

**AGREED AMENDMENTS**  
**TO THE 2016**  
**ABPI CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY**

**AMENDMENT NUMBER 1**

**Clause 1.2 Definition of Promotion**

**Current text** (extract)

‘It includes:

- all other sales promotion in whatever form, such as participation in exhibitions, the use of audio or video recordings in any format, broadcast media, non-print media, the Internet, interactive data systems, social media and the like.’

**Amendment**

To remove the examples to the Q&A.

To read:

- all other sales promotion in whatever form.’

\* \* \* \* \*

**AMENDMENT NUMBER 2**

**Clause 1.2 Definition of Promotion**

**Current text** (extract)

It does not include:

- summaries of product characteristics
- European public assessment reports
- UK public assessment reports ...’.

**Amendment**

Add a reference to risk minimisation material.

To read:

- risk minimisation material’

\* \* \* \* \*

**AMENDMENT NUMBER 3**

**Supplementary Information to Clause 1.2**

**Amendment**

To add new supplementary information.

To read:

*‘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’.*

\* \* \* \* \*

**Supplementary information to Clause 1.10 Excluded Disclosures.**

Amendment Number 27 includes an amendment to the supplementary information to Clause 1.10 Excluded Disclosures.

\* \* \* \* \*

**AMENDMENT NUMBER 4**

**Clause 3**

**Amendment**

To add new supplementary information.

To read:

*‘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.*

*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.*

### 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.'*

\* \* \* \* \*

### **AMENDMENT NUMBER 5**

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

##### **Current 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.*

*At the time this information is required, the medicines concerned (or the changes to them) will not be the subject of marketing authorizations (though applications will often have been made) and it would be in breach of the Code for them to be promoted. Companies wishing to provide advance notification must ensure that information is also provided wherever possible for inclusion in national horizon scanning databases. Non-promotional information can be provided as advance notification but it must:*

- i) relate to:
 
  - a) a product which contains a new active substance, or*
  - b) a product which contains an active substance prepared in a new way, such as by the use of biotechnology, or*
  - c) a product which is to have a significant addition to the existing range of authorized indications, or*
  - d) a product which is to have a novel and innovative means of administration**
- ii) only be directed to those responsible for making policy decisions on budgets and not those expected to prescribe*
- iii) state whether or not a new medicine or a change to an existing medicine is the subject of a marketing authorization in the UK*
- iv) state the likely cost or savings and budgetary implications which must be such that they will significantly change the organisation's likely expenditure*

- v) *be factual and limited to that sufficient to provide an adequate but succinct account of the product's properties; other products should only be mentioned to put the new product into context in the therapeutic area concerned*

*The information provided must not:*

- i) *be promotional in style – product logos should be avoided but company logos may be used; the brand name of the product may be included in moderation but it should not be stylised or used to excess*
- ii) *include mock up drafts of either summaries or product characteristics or package leaflets.*

*If requested further information may be supplied or a presentation made.'*

### **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)'*.

To read:

*'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.*

*At the time this information is required, the medicines concerned (or the changes to them) will not be the subject of marketing authorizations (though applications will often have been made) and it would be in breach of the Code for them to be promoted. Companies wishing to provide advance notification must ensure that information is also provided wherever possible for inclusion in national horizon scanning databases. Non-promotional information can be provided as advance notification but it must:*

- i) *relate to:*
- a) *a product which contains a new active substance, or*
  - b) *a product which contains an active substance prepared in a new way, such as by the use of biotechnology, or*
  - c) *a product which is to have a significant addition to the existing range of authorized indications, or*
  - d) *a product which is to have a novel and innovative means of administration.*
- ii) *only be directed to those responsible for making policy decisions on budgets and not those expected to prescribe*

- iii) *state whether or not a new medicine or a change to an existing medicine is the subject of a marketing authorization in the UK*
- 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)*
- v) *be factual and limited to that sufficient to provide an adequate but succinct account of the product's properties; other products should only be mentioned to put the new product into context in the therapeutic area concerned.*

*The information provided must not:*

- i) *be promotional in style – product logos should be avoided but company logos may be used; the brand name of the product may be included in moderation but it should not be stylised or used to excess*
- ii) *include mock up drafts of either summaries or product characteristics or package leaflets.*

*If requested further information may be supplied or a presentation made.'*

\* \* \* \* \*

## **AMENDMENT NUMBER 6**

### **Supplementary Information to Clause 4.1 Legibility of Prescribing Information**

#### **Current text**

*'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.*

*Legibility is not simply a question of type size. The following recommendations will help to achieve clarity:*

- *type size should be such that a lower case "x" is no less than 1mm in height*
- *lines should be no more than 100 characters in length, including spaces*
- *sufficient space should be allowed between lines to facilitate easy reading*
- *a clear style of type should be used*
- *there should be adequate contrast between the colour of the text and the background*
- *dark print on a light background is preferable*
- *boldening headings and starting each section on a new line aids legibility.'*

#### **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.'*

\* \* \* \* \*

## **AMENDMENT NUMBER 7**

### **Supplementary Information to Clause 4.4 Use of Links for Prescribing Information**

#### **Current text**

*'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 or 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, emails and the like, 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.'*

#### **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.'*

\* \* \* \* \*

## **AMENDMENT NUMBER 8**

### **Clause 4.5 Prescribing Information and Other Obligatory Information**

#### **Current text**

'In the case of audio-visual material such as films, DVDs and suchlike and in the case of 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.’

### **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:’

\* \* \* \* \*

## **AMENDMENT NUMBER 9**

### **Clause 4.9 Adverse event reporting**

#### **Current text**

‘All promotional material must include the prominent statement ‘Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). Adverse events should also be reported to [relevant pharmaceutical company]’.

#### **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]”’

\* \* \* \* \*

## **AMENDMENT NUMBER 10**

### **Supplementary Information to Clause 4.9 Adverse Event Reporting**

#### **Current text**

*‘In the event that the website address given in Clause 4.9 is changed by the Medicines and Healthcare products Regulatory Agency, companies may use a statement incorporating the new address as soon as the change is made and must use the new address within one year of the change.’*

**Amendment**

To amend this supplementary information 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.'*

\* \* \* \* \*

**AMENDMENT NUMBER 11****Supplementary Information to Clause 5.2 Professional Publications****Current text**

*'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 journals on the Internet. Such advertisements cannot be deemed abbreviated advertisements.'*

**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.'*

**Note**

Given the consultation responses that some companies still use DVDs, the proposal to remove references to DVDs (Amendment Number 30) was withdrawn. The use of DVDs will be discussed further, including with the Compliance Network with a view to changes for the next Code (2020).

As DVDs are to remain (Amendment Number 30), much of Amendment Number 11 is not needed.

\* \* \* \* \*

**AMENDMENT NUMBER 12****Clause 6.1 Journal Advertising****Current text**

'6.1 Where the pages of a two page advertisement are not facing, neither must be false or misleading when read in isolation.'

**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'

\* \* \* \* \*

**AMENDMENT NUMBER 13**

**Clause 6.3 Journal Advertising**

**Current text**

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

**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.'

\* \* \* \* \*

**AMENDMENT NUMBER 14**

**Clause 6.2 Journal Advertising**

**Current text**

'6.2 No advertisement taking the form of a loose insert in a 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.'

**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.'

\* \* \* \* \*

### **AMENDMENT NUMBER 15**

#### **Supplementary information to Clause 6 Journal Advertisements**

##### **Current text (extract)**

*'A two page 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.'*

##### **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.'*

\* \* \* \* \*

### **AMENDMENT NUMBER 16**

#### **Supplementary information to Clause 6.2 Advertising on the Outside of Journals**

##### **Current text**

*'Advertising such as cards stapled to a journal and 'wraparounds' must not have a greater surface area than that outlined for loose inserts under Clause 6.2'*

##### **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’*

\* \* \* \* \*

**AMENDMENT NUMBER 17**

**Supplementary information to Clause 6.3 Limitations on Number of Pages of Advertising**

**Current text**

*‘Advertisements taking the form of inserts, whether loose or bound in, count towards the two pages allowed by Clause 6.3. 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 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 6.2 and 6.3.’*

**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.’*

\* \* \* \* \*

**AMENDMENT NUMBER 18**

**Clause 10.1 Provision of Reprints and the Use of Quotations**

**Current text**

‘Reprints of articles in journals must not be provided unsolicited unless the articles have been refereed.’

**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.’

\* \* \* \* \*

**AMENDMENT NUMBER 19****Supplementary Information to Clause 10.1 Provision of Reprints****Current text**

*‘The provision of an unsolicited 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 providing an unsolicited reprint of an article about a medicine, it should be accompanied by prescribing information.’*

**Amendment**

*‘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.’*

\* \* \* \* \*

**AMENDMENT NUMBER 20****Clause 14.1 Certification****Current text**

‘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. 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.'

### **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

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.'

\* \* \* \* \*

### **AMENDMENT NUMBER 21**

#### **Supplementary Information to Clause 14.1 Certification**

##### **Current text**

*'Clause 14.1 Supplementary Information – Certification*

*An acceptable way to comply with Clause 14.1 is for the final proof to be certified but this is not obligatory provided that that which is certified is in its final form to which no subsequent amendments will be made. Companies may use validated electronic signatures for certifying material. Paper or electronic copies of certificates and the final form of material etc must be preserved in order to comply with Clause 14.6.*

*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 any one of the company's signatories has checked and signed the item in its final form. In such circumstances the material will have two certificates and both must be preserved.'*

##### **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.’*

\* \* \* \* \*

## **AMENDMENT NUMBER 22**

### **Supplementary Information to Clause 14.1 Certifying Digital Materials**

#### **Current text**

*‘When certifying dynamic content for websites, care must be taken to ensure the dynamic content meets the requirements of the Code both as a standalone item and within the context in which it appears. The final form of digital material might not be static.’*

#### **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.’*

\* \* \* \* \*

## **AMENDMENT NUMBER 23**

### **Clause 14.2**

#### **Current text**

‘14.2 All meetings involving travel outside the UK where a UK company funds UK delegates must be certified in advance in a manner similar to that provided for by Clause 14.1.’

In addition, all meetings involving travel outside the UK that are wholly or mainly for UK delegates must also be certified in advance in a manner similar to that provided for by Clause 14.1.’

#### **Amendment**

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.’

There is no need for a health professional to certify arrangements relating to travel, accommodation and subsistence. Pharmaceutical companies are required to disclose support to attend meetings so more information is in the public domain.

\* \* \* \* \*

## **AMENDMENT NUMBER 24**

### **Supplementary Information to Clause 14.2 Meetings Involving Travel Outside the UK**

#### **Current text**

#### ***'Clause 14.2 Meetings Involving Travel Outside the UK***

*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 neither certification nor examination is required.*

*If a UK company's only role for meetings which are not wholly or mainly for UK delegates is to select or invite but not fund UK speakers and/or delegates, then the arrangements for such meetings should be examined by the UK company to ensure they do not contravene the Code or relevant statutory requirements.*

*There is no requirement to certify arrangements for meetings held outside the UK that are wholly organised and/or funded by any overseas legal entity of a pharmaceutical company even if UK delegates are selected and invited by the overseas company unless such meetings are wholly or mainly for UK delegates. The UK company must be informed and the arrangements for meetings which involve UK delegates travelling outside the UK where the UK company has not funded the delegates should be examined by the UK company to ensure they do not contravene the Code or relevant statutory requirements.'*

#### **Amendment**

Delete paragraphs four and five.

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.'*

\* \* \* \* \*

## **AMENDMENT NUMBER 25**

### **Supplementary Information to Clause 14.2**

#### **Amendment**

New supplementary information to set out what is required.

To read:

***'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.'*

\* \* \* \* \*

## **AMENDMENT NUMBER 26**

### **Clause 14.4**

#### **Current text**

'The names of those nominated as signatories as set out in Clause 14.1, 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.'

#### **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.'

\* \* \* \* \*

## **AMENDMENT NUMBER 27**

### **Supplementary information to Clause 18.1 Package Deals**

#### **Current text**

*'Clause 18.1 does not prevent the offer of package deals which are commercial arrangements whereby the purchase of a particular medicine is linked to the provision of certain associated benefits as part of the purchase price, such as apparatus for administration, the provision of training on its use or the services of a nurse to administer it. The transaction as a whole must be fair and reasonable and the associated benefits must be relevant to the medicine involved.'*

#### **Amendment**

To keep the current text, including the reference to the services of a nurse to administer it, and to add a reference to package deals relating to ordinary course purchases being exempt from the requirement to disclose. To similarly amend the supplementary information to Clause 1.10 Excluded Disclosures.

To read:

*'Clause 18.1 does not prevent the offer of package deals which are commercial arrangements whereby the purchase of a particular medicine is linked to the provision of certain associated benefits as part of the purchase price, such as apparatus for administration, the provision of training on its use or the services of a nurse to administer it. The transaction as a whole must be fair and reasonable and the associated benefits must be relevant to the medicine involved.'*

*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.'*

### **Supplementary Information to Clause 1.10 Excluded Disclosures**

#### **Current text**

#### ***'Clause 1.10 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 22.1.*

**Clause 1.10 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 certain package deals as defined in the supplementary information to Clause 18.1 Package Deals*
- *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.'*

\* \* \* \* \*

**AMENDMENT NUMBER 28****Supplementary information to Clause 18.1 Package Deals****Amendment**

To add:

*'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.'*

\* \* \* \* \*

**AMENDMENT NUMBER 29****Supplementary Information to Clause 18.1 Health Professionals' Codes of Conduct****Current text**

*'The General Medical Council is the regulatory body for doctors and is responsible for giving guidance on standards of professional conduct and on medical ethics. In its guidance, the GMC advises doctors that "You must not allow any interests you have to affect the way you prescribe for, treat, refer or commission services for patients" and "You must not ask for or accept – from patients, colleagues or others – any inducement, gift or hospitality that may affect or be seen to affect the way you prescribe for, treat or refer patients or commission services for patients. You must not offer these inducements".'*

*The General Pharmaceutical Council is the regulatory body for pharmacists and pharmacy technicians. The Council's Standards of conduct, ethics and performance state "Do not ask for or accept gifts, rewards or hospitality that may affect, or be seen to affect, your professional judgement".'*

*The Code of the Nursing & Midwifery Council, Standards of conduct, performance and ethics for nurses and midwives, states "You must not abuse your privileged position for your own ends" and*

*“You must ensure that your professional judgement is not influenced by any commercial considerations”.*

### **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 Medical Council is the regulatory body for doctors and is responsible for giving guidance on standards of professional conduct and on medical ethics. In its guidance, the GMC advises doctors that “You must not allow any interests you have to affect the way you prescribe for, treat, refer or commission services for patients” and “You must not ask for or accept – from patients, colleagues or others – any inducement, gift or hospitality that may affect or be seen to affect the way you prescribe for, treat or refer patients or commission services for patients. You must not offer these inducements”.*

*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”.*

*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’.*

\* \* \* \* \*

### **Supplementary Information to Clause 18.1 Patient Access Schemes**

#### **Current text**

*‘Patient access schemes are acceptable in principle under the Code but they must be carried out in conformity with its requirements.*

*The 2014 Pharmaceutical Price Regulation Scheme describes patient access schemes as schemes proposed by a pharmaceutical company and agreed with the Department of Health (with input from the National Institute for Health and Care Excellence) in order to improve the cost-effectiveness of a medicine and enable patients to receive access to cost-effective innovative medicines. Corresponding arrangements apply in the devolved nations.’*

A reference will be added ‘The outcome of discussions regarding the next Pharmaceutical Price Regulation Scheme will be available in 2019’. The current wording will remain and will be

reviewed for the next Code (2020). This statement of fact addition has not been consulted upon other than a general reference in Amendment Number 39.

\* \* \* \* \*

**AMENDMENT NUMBER 30 – WITHDRAWN FOLLOWING CONSULTATION**

**Supplementary Information to Clause 18.1 DVDs**

**Current text**

*‘Clause 18.1 does not preclude the provision to health professional and other relevant decision makers of inexpensive DVDs etc which bear educational or promotional material compliant with the Code, provided that they cannot be used by the recipient to store other data.’*

**Proposal**

The proposal to delete as access to material previously stored on DVDs can be provided by other means is withdrawn following consultation.

**Reason**

Some companies said companies still provide DVDs so this will continue to be permitted. The use of DVDs will be discussed further and changes considered for the next Code (2020).

\* \* \* \* \*

**AMENDMENT NUMBER 31**

**Supplementary Information to Clause 18.2 Patient Support Items**

**Current text**

*‘An “inexpensive” item means one that has cost the donor company no more than £6 excluding VAT. The perceived value to the health professional and the patient must be similar.’*

**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.’*

\* \* \* \* \*

**AMENDMENT NUMBER 32**

**Supplementary Information to Clause 22.1 Health Professionals’ Codes of Conduct**

## Current text

*'The General Medical Council is the regulatory body for doctors and is responsible for giving guidance on standards of professional conduct and on medical ethics. In its guidance, the GMC advises doctors that "You must not allow any interests you may have to affect the way you prescribe for, treat, refer or commission services for patients" and "You must not ask for or accept – from patients, colleagues or others – any inducement, gift or hospitality that may affect or be seen to affect the way you prescribe for, treat or refer patients or commission services for patients. You must not offer these inducements".'*

*The General Pharmaceutical Council is the regulatory body for pharmacists and pharmacy technicians. The Council's Standards of conduct, ethics and performance state "Do not ask for or accept gifts, rewards or hospitality that may affect, or be seen to affect, your professional judgement".'*

*The Code of the Nursing & Midwifery Council, Standards of conduct, performance and ethics for nurses and midwives, states "You must not abuse your privileged position for your own ends" and "You must ensure that your professional judgement is not influenced by any commercial considerations".'*

## Amendment

Update to reflect changes to the various guidance.

To read:

*'The General Medical Council is the regulatory body for doctors and is responsible for giving guidance on standards of professional conduct and on medical ethics. In its guidance, the GMC advises doctors that "You must not allow any interests you have to affect the way you prescribe for, treat, refer or commission services for patients" and "You must not ask for or accept – from patients, colleagues or others – any inducement, gift or hospitality that may affect or be seen to affect the way you prescribe for, treat or refer patients or commission services for patients. You must not offer these inducements".'*

*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".'*

*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".'*

\* \* \* \* \*

**AMENDMENT NUMBER 33****Supplementary Information to Clause 24.1 Consent to Disclosure****Current text**

*‘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.’*

**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’*

\* \* \* \* \*

**AMENDMENT NUMBER 34****Supplementary Information to Clause 26.2 Financial Information****Current 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 factual and presented in a balanced way. Business press releases should identify the business importance of the information.’*

**Amendment**

Financial information be exempted from the requirements of Clause 7. Add a reference to *‘taking into account the information needs of the target audience’*.

To read:

*‘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 factual 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.’*

\* \* \* \* \*

**AMENDMENT NUMBER 35****Supplementary Information to Clause 26.3 Black triangle symbol****Current text**

*'Details of the black triangle symbol can be found on the supplementary information to Clause 4.11.'*

**Amendment**

To amend reference to 4.11 to reference to 4.10.

To read:

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

\* \* \* \* \*

**AMENDMENT NUMBER 36****Clause 27.7****Current text**

'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 updated at least once a year.'

**Amendment**

To delete the final sentence and replace with '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.'

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.'

\* \* \* \* \*

**AMENDMENT NUMBER 37****Clause 28 The Internet****Amendment**

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

\* \* \* \* \*

**AMENDMENT NUMBER 38****Clause 28.2****Current text**

'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 or an affiliate of a UK company or at the instigation or with the authority of such a company and it makes specific reference to the availability or use of the medicine in the UK.'

**Amendment**

Change layout

'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.'

\* \* \* \* \*

**AMENDMENT NUMBER 39****GENERAL****Amendment**

Names of organisations, titles of publications etc and the index in the Code of Practice Booklet will be updated. A reference that the outcome of the next Pharmaceutical Price Regulation Scheme will be available in 2019 will be added to the supplementary information to Clause 18.1 Patient Access Schemes.

\* \* \* \* \*

**AMENDMENT NUMBER 40****Amendment**

A statement at the beginning of the Code of Practice booklet to read:

'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.'

\* \* \* \* \*

#### **AMENDMENT NUMBER 41**

##### **Disclosure template**

##### **Amendment**

To make the link to 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 24.10).

\* \* \* \* \*

#### **AMENDMENT NUMBER 42**

##### **Disclosure template**

##### **Amendment**

Removal the option to put payments to healthcare organisations in aggregate.

\* \* \* \* \*

#### **AMENDMENT NUMBER 43**

##### **Disclosure template**

##### **Amendment**

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.

\* \* \* \* \*

#### **AMENDMENT NUMBER 44**

##### **Disclosure template**

##### **Amendment**

To add notes to make it clear that data in columns headed 'registration fees', 'travel and accommodation', 'fees for services' and 'related expenses agreed' relate to that column.

\* \* \* \* \*

**AMENDMENT NUMBER 45**

**Disclosure template**

**Amendment**

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 some in aggregate.

\* \* \* \* \*

5 December 2018