

Summary of responses and proposed changes

The PMCPA received responses from 40 ABPI members, 8 non member companies and responses from patient organisations and others (16) including an Academic Health Science Network, providers of services to support implementation of the ABPI Code, pharmaceutical physicians including signatories and the ABPI. In addition, responses were received from the Medicines and Healthcare products Regulatory Agency (MHRA). No response was received from The Serious Fraud Office (SFO) and The Competition and Markets Authority. No response was received from the Royal Pharmaceutical Society (RPS), the British Medical Association (BMA) and the Royal College of Nursing (RCN).

The responses are detailed in this document. Where organisations other than pharmaceutical companies made similar suggestions to pharmaceutical companies these have not been separately added to try to reduce duplication.

The PMCPA read and assessed all the responses and its comments are included. Where the ABPI has a different view to the PMCPA details of the ABPI's view is also included. The Working Group was given a short time to comment on the PMCPA view before the papers were provided to the ABPI Board. At its meeting on 6 November the ABPI Board reviewed the comments and suggested response and agreed the final proposals to be considered by ABPI members in December 2018.

The agreed approach to the extensive feedback received in 2017 and 2018 regarding changes to the Code was that suggestions would be dealt with by Q and A wherever possible, if not possible then PMCPA Guidance would be updated or produced. Failing this there would be changes to the supplementary information and only where necessary changes to the Code. Changes to the PMCPA website would link the Code, supplementary information, PMCPA guidance and the Q and A. Once the ongoing EFPIA Codes consolidation exercise was completed (expected in late 2018/early 2019) the topics would be revisited and a new ABPI Code would be required in 2020. Draft principles and an overview of self regulation would also be developed. The current PMCPA Guidance would be updated. The ABPI was working on guidance for working with patient organisations which would include into account all the existing guidance in this area.

GENERAL COMMENTS

Many companies were supportive of the changes and believed they would help in modernising, simplifying and clarifying the Code.

One company did not consider that the proposals had gone as far and as wide as it believed was required or initially intended.

One company considered that the Code should only include requirements from the EFPIA Codes.

Some companies were concerned that not all irrelevant supplementary information was removed from the Code, pointing out that the supplementary information to Clause 3 was a requirement, that to Clause 4.1 was guidance and the supplementary information to Clause 6 was not needed at all.

One company was concerned about the impact of Brexit.

PMCPA Response

There is further work to do once the proposals for amending the Code and PMCPA Constitution and Procedure are agreed. Some of the responses would be looked at again as part of the work for the 2020 Code.

In relation to matters covered by the Code and Brexit, the law relating to advertising is a national responsibility as there is already UK law in this area (The Human Medicines Regulations) no new law will be required. The ABPI is a member of EFPIA and as a result it has to ensure that the ABPI Code reflects the EFPIA Codes. This will not change when the UK leaves the EU. The position will have to be reviewed as the impact (if any) on the Code becomes clearer.

A SPECIFIC COMMENTS ON THE CODE

1 Definition of Promotion (Amendment Numbers 1, 2, 3)

Sales promotion

A few companies commented about simplifying the final bullet point in Clause 1.2 (Amendment Number 1) to refer to written, digital, verbal etc.

One company suggested further simplification to 'all other sales promotion in whatever form'.

One company suggested replacing 'electronic' with 'digital' to the description of materials used by representatives (not the subject of an amendment).

PMCPA Response

Much of the wording in this section comes from various codes and legislation. Amendment Number 1 was to add digital as another example to the list of examples which reflect what is mentioned elsewhere in the Code. The examples could be removed and added to the Q and A together with a reference to electronic, digital, written and verbal.

The use of the phrases elsewhere in the Code will be looked at in relation to the 2020 Code. It could be argued that there is no need for the descriptor 'any electronic or printed' in relation to materials used by representatives.

Proposal

Amendment Number 1 changed to read 'all other sales promotion in whatever form' and the examples put in the Q and A.

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Risk management plan and risk minimisation material

One company commented that it would be helpful to add 'approved' and examples of risk minimisation material and suggested the wording be revised to read:

'... such approved documentation (such as patient alert cards) is exempt from the definition of promotion and can be delivered by a representative ...'

One company commented that the Code appeared to be referring to activities other than the Risk Minimisation Plan and routine pharmacovigilance activities. This should be made clear in the supplementary information (Amendment Number 3).

One company was concerned that delivery of MHRA approved materials by a representative implied an element of promotion. Should they be delivered in a separate call, was a briefing document needed, did it need certification?

A few companies commented that the text should refer to 'additional risk minimisation materials' to distinguish from the summary of product characteristics (a routine risk minimisation measure) which was already stated in Clause 1.2 as an exemption.

One company wanted to remove the reference to representatives delivering the risk minimisation plan as it would not be distributed by a representative.

One company was concerned that representatives might use risk minimisation material delivery as a reason for calling upon health professionals and then go on to promote medicines. It suggested amendments to the supplementary information.

One other respondent referred to other pharmacovigilance documents that were regulatory based and should not be used promotionally. The provision should be broader than risk minimisation materials.

The MHRA view was that the supplementary information (Amendment Number 3) was an important restrictor to ensure that only MHRA approved materials mandated under the risk management plan were included. Any other safety related material that might be developed by a company should be subject to the Code in the normal way and not excluded by the reference to certain risk minimisation material (Amendment Number 3).

PMCPA Response

It is important that only the statutory MHRA approved information be exempted as set out in the supplementary information (Amendment Number 3). The examples can be added to the Q and A.

The need to circulate MHRA approved risk minimisation material means that in this instance the representative can deliver the MHRA approved materials without that being seen as promotion. MHRA approved materials do not need certification (this is similar to the provision of summaries of product characteristics (SPCs) and other regulatory documents). Companies will know that the use of non-promotional material for a promotional purpose would bring the material within the scope of the Code. Companies would be well advised to have briefing material to ensure that the representative only delivers the MHRA approved material. There is no need for it to be delivered in a separate call.

The suggestion to add 'additional' to describe the material was thought to be confusing. The point will be covered in the Q and A.

The suggestion to add 'approved' to the text would be inconsistent with the descriptions of SPCs, package information leaflets. It was made clear in the supplementary information.

If representatives gained agreement from a health professional to visit to deliver approved risk minimisation materials and then used this as an opportunity to promote medicines then it would be likely that the company had not met the requirements of Clause 12.1 Disguised Promotion. This will be covered in the Q and A.

Proposal

No change to Amendment Number 2.

Amendment Number 3 should refer to a risk management plan and risk minimisation material approved by the MHRA rather than 'risk minimisation plans and material ...', 'such approved documentation' should be replaced with 'Risk minimisation matter approved by the MHRA ...'.

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2 Clause 3 Marketing Authorization

Conditional Licences, Early Access to Medicines Scheme and Compassionate Use (Amendment Numbers 4 and 5)

A number of companies queried the reference in Amendment Number 4 to including relevant information wherever possible in national horizon scanning databases wanting clarity/examples of what was meant by 'relevant information' and 'wherever possible'.

A number of companies did not consider that the promotional material for products with a conditional licence needed a statement.

One company pointed out that some products in the Early Access to Medicines Scheme (EAMS) related to products with a marketing authorization but without a licence for the EAMS indication. The wording should be amended to reflect this.

Some companies wanted guidance on how companies could appropriately inform NHS organisations and relevant healthcare professionals of EAMS programmes.

One company gave detailed comments regarding additions to the PMCPA Guidance on Clause 3.

Some companies wanted additional clarity regarding the supply of medicines on a compassionate use to make it clear that these were unlicensed medicines or unlicensed for the indication.

One company noted that the provision of early access or compassionate use programmes should only be provided in response to an unmet need. The existence of such programmes should not be proactively communicated to healthcare providers. The company suggested adding 'The existence of compassionate use or early access programmes must only be communicated in a reactive manner to a relevant query from a health professional'.

One company, whilst in agreement with the proposed changes in relation to advanced budgetary notification, wanted an acknowledgement that for some complex therapies it was highly likely that appropriate contact with health professionals, including potential prescribers would be required.

One company suggested that the supplementary information for Clause 3.1 Advance Notification of New Products etc should be clear that such information should only be provided by the medical department and that only the requested information could be provided.

One respondent referred to the inconsistency in use of the terms marketing authorization/licence.

PMCPA Response

The wording proposed for horizon scanning databases reflects the wording used in relation to the supplementary information to Clause 3.1 Advanced Notification of New Products of Product Changes which may Significantly Affect Expenditure which is already agreed by the industry. The purpose of the reference to horizon scanning is to ensure that full use is made of appropriate mechanisms for communicating about unlicensed medicines.

The proposal to refer to medicines as having conditional licences in their promotional material was to ensure that health professionals were aware of the position and to assist with rational prescribing. There is a difference between a conditional marketing authorization and a marketing authorization. A conditional marketing authorization is for 12 months which may be renewed. Clearly companies need to ensure that they do not refer to the MHRA in mentioning conditional licences (Clause 9.5). This will be covered in the Q and A.

Compassionate use is defined by the European Medicines Agency (EMA) by referring to products in development. This new supplementary information will not stop a company providing medicines which have marketing authorizations.

The proactive provision of information about early access programmes is covered in the proposal. There are ways that companies can communicate and therefore the limitation suggestion by one company is not needed.

The supplementary information for Advanced Notification of New Products or Product Changes which May Significantly Affect Expenditure makes it clear that further information or a presentation may be supplied on request. Prescribers could be involved at this stage rather than being the recipients of the first approach.

It is for companies to decide which part of the company should respond to requests for more information for budget planning purposes. It is the context and content that is important rather than which part of the company sent the response. There is a well-established procedure for responding to individual enquiries in that the responses relate solely to the subject matter of the enquiry, were accurate and not misleading.

The PMCPA Guidance on Clause 3 will be updated to look at including references to advanced therapy medicinal products (ATMP).

Proposal

The reference to horizon scanning database in Amendment Number 4 should remain.

The wording for conditional licence changed to conditional marketing authorization. The requirement to make this clear on material remains. 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

The wording for the Early Access to Medicines Scheme (EAMS) to be amended to read:

'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.'

The wording with regard to compassionate use to be amended to refer to unlicensed use and to remove the reference to conditional licence as it is covered by 'relevant marketing authorization' to read:

'Companies sometimes need 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. These medicines do not have a relevant marketing authorisation and therefore must not be promoted.'

No change to Amendment Number 5.

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3 Clause 4 Prescribing Information and Other Obligatory Information (Amendment Numbers 6, 7, 8, 9, 10)

Legibility

One company wanted reassurance about whether material setting out recommendations for legibility when moved to the Q and A, (Amendment Number 6) became a requirement of the Code.

One company did not see the advantage of removing this supplementary information. It should stay. One company commented that if the Q and A had to be adhered to there was no point in moving it. Could there be a way to link both or to refer clearly to the Q and A as providing the frame to comply with the clause.

Some companies queried why all irrelevant supplementary information was not removed.

PMCPA Response

As the current supplementary information refers to a list of recommendations which will help to achieve clarity, a company would not be ruled in breach of the Code for not following one of the recommendations if overall the prescribing information was legible, perhaps by the layout, style of type etc. Legibility is a result of many factors.

The Code of Practice Panel and Appeal Board would give reasons as to why something was ruled to be illegible. Amendment Number 6 should remain.

Once the EFPIA Codes consolidation exercise is completed the need for the supplementary information in general will be looked at again. The industry appears to be very divided about whether it wants to maintain it or move it elsewhere and have to cross-refer. The update to the PMCPA website should make a difference with the proposals for improved linking. Until companies see this and become familiar with it and given the response to the consultation, the current format should remain.

Proposal

No change to Amendment Number 6.

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Use of links for Prescribing Information

Companies commented that there were two references to electronic detail aids in Amendment Number 7 and this was confusing.

One company wanted the addition of a reference to social media as this might be used for promotion to closed user groups.

Companies commented that the term 'advertisements in online journals' was not the same as online advertisements and wanted the examples to be removed.

One company was concerned that if an individual received and downloaded a promotional email and only read that off line, any link to prescribing information would be invalid if internet access was unavailable. The utilisation of the word 'generally' might cover this eventuality. Omitting this change (whilst cumbersome) would continue to provide accuracy.

One company suggested the term 'electronic journal' was defined in the supplementary information. It could mean an off-line portable document format (PDF) version of the online electronic journal, in which case any link to prescribing information might not function. Furthermore, once an electronic journal was archived, publishers normally allowed the item to be available beyond the signatory approved life of the advertisement, based on this observation, should companies reapprove advertisements in archived electronic journals and always provide a link to the current prescribing information? These two anomalies should be addressed in future revisions of the Code.

One company wondered about cross-referencing to the summary of product characteristics or the electronic Medicines Compendium (eMC) if the need to include the list price was removed.

PMCPA Response

The listing of detail aids in both online and offline use was deliberate. One reference was to electronic detail aids used remotely which was expected to be online use and the other was a reference to an electronic detail aid used by a representative visiting a health professional which was likely to be offline use.

Amendment Number 7 did not refer to 'advertisements in online journals' it referred to '...material expected to be viewed online, for example advertisements in electronic journals'.

The list of examples was not exhaustive. The examples were helpful to those trying to decide what to do and to illustrate the principle.

Some readers might look at emails offline but the vast majority would view them online and thus the change was a pragmatic approach.

It was reasonable to expect advertisements in online journals when archived to be consistent with the requirements in place at that time. Unless archived journals were proactively circulated rather than only available as a library resource, then there should be no need to reapprove advertisements.

The inclusion of cost is a legal requirement.

The 2020 Code will look at making further changes to the requirements for prescribing information and the responses to this consultation will be looked at again. Including the provision of a table setting out the requirements.

Proposal

No change to Amendment Number 7.

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Audio-visual Materials Information and Other Obligatory Information

Companies proposed amending the reference to 'interactive data system' in Amendment Number 8 and requested a definition.

PMCPA Response

An interactive data system is where information is to be added, either by a health professional working on their own, or by a member of staff from a pharmaceutical company to give outcomes for a particular scenario. An explanation will be added to the Q and A.

Proposal

No change to Amendment Number 8.

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Adverse Event Reporting (Amendment Numbers 9 and 10)

Companies proposed leaving the wording around timelines in the supplementary information to Clause 4.9 so that if the address for reporting yellow cards is changed reference remained as to how soon the change must be made.

Companies wanted to include a reference to searching for the MHRA Yellow Card in the Google Play or Apple App Store.

The MHRA did not object to the proposal.

PMCPA Response

The proposal to remove the supplementary information (Amendment Number 10) is changed such that the statement in the current supplementary information that companies are required to use the new address within one year of the change remains.

Companies could refer to searching for the MHRA yellow card in Google Play or Apple App Store if they wished.

Proposal

To remove 'may use a statement incorporating the new address as soon as the change is made and' from the current 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.'

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Supplementary information to Clause 5.2 Professional Publications (Amendment Number 11)

One company stated that DVDs are still produced and wanted to keep the wording around DVDs and their boxes. A number of companies referred to other smaller companies still wanting to produce DVDs and the wording must remain to allow abbreviated advertisements to appear on the box.

A number of companies suggested amending the references to 'journals online' to 'online journals'.

PMCPA Response

No company has responded to state that it actually produces DVDs and they should remain. The content can be provided via other means, for example a memory stick, a website download etc. Do recipients have the equipment to play DVDs? See also Amendment Number 30.

Proposal

Given the responses to the consultation comments the proposal to no longer allow DVDs will be withdrawn and further investigations made with a view to including the proposals for the next Code (2020).

Amendment Number 11 changed to continue with DVDs and to replace 'journals online' with 'online journals'.

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4 Clause 6 Journal Advertising (Amendment Numbers 12, 13, 15, 16 and 17)

Some companies suggested that the two page limit in print journals be applied to all media.

One company wanted clarity that the two pages for a print advertisement included prescribing information.

Companies stated that a digital advertisement made up of several screens is a banner advertisement and the additional wording was not needed as banner advertisements were already covered by the supplementary information to Clause 4.1.

Companies stated that if the limit on digital advertising was lifted then it should be lifted for print advertising. Another company wanted all the restrictions regarding the number of pages to be deleted.

One company suggested changing the heading to advertising rather than journal advertising.

One company queried whether the statement that no page or screen must be false or misleading when read in isolation appeared to contradict the supplementary information to Clause 4.1 Electronic Journals.

One company suggested to account for animated digital advertisements, in which two pages might be displayed in successive frames without a screen change, to add a reference to frames to Amendment Number 12.

A patient organisation wanted the amendments to be clear on whether the requirements for print advertising applied to printed conference/event guides.

PMCPA Response

The restrictions in Clause 6 were introduced for print advertising and related to the unfavourable impression given by multiple pages of advertising for the same product in one journal and the need for health professionals to spend time searching for the journal's editorial text and the impact on the view that the industry was spending too much on marketing medicines. With online journals mostly the reader has to click on the advertisement to see it and then click further if the reader wishes to see the next page or more information, this was different to printed journals and hence the difference in the limit on advertising.

Clause 11 restrictions on distribution of material and volume of advertising still apply.

Given the view of some companies to move to a more principles-based Code, the pragmatic approach is to continue the limitation on print advertising and that if a printed journal appears online as a pdf then the print requirements should apply and leave companies to make their own decisions regarding other types of journal advertising. A Q and A will be added on this point.

A Q and A will be added to make it clear that the two pages in printed journals must include prescribing information.

If a complaint were received that a page/screen was false or misleading, then all the relevant factors and requirements of the Code would be taken into account in reaching a decision.

The requirements for print advertising would apply in printed conference guides etc and this will be added to the Q and A.

Proposal

No changes to Amendment Numbers 12, 13, 15 and 16.

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Loose inserts (Amendment Number 14)

Some companies considered it was not necessary to add print to the requirements for loose inserts or for cards stapled to a print journal as it was not possible to do this for digital advertising.

One company suggested that sizing requirements for both loose-leaf advertisements and their digital equivalents be addressed and stipulated in this clause.

One patient organisation queried whether the requirements for loose inserts would apply in printed conference guides etc.

PMCPA Response

The PMCPA was unsure of the features that could be employed in digital advertising which was a rapidly developing area. It considered it would help clarity to set the restrictions for print advertising. See response above.

The requirements would apply in printed conference guides etc and this will be added to the Q and A.

Proposal

No change to Amendment Number 14.

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Limitations on the Number of Pages of Print Advertising (Amendment Number 17)

One company pointed out a typographical error in Amendment Number 17.

A patient organisation queried whether the limitation would apply in printed conference guides etc.

PMCPA Response

The requirements would apply in printed conference guides etc and this will be added to the Q and A.

Proposal

Amendment Number 17 changed to correct the typographical error, 'regard' replaced with 'regarded'.

The requirements would apply in printed conference guides etc and this will be added to the Q and A.

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5 Clause 10 Provision of Reprints and the Use of Quotations (Amendment Numbers 18 and 19)

One company stated that if something had been peer reviewed it should not need to be strictly in line with the Code. As almost all articles will include either an unlicensed arm or a statement that went against the Code this clause should be relaxed, especially for pivotal studies with which the licence was granted.

One company suggested another amendment to make it clear that the prescribing information must always remain associated with the reprint.

PMCPA Response

The clause relates to the proactive circulation of a peer reviewed study and that such an activity is promotional and needs to comply with the Code. Companies can provide studies to substantiate claims. The supplementary information to Clause 26.2 regarding reference information refers to making available studies about medicines which are licensed.

The supplementary information requires the prescribing information to accompany the reprint. It might not always be possible to attach it due to copyright requirements.

Proposal

No changes to Amendment Numbers 18 and 19.

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6 Clause 14 Certification (Amendment Numbers 20, 21, 22, 23, 24, 25, 26)

Certificates for electronic certification and certifying the final form (Amendment Numbers 20 and 21)

Some companies wanted one certificate with two actions rather than the need for two certificates.

Some companies and other respondents wanted to use a different term to qualified person to avoid confusion with those that were responsible for certifying meeting arrangements under Amendment Number 23.

One company commented it was not possible to certify in final form for example, local invitations, automated tailored email content. Companies should not have to certify numerous combinations of content.

One company suggested re-ordering the sentence in relation to support.

One company wanted to keep some of Paragraph 5 in relation to Amendment Number 24.

PMCPA response

It was for companies to determine how they will meet these requirements. The Code refers to two certificates but there is no reason why the two certificates cannot be presented as one document.

There are to be three types of certification (in brief (a) promotional material etc (b), those that proof check final form of material certified digitally and (c) support for travel outside the UK). The qualifications for those carrying out the functions might be different. It is for companies to determine what the appropriate qualifications are for those who have a certification role, other than when a registered medical practitioner or UK registered pharmacist has to certify. The changes to who can certify some materials/activities need to have a chance to settle before further changes are made.

It could be argued that what is proposed in Amendment Number 21 is not in line with the EFPIA Code that materials are certified in their final form by a registered medical practitioner or a pharmacist (EFPIA HCP Code section 18.02a). The ABPI Board needs to be aware of the discrepancy although it could be argued that the proposal is a pragmatic way of dealing with the decreasing number of printed materials.

The certification of invitations will be covered in the Q and A. Certifying dynamic content is covered below.

Paragraph 5 of Amendment Number 24 is superceded by the need to certify (Amendment Number 23).

Proposal

No changes to Amendment Numbers 20, 21 and 26.

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Certifying Digital Dynamic Content Materials (Amendment Number 22)

Some companies have commented that dynamic content can be used on other channels and the reference to websites should be removed.

Some companies have referred to other channels with dynamic content such as personalised websites, emails and e-details where each section can be certified but there are many combinations that could be used.

One company wanted a broader term to be used 'dynamic or interchangeable' content.

One company thought this was ambiguous and queried how signatories would know when final certification was complete.

One company proposed that a qualified person could verify that the digital content certified by the medical signatory displayed correctly on multiple platforms eg PC, tablet, smartphone.

One company commented that it should not have to certify numerous combinations of content. It was not clear whether this related to content owned by the company, ie within a company website.

PMCPA Response

Companies could, of course, continue with certification of all possible combinations of content.

As the current supplementary information referred to dynamic content on websites the relaxation should only apply to that situation. There was no mention in the proposal of the audiences for the websites. The comments from companies appear to relate to promotional use and the proactive provision of information.

Further work will be done regarding other uses of dynamic content including whether such information is proactively provided or not.

The PMCPA Digital Guidance includes a question on the platform for display (question 14).

Proposal

No change to Amendment Number 22.

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Certification of meetings outside the UK (Amendment Numbers 23, 24 and 25)

One company has suggested that this be changed to meetings organised by a UK company which require travel outside the UK.

Some companies have suggested that due to confusion about signatories and certification and whether current systems could differentiate between signatories for different activities, arrangements for overseas meetings should be examined rather than certified. One company wanted to change the use of certification for travel etc to be re termed 'approval'.

One company wanted the supplementary information regarding supporting speakers to present to remain.

One company wanted advice on meetings and certification guidance setting out the different scenarios.

One company wanted an amendment to the paragraph about supporting a speaker to present at a meeting and that this activity should be treated as a grant.

One company wanted it made clear that for certification of meeting arrangements experience outwith the industry was not a prerequisite.

One company has suggested that the approval of meetings where UK health professionals travel outside the UK should not be required to produce a certificate provided that the company could show that the process and documentation provided evidence that the signatory had examined all the proposed arrangements for the meeting and that in his/her belief the arrangements were in accordance with the relevant regulations relating to advertising and the Code.

One company welcome the decreased burden but thought it would be prudent to have some minimum standards relating to the experience (and possibly other key parameters) of such individuals, regardless of whether they had demonstrated passing a code awareness exam. Amendment 25 provided some guidance for these minimum standards but there should be agreement upon absolute indices for them. The debate on experience should be applied to registered medical practitioners and pharmacists. Many companies were increasingly observing an increase in the number of employees needed for sign off purposes, whilst examinations demonstrated a knowledge of the Code the ability to implement it was improved with experience. This debate must be conducted before future revisions of the Code.

A patient group considered that the contracted arrangements such as air travel bookings should be mentioned as this would make things easier. It should be made clear that this referred to meetings outside the UK.

The MHRA did not object to the changes on the understanding that the UK company must ensure that the ABPI Code requirements are reflected in the arrangements for all meetings outside the UK where UK healthcare professionals are invited to attend, regardless of whether the UK company was funding the arrangements.

PMCPA Response

The requirements for certification related to the involvement of a UK health professional and not whether the meeting etc is organised by a company in the UK.

The current requirement to examine certain meetings has been replaced by certification which can be done by someone other than a registered medical practitioner or a UK registered pharmacist.

There was no proposal to remove the supplementary information regarding supporting speakers to present.

There will be a review of the certification requirements for the 2020 Code. This would include looking at providing guidance as requested.

It was for companies to decide whether supporting a speaker was classified as a grant.

The proposal for qualifications did not require that the person had to have experience outwith the industry. Having no such experience did not mean that person was not able to certify meetings.

There are formal examination requirements for representatives but not for those that certify materials/activities. It should not be developed until the review of certification for the 2020 Code has been completed. The PMCPA is looking at the training it provides. The ABPI is also looking at training. If a qualification for signatories were to be introduced it should be in place well before any requirements in the Code. Consideration should be given to such a requirement being added to the EFPIA Code before national codes.

The suggestion to only certify contracted arrangements might not meet the requirements for certification. The section of the supplementary information is clearly headed 'meetings involving travel outside the UK'.

Proposal

No changes to Amendment Numbers 23, 24 and 25.

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7 Clause 18.1 Prohibition on Inducements, Package Deals etc (Amendment Numbers 27, 28, 29, 30, 31, 32)

Many companies and other respondents commented on Amendment Number 27 to remove references to 'or a nurse to administer it' from the reference to package deals.

Three companies were concerned that the proposed amendment would mean that homecare services would have to be considered as medical or educational goods and services (MEGS) and these could not be linked to a particular product.

One company suggested retaining the reference to a nurse to administer it and state that this must be disclosed.

Companies considered that the EFPIA Disclosure Code (Section 1.02) exempted package deals from disclosure.

Companies did not consider that it was necessary to disclose payments to homecare organisations as these were not healthcare organisations. One company stated if payments were to be disclosed, then the homecare organisations would not want the confidential nature of their contracts disclosed and this was why research and development payments were disclosed in aggregate.

One company referred to the provision of patient support programmes for their products which they considered to be part of a package deal. These programmes were conducted by third parties to ensure independence and patient confidentiality. Nurses employed by these third parties were salaried staff working for the homecare organisation. Clarity was required about what companies were expected to disclose. Any salaried nurse would not consent to their salary being disclosed as this was not a transfer of value. Nurses often worked across several accounts and not for just one pharmaceutical company. It would be a challenge for all companies to obtain this information. Companies paid a fee for the service and only part went towards the nurse's salary. If third parties provided a total salary bill should that be disclosed against the third party? Would they become healthcare organisations as they engaged health professionals? Should payments to these third parties be disclosed or were they excluded because the pharmaceutical company is paying for a service?

Why was the provision of nurses as part of patient support programme not part of a package deal? It should be clarified that nursing support service could be provided as part of a package deal so long as it follows the same criteria of fairness and reasonability and relevance to the associated medicines.

One company requested an additional statement to clarify that this did not preclude the use of a nurse administration service as a package deal provided the company disclosed the transfer of value (TOV) associated with the provision of the service. The company should determine how best to disclose the ToV. The impact on Clauses 1.10 and 24 should also be considered and

whether guidance was needed to drive consistency in reporting. In addition, guidance was needed for what was in scope for disclosure for home delivery services and consider including this as a Q and A.

One company stated that whilst the need to disclose payments (either directly to indirectly) to health professionals was clear and the provision of homecare services through a third party (engaged by the pharmaceutical company) as part of package deal, the need for disclosure of payments to individuals employed by the third party warranted further discussion. These particular individuals would not consider themselves as being in public employment but rather employed by a private company. Either; the proposed amendment should not be a deletion but provide more text for clarity or should be postponed to allow for further discussion.

One company considered that the change was significant and should not be included in the 2019 Code. It should be discussed further and added to the 2020 Code update.

One company stated that where nurses were working for a homecare provider, in the context of company funded support services, the health professionals were performing their duties as employees of the homecare provider. Just as registered nurses who worked within a pharmaceutical company as a salaried employee were not within the scope of the Code in terms of disclosure (ie their salaries were not disclosed), the payments made to the homecare provider for the services of a salaried employee acting on the company's behalf should not be within scope. The homecare providers who employed the nurses would also not be seen as a healthcare organisations within the definition of the Code. It seemed that this had been the obvious conclusion that many pharmaceutical companies had drawn.

One company stated that the issue of disclosing ToVs to nurses formed part of Case AUTH/2883/10/16, this finding should bear upon whether all nurses providing nursing services should be established as health professionals for the purposes of disclosure. It was for each company to determine the nurses' status based upon the nature of the arrangements for their services. Further, costs paid to homecare providers which included a component for the nurse services were confidential between the provider and company. This was further complicated by the fact that some NHS trusts ran their own procurements for homecare services. Other practical concerns existed. For example, who should the ToV be declared against? There was a general principle within disclosure that the ToV should be declared against the individual whenever possible (ie when known and when their consent was provided). If the proposed amendment was implemented, the attribution of ToV could be misleading as the payments to the homecare provider would not be fully transferred to the nurse (the homecare provider would be including its own fees and costs within the 'price to the company'). If it was decided that the payment should be disclosed against the homecare provider (essentially treating it as a healthcare organisation) then other issues arose. The homecare provider was unlikely to want the confidential value of its contracts disclosed. These concerns were part of the reason why research and development ToVs were currently disclosed in aggregate.

The company also noted that Section 3.02 of the EFPIA Disclosure Code stated that 'Individual Disclosure' was an issue where a ToV 'cannot be disclosed on an individual basis for legal reasons'. In such circumstances TOVs were disclosed in aggregate. There was a potential Competition Law risk and the current confidentiality terms within the company's contracts with the homecare providers constituted 'legal reasons' as defined within the EFPIA Code and ABPI Code, (Clause 24.9). If, as a result of the 'legal reasons' disclosure was in aggregate, was the proposed amendment achieving any improvement in terms of transparency?

One company was concerned about individual disclosure requirements in relation to patient support programmes and homecare programmes. These concerns were that disclosing the amounts paid to healthcare organisations for health professional services potentially revealed

competitively sensitive information on commercial arrangements with suppliers of services. Where the identity of an individual was known due to adverse event report training and SPC training, disclosure at an individual level could lead to disclosure of primary income. The company queried whether individual disclosure could be removed where the pharmaceutical company had no involvement or influence over the selection of individual health professionals engaged by a healthcare organisation to deliver services on behalf of that company and where the engaged individual was not involved in the recommendation or prescription of medicines, the primary income was derived from working for the supplier engaged to provide the service.

PMCPA Response

Section 1.02 of the EFPIA Code excludes transfers of value that are part of ordinary course purchases and sales of medicines by and between a pharmaceutical company and health professional (such as a pharmacist) or a healthcare organisation.

This relates to discounts for the purchase of medicines etc rather than the provision of a service included in the price of the medicine. The EFPIA Code does not specifically exclude package deals.

The reason for Amendment Number 27 was to remove an anomaly as such services should be disclosed as transfers of value.

Amendment Number 27 was not intended to stop the provision of nurses to administer medicines. The intention was to remove the exclusion for disclosure to ensure the ABPI Code was in line with the EFPIA Disclosure Code.

The premise of the EFPIA Disclosure Code was for pharmaceutical companies to be looking to disclose payments for fees for services, whether these were to individual health professionals/other relevant decision makers or to healthcare organisations.

The definition of a healthcare organisation under Clause 1.9 of the ABPI Code is broad. It is difficult to see that organisations through which nurses provided services in the healthcare area are not healthcare organisations. The principle is that the pharmaceutical industry should be looking to disclose. 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 on behalf of a company for the benefit of a recipient or through an intermediate and where the company knows or can identify the recipient that will benefit from the transfer of value (Clause 1.10).

Clearly companies will know their own arrangements with organisations and the PMCPA is not aware of every type of arrangement so it can only make general comments bearing in mind the principles set out above.

The provision of homecare and patient support services is allowed under the Code. It is very difficult to see that when third parties provide such services on behalf of a pharmaceutical company those third parties do not meet the definition of a healthcare organisation. Thus they should be disclosed.

The reason research and development was disclosed in aggregate was not for legal reasons. Research and development, and in particular clinical trials, were subject to transparency legislation under the EU Clinical Trial Regulation (2001/20) and the European Medicines Agency Transparency Policy (Policy 0070). The names of investigators working on industry-sponsored trials would be disclosed publicly in the Clinical Study Reports published by the European Medicines Agency.

One solution would be to amend the supplementary information to Clause 1.10 so that only some package deals are excluded from disclosure and amend the supplementary information to Clause 18.1 to make it clear that when a company employs a health professional or a healthcare organisation to provide a fee for service then this must be disclosed.

Companies would then have to decide whether the payments were to known or identifiable individuals or to an organisation. The fee for service element could then be disclosed.

There should be further discussion about how the payments were disclosed with EFPIA and others. Further changes, if needed, could be made to the 2020 Code.

Proposal

Amend the supplementary information to Clause 1.10 Excluded Definitions to add 'certain' to the exemption for package deals to read:

'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.'*

Companies would then have to show that the package deal was an ordinary course purchase for it to be exempt from disclosure.

Add to the current supplementary information to Clause 18.1 Package Deals a reference that package deals relating to ordinary course purchases and sales of medicines are exempt from the requirement to disclose as set out in the supplementary information to Clause 1.10.

Other package deals which include the provision of services will need to be disclosed in accordance with Clause 24. To read:

'Clause 18.1 Package Deals

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.'

Addition of reference to genetic testing to Clause 18.1 supplementary information package deals (Amendment Number 28)

Companies requested that the proposed addition of genetic testing be expanded to other diagnostic testing.

Companies suggested that it should also include 'or other biomarkers/specific diagnostic testing'.

PMCPA Response

It should be clear that the testing is a requirement prior to the use of that medicine.

Proposal

Amendment Number 28 amended 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 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.'

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Supplementary Information to Clause 18.1 Health Professionals Codes of Conduct and Clause 22 Meetings, Hospitality and Sponsorship (Amendment Numbers 29 and 32)

One company suggested including a reference to physiotherapists and their regulator.

PMCPA Response

The references to regulators for medical practitioners, pharmacists and nurses are used because these are the most common health professionals with whom the industry interacts. Amendment Numbers 29 and 32 are to add a reference to statutory regulators of health and care professionals and this includes physiotherapists. There is no need to specifically refer to physiotherapists. A Q and A could be added to list what is covered by the health and care professionals.

Proposal

No changes to Amendment Numbers 29 and 32.

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Supplementary Information to Clause 18.1 DVDs (Amendment Number 30)

One company requested that this should remain as it still provided DVDs in a box to health professionals.

Companies referred to smaller companies that did not have UK websites or permission to send promotional emails might still need to provide DVDs particularly with very large documents such as clinical trial protocols, commercially sensitive information or patient packs. There was no good reason for the PMCPA to prohibit the provision of DVDs in such situations.

PMCPA Response

See response in relation to the supplementary information to Clause 5.2 above.

The materials listed could be provided on memory sticks or as downloads rather than DVDs.

Proposal

DVDs should continue and Amendments Number 11 and 30 amended/deleted.

* * * * *

Supplementary Information to Clause 18.2 Patient Support Items (Amendment Number 31).

One company suggested that the cost for patient support items should be further increased to £15 as the majority of peak flow meters were more than £10.

One company wanted guidance on the value of digital items for example apps provided to patients as part of a patient support programme, for inclusion in Q and As or Clause 18 guidance. Currently only the value of a patient support item as part of a wider patient support programme was provided under Clause 18.2.

One company wanted clarity that the limit for patient support items does not apply to nurse support.

A patient organisation recommended that this cost should be raised for hospitality/giveaways at conferences and events for health professionals.

PMCPA Response

It is difficult to justify such a large increase from £6 to £15. This will be looked at again for the 2020 Code. Further work would be done on patient support programmes for 2020. The Q and A would be expanded.

The limit is in relation to physical items such as a peak flow meter etc.

The pharmaceutical industry was very limited as what could be given to health professionals. There had been no request from companies to raise the limit for pens and pads, memory sticks and DVDs. No other giveaways were allowed. The restrictions for the maximum cost of a meal were set out in the supplementary information to Clause 22.2 and there was no proposal to increase this figure.

Proposal

No change to Amendment Number 31.

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8 Clause 26 Relations with the Public and the Media (Amendment Number 34)

Supplementary Information to Clause 26.2 Financial Information

Companies did not understand the intent of the proposal and suggested that if financial press releases were to be outside the scope of the Code then financial press releases should be exempted under Clause 1.2.

Companies were unclear as to where the suggestion came from and it was also unclear why the PMCPA suggested that Clause 7 did not apply.

One company stated that not applying Clause 7 to such information gave the impression that there were no restrictions on what could be said in shareholder announcements. The company suggested that this phrase was removed and emphasis put on the preceding statement that: 'Such information must be factual and presented in a balanced way taking into account the information needs of the target audience'.

One company considered that Amendment Number 34 potentially reduced standards.

One company disagreed with this proposal as Clause 7 was the standard that applied across all materials and activities and will be covered by the key principles of the Code. Removing this as a requirement might introduce risk.

One company welcomed the recognition that all elements of Clause 7 were not applicable to financial information however describing financial information as being exempt from Clause 7 could cause confusion. Clause 7 should represent the information standard for the industry and relevant elements be applied to information as appropriate. The company suggested adding 'The requirements of Clause 7 relating to information (Clauses 7.2, 7.4, 7.5, 7.8, 7.9, 7.10, 7.11) also apply to financial information'.

One company welcomed this suggested amendment as progress towards alignment with some other European and Global codes. It would not result in a reduction of standards. Companies would have the ability to present and provide information in a way which was more accessible to, and appropriate for, the financial audience. To ensure that press releases were transparent the final sentence could be changed to: *Business press releases should identify the business importance of the information and should be appropriately worded for the intended audience.* This addition would require greater explanation or limit the use of technical, scientific or clinical terms in a press release, especially if the primary audience was heterogeneous and composed mainly of lay public investors. The amendment would bring the Code into line with the MHRA Blue Guide. Much financial information was covered by other regulations (Listing Rules, Market Abuse Regulations as supervised by the financial conduct authority). Recent cases, Case AUTH 3011/1/18 and AUTH/2046/9/07 showed that clarity was needed as the PMCPA had taken differing positions on the same Code provisions.

One other respondent did not see the need for the proposal. If Clause 7 did not apply, would it be appropriate for the medicine to be referred to as 'safe' in financial information? It was an established principle that any information must take account of the informational needs of the recipient and be appropriately tailored in content and form. There was no justification for the financial community to be given any special treatment. It was difficult to understand how Clause 7 was burdensome for companies and this would not be understood by recipients. Changing a requirement because it was burdensome seemed contrary to the spirit and principles of the Code and played to the view that the industry preferred commercial expediency to effectiveness of self regulation.

The MHRA did not support the original proposal. It understood that companies might need to disclose information that was relevant to the financial markets and there was an existing exemption in the Code and in UK law for factual, informative announcements that did not include product claims. This would exclude the majority of corporate and stock market related communications because these would not usually include product claims. Care should always be taken that corporate communications provide accurate, factual information in a non promotional format and were appropriately targeted. This would serve to ensure companies could take advantage of the existing exemptions. The MHRA referred to a recent case (Case

AUTH/3011/1/18) and did not consider that a clear case had been made to exclude press releases that gave extensive details of the clinical benefits of a medicine (product claims) from the ABPI Code simply because they are badged as corporate or financial communications. Such announcements might be widely distributed and reported on in the general press. The Code and PMCPA complaint process promoted high standards and also provided a speedy and effective remedy if any pharmaceutical company should issue promotional or misleading information about specific medicines.

In response to the MHRA's concerns, the ABPI and a particular company discussed the change with the MHRA. The MHRA maintained its position that a clear case for the amendment had not been made. Notwithstanding this should the ABPI wish to proceed it would be essential for additional safeguards to be incorporated to the supplementary information to Clause 26.2 so that any breaches could be addressed under Clause 26.2. ABPI's suggested form of words to achieve this was agreed by the MHRA. The proposal was amended to include references to 'non-promotional', 'accurate' presented in a 'factual' and balanced way 'and not misleading'. A further amendment was made to add 'and should only be aimed at the intended financial and investment audience'. The MHRA saw these revisions as ensuring that the key quality standards and safeguards were now present in the supplementary information to Clause 26.2 and considered that this was an acceptable alternative.

PMCPA Response

The PMCPA did not support the original proposal which was from the ABPI following discussions with a company. The PMCPA has always considered that the relevant quality standards in Clause 7 should apply to all information issued to the media, irrespective of whether the information was to financial journalists, medical journalists or the lay media. There was no additional burden in relation to application of relevant parts of Clause 7.

When considering cases, the PMCPA always took into account the intended audience of the material (as covered by Clause 11) so the addition of such language to Clause 26 was superfluous.

Following the ABPI discussions with the MHRA and the update to the proposal, the PMCPA noted that some of the quality standards of Clause 7 were now repeated in the proposed supplementary information to Clause 26.2. The PMCPA considered that companies would be well advised to apply the Clause 7 quality standards to the material covered by the proposed amended supplementary information to Clause 26.2. It noted that the proposed amendment meant that if companies met the conditions set out at the start and end of the proposed amendment, ie information made available in order to inform shareholders, the stock exchange and the like by way of annual reports and announcements only aimed at the financial and investment audience, then a failure to meet the required quality standards (non-promotional, accurate, presented in a factual and balanced way and not misleading), would be a potential breach of Clause 26.2 rather than Clause 7. The PMCPA did not see the need for the amendment and queried whether it was a proportionate response to previous cases.

PMCPA Proposal

Amendment Number 34 should be withdrawn.

ABPI Response

The ABPI believes that it is essential to update the Code to better reflect the needs of the financial community and to provide consistency across Europe and internationally. In the ABPI's view, the

PMCPA has, over the years, extended its application of multiple clauses of the Code in this space, where Clause 26.2 is sufficient alone.

Amendment Number 34 should remain.

ABPI Board decision

Amendment Number 34 as amended following discussions with the MHRA to remain.

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9 Supplementary Information to Clause 26.3 Black Triangle Symbol (Amendment Number 35)

One company wanted it made clear whether a black triangle was required to be included on press releases or not.

PMCPA Response

The use of black triangles on press releases will be covered in the Q and A.

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10 Clause 27 Relationships with Patient Organisations (Amendment Number 36)

Work was ongoing with regard to guidance in this area. The responses would be assessed as part of that work.

Clause 27.7 timing of declarations of patient organisation support

Some companies did not agree with the proposed harmonisation of timing for the patient organisation declarations of interest.

PMCPA Response

The proposed harmonization of timing is in line with the EFPIA Board view that all the disclosures should where possible be at the same time.

Companies could of course disclose patient organisation payments ahead of June in the calendar year. They just could not do after 30 June in the calendar year.

Proposal

No changes to Amendment Number 36.

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11 Clause 28 The Internet (Amendment Numbers 37 and 38)

One company agreed with renaming the clause if more content was added as currently the content only includes the internet.

Companies suggested changes to add clarity including 'if it were placed by a UK company or with a UK company's authority or if it were placed on the Internet outside the UK by an affiliated company and makes specific reference to the availability or use of the medicine in the UK.

Some responders thought the requirements were clear.

PMCPA Response

Amendment Number 38 should be made clearer to set out the two different approaches.

Proposal

Amendment Number 38 changed to read:

'28.2 Information or promotional material about medicines covered by Clause 28.1 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.'

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12 Disclosure Template (Amendment Numbers 40, 41, 42, 43, 44 and 45)

One company wanted more information about the implementation date for changes to the template. Clarity would be helpful.

One company wanted a recommendation to explain how the totals were to be provided so there was one method across the industry.

One company commented that in its experience health professionals typically gave consent for all transactions reported from a single company not just some. However, there was varying consent values across companies. The company recommended that this was done at a higher level by the ABPI to show the number of health professionals who had given consent to some companies but not to others. This might be more effective in reaching the goal of analysing industry wide data more accurately.

One company wondered whether the template could be updated to include a facility to submit numbers of individuals with partial disclosure.

One company commented on how the change to the methodological note would work and how they were to be stored. They were currently only filed as an internal file.

One company queried whether the reference to Cegedim (Note 3) should be replaced with IMS or IQVIA.

One company wanted the 'freeze pane' feature to be added to the template.

One company disagreed with the proposal to remove the option for aggregate information to be provided in relation to healthcare organisations (Amendment Number 42). This was interpreted by that company as removing the requirement to disclose payments to healthcare organisations.

One company was concerned about removal of the option for aggregate for healthcare organisations. It had a small number of long term pre-disclosure healthcare organisation contracts for which it had not been possible to include a disclosure clause. Also, as the definition of healthcare organisation was very broad some organisations did not agree with the company's assessment of them as a healthcare organisation. Removing the option for reporting transfers of value (ToVs) to such organisations under healthcare organisation aggregate would cause difficulties.

Disclosing at the named healthcare organisation level without consent could lead to issues between the pharmaceutical company and the healthcare organisation. It would not be appropriate to disclose such ToVs under aggregate research and development as this would not be accurate. There would be no other way to disclose such ToVs leading to potential lack of compliance with the Code and decreased transparency of such payments. For these reasons the option to report payments under aggregate healthcare organisation should remain.

One company which did not allow partial disclosure of payments to individuals suggested that the Code was amended to only allow companies to individually disclose all payments. However, it understood the current position that partial disclosure should continue to be allowed to avoid any criticism from health professionals that they were willing to disclose certain payments and the Code did not allow them to due to partial disclosure not being allowed.

PMCPA Response

The PMCPA was mindful that any changes to the template had implications for companies particularly if their systems had been amended to follow its format.

The template would be agreed in 2018 and should therefore be used for the disclosure of 2018 data to be submitted to Disclosure UK in March 2019 for publication in June 2019. The previous template should be used for 2015, 2016 and 2017 data.

The EFPIA Codes consolidation included looking at adding clarity regarding the columns.

The totals were thought to be explained by the notes but given the comments further information has been added to the notes.

The reference to Cedigem has been changed.

There are two variables to the data. Amendment Number 45 was trying to deal with the within company data where an individual working for one company has agreed to some payments from that company being disclosed individually and others from the same company in aggregate. The publication of this information would assist the ABPI in its calculations as this would give an indication of the numbers of individuals that that company worked with.

It is not possible for Disclosure UK to provide information about whether one individual agreed to named disclosure for all the companies that individual works with or only some of them ie between company variability.

The ABPI and NHS England are working together to increase individual disclosure.

The methodological note was in the public domain and the proposal for it to include additional information would not alter that.

Adding 'freeze pane' to the template would be a change of structure which was very likely to have other consequences. This would be raised with EFPIA.

The current Code requires payments to healthcare organisations to be disclosed on an individual project basis and the healthcare organisation to be named. The aggregate column for healthcare organisations should not be used which is the reason for Amendment Number 42 ie to remove the option for companies to aggregate payments and not name the individual healthcare organisation.

Further changes would be needed following the EFPIA Codes consolidation. The date of the implementation of the template should be added to make it clear that the template agreed for the 2019 Code should be used for submission of the 2018 data in March 2019. The template for the 2016 Code should continue to be used for the 2015, 2016 and 2017 data.

Change Amendment Number 40 to add to the statement in the beginning of the book about the date of operation. The template for disclosure agreed for the 2019 Code should be used to submit the 2018 data to Disclosure UK.

Proposal

Changes to Amendment Number 40 to clarify expectations regarding the timing of the implementation of the updated template.

Changes to Amendment Number 43 to add clarity to Note F to read 'Total number of individuals disclosing in aggregate WARNING this is not necessarily a sum of columns V, W, X and Y as individuals might appear in more than one category ie receive fees and expenses'.

The reference in Note 3 to Cedigem to be removed and 'This can be left blank' to be added to Note 3.

Note K to be changed to 'Total £ for that HCO across all activities except R&D'.

No changes to Amendment Numbers 41, 42, 44 and 45.

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Other suggestions to change the Code (not included in the consultation)

- a) One company asked what exceptions could be made when dealing with innovative medicines, particularly for companies operating in a non-competitive space. The company referred to education of health professionals, patient advocates and patients. What guidance could be provided for information on health, science, technology education? There should be recognition of professional patient advocates or expert patients.

PMCPA Response

The requirements in various codes, regulations and the ABPI Code are the same for all medicines. Some of these points were being addressed by the group looking at guidance on interactions with patient organisations.

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- b) One company wanted a new sub-clause in Clause 3 to refer to the legitimate exchange of medical and scientific information during the development of a medicine. As the UK should be able to participate in activities considered as scientific exchange by other countries.

PMCPA Response

There is already supplementary information about the legitimate exchange of medical and scientific information. The guidance to Clause 3 is to be updated. The proposal to change the Code should be discussed with the MHRA given the requirements in UK law. Further details will be obtained and this will be considered for the 2020 Code.

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- c) Some companies wanted more in Clause 4.2 about how serious adverse events were listed in the prescribing information. Most if not all companies set out common adverse events however there was a large inconsistency as to whether serious adverse events were highlighted in the same way. Clarification was essential and long overdue despite requests for clarification.

One company wanted further changes to the requirement for prescribing information to include hyperlinks as this would be easier to update and save resource.

PMCPA Response

This would be followed up with companies if it was a problem with categorization of an adverse event to decide whether a particular adverse event was serious or common, this was an issue. Clause 4.2 point (v) currently stated that the prescribing information included:

'a succinct statement of common adverse reactions likely to be encountered in clinical practice, serious adverse reactions and precautions and contra-indications relevant to the indications in the advertisement, giving in an abbreviated form the substance of the relevant information'

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- d) One company wanted further clarification of providing prescribing information on audio visual materials such as a podcast and proposed additional supplementary information to Clause 4.5. For audio-visual materials that are downloadable such as podcasts, it would be

acceptable to have the prescribing information available at the point of download and not as part of the advertisement. The prescribing information could be made available as part of the website where the downloadable item is hosted.

One company believed that the requirement to certify a transcript of audio visual materials should be removed (Supplementary information to Clause 14.1 Certification). A company remained fully accountable for all items and it was for the company to determine which source documentation was needed to aid this approval and certification.

PMCPA Response

The PMCPA needs to be provided with a transcript in the event of a complaint.

Further work on the provision of prescribing information would start shortly.

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- e) One company wanted an addition to Clause 6 to refer to ensuring that on line advertising was placed to ensure that it is aimed at a healthcare professional audience.

PMCPA Response

There is a general requirement in Clause 11.1 to tailor the material to suit the audience. Clause 28 refers to the open and closed access. The suggestion will be explored further.

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- f) One company wanted references in Clause 9.9 to obsolete channels of communication to be removed, for example facsimile and automated calling systems.

PMCPA Response

This would be followed up. Facsimile machines/options were still available as were automated calling systems.

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- g) Two companies wanted to delete the supplementary information to Clause 11.2 reference to the limitation of 8 mailings/year as this was common sense. There had been no breaches of this clause looking at the last 10 years. A complainant could still complain that the manner and frequency of mailings is unacceptable.

PMCPA response

This requirement was introduced to counter criticism that health professionals were overwhelmed with advertising. It has been helpful to have limitations on the volume of advertising and being clear as to what is reasonable is often helpful and stops companies having long discussions about whether 8 mailings per year is ok or not. There is a proposal to look at all limitations on the volume of material/activities for the 2020 Code.

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- h) Some companies wanted more consistency in relation to the standards applied for examining material for example as set out in the supplementary information to Clause 14.3 and who

conducts this examination. The reference to ‘ensure it does not contravene the Code or the relevant statutory requirements’ implied that the standard required was the same as that required in certification but clarification would be helpful. Clarification in relation to the experience and qualification for those that examine material would also be helpful.

PMCPA Response

This would be looked at for the 2020 Code.

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- i) One company wanted the Code to align between email communication and the need to obtain prior permission and mailings where consent was needed and physical mailings. It also referred to the impact of the General Data Protection Regulation (GDPR) on market research.

PMCPA Response

The Code includes a general requirement about the need to comply with applicable codes, laws and regulations (Clause 1.11). Companies sending hard copy mailings needed to be confident that the mailing house/source of names and address met GDPR requirements but did not see a need for the Code to require permissions in addition to GDPR requirements before sending materials in the post.

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- j) Companies noted that the MHRA blue guide did not refer to the need to notify the PMCPA of signatories and doing so in addition to the MHRA was an administrative burden. It should no longer be required, particularly as the case preparation manager asked for the certificate for materials. One company was concerned that maintaining an up to date list would result in a significant burden for the PMCPA and MHRA.

PMCPA response

The requirement to inform the PMCPA and the MHRA of the identity of signatories is a requirement of the Code. It is not a requirement of UK law.

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- k) One company wanted to remove the reference to 3 calls per year from the supplementary information to Clause 15.4 in relation to calls on prescribers as an absolute number of 3 was not helpful. The company also wanted clarification of what was classed as solicited calls versus unsolicited calls including the following, turning up at a healthcare professional office without an appointment, arranging an appointment that the healthcare professional has agreed to and a meeting which was a follow up and requested by the health professional.

PMCPA Response

The reasons for the limitation and the differences in solicited calls and unsolicited calls would be covered in the Q and A.

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- l) One company wanted to include life sciences PhDs as signatories in addition to registered medical practitioners, pharmacists registered in the UK and UK registered dentists to those that can certify.

PMCPA Response

EFPIA Codes set out the requirements for signatories and this does not include PhDs. The professional codes of registered medical practitioners and UK registered pharmacists include obligations to patients. This will be covered in a Q and A.

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- m) Some companies wanted more guidance about the expectations in relation to the content and oversight of patient support programmes (Clause 18.3). The prohibition of giving patient support materials out at exhibition stands is due to the EFPIA HCP Code.

PMCPA response

It would be helpful to have more details about what would be in such guidance. This would be discussed with the Compliance Network. Exhibition stands should be about the information displayed and provided and not about what can be given to health professionals etc

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- n) Companies wanted Clause 23 to be expanded to encompass non health professionals and other relevant decision makers when engaged to provide services for example journalists and patients.

PMCPA response

This will be covered in the Q and A in so far as companies should follow the guidance in Clause 23. It needs further discussion and consideration as disclosure is required under Clause 23 and should this apply to patients and journalists? Should the industry be paying patients and if so is there a difference between paying a patient to talk to company staff about the impact of a disease to asking that patient to speak on behalf of the company at meetings etc? These topics were being discussed as part of the work on patient organisations.

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- o) Companies wanted a definition of a patient in Clause 1.

PMCPA response

This was currently being discussed as part of the EFPIA exercise to consolidate the three EFPIA Codes. It would be considered for the 2020 ABPI Code.

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- p) Companies wanted the EFPIA definition of a patient organisation to be used in the ABPI Code and for it to appear in Clause 1.

PMCPA response

The current definition in the ABPI Code is broader than the EFPIA Code. Does this mean that companies do not need the broader definition? What will happen to those companies who interact with the additional groups? What rules should cover them?

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- q) One company wanted the detail for what should be included in a written agreement (supplementary information to Clause 27.1) to be removed as well as the need to certify the agreement.

PMCPA Response

This would be looked at as part of the work on guidance for working with patient organisations. Some of the wording was from the EFPIA Patient Organisation Code and would be looked at following the completion of the EFPIA Codes consolidation.

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- r) The MHRA referred to an advisory board for journalists and the action it took including advice issued in the MHRA report. It invited the ABPI and PMCPA to consider if additional advice or any Code changes were needed to ensure journalists were not incentivised or rewarded by pharmaceutical companies for writing articles about specific prescription only medicines.

PMCPA Response

There is a Q and A on this area with the advice to follow the requirements of Clause 23. If a complaint were to be received, Clause 9.1 to maintain high standards, Clause 26 Relations with the public and Clause 2 might be relevant. This will be looked at for the 2020 Code.

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- s) one AHSN wanted the joint working process to be adjusted as it was slow cumbersome and complex.

PMCPA Response

The Joint Working Agreement process was issued jointly by the ABPI and the Department of Health. This would be taken up with the ABPI.

ABPI Response

This will be looked at and include input from the ABPI NHS Engagement Team.

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B CONSTITUTION AND PROCEDURE

Change in Job Titles (Amendment Number 3)

One company wanted reassurance that the change in job title of staff who might act in the absence of the Director and Deputy Director did not denote that decisions might in the future be taken by less experienced or less senior staff.

PMCPA Response

The change in job title does not reflect on the seniority of the staff. Appointments to the PMCPA are made by the ABPI Board and account is taken of the role. Obviously newer appointees have less experience but staff are developed.

Proposal

No change to Amendment Number 3.

Co-option (Amendment 4)

One company was concerned with the proposal to allow co option to the Code of Practice Panel it wanted additional guidance on whom might be co-opted and appropriate direction on how to address potential conflicts of interest.

One company was concerned that someone employed in any capacity within or by the industry could have a potential conflict of interest.

PMCPA Response

The proposal refers to the need to assess potential conflicts of interest and possible candidates being previous members of the Authority or Appeal Board. It is not envisaged that this would be used frequently. A system similar to the Appeal Board could be introduced ie a list of names approved by the ABPI Board.

Proposal

Changes to Amendment Number 4 to refer to following procedures for appointing the Authority.

Reintroduction of no *prima facie* case (Amendment Number 5)

One company was concerned that the reintroduction of no *prima facie* case meant there was no option to appeal.

PMCPA Response

If the complainant does not accept that there is no *prima facie* case, he/she can ask that the matter be referred to the Panel in the usual way. This is the appeal of the decision that there is no *prima facie* breach. The complaint will be considered in the usual way and the Panel's ruling can be appealed either to the Code of Practice Appeal Board if a breach is ruled (Paragraph 7.1 of the current Constitution and Procedure). If the Panel rule no breach as the matter is outside the scope of the Code then this can be appealed to an independent referee (Paragraph 7.6 of the current Constitution and Procedure).

If there are learnings from cases ruled outside the scope of the Code these are currently included in articles in the Code of Practice Review etc where this is meaningful and does not identify the product or the company. This would continue under the new arrangements.

Proposal

No change to Amendment Number 5.

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Other comments

- a) Some companies stated that there had been considerable concern for some time about the time taken for the Panel to consider a complaint and notify a company about its outcome. There was a lack of transparency overall in the complaints process. In addition, there had been a number of mistakes by the case preparation manager and the Panel with no obvious oversight of the process or mechanism whereby any lessons learned as a result of the mistakes to ensure that they are not repeated. Companies referred to a standard operating procedure developed by a third party which provided standardisation and transparency in relation to the complaints process as well as an element of oversight. This should be incorporated into the PMCPA Constitution and Procedure.

One company wanted an online form for complaints to be provided.

One company wanted case reports to be enhanced to include a rationale for the clauses cited by the case preparation manager, clauses ruled in breach and the learnings for companies.

One company recommended a better framework around the current complaint process.

One company wanted complaints with patient safety implications to be prioritised.

One company wanted the PMCPA to explore ways of dealing with anonymous complaints to ensure that this route was not being exploited to avoid inter company dialogue.

PMCPA response

The PMCPA always looks to complete consideration of cases as quickly as possible. There has been an increase in complexity and the volume of material to be assessed. The ABPI Board has regularly been informed of the pressures on the PMCPA. In addition the has been short staffed for 18 months due to circumstances outside its control. However, a new member of staff recently joined the PMCPA and this should help ensure cases are dealt with more quickly. This point will be highlighted in relevant PMCPA annual reports. The published case reports provided full details of the cases and it is difficult to understand what is meant by a lack of transparency. Where the case preparation manager and the Panel have made mistakes, these are discussed with the Appeal Board which has oversight responsibility for the complaints process (Paragraph 1.3 of the PMCPA Constitution and Procedure).

The Panel prioritises complaints already. Complaints about materials in use are generally prioritised over other cases. The parties to complaints often submit a lot of detailed information which must be considered carefully and such work is very time consuming. There is an extremely high work load which needs much attention to detail. The increase in time taken by the Panel is concerning but the Panel's decisions are often upheld on appeal (data published in the PMCPA annual reports). The Authority has also been involved in a number of audits and other activities

which have had to take priority at certain times and again this involves consideration of large quantities of detailed information.

The PMCPA understands the frustrations surrounding anonymous complaints.

The suggestions made will be considered and discussed further.

ABPI Response

The ABPI acknowledges the pressures on the PMCPA and suggests that in addition to the PMCPA Constitution and Procedure, development of a standard operating procedure (SOP) for the complaints procedure is considered including turnaround times for complaints and queries. An update on this work will be provided in 2019.

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- b) One company suggested it would be helpful to clarify the approach to companies that are not members of the ABPI and which have not agreed to comply with the Code.

PMCPA response

Paragraph 5.2 of the Constitution and Procedure deals with this, as does other parts of the Code booklet. It will be added to the Q and A.

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- c) The ABPI suggested an amendment to Paragraph 6.1 of the Constitution and Procedure, Complaints Arising from Media Criticism. The ABPI proposed that such matters *may* be treated as a complaint (rather than *is* treated as a complaint as currently) and that before contacting the respondent company the Director should first make an initial assessment of the veracity of any reporting by enquiring within the ABPI and with the company concerned. If the reporting appeared to be accurate, the matter would then be progressed as a complaint. This change would rule out articles that were spurious or otherwise mistaken, before the full rigour of PMCPA formal process was applied.

PMCPA Response

The PMCPA noted that this would mean a fundamental change in that the operation of the Code would no longer be separate from the ABPI itself given that the PMCPA would have to discuss matters with the ABPI and the respondent company prior to taking action.

The PMCPA understood the concerns of companies but any company that wanted input from the ABPI on a response to a complaint was able to do so under the current arrangements. The accuracy or otherwise of a media report could be addressed by the company in responding to the complaint as it is currently. The proposal to reintroduce a ruling of no *prima case* to answer was to deal with these situations so in the event there was no case to answer, the Code of Practice Panel would not have to consider the matter. There was also the question of whether every company would want such matters discussed by the PMCPA with the ABPI. What would be the ABPI role if the company was not a member of the ABPI? Should the author of the media report be contacted for a view?

The PMCPA has serious concerns about this proposal and the ABPI response (see below). The PMCPA considered that the proposal should be discussed further with the ABPI, companies and stakeholders such as the MHRA. If the ABPI proposal reflected the approach that the industry

wanted then the implications for other complaints must be considered. As it was such a fundamental change it must be fully consulted upon.

ABPI Response

The ABPI will consider a simple process whereby it alerts companies to media coverage and media criticism. The PMCPA should include ABPI in any communications to companies about action it planned to take in the light of media criticism.

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- d) The MHRA stated that it supported the work in auditing companies where there have been serious breaches of the Code. It was concerning that these often discovered procedural deficiencies leading to a re-audit. In other areas it was routine to have some form of regular internal audit that might help to pick up problems before they reached the level of PMCPA involvement. The MHRA stated that this was raised by a company when the MHRA met that company to express its concerns about the company’s compliance record and the PMCPA re-audit findings. In response to a question from the MHRA about whether there were any pointers that could have alerted them or regulators to the company’s problems earlier, the company suggested that internal audits of procedures might have helped. Thus the MHRA invited the PMCPA and ABPI to consider whether it would be useful to add regular audit to the compliance requirements under the Code, particularly as only a single signatory was required for materials/activities.

PMCPA Response

The PMCPA will always ask companies being audited for details about the company’s internal checks on materials and processes. The PMCPA understands from other discussions that some companies that have not been required to be audited by the PMCPA have regular internal audits.

Proposal

That companies should consider routine internal audits as means of assisting with compliance will be added to the Guidelines on Company Procedures relating to the Code.

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GUIDANCE

One company proposed it would be helpful to produce a simple guide to help with health professionals' understanding of what companies could provide. Reference was made to requests for sponsorship to attend meetings, what can be provided at meetings, food, drink and who can be provided with this, timescales and expectations when agreeing to present at meetings or when asked for company support for meetings, limitations on fees and hospitality.

PMCPA Response

The PMCPA guidance would be updated and new guidance developed including working with patient organisations.

Q AND A

A number of companies were concerned about the proposed use of Q and A and that the Code would be looked at in isolation. There were also concerns about how frequently the Q and A would be updated and how companies and others would be made aware of updates.

Two companies urged the PMCPA to use the expertise in the ABPI Code Working Group and the PMCPA Compliance Network to consider how the Code and associated documents could be formatted to provide clarity and consistency. The use of tables, flowcharts and colour could vastly enhance the interpretation of the requirements which would improve adherence.

One company was concerned that there were no answers which would be needed to fully assess the usefulness of the approach. The introduction of Q and A should not replace comprehensive guidance on complex areas such as the legitimate exchange of medical/scientific information during the development of a medicine.

Suggestions for additions to the Q and A from a number of pharmaceutical companies and others have been included in the update

PMCPA Response

Companies would only be ruled in breach if they failed to meet the requirements of the Code/Supplementary Information. A company could not be ruled in breach for failing to follow PMCPA Guidance or the PMCPA Q and A. However, the content of the PMCPA Guidance and Q and A should assist companies in making decisions and provide clarity including reasons for the Code requirements. The development of Q and A is not a means to add requirements to the Code/Supplementary Information. The proposals to improve the PMCPA website will mean that relevant Q and A and guidance are highlighted with relevant clauses.

Updates to the Q and A would be e alerted by the PMCPA so companies would have to sign up for PMCPA e-alerts.

The more detailed guidance would remain and be developed for more complex areas, including working with patient organisations, digital sphere.

DRAFT PRINCIPLES

One company commented that the first three principles seemed to be the main ones and the others essentially fell out from these. Perhaps they could be simplified further and grouped accordingly.

One company wanted Principle 2 to be amended to read that all information relating to safety must be shared accurately and transparently rather than 'is shared'

One company suggested that Principle 3 be amended as the Code went well beyond promotion.

Two companies wanted Principle 8 amended to add 'in the industry' to 'Transparency is an important means of building and maintaining confidence'.

One company wanted 'and must not be misleading or disguised and must not disparage' added to Principle 9.

One company said that Principle 10 should explicitly refer to training on the Code rather than training.

One company said it agreed that all breaches of the Code should be taken as serious but that not all complaints were serious. This should be taken into account in Principle 12.

One company suggested that the rationale for the material would be easier to understand if the principles were grouped into statements of principles and those which described the basis of self regulation.

Other comments included that the principles were a good starting point. Could they be called an executive summary? There was a need for a reciprocal document for the NHS setting out how it dealt with the industry.

A group for public involvement in research comments included that Principle 1 needed to convey that industry worked with patients in achieving benefits. Principle 4 should refer that awareness of the relevant prescription medicines was necessary when working with patients and patient organisations towards patient centred development. Principle 5 should be more encouraging of working with patients and patient organisations and could principle be higher up the list. Principle 9 should include a commitment to plain English standards.

PMCPA response

The Draft Principles were set within the scope of the Code and the relationship with health professionals to provide high quality patient care. They were grouped in relation to patients, health professionals, transparency and quality, membership of the ABPI and the seriousness with which complaints are taken.

Principle 1 related to the broadness of the industry's work. There was no mention of with whom the industry worked. Patients were not excluded but the ultimate aim was to benefit patients.

Principle 2 can be amended as suggested.

Principle 3 should be amended to make it clear that this is only one of the aims of the Code.

It is useful to have Principle 4 as drafted as this is a requirement of UK law and is seen as applying to all parties, not just to pharmaceutical companies.

A new Principle 5 could be added that the industry can provide information about prescription only medicines to the public.

Principle 8 is broader than the pharmaceutical industry it applies to all in healthcare.

Principle 9 can add a reference to 'tailored to the audience'.

The reference to training in Principle 10 is more than training on the Code. Companies are responsible for training on products, training on pharmacovigilance etc.

Principle 12 is from the introduction to the current Code. As only one company had commented it should be left as it is.

The principles will be further discussed and amended in 2019 for the 2020 Code.

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5 December 2018