PMCPA | Prescription Medicines Code of Practice Authority

ABPI Code of Practice

Wednesday, 12 February 2014

Heather Simmonds
Director
Prescription Medicines Code of Practice Authority
www.pmcpa.org.uk

Prescription Medicines Code of Practice Authority

Heather Simmonds, Director
Etta Logan, Deputy Director
Jane Landles, Secretary
Tannyth Cox, Deputy Secretary

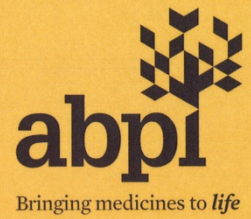
Appointed by and reports to ABPI Board of Management.

ROLE:

Responsible for administration of the Code and complaints procedure including provision of advice, guidance and training.

Arranging the scrutiny of advertising and meetings.

Arranging conciliation.



CODE OF PRACTICE

for the

PHARMACEUTICAL INDUSTRY

2014

PMCPA | Prescription Medicines Code of Practice Authority

Confidential **Not for Publication**

CODE OF

SALES PROMOTION PRACTICE

FOR

MEDICAL SPECIALITIES

IN THE UNITED KINGDOM

October, 1958

THE ASSOCIATION OF BRITISH PHARMACEUTICAL INDUSTRY

Tavistock House South
Tavistock Square
London W.C.1
EUSton 2531/3

International Codes, Guidelines & Legislation

- IFPMA, EFPIA
- WHO
- UK & European Law

efpia

European Federation of Pharmaceutical Industries and Associations

EFPIA HCP/HCO DISCLOSURE CODE

EFPIA CODE ON DISCLOSURE OF TRANSFERS OF VALUE FROM PHARMACEUTICAL COMPANIES TO HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS

Adopted by the EFPIA Statutory General Assembly of 24 June 2013, and requiring implementation in national codes by 31 December 2013

FINAL EDITED VERSION
Following General Assembly Approval

efpia
European Federation of Pharmaceutical Industries and Associations

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

Amended following Statutory General Assembly approval of 14 June 201

Member Associations are required to implement th of the EFPIA HCP Code, and no later than 31 Dec

efpia
European Federation of Pharmaceutical Industries and Associations

EFPIA CODE OF PRACTICE ON RELATIONSHIPS BETWEEN THE PHARMACEUTICAL INDUSTRY AND PATIENT ORGANISATIONS

Initially approved in 2007
Amended by decision of the General Assembly in June 2011

This updated EFPIA Patient Organisation Code of Practice was adopted by the Statutory General Assembly on 14 June 2011. Member Associations are asked to implement the revised code provisions by 31 December 2011.

EFPIA
14 June 2011

1

International Federation
of Pharmaceutical
Manufacturers & Associations

IFPMA Code of Practice

2012

IFPMA

Highlights of EFPIA Disclosure Code

More transparent about payments:

- donations and grants
- sponsorship
- fees for service

Disclosure on an individual named basis (other than certain R&D)

2015 data to be collected for disclosure in 2016

Consequential changes to ABPI Code

Monetary limit for subsistence

Changes regarding promotional aids

Other changes to ABPI Code

Certification

Changes to monetary amount for hospitality

Black triangle, AE reporting

Examination accreditation

Usual updates

Statutory control

MHRA Acts on behalf of health ministers but supports self-regulation

The Blue Guide

Memorandum of understanding

SFO Memorandum of understanding

Aim of the Code

To ensure the promotion of medicines to health professionals and to administrative staff is carried out in a robust framework to support high quality patient care.

Also sets standards for the provision of information to patients and the public as well as relationships with patient groups.

CLAUSE 1 Scope of Code and Definition of Certain Terms

Code applies to:

- The promotion of medicines to members of the UK health professions and to appropriate administrative staff
- Interactions with health professionals and certain non promotional activities
- Information made available to the public about prescription only medicines
- Relationships with patient organisations

CLAUSE 1 Scope of Code and Definition of Certain Terms

The Code does not apply to:

- The promotion of over-the-counter medicines when the object is to encourage their purchase by the public

Promotion must be:

- in accordance with marketing authorization *(Clause 3)*
- accurate, balanced, up-to-date and must not mislead or exaggerate *(Clauses 7.2, 7.3 and 7.10)*
- substantiable *(Clauses 7.4 and 7.5)*

Obligatory Information Requirements

Promotion must also:

- be of a high standard *(Clause 9.1)*
- recognise special nature of medicines and professional standing of audience and not be likely to cause offence *(Clause 9.2)*
- be tailored to audience to whom it is directed *(Clause 11.1)*

Promotion must not:

- bring discredit upon or reduce confidence in the pharmaceutical industry *(Clause 2)*
- disparage competitors or health professionals *(Clause 8)*
- be disguised *(Clause 12)*

Code also covers:

Non-interventional studies	Clause 13
Certification	Clause 14
Representatives	Clause 15
Training	Clause 16
Samples	Clause 17
Gifts and Inducements	Clause 18

Code also covers:

Hospitality and meetings	Clause 19
Use of consultants	Clause 20
Transfers of Value	Clause 21
Scientific Services	Clause 22
Relations with the Public	Clause 23
Relations with patient organisations	Clause 24
Internet	Clause 25
Compliance With Undertakings	Clause 26

CLAUSE 1.2 Definition of Promotion

- Promotion means any activity undertaken by a pharmaceutical company or with its authority which promotes the administration, consumption, purchase, prescription, recommendation, sale, supply or use of its medicines
- Clause 1.2 also lists items which are specifically included or excluded

CLAUSE 1.8 – Definition of ‘transfer of value’

- ‘The term ‘transfer of value’ means a direct or indirect transfer of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development or sale of medicines. A direct transfer of value is one made directly by a company for the benefit of a recipient. An indirect transfer of value is one made by a third party on behalf of a company for the benefit of a recipient where the identity of the company is known to, or can be identified by, the recipient.’
- Supplementary information lists excluded disclosures

CLAUSE 1 – Scope of the Code and definition of certain terms

*'**Excluded Disclosures***

The following are not transfers of value for the purposes of the Code:

- *transfers of value that are solely related to over-the-counter medicines*
- *ordinary course purchases and sales of medicines by and between a company and a health professional or a healthcare organisation including package deals as defined in the supplementary information to Clause 18.1*
- *samples of medicines provided in accordance with Clause 17*
- *transfers of value provided in accordance with Clauses 18.2 and 18.3*
- *subsistence provided to health professionals in accordance with Clause 19.1.'*

CLAUSE 9 – High standards etc

Clause 9.7

2012 text

‘Extremes of format, size or cost of material must be avoided.’

Add a new paragraph:

‘Informational or educational materials must be inexpensive, directly relevant to the practice of medicine or pharmacy and directly beneficial to the care of patients.’

CLAUSE 13 – Clinical trials and non-interventional studies in marketed medicines

Clause has been retitled.

What was Clause 21.3 and its supplementary information in the 2012 Code has been moved to become Clause 13.1 and supplementary information.

New paragraph added to the supplementary information for Clause 21.3 (now 13.1):

> 'Companies must include on the homepage of their website information as to where details of their clinical trials can be found'

* * * * *

Existing Clauses 13.1, 13.2 and 13.3 renumbered.

CLAUSE 14 – Certification

Clause 14.1

Amended text

Add ‘UK registered’ before ‘dentist’.

Amendment

The requirement for Clause 14.3 material to be certified by a registered medical practitioner has been deleted.

Remit of pharmacists registered in the UK has been extended in relation to materials which previously had to be certified by a registered medical practitioner.

The PMCPA to monitor this change.

CLAUSE 18 – Items for patients etc

Clause 18.1 – Supplementary information, Promotional aids

2012 text (paragraphs 4–8) edited and replaced with:

'Gifts such as coffee mugs, stationery, computer accessories, diaries, calendars and the like are not acceptable. Gifts of items for use with patients in the clinic, surgery or treatment room etc, such as surgical gloves, nail brushes, tongue depressors, tissues and the like, are also not acceptable. Items such as toys and puzzles intended for children to play with while waiting must not be provided. Gifts of items for use in the home or car are unacceptable.

Pharmaceutical companies cannot give diaries and desk pads etc to health professionals and appropriate administrative staff but there is nothing to prevent them being given by other parties which are not pharmaceutical companies. Advertisements for prescription medicines must not appear on any items, such as diaries and desk pads, which pharmaceutical companies could not themselves give.'

CLAUSE 18 – Items for patients etc

Clause 18.1 – Supplementary information, DVDs, memory sticks

New text

‘inexpensive’ has been added.

‘… provision … of inexpensive DVDs etc that bear …’.

‘… provision … of inexpensive memory sticks that bear …’.

CLAUSE 18 – Items for patients etc

Clause 18.3 - Supplementary information, Notebooks, Pens and Pencils

New text added

'Notebooks, pens and pencils must not be given out from exhibition stands.'

'Notebooks, pens and pencils provided by one or more companies can be included in conference bags. The total cost of the items provided to an individual recipient must not exceed £6, excluding VAT. The perceived value to the recipient must be the same. The items may bear the names of the donor companies but not the name of any medicine or any information about medicines. No individual attendee should receive more than one notebook and one pen or pencil.'

CLAUSE 18 – Items for patients etc

Clause 18.5 – Joint working

A new paragraph has been added:

‘Transfers of value made by companies in connection with joint working must be publicly disclosed.’

New supplementary information added to Clause 18.5:

‘Clause 18.5 Disclosure

The information required by Clause 18.5 as to transfers of value must be publicly disclosed in relation to transfers of value made in 2015 and each calendar year thereafter, giving in each case the financial amount or value and the name of the recipient.

Companies must ensure that the amount spent on joint working projects is made public irrespective of whether the value is transferred to a healthcare organisation or some other funding model is used.

Disclosure must be carried out in accordance with Clause 21 below.’

CLAUSE 18 – Items for patients etc

Clause 18.6 – Supplementary information

New text

'benefit in kind' has been added to 'donation or grant'.

The complete new text is:

'Clause 18.6 Donations, Grants and Benefits in Kind

Donations and grants to individual health professionals are not covered by this clause. Company sponsorship of health professionals to attend events is covered by Clause 19.

Details of each grant, donation or benefit in kind (transfer of value) must be publicly disclosed, giving in each case the financial amount or value and the name of the recipient institution, organisation or association. Companies are also encouraged to ask recipients to make such funding public.

Fees and agreed expenses should be disclosed separately.

The information required by Clause 18.6 must be publicly disclosed in respect of donations, grants and benefits in kind made in 2015 and each calendar year thereafter.

Disclosure must be carried out in accordance with Clause 21 below.' cont…

CLAUSE 18 – Items for patients etc

New supplementary information added (continued)

‘***Disclosure for Calendar Years 2013 and 2014***

For disclosures in relation to donations and grants made in calendar years 2013 and 2014, the requirements and procedures in Clause 18.6 and its supplementary information in the Second 2012 Edition of the Code continue to apply.’

CLAUSE 18 – Items for patients etc

Clause 18.7

New text added

‘Pharmaceutical companies must publicly disclose details of transfers of value made to such institutions, organisations or associations.’

New supplementary information to Clause 18.7 added:

‘The information required by Clause 18.7 must be publicly disclosed in relation to transfers of value made in 2015 and each calendar year thereafter, giving in each case the financial amount or value and the name of the recipient institution, organisation or association.

Fees and agreed expenses should be disclosed separately.

Disclosure must be carried out in accordance with Clause 21 below.’

CLAUSE 19 – Meetings, hospitality and sponsorship

New Clause 19.2:

'The cost of a meal (including drinks) provided by way of subsistence must not exceed £75 per person, excluding VAT and gratuities.'

New supplementary information to new Clause 19.2:

'The maximum of £75 plus VAT and gratuities is appropriate only in very exceptional circumstances, such as a dinner at a residential meeting for senior consultants or a dinner at a learned society conference with substantial educational content. The cost of a meal (including drinks) should normally be well below this figure. The requirements relating to hospitality in Clause 19.1 and its supplementary information still apply.'

* * * * *

Existing Clauses 19.2, 19.3 and 19.4 renumbered.

CLAUSE 19 – Meetings, hospitality and sponsorship

Clause 19.5 (previously Clause 19.4)

New replacement text

‘Pharmaceutical companies must publicly disclose financial details of sponsorship of UK health professionals and appropriate administrative staff in relation to attendance at meetings. Sponsorship in this context includes registration fees and the costs of accommodation and travel, both inside and outside the UK.’

CLAUSE 19 – Meetings, hospitality and sponsorship

Clause 19.5 – Supplementary information

New replacement text

'Disclosure of this information must be carried out in accordance with Clause 21 below.

Meetings at which attendance is sponsored by companies must also comply with Clause 19.1.

The information required by Clause 19.4 must be made publicly available in respect of sponsorship for attendance at meetings held in 2015 and each calendar year thereafter.

The information which must be disclosed comprises registration fees and the costs of accommodation and travel, both inside and outside the UK. The name of each recipient and the cost of the sponsorship of that recipient must be given.

Where a transfer of value is made to a health professional indirectly via a healthcare organisation such a transfer should be disclosed once only, preferably as being a transfer to the health professional.'

CLAUSE 19 – Meetings, hospitality and sponsorship

New supplementary information (continued)

'Disclosure for Calendar Years 2013 and 2014

For disclosures in relation to calendar years 2013 and 2014, the requirements and procedures in Clause 19.4 and its supplementary information in the Second 2012 Edition of the Code still apply.'

CLAUSE 20 – The use of consultants

Clauses 20.2, 20.3 and 20.4

New replacement text

‘**20.2** Pharmaceutical companies must publicly disclose details of the fees paid to consultants in the UK, or to their employers on their behalf, for certain services rendered by them such as chairing and speaking at meetings, assistance with training and participation in advisory boards etc. It includes payments to consultants in relation to research and development work, including the conduct of clinical trials.

20.3 In addition to the information required to be made public by Clause 20.2, companies must publicly disclose details of payments made to consultants in relation to market research (unless the company concerned is not aware of the identities of those participating in the market research).

20.4 Fees, expenses and the like due to consultants in relation to Clauses 20.2 and 20.3 must be disclosed whether paid directly to them or to their employers or to healthcare organisations or to companies or charities etc.’

CLAUSE 20 – The use of consultants

Clauses 20.2 – Supplementary information

New replacement text

*'**Clause 20.2 Disclosure***

The information required by Clause 20.2 must be publicly disclosed in respect of the calendar year 2015 and each calendar year thereafter.

Disclosure must be carried out in accordance with Clause 21 below.

The information which must be disclosed is the total amount paid in a calendar year to each consultant who has provided services. Companies may, of course, give greater detail, for example by giving separate figures for different categories of service.

Fees and agreed expenses should be disclosed separately.

The names of the consultants must be disclosed except in relation to payments in relation to research and development work, including clinical trials, as defined below, where disclosure should be on an aggregate basis.'

CLAUSE 20 – The use of consultants

Clause 20.2 – Supplementary information (continued)

New additional text

'Clause 20.2 Research and Development Transfers of Value

For the purpose of disclosure research and development transfers of value are transfers of value to health professionals or healthcare organisations related to the planning or conduct of:

- *non-clinical studies (as defined in the OECD Principles of Good Laboratory Practice)*
- *clinical trials (as defined in Directive 2001/20/EC)*
- *non-interventional studies that are prospective in nature and involve the collection of data from, or on behalf of, individual or groups of health professionals specifically for the study.*

Costs that are subsidiary to these activities can be included in the aggregate amount.'

CLAUSE 20 – The use of consultants

Clause 20.3 – Supplementary information

New replacement text

'Clause 20.3 Disclosure

Clause 20.3 relates only to market research using consultants where the pharmaceutical company knows the identity of the consultants. This is because the focus of the requirements concerning transparency is on areas where there are direct relationships between the parties and that is not so where the company does not know the identity of the participants.

Disclosure for Calendar Years 2013 and 2014

For disclosures in relation to the calendar years 2013 and 2014, the requirements and procedures in Clauses 20.2 and 20.3 and their supplementary information in the Second 2012 Edition of the Code still apply.'

NEW CLAUSE 21 – Transfers of value to health professionals and healthcare organisations

‘**21.1** Companies must document and publicly disclose certain transfers of value made directly or indirectly to health professionals and healthcare organisations located in Europe.

21.2 The transfers of value covered by Clause 21.1 are:

- joint working in accordance with Clause 18.5
- donations, grants and benefits in kind provided to institutions, organisations and associations in accordance with Clause 18.6
- contracts between companies and institutions, organisations and associations in accordance with Clause 18.7
- sponsorship of attendance by health professionals and appropriate administrative staff at meetings in accordance with Clause 19.5

cont …

NEW CLAUSE 21 – Transfers of value to health professionals and healthcare organisations

- fees paid to health professionals and appropriate administrative staff, or to their employers on their behalf, in accordance with Clauses 20.2 and 20.3

- contributions towards the cost of meetings paid to healthcare organisations or to third parties managing events on their behalf, which may include sponsorship of health professionals by way of registration fees and accommodation and travel

- **21.3** Clause 21.1 does not apply to transfers of value to patient organisations. These transfers of value are covered by Clauses 24.7 and 24.8. [Note: 2012 Code Clauses 23.7 and 23.8]

cont…

NEW CLAUSE 21 – Transfers of value to health professionals and healthcare organisations

New Clause 21 (continued)

'**21.4** Disclosures must be made annually in respect of each calendar year. Disclosure must be in the first six months after the end of the calendar year in which the transfers of value were made.'

'**21.5** The information disclosed must remain in the public domain for at least three years from the time of disclosure.

21.6 Companies must document all disclosures and retain the records for at least five years after the end of the calendar year to which they relate.

21.7 Different categories of transfers of value can be aggregated on a category by category basis, provided that itemised disclosure would be made available upon request to the relevant recipient or the relevant authorities.

NEW CLAUSE 21 – Transfers of value to health professionals and healthcare organisations

21.8 Where a transfer of value is made to a health professional indirectly via a healthcare organisation such a transfer should be disclosed once only, preferably as being a transfer to the health professional.

21.9 Where recipients of transfers of value cannot be identified for legal reasons, the amount attributable to such transfers must be disclosed on an aggregate basis. The number of recipients involved must be stated together with the percentage of all recipients that they represent and the aggregate amount attributable to transfers of value to such recipients.

cont…

NEW CLAUSE 21 – Transfers of value to health professionals and healthcare organisations

21.10 Each company providing transfers of value must publish a note summarising the methodologies used by it in preparing the disclosures and identifying each category of transfer of value. The note, including a general summary and/or country specific considerations, must describe the recognition methodologies applied and should include the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues relating to the timing and amount of transfers of value for the purposes of this Code.'

* * * * *

Current Clauses 21, 22, 23, 24 and 25 renumbered.

NEW CLAUSE 21 – Transfers of value to health professionals and healthcare organisations

Supplementary information

'Clause 21.1 Transfer of Value

The term 'transfer of value' is defined in Clause 1.8 above. [A new clause]

The term 'Europe' comprises those countries that are within the EU and other countries with a trade association that is a member of EFPIA.

Disclosure is required even if the payments etc are made by overseas affiliates, head offices in the UK or overseas and UK based offices.

cont …

NEW CLAUSE 21 – Transfers of value to health professionals and healthcare organisations

Supplementary information

'Clause 21.1 Consent to Disclosure

Companies are encouraged to include in a contract involving a transfer of value provisions regarding the consent of the recipient to its disclosure. In addition, companies are encouraged to renegotiate existing contracts at their earliest convenience to include such consent to disclosure. Companies must ensure that they have appropriate arrangements in place to lawfully disclose information about transfers of value.'

cont…

NEW CLAUSE 21 – Transfers of value to health professionals and healthcare organisations

Supplementary information

'Clause 21.1 Mode of Disclosure

Disclosure will be on the company's website but, if a central platform for disclosure in the UK is established, the use of that platform is likely to be obligatory.

The decision as to whether there will be a central platform for disclosure in the UK will be made by the end of 2014.

A template which can be used is available to download from the Authority's website (www.pmcpa.org.uk).'

cont…

NEW CLAUSE 21 – Transfers of value to health professionals and healthcare organisations

Supplementary information

*'**Clause 21.1 Date of Implementation***

The information required by Clause 21.1 must be disclosed in respect of transfers of value made in 2015 and each calendar year thereafter.

The disclosure of information about certain transfers of value was a requirement of the Second 2012 Edition of the Code and its immediate predecessors. The provisions in the Second 2012 Edition of the Code (Clauses 18.6, 19.4, 20.2 and 20.3) continue to apply in relation to transfers of value made in calendar years prior to 2015.'

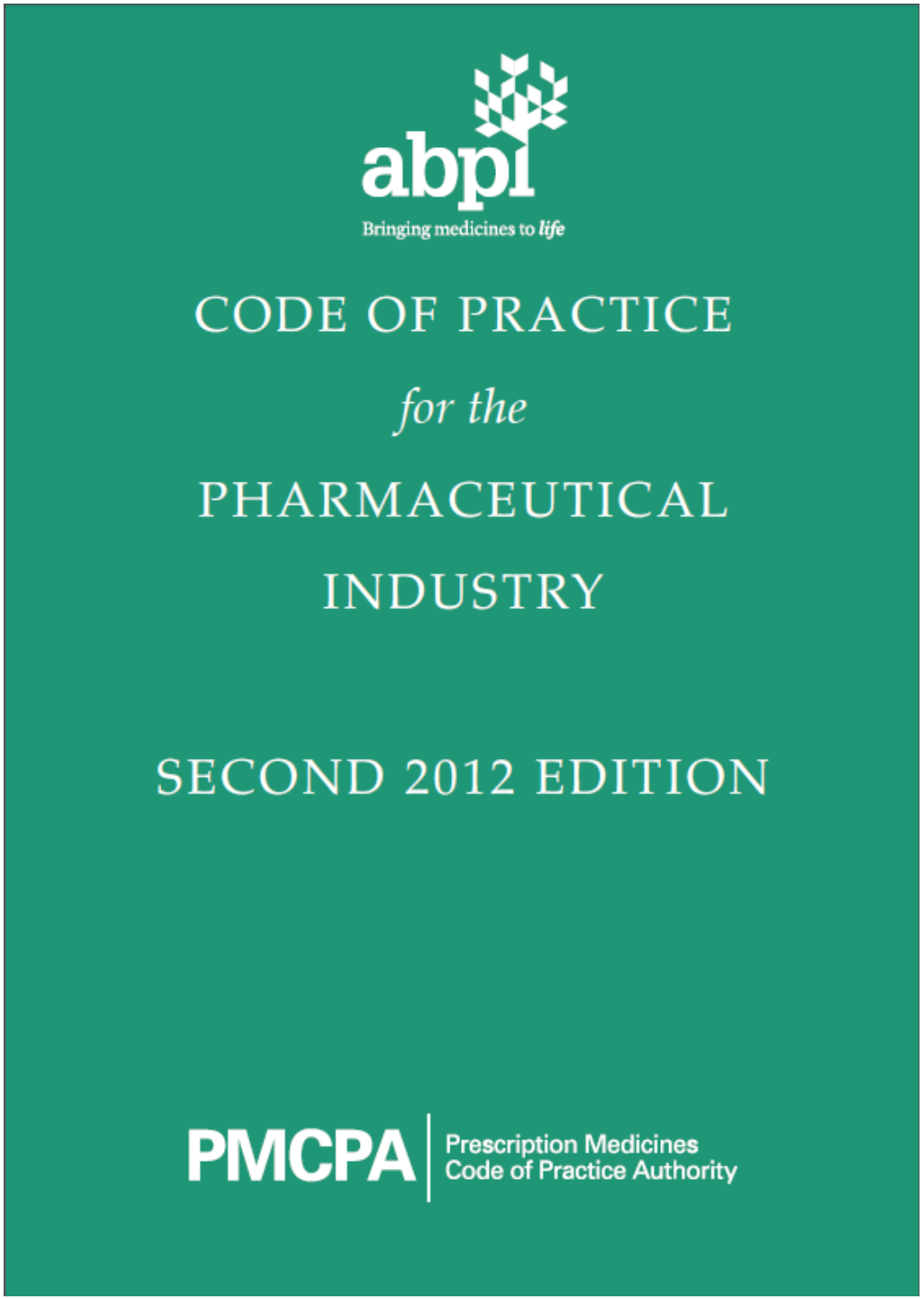
cont…

NEW CLAUSE 21 – Transfers of value to health professionals and healthcare organisations

Supplementary information

'Clause 21.2 Further Information

The clauses of the Code noted in Clause 21.2 should be consulted for further information about the requirements. In addition, the requirements of Clauses 19.1 and 19.4 should be borne in mind in relation to sponsorship of meetings.'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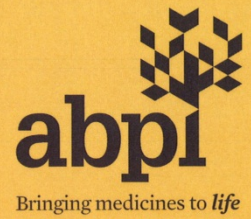

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2015 Code

How the data is to be disclosed

Proposals from the ABPI Board review of the Code and its operation

Any changes in EFPIA Codes

Discussion