- Other company websites:
  - captured on current materials list
- Social media:
  - Twitter
  - LinkedIn
- Company guidance on social media:
  - local guidance
  - regulatory updated
- Black triangle

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