PROCEA Prescription Medicines Code of Practice Authority Main changes to the 2016 ABPI Code of Practice for the **Pharmaceutical Industry** and to the

PMCPA Constitution and Procedure

Changes to the 2016 Code

- Agreed by ABPI Members 4 December 2018
- To come into operation on 1 January 2019

Changes due to:

- Outcome of ABPI Board Review
- Feedback from pharmaceutical companies and others
- Regular updating/tidying up

2019 Code

Operative on 1 January 2019

Transition period until 30 April 2019 to comply with newly introduced provisions

2019 Disclosure Template to be used to submit 2018 data to Disclosure UK in March 2019

Main changes Clause 1 Scope and Definitions

Clause 1.2 Definition of Promotion

Amendment

To shorten the final bullet point of 'It includes' by removing the examples which have been added to the Q&A

To read

• all other sales promotion in whatever form.

Main changes

Clause 1 Scope and Definitions

Clause 1.2 Definition of Promotion

Amendment

Add to 'It does not include' a reference to risk minimisation material.

New text

- ... summaries of product characteristics
- European public assessment reports
- UK public assessment reports
- risk minimisation material....

Main changes Clause 1 Scope and Definitions

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.'

Main changes Clause 1.10

(a consequence of amendment to Clause 18.1 Supplementary Information – Package Deals)

Amendment

To exempt package deals relating to ordinary course purchases and sales of medicines from the requirement to disclose (bullet point 2). Transfers of value made in the course of other package deals would need to be disclosed in accordance with Clause 24.

To read

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

• ... ordinary course purchases and sales of medicines by and between a company and a health professional or a healthcare organisation including certain package deals as defined in the supplementary information to Clause 18.1 ...

Main changes Clause 3 Marketing Authorization

Clause 3 Supplementary Information

Amendment

To add new supplementary information.

New text

Clause 3 Conditional Marketing Authorizations

If a medicine has been granted a conditional marketing authorization then it can be promoted in accordance with the terms of that licence and is considered to meet the requirements of Clause 1.3 as having a marketing authorization. Material should clearly state at the outset that the medicine has a conditional marketing authorization.

Relevant information should be added wherever possible to national horizon scanning databases.

Main changes

Clause 3 Marketing Authorization

Clause 3 Supplementary Information

Amendment

To add new supplementary information.

New text

Clause 3 Early Access to Medicines Scheme

Medicines that are approved for the Early Access to Medicines Scheme (EAMS) meet one of the following two conditions. Either the medicine does not have a marketing authorization or the medicine has a marketing authorization but no licence for the specific indication.

Medicines or indications that are approved for EAMS will not have either a marketing authorization for the medicine or for the indication and therefore must not be promoted.

Relevant information should be added wherever possible to national horizon scanning databases.

Main changesClause 3 MarketingAuthorization

Clause 3 Supplementary Information

Amendment

To add new supplementary information.

New text

Clause 3 Compassionate Use

Companies sometimes decide to provide an unlicensed medicine or a medicine for use in an unlicensed indication on a compassionate use basis for those with an unmet medical need. Such availability is for companies to decide in line with relevant requirements. If these medicines do not have a relevant marketing authorization then they cannot be promoted.'

Main changes Clause 3 Marketing Authorization

Clause 3 Supplementary Information – Advance Notification of New Products or Product Changes which May Significantly Affect Expenditure

Amendment

To add a reference to service redesign/patient pathways. To add clarity that the budget impact of a new medicine might include the need for service redesign. Add to the final sentence of the first paragraph *'including that which might arise from changes in the patient pathway and/or service delivery'* and to paragraph iv *'(the budgetary implication might include the need for service redesign)'*.

Main changes Clause 3 Marketing Authorization

Clause 3 Supplementary Information – Advance Notification of New Products or Product Changes which May Significantly Affect Expenditure (Cont'd)

New text

'NHS organisations and others involved in the purchase of medicines need to estimate their likely budgets in advance and there is a need for them to receive advance information about the introduction of new medicines, or changes to existing medicines, which may significantly affect their level of expenditure including that which might arise from changes in the patient pathway and/or service delivery.

Main changes Clause 3 Marketing Authorization

Clause 3 Supplementary Information – Advance Notification of New Products or Product Changes which May Significantly Affect Expenditure

New text

iv) state the likely cost or savings and budgetary implications which must be such that they will significantly change the organisation's likely expenditure (the budgetary implication might include the need for service redesign)

Clause 4.1 Supplementary Information – Legibility of Prescribing Information

Amendment

Delete the second paragraph and recommendations.

To read

The prescribing information is the essential information which must be provided in promotional material. It follows therefore that the information must be given in a clear and legible manner which assists readability.

To add the recommendations to the Q and A

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.

Clause 4.5 Prescribing Information on Audio-Visual Material

Amendment

Amend the first sentence to remove references to films, DVDs and suchlike.

To read

In audio-visual material and in interactive data systems, the prescribing information may be provided either:

- by way of a document which is made available to all persons to whom the material is shown or sent, or
- by inclusion on the audio-visual recording or in the interactive data system itself.

When the prescribing information is included in an interactive data system instructions for accessing it must be clearly displayed.

Clause 4.9 Adverse Event Reporting

Amendment

Change to describe the web address needed rather than including https://yellowcard.mhra.gov.uk.

To read

All promotional material must include the prominent statement "Adverse events should be reported. Reporting forms and information can be found at [a web address which links directly to the MHRA yellow card site]. Adverse events should also be reported to [relevant pharmaceutical company]".

Clause 4.9 Supplementary Information – Adverse Event Reporting Amendment

To amend the supplementary information to read:

To read

In the event that the website address required in Clause 4.9 is changed by the Medicines and Healthcare products Regulatory Agency, companies must use the new address within one year of the change.

Main changes Clause 5 Abbreviated Advertisements

Clause 5.2 Supplementary Information – Professional Publications

Amendment

Changes to the second sentence add 'online' and delete the second use of 'internet'.

To read

DVDs and suchlike sent to doctors etc. may be considered professional publications and an abbreviated advertisement may be included on a box containing a DVD. The prescribing information must, however, be made available for any advertisement for a medicine appearing on audio-visual material or in an interactive data system or on the Internet, including online journals. Such advertisements cannot be deemed abbreviated advertisements.

Clause 6.1 Journal Advertising

Amendment

Amend to add a reference to digital advertising as well as to print advertising. Renumber as Clause 6.2.

To read

6.2 Where the pages of a two page print advertisement are not facing or where a digital advertisement is made up of a number of screens, no page or screen must be false or misleading when read in isolation.

Clause 6.3 Journal Advertising

Amendment

Amend to add a reference to print advertising. Renumber as Clause 6.1.

To read

6.1 No issue of a print journal may bear advertising for a particular product on more than two pages.

Clause 6.2 Journal Advertising

Amendment

Amend to add a reference to print advertising. Renumber as Clause 6.3.

To read

6.3 No advertisement taking the form of a loose insert in a print journal may consist of more than a single sheet of a size no larger than the page size of the journal itself, printed on one or both sides.

Clause 6.2 Supplementary Information – Journal Advertising

Amendment

Amend to add a reference to print advertising. Renumber as supplementary information to Clause 6.1.

To read

Clause 6.1 Printed Advertisements

A two page printed journal advertisement is one where the pages follow on without interruption by intervening editorial text or other copy. Thus, for example, promotional material on two successive right hand pages cannot be a single advertisement. Each such page would need to be treated as a separate advertisement for the purposes of prescribing information.

Similarly, if promotional material appears on the outer edges of the left and right hand pages of a double page spread, and the promotional material is separated by intervening editorial matter, then again each page would need to be treated as a separate advertisement.

Clause 6.2 Supplementary Information – Advertising on the Outside of Journals

Amendment

Amend to add a reference to print advertising. Change cross reference and renumber as supplementary information to Clause 6.3.

To read

Clause 6.3 Advertising on the Outside of Print Journals

Advertising such as cards stapled to a print journal and "wraparounds" must not have a greater surface area than that outlined for loose inserts under Clause 6.3.

Clause 6.3 Supplementary Information – Limitations on Number of Pages of Advertising

Amendment

Amend to add a reference to print advertising. Renumber cross references and as supplementary information to Clause 6.1.

To read

Clause 6.1 Limitations on Number of Pages of Print Advertising

Advertisements taking the form of inserts, whether loose or bound in, count towards the two pages allowed by Clause 6.1. An insert printed on both sides counts as two pages.

A summary of product characteristics is permitted as an insert in addition to the two pages of advertising which is allowed.

Inserts and supplements to print journals which are not advertisements as such, though they may be regarded as promotional material, for example reports of conference proceedings, are not subject to the restrictions of Clauses 6.1 and 6.3.

Main changes Clause 10 Provision of Reprints and the Use of Quotations

Clause 10.1 Provision of Reprints and the Use of Quotations

Amendment

Amend to refer to 'peer reviewed' rather than refereed and to 'proactively' rather than 'unsolicited'.

To read

Reprints of articles in journals must not be provided proactively unless the articles have been peer reviewed.

Main changes Clause 10 Provision of Reprints and the Use of Quotations

Clause 10.1 Supplementary Information – Provision of Reprints

Amendment

To align with the Clause change

To read

The proactive provision of a reprint of an article about a medicine constitutes promotion of that medicine and all relevant requirements of the Code must therefore be observed. Particular attention must be paid to the requirements of Clause 3.

When proactively providing a reprint of an article about a medicine, it should be accompanied by prescribing information.

Clause 14.1 Certification

Amendment

Change the title of the clause to reflect that it will also refer to examination. To allow for checking of printed material which has been certified electronically by someone other than a signatory.

To read

Clause 14 Certification and Examination

14.1 Promotional material must not be issued unless its final form, to which no subsequent amendments will be made, has been certified by one person on behalf of the company in the manner provided for by this clause subject to the provisions of the supplementary information to this clause where relevant. This person must be a registered medical practitioner or a pharmacist registered in the UK or alternatively, in the case of a product for dental use only, a UK registered dentist.

The person certifying on behalf of the company must not be the person responsible for developing or drawing up the material.

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.

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.

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.

Clause 14.2 Supplementary Information – Meetings Involving Travel Outside the UK

Amendment

Delete paragraphs four and five to reflect changes to the Clause.

To read

UK Companies have responsibilities under the Code for meetings which they organise and when UK delegates and/or UK speakers are invited or supported to go to meetings outside the UK. Clauses 23 and 24 in relation to disclosure of transfers of value will also need to be followed.

When certifying arrangements for meetings which involve travel outside the UK all the relevant documents and arrangements must be considered including the programme, the venue, the reasons for using that venue, the intended audience, the anticipated cost and the nature of the hospitality and the like.

If the company's only involvement is to support a speaker to present at the meeting and there is no pharmaceutical company involvement with the meeting at all, for example a learned society meeting, then certification is not required.

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.

Clause 14.4 Notification of Signatories

Amendment

To add in a reference to Clause 14.2.

To read

The names of those nominated as signatories as set out in Clauses 14.1 and 14.2, together with their qualifications, shall be notified in advance to the Advertising Standards Unit, Vigilance and Risk Management of Medicines of the Medicines and Healthcare products Regulatory Agency and to the Prescription Medicines Code of Practice Authority. The names and qualifications of designated alternative signatories must also be given. Changes in the names of nominees must be promptly notified.

Main changes Clause 18

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.

Main changes

Clause 1.10

(a consequence of amendment to Clause 18.1 Supplementary Information – Package Deals)

Amendment

To exempt package deals relating to ordinary course purchases and sales of medicines from the requirement to disclose (bullet point 2). Transfers of value made in the course of other package deals would need to be disclosed in accordance with Clause 24.

To read

'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 certain 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 22.1.'

Clause 18.1 Supplementary Information – Package Deals

Amendment

To add a reference to testing

To read

Companies can provide genetic testing or other biomarkers/specific testing in relation to the rational use of one of its medicines.

Where the use of a medicine requires specific testing prior to prescription, companies can arrange to provide such testing as a package deal even when the outcome of the testing does not support the use of the medicine in some of those tested.

Clause 18.1 Supplementary Information – Health Professionals' Codes of Conduct

Amendment

Update to reflect changes made by the General Pharmaceutical Council and to the Code of the Nursing and Midwifery Council. To add a reference to other regulators.

To read

The General Pharmaceutical Council is the regulatory body for pharmacists and pharmacy technicians. The Council's Standards for pharmacy professionals includes that they must use their professional judgement and must behave in a professional manner. They are expected to "declare any personal or professional interests and manage these professionally".

The Code of the Nursing & Midwifery Council, Professional standards of practice and behaviour for nurses and midwives states "You must act with honesty and integrity in any financial dealings you have with everyone you have a professional relationship with, including people in your care".

Cont...

Clause 18.1 Supplementary Information – Health Professionals' Codes of Conduct

New text

In a joint statement, the Chief Executives of statutory regulators of health and care professionals (which refers to individuals regulated by one of nine regulators overseen by the Professional Standards Authority including those referred to above) expect health and social care professionals to 'Ensure their professional judgement is not compromised by personal, financial or commercial interests, incentives, targets or similar measures' and to 'Refuse all but the most trivial gifts, favours or hospitality if accepting them could be interpreted as an attempt to gain preferential treatment or would contravene your professional code of practice'.

Clause 18.1 Supplementary Information – Patient Access Schemes

Amendment

A reference will be added

The outcome of discussions regarding the next pharmaceutical Price Regulation Scheme will be available in 2019.

Clause 18.2 Supplementary Information – Patient Support Items

Amendment

To increase the cost to no more than £10.

To read

An "inexpensive" item for patient support means one that has cost the donor company no more than £10, excluding VAT. The perceived value to the health professional and the patient must be similar.

Main changes Clause 22 Meetings, Hospitality and Sponsorship

Clause 22.1 Supplementary Information – Health Professionals' Codes of Conduct

Amendment

As for the Supplementary Information to Clause 18.1

Update to reflect changes made by the General Pharmaceutical Council and to the Code of the Nursing and Midwifery Council. To add a reference to other regulators.

Main changes Clause 24 Transfers of Value to Health Professionals and Healthcare Organisations

Clause 24.1 Supplementary Information – Consent to Disclosure

Amendment

Delete first two sentences. Add to the final sentence 'and that recipients are aware of the process for disclosure'.

To read

'Companies must ensure that they have appropriate arrangements in place to lawfully disclose information about transfers of value and that recipients are aware of the process for disclosure.'

Main changes Clause 26 Relations with the Public and the Media

Clause 26.2 Supplementary Information – Financial Information

Amendment

Certain financial information to be exempted from the requirements of Clause 7. Add a reference to 'taking into account the information needs of the target audience'.

New text

Information made available in order to inform shareholders, the Stock Exchange and the like by way of annual reports and announcements etc may relate to both existing medicines and those not yet marketed. Such information must be non-promotional, accurate, presented in a fatual and balanced way and not misleading taking into account the information needs of the target audience. Clause 7 shall not apply to such information. Business press releases should identify the business importance of the information and should only be aimed at the intended financial and investment audience.

Main changes Clause 26 Relations with the Public and the Media

Clause 26.3 Supplementary Information – Black triangle symbol Amendment

To amend reference to 4.11 to reference to 4.10.

New text

'Details of the black triangle symbol can be found on the supplementary information to Clause 4.10.'

Main changes Clause 27 Relationships with Patient Organisations

Clause 27.7

Amendment

To change the time for disclosure to in the first six months after the end of the calendar year in which the transfers of value were made.

To read

Each company must make publicly available, at a national or European level, a list of patient organisations to which it provides financial support and/or significant indirect/non-financial support, which must include a description of the nature of the support that is sufficiently complete to enable the average reader to form an understanding of the significance of the support. The list of organisations being given support must be disclosed 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.

Main changes Clause 28 The Internet

Clause 28 The Internet

Amendment

Change heading to 'The internet and Other Digital Platforms'.

Main changes Clause 28 The Internet

Clause 28.2 The Internet

Amendment

Change layout

To read

Information or promotional material about medicines covered by Clause 28.1 which is placed on the Internet outside the UK will be regarded as coming within the scope of the Code if:

- it was placed there by a UK company/with a UK company's authority or
- It was placed there by an affiliate of a UK company or with the authority of such a company and it makes specific reference to the availability or use of the medicine in the UK.

Main changes Statement at the beginning of the Code of Practice booklet

Amendment

Update with the requirement for the template for disclosure agreed for the 2019 Code should be used to submit the 2018 data to Disclosure UK

New text

This edition of the Code of Practice comes into operation on 1 January 2019. During the period 1 January 2019 to 30 April 2019, no material or activity will be regarded as being in breach of the Code if it fails to comply with its provisions only because of requirements which this edition of the Code newly introduces. The template for disclosure agreed for the 2019 Code should be used to submit the 2018 data to Disclosure UK.

Main changes Disclosure Template

Amendments

- To make the link to the executive summary optional for inclusion in the template. If the link is not in the template it must be included in the methodological note (as required by Clause 24.1).
- Removal of the option to put payments to healthcare organisations in aggregate.
- To require companies to provide totals (previously optional) and to add notes to make it clear what is required. A warning has also been added to remind companies that individuals might appear in more than one of the categories, ie receive a fee for service and expenses.
- To add notes to make it clear that data in columns headed 'registration fees', 'travel and accommodation', 'fees for service' and 'related expenses agreed' relate to that column.
- To add a note to make it clear that the methodological note must include the number of individuals who have agreed to some payments being disclosed individually and others in aggregate.

PMCPA Constitution and Procedure

PMCPA Prescription Medicines Code of Practice Authority

Main changes Constitution and Procedure

Paragraph 1.3 Code of Practice Appeal Board – Constitution

Amendment

- To replace the Board of Management with ABPI Board
- Add a reference to the ABPI Vice President
- Job titles for PMCPA Secretary and Deputy Secretary to become Managers
- References to be changed to his/her

Main changes Constitution and Procedure

Paragraph 2.2 Code of Practice Panel

Amendment

To allow co-option of persons to the Panel. Chairman of Appeal Board to agree.

A list of potential co-optees to be drawn up following the procedures for appointing the Authority.

Main changes Constitution and Procedure

Paragraph 5.5 Prima facie case

Reintroduction of decision following receipt of response

Case preparation manager to determine whether there is a *prima facie* case to answer. If so, papers to be circulated to the Code of Practice Panel if not complainant informed and can ask for papers to go to Panel

Transition provisions

'This edition of the Code of Practice comes into operation on 1 January 2019. During the period 1 January 2019 to 30 April 2019, no material or activity will be regarded as being in breach of the Code if it fails to comply with its provisions only because of requirements which this edition of the Code newly introduces.'

Principles and overview of self-regulation – to be listed in the introduction to the 2019 ABPI Code

- 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.

Principles and overview of self-regulation – to be listed in the introduction to the 2019 ABPI Code

- 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.

Principles and overview of self-regulation – to be listed in the introduction to the 2019 ABPI Code

- 8. The Code supports the independence of 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.

Principles and overview of self-regulation – to be listed in the introduction to the 2019 ABPI Code

- 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.