PMCPA | Prescription Medicines Code of Practice Authority

PMCPA WORKING DOCUMENT ONLY

Document Objective

This document is being made available to support those working to identify the main changes and updates made by the PMCPA during the development of the proposed 2021 ABPI Code of Practice.

DISCLAIMER

This document was developed during the initial stages of the Code update. Following the publication of the proposed 2021 Code this document has been retrospectively updated to a basic extent.

The PMCPA does not guarantee accuracy of this working document. For accuracy, the published proposed 2021 ABPI Code of Practice should be consulted.

Key

- Red Text (Red Text) – New EFPIA Requirements
- Green Text with grey highlight (Green Text with grey highlight) – Wording added by the PMCPA as a change or addition of text or where changes are extensive versus the 2019 ABPI Code of Practice the whole section may be in green
- Score through text with grey highlight ~~(Score through text with grey highlight)~~ - Wording deleted
- Text highlighted with turquoise ~~(Text highlighted with turquoise)~~ – Comment or reason

OVERARCHING REQUIREMENTS

SCOPE OF THE CODE AND DEFINITION OF CERTAIN TERM

Clause 1 Scope of the Code and Definition of Certain Terms

1.1. This Code applies to the promotion of medicines to members of the United Kingdom health professions and to other relevant decision makers. For the purposes of the application of the Code, the United Kingdom includes the Channel Islands and the Isle of Man. (added from supp info). The Code also applies to a number of areas which are non-promotional, including information made available to the public about prescription only medicines. It does not apply to the promotion of over-the-counter medicines to members of the health professions when the object of that promotion is to encourage their purchase by members of the public.

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

- ~~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.

Definition of Certain Terms

'Collaborative Working' refers to pharmaceutical companies working with other parties to deliver initiatives which either enhance patient care or are for the benefit of patients or alternatively benefit the NHS and, as a minimum, maintain patient care.

'Contribution to costs related to events' in relation to the disclosure of transfers of value means ~~support~~ providing or covering the costs of ~~meals~~, deleted to ensure it is clear meals do not need to be disclosed for individuals travel, accommodation and/or registration fees to support the attendance of an individual to an event organised or created by a company and/or third party. When providing sponsorship of events/meetings to organisations, associations, third parties etc such contributions may include costs for subsistence (food and drink). Added to make it clear sponsorship to organisations etc can include the sponsorship of meals

'Donations and grants' collectively, mean providing funds, benefits in-kind or services freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient organisation, institution and the like to provide goods or services to the benefit of the company in return. Donations and grants to individuals are prohibited.

In general donations are physical items, services or benefits in-kind. Grants are the provision of funds. Donations and grants may be offered or requested. added to ensure it is clear, for the purposes of the code ,what each are generally defined as

24.1 si **'Europe'** comprises those countries that are within the European Union and other countries with a trade association that is a member of the European Federation of Pharmaceutical Industries and Associations (EFPIA).

'Events' includes all professional, promotional, scientific and educational meetings, congresses, conferences, symposia, and other similar events (including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) organised or sponsored by or on behalf of a company (examples can be found in the supplementary information to Clause 22.1).

1.9 **'Healthcare organisation'** means either a healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university or other teaching institution or learned society whose business address, place of incorporation or primary place of operation is in Europe or an organisation through which one or more health professionals or other relevant decision makers provide services.

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If a healthcare organisation consists of only one health professional or other relevant decision maker, then it would be subject to the requirements in the Code regarding individual health professionals added from supp info.

1.4 **'Health professional'** includes members of the medical, dental, pharmacy and nursing professions and any other persons who in the course of their professional activities may administer, prescribe, purchase, recommend or supply a medicine. Added from 24.1 si. In relation to disclosure of transfers of value (clause 24), the term also includes any employee of a pharmaceutical company whose primary occupation is that of a practising health professional.

'Hospitality' is limited to travel, subsistence (food and drink), accommodation and genuine registration fees extended in connection with events/meetings.

1.3 **'Medicine'** means any branded or unbranded medicine intended for use in humans which requires a marketing authorization.

13.2 **'Non-interventional study'** is defined as a study of a marketed medicine where the medicine is prescribed in the usual manner in accordance with the terms of its marketing authorization. The assignment of the patient to a particular therapeutic strategy is not decided by a study protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures are applied to the patients and epidemiological methods are used for the analysis of collected data.

1.5 **'Other relevant decision makers'** particularly includes those with an NHS role who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who are not health professionals.

1.6 **'Over-the-counter medicine'** means those medicines or particular pack of medicines which are primarily advertised to the public for use in self-medication.

~~**The term 'patient organisation' means** non-for-profit legal person/entity (including the umbrella organisation to which it belongs), mainly composed of patients and/or caregivers, that represents and/or supports the needs of patients and/or caregivers and which business address, place of incorporation or primary place of operation is in Europe.~~
ABPI Working Group agreed the current ABPI definition will be maintained

27.1 The term **'patient organisations'** means an ~~patient~~ organisation mainly comprised of patients and/or caregivers or any user organisation such as disability organisations, carer or relative organisations and consumer organisations that represent and/or supports the needs of patients and/or caregivers.

'Patient organisation representative' means a person who is mandated to represent and express the views of a patient organisation.

1.2 **'Promotion'** means any activity undertaken by a pharmaceutical company or with its authority which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines.

It includes:

- journal and direct mail advertising
- the activities of representatives including any electronic or printed material used by them
- the supply of samples
- the provision of inducements to prescribe, supply, administer, recommend, buy or sell medicines by the gift, offer or promise of any benefit or bonus, whether in money or in kind
- the provision of hospitality for promotional purposes
- the sponsorship of promotional events/meetings

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- the sponsorship of scientific events/meetings including payment of travelling and accommodation expenses in connection therewith
- all other ~~sales~~ promotion ~~in whatever form~~

It does not include:

- replies made in response to unsolicited individual enquiries from members of the health professions or other relevant decision makers or in response to specific communications from them whether of enquiry or comment, including letters published in professional journals, but only if they relate solely to the subject matter of the letter or enquiry, are accurate and do not mislead and are not promotional in nature
- factual, accurate, informative announcements and reference material concerning licensed medicines and relating, for example, to pack changes, adverse reaction warnings, trade catalogues and price lists, provided they include no product claims
- price lists relating to unlicensed medicines, provided they include no product claims and they make clear that the products are unlicensed
- information supplied by pharmaceutical companies to national public organisations, such as the National Institute for Health and Care Excellence (NICE), the All Wales Medicines Strategy Group (AWMSG) and the Scottish Medicines Consortium (SMC) is exempt from the Code provided the information is factual, accurate and not misleading
- measures or trade practices relating to prices, margins or discounts which were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993
- summaries of product characteristics
- European public assessment reports
- UK public assessment reports
- Risk minimisation material approved by the Medicines and Healthcare products Regulatory Agency (MHRA)
- the labelling on medicines and accompanying package leaflets insofar as they are not promotional for the medicines concerned; the contents of labels and package leaflets are covered by regulations
- information relating to human health or diseases provided there is no reference, either direct or indirect, to specific medicines.

1.8 **'Promotional aid'** means a non-monetary ~~gift~~ item ~~made~~ given for a promotional purpose. Promotional aids may be given to health professionals and other relevant decision makers only in accordance with Clause 18.3. Health professionals may, however, be provided with items which are to be passed on to patients in accordance with Clause 18.2. ABPI Decision Group agreed the current ABPI definition will be maintained, with the amendment of the word gift to item

~~The term **'promotional aid'** means a non-monetary item given for a promotional purpose. Providing or offering them to HCPs, HCOs' members or POs' Representatives in relation to the promotion of POM is prohibited.~~

1.7 **'Representative'** means a representative calling on members of the health professions and other relevant decision makers in relation to the promotion of medicines.

23.2 *si.* **'Research and Development Transfers of Value'** means, for the purposes of disclosure, transfers of value to health professionals or health care organisations related to the planning or conduct of:

(i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice)
(ii) clinical trials (as defined in Regulation 536/2014)
(iii) non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, health professionals specifically for the study.

17 *si* **'Sample'** means a small supply of a medicine provided to health professionals so that they may familiarise themselves with it and acquire experience in dealing with it. A sample of a medicine may be provided only to a health professional qualified to prescribe that particular medicine.

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A company can provide sponsorship for an activity to certain organisations. **'Sponsorship'** means ~~support~~ a contribution, financial or otherwise, in whole or in part provided by or on behalf of a company, towards ~~support~~ an activity (including an event/meeting or material) ~~or materials~~ performed, organised or created etc by a healthcare organisation, patient organisation or ~~a~~ other third party organisation.

A company can provide support for individual health professionals or other relevant decision makers to attend events/meetings. **'Support'** in this context is the provision of a financial contribution, in whole r in part, whether paid directly, indirectly or via a third party to individual health professionals or other relevant decision makers to attend such events/meetings.

'Third party' means a legal person/entity or individual that represents a company or interacts with other third parties on behalf of a company or relating to a company's medicine ~~medicinal product~~, such as distributors, wholesalers, consultants, contract research organisations, professional congress organisers, contracted sales forces, market research companies, advertising agencies, media buyers, providers of services related to events, public relations services, non-clinical services, non-interventional studies management services etc.

Companies are responsible under the Code for the acts and omissions of their third parties which come within the scope of the Code, even if they act contrary to the instructions which they have been given.

1.10 The term **'transfer of value'** means a direct or indirect transfer of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development or sale of medicines. A direct transfer of value is one made directly by a company for the benefit of a recipient. An indirect transfer of value is one made 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.

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.

OBLIGATIONS AND RESPONSIBILITIES

~~Discredit to, and Reduction of~~ Upholding Confidence in, the Industry

2.0 Activities or materials ~~associated with promotion~~ must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry. Wording deleted to broaden the application.

Clause 3 Obligations

3.1 A medicine must not be promoted prior to the grant of the marketing authorization which permits its sale or supply.

26.1 Prescription only medicines must not be advertised to the public. This prohibition does not apply to vaccination campaigns carried out by companies and approved by the health ministers.

29. When an undertaking has been given in relation to a ruling under the Code, the company concerned must ensure that it complies with that undertaking.

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1.11 ~~Pharmaceutical~~ Companies must comply with all applicable codes, laws and regulations to which they are subject.

(New Clause) Gifts for personal benefit (such as sporting or entertainment tickets, social courtesy gifts) are prohibited and must not be given, either directly or indirectly, to any individual health professionals, other relevant decision maker or individual~~s~~ associated with a healthcare organisation~~s~~ or patient organisation~~s~~.

Providing or offering cash, cash equivalents or the provision of services that confer a personal benefit to the recipient is prohibited.

12.1 Materials and activities must not be disguised promotion. wording rearranged

1.12 Each company must appoint a senior employee to be responsible for ensuring that the company meets the requirements of the Code. ~~and must have a scientific service.~~

~~**Compliance with Undertakings**~~

~~**Scientific Services**~~

Clause 4 Responsibilities

25.1 Companies must have a scientific service to compile and collate all information, ~~whether~~ received from ~~medical representatives or from~~ any ~~other~~ source, about the medicines which they market.

25.2 Companies must also have a scientific service to deal with the approval and supervision of non-interventional studies. This scientific service must include a registered medical practitioner, or a pharmacist registered in the UK, who will be responsible for the oversight of non-interventional studies (including the review of any responsibilities relating to such studies, particularly those given to ~~medical~~ representatives) and certification of the protocol.. ~~That person must state in writing that he or she has examined the~~ from here moved to final bullet point of Clause 14.3 ~~protocol relating to the non-interventional study and that in his or her belief it is in accordance with the requirements of the Code~~.

Disclosure ~~of Clinical Trial Results~~

24.1 Companies must document and publicly disclose certain transfers of value made directly or indirectly to health professionals, other relevant decision makers and healthcare organisations located in Europe. This includes any employee of a pharmaceutical company whose primary occupation is that of a practising health professional. Added instead of being in 24.1 si (also in definitions)

27.7 & 27.8 Companies must document and publicly disclose annually donations and grants whether, whether financial, non-financial or a benefit in-kind, and sponsorship (including in relation to events/meetings) made to patient organisations. Fees and expenses paid for the provision of contracted services performed by individuals representing patient organisations which should be paid to patient organisations must also be publicly disclosed annually as set out in Clause xx

(New clause) Companies must document and publicly disclose annually fees and expenses made to individual members of the public including patients, carers, journalists etc for the provision of contracted services performed as set out in Clause xx

13.1 Companies must disclose details of clinical trials in accordance with the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature.

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13.3 Companies must publish the summary details and results of non-interventional studies of marketed medicines in a manner consistent with their parallel obligations with respect to clinical trials.

QUALITY STANDARDS

High Standards~~, Format,~~ and Suitability ~~and Causing Offence, Sponsorship~~

9.1 High standards must be maintained at all times.

9.2 All material and activities must recognise the special nature of medicines and the ~~professional~~ delete so, this would then cover patients in some circumstances standing of the audience to which they are directed and must not be likely to cause offence.

9.3 The name or photograph of a member of a health profession must not be used in any way that is contrary to the conventions of that profession.

9.7 Extremes of format, size or cost of material must be avoided. Informational or educational materials must be inexpensive, directly relevant to the practice of medicine or pharmacy and directly beneficial to the care of patients.

9.10 Material relating to medicines and their uses, whether promotional or not, and information relating to human health or diseases which is sponsored by a pharmaceutical company or in which a pharmaceutical company has any involvement must clearly indicate the role of the ~~it has been sponsored by that~~ pharmaceutical company.

The only exception to this is market research material which need not reveal the name of the company involved but must state that it is sponsored by a pharmaceutical company.

11.1 Material should only be provided or made available ~~sent or distributed~~ to those categories of persons whose need for, or interest in, it can reasonably be assumed. Material should be tailored to the audience to whom it is directed.

28.6 It should be made clear when a user is leaving any of the company's websites, or websites sponsored by the company, or is being directed to a website which is not that of the company.

Information, Claims and Comparisons

7.2 Information claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. They must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis.

Material must be sufficiently complete to enable the recipient to form their own opinion of the therapeutic value of the medicine.

7.4 Any information claim or comparison must be capable of substantiation.

Companies must provide substantiation following a request for it, as set out in Clause 7.5. In addition, when data from a clinical trial is used companies must ensure that where necessary that trial has been registered and the results disclosed in accordance with Clause 13.1. moved from si of 7.5

7.8 All artwork including illustrations, graphs and tables must conform to the letter and spirit of the Code and, when taken from published studies, a reference must be given. Graphs and tables must be presented in such a way as to give a clear, fair, balanced view of the matters with which they deal, and must not be included unless they are relevant to the claims or comparisons being made.

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7.9 Information and claims about adverse reactions must reflect available evidence or be capable of substantiation by clinical experience. It must not be stated that a product has no adverse reactions, toxic hazards or risks of addiction or dependency. The word 'safe' must not be used without qualification.

7.11 The word 'new' must not be used to describe any product or presentation which has been generally available, or any therapeutic indication which has been promoted, for more than twelve months in the UK.

8.1 The medicines, products and activities of other pharmaceutical companies must not be disparaged.

8.2 The health professions and the clinical and scientific opinions of health professionals must not be disparaged.

Use of Quotations

10.2 Quotations from medical and scientific literature or from personal communications must be faithfully reproduced, ~~(except where adaptation or modification is required in order to comply with the Code) and must~~ accurately reflect the meaning and current views of the author and otherwise comply with the Code. ~~and current views of the author.~~ The precise source of the quotation must be identified.

10.3 Quotations relating to medicines taken from public broadcasts, for example on radio and television, and from private occasions, such as medical conferences or symposia, must not be used without the formal permission of the speaker.

~~10.4 The utmost care must be taken to avoid ascribing claims or views to authors when these no longer represent the current views of the authors concerned.~~ Incorporated in Clause 10.2

Certification and Examination

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

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

14.2 All events/meetings involving travel outside the UK, unless the company's only involvement is to support a speaker to present at the meeting, must be certified in advance as set out in Clause 14.1 or by an appropriately qualified person (AQP) signatory. ~~by an appropriately qualified person.~~ That person does not need to be either a registered medical practitioner or a ~~UK registered~~ pharmacist registered in the UK.

14.3 The following must be certified in advance in a manner similar to that provided for by Clause 14.1:

- educational material for the public or patients issued by companies which relates to diseases or medicines but is not intended as promotion for those medicines
- material relating to working with patient organisations as described in Clause 27 and its supplementary information
- material relating to ~~joint~~ collaborative working as described in Clause 20 and its supplementary information
- material and items relating to a patient support programme whether provided directly to patients or to ~~involving the provision~~ to health professionals ~~of items~~ to be passed on to patients as described in Clauses 18.2, 18.2 *si* and associated ~~its~~ supplementary information
- ~~non-promotional material for patients or health professionals relating to the provision of medical and educational goods and services~~ donations and grants including relevant internal company and service provider instructions,

as described in Clause 19.1 and the written agreement for donations and grants to patient organisations. ~~paragraph 8 of its supplementary information.~~

- protocols relating to a non-interventional studies moved from Clause 25.2

14.4 The names of those nominated as signatories as set out in Clauses 14.1 and 14.2, together with their qualifications, ~~shall~~ must be notified in advance to the Advertising Standards and Outreach Unit, Vigilance and Risk Management of Medicines Division of the MHRA and to the Prescription Medicines Code of Practice Authority (PMCPA). The names and qualifications of designated alternative signatories must also be given. Changes in the names of nominees must be promptly notified.

14.5 The certificate for promotional material must certify that the signatory has examined the final form of the material to ensure that in his/her belief it is:

- in accordance with the requirements of the relevant regulations relating to advertising and this Code
- ~~is~~ not inconsistent with the marketing authorization and the summary of product characteristics ~~and~~
- is a fair and truthful presentation of the facts about the medicine.

The certificate for material covered by Clause 14.3 above must certify that the signatory has looked at the final form of the material to ensure that in his/her belief it complies with the Code.
Material which is still in use must be recertified at intervals of no more than two years to ensure that it continues to conform with the relevant regulations relating to advertising and the Code.
The certificate for events/meetings involving travel outside the UK must certify that the signatory has examined all the proposed arrangements ~~for the meeting~~ and that in his/ her belief ~~the arrangements~~ they are in accordance with the relevant regulations relating to advertising and the Code.

14.6 Companies ~~shall~~ must preserve ~~all~~ certificates. ~~In relation to certificates for promotional material, the~~ Material in the form certified and information indicating the persons to whom it was addressed, the method of dissemination and the date of first dissemination must also be preserved. In relation to certificates for events/meetings involving travel outside the UK, details of the programme, the venue, the reasons for using the venue, the audience, the anticipated and actual costs and the nature of the hospitality and the like must also be preserved.
Companies shall preserve certificates and the relevant accompanying information for not less than three years after the final use of the promotional material or the date of the event/meeting and produce them on request from the MHRA or the PMCPA.

~~The certificates for material covered by Clause 14.3 above shall be preserved for not less than three years after the final use of the material and companies shall produce them on request from the Medicines and Healthcare products Regulatory Agency or the Prescription Medicines Code of Practice Authority.~~ Paragraph no longer required as this is now encompassed in paragraph above

Training

16.1 All relevant personnel including representatives and members of staff, and others retained by way of contract, concerned in any way with the preparation or approval of material or activities covered by the Code must be fully conversant with the Code and the relevant laws and regulations.

16.2 All personnel (and others retained by way of contract) must be fully conversant with pharmacovigilance requirements relevant to their work and this must be documented.

15.1 Representatives must be given adequate training and have sufficient scientific knowledge to enable them to provide full and accurate information about the medicines which they promote.

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16.3 Representatives must take an appropriate examination within their first year of employment as a representative and must pass it within two years of starting such employment. To be acceptable, an appropriate examination must have been accredited to at least Level 3 by an external awarding body recognised by Ofqual.

An appropriate examination for **medical representatives** is one that requires a broad understanding of body systems, diseases and treatments, the development of new medicines and the structure and function of the NHS and of the pharmaceutical industry. Such an examination must be a Diploma (equivalent to at least 480 hours Total Qualification Time). ~~(at least 37 credits or equivalent learning hours).~~

An appropriate examination for **generic sales representatives** is one that requires a broad understanding of body systems, the structure and function of the NHS and of the pharmaceutical industry. Such an examination must be a Certificate (equivalent to at least 330 hours Total Qualification Time). ~~(at least 13 credits or equivalent learning hours).~~

An appropriate examination can be either the relevant ABPI examination (for medical or generic sales representatives) or an examination of at least the same standard as the ABPI examinations and covering similar content and learning material as the corresponding ABPI examination.

16.4 Details of the numbers of representatives who have passed an examination, together with the examination status of others, must be provided to the PMCPA on request.

Meetings Clause and Supplementary information completely re-worked, not possible to track all changes

Events/**Meetings and Hospitality** ~~**and Sponsorship**~~ deleted as definition has now changed in EFPIA

22.1 Pharmaceutical companies may hold, sponsor, or support delegates to attend, a wide range of events/meetings providing such events/meetings meet the requirements of the Code.

Companies must not provide hospitality to health professionals, other relevant decision makers etc except in association with scientific meetings, promotional meetings. Scientific congress and other such meetings and training.

The content and arrangements for any event or meeting must also, to the extent relevant to the particular event/meeting, fulfil the following criteria:

- the event/meeting must have a clear educational content. It should be the programme that attracts delegates to attend ~~the event/meeting~~ and not the associated hospitality or venue
- the content must be appropriate and relevant for the attendees Added due to application for meetings in the Code now applies to POs , members of the public
- the venue must be appropriate and conducive to the main purpose of the event/meeting; lavish, extravagant or deluxe venues must not be used
- any associated ~~hospitality~~ ~~with the meeting~~ subsistence (food and drink) accommodation and travel costs must be strictly limited to the main purpose of the event/meeting, must be of secondary consideration ~~to the purpose of the meeting~~ ~~ie subsistence only,~~ and must be appropriate and not out of proportion to the occasion
- companies must not sponsor, support or organise entertainment (such as sporting or leisure activities etc.)
- ~~events/meetings organised which are wholly or mainly of a social, leisure or sporting nature are unacceptable.~~ Deleted already covered in the Code
- any hospitality provided must not extend to an accompanying person ~~spouse or other such person~~ unless that person qualifies as a proper delegate or participant at the meeting in their own right. In exceptional cases of established clear health needs of the delegate (eg disability or injury), ~~the~~ similar hospitality may be provided for an accompanying person. ~~can be reimbursed within the same parameters.~~

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- ~~spouses and other accompanying persons, unless qualified as above, may not attend the actual meeting and may not receive any associated hospitality at the company's expense; the entire costs which their presence involves are the responsibility of those they accompany.~~ Deleted already clear in Code

(new clause, previously si 22.1) No payment must be offered or paid to individuals to compensate merely for the time spent ~~by health professionals, other relevant decision makers, individuals representing either healthcare organisations or, patient organisations or patients~~ in attending events/meetings.

27.3 Sponsorship of patient organisations (including individuals representing patient organisations to attend events/meetings) must have a written agreement in place setting out ~~exactly~~ what has been agreed including, where possible, a breakdown of agreed costs.

18.3 Attendees of company organised events/meetings may be provided with inexpensive ~~notebooks~~, pens, and pencils and notepads when required for use at those meetings. They must not bear the name of any medicine or any information about medicines but may bear the name of the company providing them. No individual attendee should receive more than one pen, pencil or notepad. Moved from 18.3 Added to meetings to ensure this section is as comprehensive as possible

18.3 si Pens/pencils and notepads provided in conference bags at third party organised meetings must not include the names of the donor companies, the name of any medicine or any information about medicines.

The total cost to the donor company of all such items provided to an individual attending an event/meeting must not exceed £6, excluding VAT. The perceived value to the recipient must be similar.

Pens/pencils and notepads must not be given out from exhibition stands. . Moved from 18.3 si. Added to meetings to ensure this section is as comprehensive as possible

18.1 si Quizzes which are intended to gauge attendees' knowledge of the subject matter of a meeting, are acceptable provided that such quizzes are non-promotional in nature and are genuine tests of skill or knowledge they must ~~that~~ recognise the professional standing or otherwise of the audience and no prizes are offered. To be acceptable a quiz must form part of the meeting's formal proceedings. Quizzes must not be conducted from or on exhibition stands. Moved from 18.1 si. Added to meetings to ensure this section is as comprehensive as possible

22.2 The cost of ~~a meal provided by way of~~ any subsistence (food and drink) added for clarity as this is the EFPIA definition provided must not exceed £75 per person, excluding VAT and gratuities.

22.3 Payments may not be made to doctors or groups of doctors, or to other prescribers, either directly or indirectly, for rental for rooms to be used for events/meetings.

22.4 When events/meetings are sponsored by pharmaceutical companies, that fact must be disclosed in all of the papers relating to the events/meetings and in any published proceedings. The declaration of sponsorship must be sufficiently prominent to ensure that readers are aware of it at the outset.

22.5 ~~Pharmaceutical~~ Companies must publicly disclose annually financial details of ~~sponsorship~~ support of UK health professionals and other relevant decision makers in relation to attendance at events/meetings.

Partly 24.2 Companies must publicly disclose annually financial details for contributions to costs related to events/meetings (sponsorship) paid to a healthcare organisation or third party organisation managing an event/meeting on their behalf.

Contracts for sponsorship of individuals representing patient organisations to attend events/meetings should be made with the patient organisation and disclosed against the patient organisation as set out in Clause xx.

Supplementary Information
Overarching Requirements

Scope of the Code and Definition of Certain Terms

Clause 1 Scope of the Code and Definition of Certain Terms

Clause 1.1 Scope of the Code

The Code applies to the promotion of medicines to members of the health professions and to other relevant decision makers as specified in Clause 1.1. This includes promotion at events/meetings for UK residents held outside the UK. It also applies to promotion to UK health professionals and other relevant decision makers at international events/meetings held outside the UK, except that the promotional material distributed at such events/meetings will need to comply with local requirements. Information om applicability of codes can be found in the supplementary information to Clause 1.11.

The Code does not apply to the promotion of over-the- counter (OTC) medicines to members of the health professions when the object of that promotion is to encourage their purchase by members of the public as specified in Clause 1.1. Thus, for example, an advertisement to doctors for an OTC ~~over-the-counter~~ medicine does not come within the scope of the Code if its purpose is to encourage doctors to recommend the purchase of the medicine by patients. Where the advertisement is designed to encourage doctors to prescribe the medicine, then it comes within the scope of the Code.

Advertisements for OTC ~~over-the-counter~~ medicines to pharmacists are outside the scope of the Code. Advertisements to pharmacists for other medicines come within the scope of the Code.

Companies should be aware that if a non-promotional item is used for a promotional purpose it would come within the definition of promotion. If an item which is covered by regulations such as the summary of product characteristics (SPC) or a patient information leaflet which is include in the pack (PIL) (excluded from the definition of promotion in Clause xx) is used for a promotional purpose then it would come within the scope of the Code.

~~*Clause 1.1 Market Extension*~~

~~*Activities which are designed to enlarge the market in a particular therapeutic area, such as disease awareness campaigns, are permitted, provided that these are carried out in a manner compatible with the Code.*~~ Deleted no longer required

~~*Clause 1.1 Joint Working*~~

~~*Joint working with the NHS and others is permitted if carried out in a manner compatible with the Code. The Department of Health definition of joint working and other information including the conduct of joint working is covered in Clause 20 and its supplementary information.*~~ Deleted no longer required

Clause 1.1 Journals with an International Distribution

The Code applies to the advertising of medicines in professional journals which are produced in the UK and/or intended for a UK audience. The identification of the country in which a journal is 'produced' is based on factors such as where it is compiled and edited, and for printed journals where it is typeset, printed and bound, rather than on factors such as the location of the head office of the publisher.

International journals which are produced in English in the UK are subject to the Code even if only a small proportion of their circulation is to a UK audience. It is helpful in these circumstances to indicate that the information in the advertisement is consistent with the UK marketing authorization.

It should be noted that the Medicines and Healthcare products Regulatory Agency's (MHRA's) guidance 'Advertising and Promotion of Medicines in the UK', The Blue Guide, differs from the above by advising that advertising material in professional journals intended primarily for circulation in the UK, whether or not in the English language, must comply with UK legislation and with the UK marketing authorization for the product.

Supplementary Information
Overarching Requirements

In addition, where a journal is produced in the UK but intended for distribution solely to overseas countries, local requirements and/or the requirements of the International Federation of Pharmaceutical Manufacturers and Associations' (IFPMA) Code of Practice should be borne in mind.

Clause 1.1 Advertising to the Public and Advertising Over-the-Counter Medicines to Health Professionals

The promotion of medicines to the public for self-medication is covered by the Consumer Code of the Proprietary Association of Great Britain (PAGB) (www.pagb.co.uk). The PAGB also has a Professional Code which applies to advertising involving over-the-counter medicines aimed wholly or mainly at persons qualified to prescribe or supply and appropriate administrative staff, where the object of the advertising is to influence sales and/or recommendations to the public.

Clause 1.1 Promotion to Other Relevant Decision Makers

Particular attention is drawn to ~~the provisions of~~ Clause 11.1. ~~and the supplementary information. to that clause, which concern the appropriateness of promotional material to those to whom it is addressed.~~

Clause 1.2 Replies Intended for Use in Response to Individual Enquiries

An unsolicited enquiry is one without any prompting from the company. In answering any unsolicited enquiry a company can offer to provide further information. If the enquirer subsequently requests additional information this can be provided and would be exempt from the Code ~~provided~~ as long as the additional information met the requirements of the exemption. A solicited enquiry would be one where a company invites or prompts a person to make a request. For example, material offering further information to readers would be soliciting a request for that information and placing documents on exhibition stands amounts to an invitation to take them. Neither can take the benefit of this exemption.

Replies intended for use in response to enquiries which are received on a regular basis may be drafted in advance provided that they are used only when they directly and solely relate to the particular enquiry. Documents must not have the appearance of promotional material.

Clause 1.2 Price Lists for Unlicensed Medicines

Price lists ~~of~~ for unlicensed medicines which include no product claims and make clear that the products are unlicensed can be sent to health professionals and other relevant decision makers at reasonable intervals or in response to enquiries. They must not be used proactively in a manner which could be seen to be promoting unlicensed medicines, such as by displaying them on exhibition stands.

Clause 1.2 Risk Minimisation Plans and Material

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

Upholding Confidence in the Industry

Clause 2 Upholding Confidence in the Industry

A ruling of a breach of this clause is a sign of particular censure and is reserved for such circumstances.

Examples of activities that are likely to be in breach of Clause 2 include prejudicing patient safety and/or public health, excessive hospitality, inducements to prescribe, unacceptable payments, inadequate action leading to a breach of undertaking, promotion prior to the grant of a marketing authorization, conduct of company employees/ agents that falls short of competent care and multiple/ cumulative breaches of a similar and serious nature in the same therapeutic area within a short period of time.

Obligations and Responsibilities

Clause x Obligations

Supplementary Information
Overarching Requirements

Clause 3 Marketing Authorization

The legitimate exchange of medical and scientific information during the development of a medicine is not prohibited provided that any such information or activity does not constitute promotion which is prohibited under this or any other clause.

Clause 3.1 Advance Notification of New Products or Product Changes which May Significantly Affect Expenditure

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

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

- *(a) relate to:*
  - *i) a product which contains a new active substance, or*
  - *ii) a product which contains an active substance prepared in a new way, such as by the use of biotechnology, or*
  - *iii) a product which is to have a significant addition to the existing range of authorized indications, or*
- *(b) a product which is to have a novel and innovative means of administration ~~only~~ be directed to those responsible for making policy decisions on budgets and not those only expected to prescribe state whether or not a new medicine or a change to an existing medicine is the subject of a UK marketing authorization ~~in the UK~~*
- *(c) state the likely cost or savings and budgetary implications which must be such that they will significantly change the organisation's likely expenditure (the budgetary implication might include the need for service redesign).*
- *(d) be factual and limited to that sufficient to provide an adequate but succinct account of the product's properties; other products should only be mentioned to put the new product or indication into context in the therapeutic area concerned*

The information provided must not:

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

Changes to future proof the Code

If requested further information may be supplied or a presentation made

Clause 26.1 Advertising of Medicines to the Public

The advertising of prescription only medicines to the public is also prohibited by the relevant regulations relating to advertising. The promotion of OTC medicines to the public for self-medication purposes is covered by the Consumer Code of the Proprietary Association of Great Britain (PAGB).

Clause 1.11 Applicability of Codes

Pharmaceutical companies must ensure that they comply with all applicable codes, laws and regulations to which they are subject. This is particularly relevant when activities/ materials involve more than one country or when a pharmaceutical company based in one country is involved in activities in another country.

Activities carried out and materials used by a pharmaceutical company located in a European country must comply with the national code of that European country as well as the national code of the country in which the activities take place or the materials are used.

Activities carried out and materials used in a European country by a pharmaceutical company located in a country other than a European country must comply with the EFPIA Code as well as the national code of the country in which the activities are carried out and materials are used.

For example a company located in the UK carrying out an activity outside the UK but within Europe, such as in France, must comply with the UK Code and the French Code regardless of whether or not UK health professionals or other relevant decision

makers are involved. Conversely a company located in France carrying out an activity in the UK must comply with the ABPI Code regardless of whether or not UK health professionals or other relevant decision makers are involved. Details of the various codes can be found at www.efpia.eu or www.ifpma.org.

~~By~~ The term 'company' ~~is meant~~ means any legal entity that organises or sponsors promotion which takes place within Europe, whether such entity be a parent company (eg the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organisation.

In the event of a conflict of requirements the more restrictive requirements would apply. There is a potential exception with regard to the limits for subsistence set in European countries where the national association is a member of EFPIA and thus covered by EFPIA Code as referred to in the supplementary information to Clause 22.2.

All international events, that is to say events that take place outside the responsible pharmaceutical company's home country, must be notified in advance to any relevant local subsidiary or local advice taken.

Companies must take reasonable steps to ensure that any other parties that they commission to design, implement or engage in activities covered by the Code but which do not act on behalf of the company, and are therefore not covered by Clause 1.2, for example joint ventures or licensees, comply with the Code.

Clause 1.12 Responsible Person

There is an assumption that the responsible person is the managing director or chief executive or equivalent unless other formal arrangements have been made within the company.

Clause x Responsibilities

Clauses 25.1 and 25.2 Scientific Services

Companies ~~are free to decide whether there is~~ can have one scientific service in charge of both responsibilities or separate services with clearly delineated duties

~~Clause 14 does not apply to the examination of non- interventional studies~~. Deleted no longer required

~~Clause 13 Good Pharmacovigilance Practices~~

~~Attention is drawn to the 'Good pharmacovigilance practices' page on the European Medicines Agency website. (www.ema.europa.eu)~~ Delete and add to references for the Code

Clause 13.1 Details of Clinical Trials

This clause requires the provision of details about ongoing clinical trials (which must be registered within 21 days of initiation of patient enrolment) and the results of completed trials for medicines licensed for use and commercially available in at least one country. Further information can be found in the current Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases and the current Joint Position on the Publication of Clinical Trial Results in the Scientific Literature, both at new link added, www.ifpma.org/resource-centre/clinical-trials-position-papers/.

Companies must include on the home page of their website information as to where details of their clinical trials can be found.

Details about clinical trials must be limited to factual and non-promotional information. Such information must not constitute promotion to health professionals, other relevant decision makers or the public.

~~Clause 13.3 Publication of Details and Results~~

~~This requirement applies to non-interventional studies completed on and after 1 May 2011 with which a UK company has had any involvement. Companies are, however, encouraged to publish details and results of such studies completed prior to that date~~. Deleted as agreed at group meeting 24 02 20

Supplementary Information
Overarching Requirements

Quality Standards

Clause x High Standards and Suitability

Clauses 9.1 and 9.2 High Standards and Suitability ~~and Taste~~

The special nature of medicines and the ~~professional~~ audience to which the ~~material~~ information is directed require that the standards set for the ~~promotion of~~ information about medicines are higher than those which might be acceptable for general commodity advertising.

It follows therefore that certain types, styles and methods of ~~promotion~~ communication, even where they might be acceptable for ~~the promotion of~~ products other than medicines, are unacceptable. These include:

- *the display of naked or partially naked people for the purpose of attracting attention to the material or the use of sexual imagery for that purpose*
- *'teaser' advertising whereby ~~promotional~~ material is intended to 'tease' the recipient by eliciting an interest in something which will be following or will be available at a later date without providing any actual information about it*
- *Care should be taken with language, use of abbreviations etc and the used of emojis and the like.*
- *~~the use of inappropriate language abbreviations or emoticons~~ ~~particularly in digital communications~~*
- *~~the provision of private prescription forms pre-printed with the name of a medicine.~~* Understood this is an outdated practice

~~Clause 9.7 Extremes of Format, Size or Cost~~

~~Particular care needs to be taken in this regard in the first six months following the launch of a medicine to avoid criticism of the industry. Not required any longer~~. This was added to the Code to ensure HCPs etc were not bombarded with information following launch

Clause 9.10 Declaration of Involvement ~~Sponsorship~~

The wording of the declaration of involvement must be unambiguous so that readers are immediately able to understand the extent of the company's involvement and influence. This is particularly important when companies are involved in the production of material which is circulated by an otherwise wholly independent party, such as supplements to health professional journals.

The declaration of sponsorship must be sufficiently prominent to ensure that readers of sponsored material are aware of it at the outset.

~~Clause 9.10 Market Research~~

~~Where market research is carried out by an agency on behalf of a pharmaceutical company, the agency must reveal the name of its client to the Prescription Medicines Code of Practice Authority when the Authority requests it to do so.~~

~~When commissioning market research, a company must take steps to ensure that its identity would be so made known to the Authority should a request for that information be made.~~ Deleted as covered in Clause 12.2 si in yellow section.

~~Clause 11.1 Distribution of Material~~

~~Material should be tailored to the audience to whom it is directed.~~ Added to Clause *~~For example, promotional material devised for general practitioners might not be appropriate for hospital doctors and, similarly, material devised for clinicians might not be appropriate for use with other relevant decision makers.~~* Deleted no longer required

Clause 28.6 Sites Linked via Company Sites

Sites linked via company sites are not necessarily covered by the Code.

Supplementary Information
Overarching Requirements

Clause x Information Claims and Comparisons

Clause 7 General

The application of this clause is not limited to information or claims of a medical or scientific nature. It includes, ~~inter alia~~ among other things, information or claims relating to pricing and market share. ~~Thus, for example, any claim relating to the market share of a product must be substantiated without delay upon request as required under~~ Clause 7.5. Deleted no longer required.
It should be borne in mind that claims in ~~promotional~~ word deleted to make it clear this applies more broadly *material must be capable of standing alone as regards accuracy etc. In general claims should not be qualified by the use of footnotes and the like.*

Clause 7.2 ~~Misleading~~ Information, Claims and Comparisons

The following are areas where particular care should be taken by companies:

- ***claims for superior potency in relation to weight** are generally meaningless and best avoided unless they can be linked with some practical advantage, for example, reduction in adverse reactions or cost of effective dosage*

- ***~~the use of~~ data derived from in-vitro studies, studies in healthy volunteers and in animals**. ~~Care must be taken with the use of such data so as~~ must not be used in a way that ~~not to~~ misleads as to its significance. The extrapolation of such data to the clinical situation should only be made where there is data to show that it is of direct relevance and significance*

- ***~~reference to~~ absolute risk and relative risk**. Referring only to relative risk, especially with regard to risk reduction, can make a medicine appear more effective than it actually is. In order to assess the clinical impact of an outcome, the*

  reader also needs to know the absolute risk involved. In that regard relative risk should never be referred to without also referring to the absolute risk. Absolute risk can be referred to in isolation

- ***economic evaluation of medicines**. ~~Care must be taken that any~~ Any claim involving the economic evaluation of a medicine ~~is~~ must be borne out by the data available and does not exaggerate its significance. To be acceptable as the basis of ~~promotional~~ claims, the assumptions made in an economic evaluation must be clinically appropriate and consistent with the marketing authorization* word deleted to make it clear this applies more broadly

- ***emerging clinical or scientific opinions** ~~Where a clinical or scientific issue exists~~ which ~~has~~ have not been resolved in favour of one generally accepted viewpoint, ~~particular care~~ must be ~~taken to ensure that the issue is treated~~ referred to in a balanced manner. ~~in promotional material~~* word deleted to make it clear this applies more broadly

- ***hanging comparisons** whereby a medicine is described as being better or stronger or suchlike without stating that with which the medicine is compared must not be made*

- ***price comparisons.** ~~Price comparisons~~, as with any comparison, must be accurate, fair and must not mislead. Valid comparisons can only be made where like is compared with like. It follows therefore that a price comparison should be made on the basis of the equivalent dosage requirement for the same indications. ~~For example, to compare the cost per ml for topical preparations is likely to mislead unless it can be shown that their usage rates are similar or, where this is not possible, for the comparison to be qualified in such a way as to indicate that usage rates may vary~~* example move to Q&A

- ***statistical information, claims and comparisons** ~~Care must be taken to ensure that there is~~ must have a sound statistical basis. ~~for all information, claims and comparisons~~ in ~~promotional~~* word deleted to make it clear this applies more broadly *~~material~~. Differences which do not reach statistical significance must not be presented in such a way as to mislead.*

  Instances have occurred where claims have been based on published papers in which the arithmetic and/or statistical methodology was incorrect. Accordingly, before statistical information is included in ~~promotional~~ word deleted to make it clear this applies more broadly *material it must have been subjected to statistical appraisal.*

Supplementary Information
Overarching Requirements

Clause 7.8 Artwork, Illustrations, Graphs and Tables

Care must be taken to ensure that artwork does not mislead as to the nature of a medicine or any claim or comparison and that it does not detract from any warnings or contra- indications. For example, anatomical drawings used to show results from a study must not exaggerate those results and depictions of children should not be used in relation to products not authorized for use in children in any way which might encourage such use.

Particular care should be taken with graphs and tables to ensure that they do not mislead, for example by ~~their incompleteness~~ being incomplete or by the use of suppressed zeros or unusual scales. Differences which do not reach statistical significance must not be presented in such a way as to mislead.

Graphs and tables must be adequately labelled so that the information presented can be readily understood. When taken from published studies, the source of the artwork must be given (see also Clause 7.6). If a graph, table or suchlike is taken from a published study it must be faithfully reproduced except where modification is needed in order to comply with the Code. In such circumstances it must be clearly stated that the material has been modified. Any such adaptation must not distort or mislead as to the significance of that graph, table etc. Care should be taken not to mislead when expressing data as percentages; patient numbers should be included wherever possible. It should also be noted that if a table, graph etc in a paper is unacceptable in terms of the requirements of the Code, because, for example, it gives a visually misleading impression as to the data shown, then it must not be used or reproduced in material.

Clause 7.9 Use of the Word 'Safe'

The restrictions on the word 'safe' apply equally to grammatical derivatives of the word such as 'safety'. For example, 'demonstrated safety' or 'proven safety' are prohibited under this clause.

~~***Clause 8.1 Disparaging References***~~

~~*Much pharmaceutical advertising contains comparisons with other products and, by the nature of advertising, such comparisons are usually made to show an advantage of the advertised product over its comparator. Provided that such critical references to another company's products are accurate, balanced, fair etc, and can be substantiated, they are acceptable under the Code.*~~ Moved to si of 7.3

~~*Unjustified knocking copy in which the products or activities of a competitor are unfairly denigrated is prohibited under this clause. Attention is drawn to the requirements for comparisons set out in Clauses 7.2 to 7.5.*~~ last 2 sentences deleted, no longer required

Clause x Use of Quotations

Clause 10.2 Quotations

Any quotation chosen by a company for use in ~~promotional~~ material must comply with the requirements of the Code itself. For example, to quote from a paper which stated that a certain medicine was 'safe and effective' would not be acceptable even if it was an accurate reflection of the meaning of the author of the paper, as it is prohibited under Clause 7.9 to state without qualification in ~~promotional~~ to cover broader application *material that a medicine is safe. Care should be taken in quoting from any study or the like to ensure that it does not mislead as to its overall significance.*

Quotations can only be adapted or modified in order to comply with the Code. In such circumstances it must be clearly stated that the quotation has been amended.

~~*(See Clause 7.2 which prohibits misleading information, claims etc in promotional material.) Attention is drawn to the provisions of Clause 7.6 which requires that when promotional material refers to published studies clear references must be given to where they can be found.*~~ Deleted no longer required

~~***Clause 10.4 Current Views of Authors***~~

~~*If there is any doubt as to the current view of an author, companies should check with the author prior to its use in promotional material.*~~ Delete move to a Q&A

Supplementary Information
Overarching Requirements

Clause X Certification and Examination

Clause 14.1 Certification

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

When certifying material where the final form is to be printed companies can certify the final electronic version of the item to which no subsequent amendments will be made. When such material is printed the company must ensure that the printed material cannot be used until an appropriately qualified person (AQP) has ~~checked~~ examined and signed the item in its final form to ensure it accurately reflects the content and presentation certified electronically. In such circumstances the material will have a certificate and a declaration approving the final form both must be preserved as they form the certification of the item.
~~In such circumstances the material will have two certificates and both must be preserved.~~

All promotional material must be certified in this way including audio and audio-visual material, promotional material on databases, interactive data systems and the Internet and relevant representatives' briefing materials. Promotional aids must also be certified. ~~A~~ although not strictly promotional material they are used for a promotional purpose.

Companies should be aware that if they use a non-promotional item for a promotional purpose it would need to be certified. ~~Account should be taken of the fact that a non-promotional item can be used for a promotional purpose and therefore come within the scope of the Code.~~

In certifying audio and audio-visual material and promotional material on databases, interactive systems and the Internet, companies must ensure that a written transcript of the material is ~~certified~~ available including reproductions of any graphs, tables and the like that appear in it. In the event of a complaint, a copy of the written material will be requested. Alternatively, companies may certify material on interactive systems by means of producing an electronic copy, for example on a CD Rom or data stick, if the electronic copy is write protected and unable to be changed. Change made so transcripts no longer need to be certified

~~The guidelines on company procedures relating to the Code which are on page 54 give further information on certification.~~

See also the supplementary information to Clause 3 regarding the certification of promotional material to be used ~~on promotion~~ at international conferences. ~~regarding the certification of such material~~.

Clause 14.1 Certifying ~~Digital Material~~ Dynamic Content

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

Clause 14.1 Suitable Qualifications for Signatories

In deciding whether a person can be a nominated signatory, account should be taken of product knowledge, relevant experience both within and ~~outwith~~ outside the industry, length of service and seniority. In addition, signatories must have an up- to-date, detailed knowledge of the Code. The registered medical practitioner should be capable of being registered in the UK without the need for additional tests of medical/clinical knowledge. To clarify the requirement

Clause 14.1 Joint Ventures and Co-Promotion

In a joint venture in which a third party provides a service on behalf of a number of pharmaceutical companies, the pharmaceutical companies involved are responsible for any activity carried out by that third party on their behalf.

It follows therefore that the pharmaceutical companies involved should be aware of all aspects of the service carried out on their behalf and take this into account when certifying the material or activity involved. Similarly, if two or more pharmaceutical companies organise a joint event/meeting each company should ensure that the arrangements for the event/meeting are acceptable.

Supplementary Information
Overarching Requirements

Under co-promotion arrangements or other arrangements where companies work together, such as collaborative working projects, the companies concerned can agree to have only one final signatory to certify on behalf of all the companies. This must all be agreed beforehand and the MHRA the Prescription Medicines Code of Practice Authority (PMCP) must be informed in advance who the signatory will be. In the event of a complaint about material certified in this way each company involved in the project/ activity would be responsible under the Code.

Clause 14.2 Events/Meetings Involving Travel Outside the UK

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

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

If the company's only involvement is to support a speaker to present at the event/meeting and there is no pharmaceutical company involvement with the event/meeting at all, for example a learned society event/meeting, then neither certification nor examination is required.

Clause 14.2 Presentations by UK Speakers at Events/Meetings Held Outside the UK

When a pharmaceutical company based outside the UK arranges via a UK company for a UK speaker to present at an event/meeting to be held outside the UK, then that speaker's presentation materials do not need to be certified or examined by the UK provided there are no UK delegates and the UK company has no role whatsoever in relation to the event/meeting or the presentation. In such circumstances the event/meeting arrangements, in as much as they apply to the UK speaker, will not have to be certified or examined.

Clause 14.2 Suitable Qualifications for Those who Certify Events/Meetings Involving Travel Outside the UK

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

Clause 14.3 Examination ~~of Other Material~~

~~Other~~ Material issued by companies which relates to medicines but which is not intended as promotional material for those medicines

as such ~~per se, such as~~ should be examined by an appropriately qualified person (AQP) who need not be a signatory, to ensure that it does not contravene the Code or the relevant statutory requirements. Such materials includes corporate advertising, press releases, market research material, financial information to inform shareholders, the Stock Exchange and the like, and written responses from medical information departments or similar to unsolicited enquiries from the public etc. ~~, should be examined to ensure that it does not contravene the Code or the relevant statutory requirements.~~

~~Clause 14.3 Non-Interventional Studies~~

~~The examination of non-interventional studies is dealt with in Clause 25.2 and is not covered by Clause 14.~~now included in Clause 14

Clause 14.4 Notification of Signatories

The names and qualifications of signatories and changes to them should be notified to the MHRA by email to signatories.advertising@mhra.gov.uk. ~~and to~~ The PMCPA can be notified ~~either~~ by completing the nominated signatory form which can be found at www.pmcpa.org.uk

Clause 14.6 Retention of Documentation

Companies should note that the MHRA is entitled to request particulars of an advertisement, including particulars as to the content and form of the advertisement, the method of dissemination and the date of first dissemination, and such a request is not subject to any time limit. This does not apply to the certificates themselves in respect of which the three year limit in Clause 14.6 is applicable.

Supplementary Information
Overarching Requirements

~~***Clause 16.1 Scope of the Code***~~

~~*The materials/activities covered by the Code include promotional materials and activities listed in Clause 1.1, information provided to health professionals and other relevant decision makers and information provided to the public, patients and patient organisations.*~~

Deleted no longer required

Clause 16.1 Training

Clause 16.1 Training

Extensive in-house training on the Code is carried out by companies and by the PMCPA. In addition, the PMCPA runs seminars on the Code which are open to all companies and personnel from advertising agencies, public relations agencies and the like which act for the pharmaceutical industry. Details of these seminars can be obtained from the PMCPA.

Clause 16.3 Representative Examinations

The ABPI offers two examinations and further details can be obtained from the ABPI.

Examinations may also be offered by other providers. A company using an examination provider other than the ABPI must be able to demonstrate that its examinations are at least equivalent to those offered by the ABPI. The syllabus studied should be mapped to and meet the requirements in the published ABPI standards. The assessment must be under invigilated examination conditions.

*The **ABPI Medical Representatives Examination** is appropriate for representatives whose duties comprise or include one or both of:*

- *calling upon doctors and/or dentists and/or other prescribers*
- *the promotion of medicines on the basis, ~~inter alia~~ among other things, of their particular therapeutic properties.*

*The **ABPI Generic Sales Representatives Examination** is appropriate for representatives who promote medicines primarily on the basis of price, quality and availability to non-prescribers. ~~those who do not prescribe medicines~~.*

~~*The ABPI examinations for medical representatives and generic sales representatives are based on material published by the ABPI.*~~

Persons who have passed the ABPI Medical Representatives Examination or similar whose duties change to those specified for generic sales representatives do not need to take another examination. However, persons who have passed the ABPI Generic Sales Representatives Examination or similar whose duties change to those specified for medical sales representatives must take an appropriate examination within one year of their change of duties and pass it within two years.

Clause 16.3 Accredited Examinations

Representatives commencing such employment on or after 1 October 2014 must take an accredited examination. The unaccredited examination ceased on 31 December 2015.

A candidate who has taken part of an ABPI examination who wishes to transfer to a new provider will have to take the whole of the new provider's examination. Similarly, a candidate who has taken part of an alternative provider's examination who wishes to transfer to an ABPI examination will have to take the whole of that examination. This will not apply if it can be demonstrated that the units already passed are equivalent to those of the new provider.

Clause 16.3 Information from Examination Provider

A company must ~~take steps to~~ ensure that its examination provider would respond to requests for information from the PMCPA.

Clause 16.3 Time Allowed to Pass an Examination

Prior to passing an appropriate examination, representatives may be engaged in such employment for no more than two years, whether continuous or otherwise and irrespective of whether with one company or with more than one company. A representative cannot, for example, work eighteen months with one company and eighteen months with another and so on, thus avoiding an examination. Maternity or paternity leave does not count towards the specified time periods.

Supplementary Information
Overarching Requirements

In the event of extenuating circumstances, such as prolonged illness or no or inadequate opportunity to take an appropriate examination, the Director of the PMCPA may agree to the continued employment of a person as a representative past the end of the two year period, subject to the representative passing an appropriate examination within a reasonable time.

Similarly, in the event of failure to take an appropriate examination within the first year, the Director may agree to an extension, subject to the representative taking an examination within a reasonable time.

An application for an extension should be made on a form available from the PMCPA. It should preferably be made by the company rather than the representative.

Service as a representative prior to 1 January 2006 by persons who were exempt from taking the appropriate examination by virtue of Clause 16.4 of the 2003 edition of the Code does not count towards the two year limit on employment as a representative prior to passing the appropriate examination.

Meetings supplementary information reworked, for details of changes please see spreadsheet

Clause X Events/Meetings and Hospitality

Clause 22.1 Events/Meetings and Hospitality

~~*As with events/meetings held in the UK*~~*, In determining whether ~~such~~ any event/meeting is acceptable or not, consideration must also be given to the educational programme, overall cost, facilities offered by the venue, nature of the audience, subsistence provided and the like.* Taken from Events/Meetings held Outside the UK to cover the broader audience now included for events/meetings

22.1 Types of Events/Meetings

Events/meetings range from small lunchtime audio-visual presentations in a group practice, hospital meetings and events/meetings at postgraduate education centres, advisory board meetings, visits to research and manufacturing facilities, planning, training and investigator meetings for clinical trials and non-interventional studies, launch events/meetings for new products, management training courses, patient support group meetings and satellite symposia through to large international events/meetings organised by independent bodies with sponsorship from pharmaceutical companies.

The hospitality costs involved in events/meetings must not exceed that level which the recipients would normally adopt when paying for themselves.

Companies should only offer or provide economy air travel to delegates ~~sponsored to~~ attending events/meetings. Delegates may organise and pay at their own expense the genuine cost of an upgrade. For flights that are scheduled to take longer than six hours companies may pay for an upgrade from economy to premium economy or similar.

Administrative staff may be invited to events/meetings where appropriate. For example, receptionists might be invited to an event/meeting in a general practice when the subject matter is related to practice administration.

A useful criterion in determining whether the arrangements for any event/meeting are acceptable is to apply the question 'would you and your company be willing to have these arrangements generally known?' The impression that is created by the arrangements for any event/meeting must always be kept in mind.

22.1 Events/Meetings Held Outside the UK

Events/meetings organised by pharmaceutical companies which involve UK health professionals at venues outside the UK are not necessarily unacceptable. There have, however, to be valid and cogent reasons for holding the event/meeting at such venues. These are that most of the invitees are from outside the UK and, given their countries of origin, it makes greater logistical sense to hold the event/meeting outside the UK or, given the location of the relevant resource or expertise that is the object or subject matter of the event/meeting, it makes greater logistical sense to hold the event/meeting outside the UK. Consideration should be given to the use of

technology to avoid travel outside the UK eg webinars, virtual meetings. wording to ensure parameters of acceptability are clear

~~*Promotional material which is displayed or provided at international events/meetings held outside the UK may, unless prohibited or otherwise regulated by local laws and regulations, refer to medicines or their indications which are not registered in the country where the event takes place, or which are registered under different conditions, so long as any such material is accompanied by a suitable statement indicating countries where the product is registered and making clear that the product is not registered locally. Any such promotional material which refers to the prescribing information authorized in a country or countries where the medicine is registered must be accompanied by an explanatory statement indicating that registration conditions differ internationally. The requirements relating to international events/meetings held in the UK are set out in the supplementary information to Clause 3.*~~ As outside the UK this is outside the remit

Clause 22.1 Events/Meetings Organised by Affiliates Outside the UK

Companies should remind their affiliates outside the UK that the ABPI Code ~~of Practice~~ must be complied with if UK health professionals attend events/meetings which they organise regardless of whether such events/meetings occur in the UK or abroad.

Clause 22.1 Certification of Events/Meetings

Pharmaceutical companies must ensure that all events/meetings which are planned are ~~checked~~ examined to see that they comply with the Code. Companies must have a written document that sets out their policies on events/meetings and hospitality and the associated allowable expenditure. In addition, events/meetings which involve travel outside the UK must be ~~formally~~ certified as set out in Clause 14.2.

Clause 22.1 Health Professionals' ~~Codes~~ Standards of Conduct

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

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

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

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

Clause 22.1 Continuing Professional Development (CPD) Meetings and Courses

The provisions of this and all other relevant clauses in the Code apply equally to meetings and courses organised or sponsored by pharmaceutical companies which are ~~continuing professional development (~~CPD~~)~~ approved. The fact that a meeting or course has

CPD approval does not mean that the arrangements are automatically acceptable under the Code. The relevant provisions of the Code and, in particular, those relating to hospitality, must be observed.

Clause 18.3 Pens/Pencils and Notepads

Pens/pencils and notepads are the only items that can be provided to health professionals and other relevant decision makers for them to keep and then only at bona fide meetings. They cannot be provided, for example, by representatives when calling upon health professionals

Supplementary Information
Overarching Requirements

Clause 22.2 Maximum Cost of Subsistence

The maximum of £75 plus VAT and gratuities is appropriate only in very exceptional circumstances, such as a dinner at a residential meeting for senior consultants or a dinner at a learned society conference with substantial educational content. The cost of subsistence (food and drink) should normally be well below this figure. The requirements relating to hospitality in Clause 22.1 and its supplementary information still apply.

The maximum of £75 plus VAT and gratuities (or local equivalent) does not apply when an event/meeting is held outside the UK in a European country where the national association is a member of EFPIA and thus covered by EFPIA Codes. In such circumstances the limits in the host country code would apply. Information can be found at www.efpia.eu.

~~***Clause 27.2 Hospitality for Carers***~~

~~*Although the requirements in Clause 22 relating to the provision of hospitality at events/meetings apply where pharmaceutical companies support patient organisation events/meetings and their representatives, in exceptional circumstances, in the case of clear health needs such as disability, companies can pay for subsistence, accommodation, genuine registration fees and reasonable travel costs for an accompanying carer.*~~ Deleted as now covered in clause

Clause 22.3 Payment of Room Rental

This provision does not preclude the payment of room rental to postgraduate medical centres and the like.

Payment of room rental to doctors or groups of doctors or to other prescribers is not permissible even if such payment is made to equipment funds or patients' comforts funds and the like or to charities or companies.

Clause 22.4 Sponsorship and Reports of Events/Meetings

Attention is drawn to Clause 9.10 which requires that all material relating to medicines and their uses, whether promotional or not, which is sponsored by a pharmaceutical company must clearly indicate that it has been sponsored by the company.

~~*It should be noted that where*~~ *Where companies are involved in the sponsorship and/or distribution of reports on events/meetings or symposia etc, these reports may constitute promotional material and thus be fully subject to the requirements of the Code.*

Clause 22.5 ~~Sponsorship~~ Support of Individual Health Professionals/ Other Relevant Decision Makers to Attend Events/Meetings

Disclosure of this information must be carried out in accordance with Clause 24.

~~*Events/Meetings at which attendance is sponsored by companies must also comply with Clause 22.1.no longer required as in clause*~~

The information required by Clause 22.5 must be publicly disclosed annually in respect of ~~sponsorship~~ support for attendance at events/meetings whether paid directly, indirectly or via a third party. ~~held in 2015 and each calendar year thereafter.~~ Support in this context includes ~~The information which must be disclosed comprises~~ registration fees and the costs of accommodation and travel, both inside and outside the UK whether paid directly, indirectly or via a third party.

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

Where a transfer of value is made to a health professional or other relevant decision maker indirectly via a healthcare organisation, institution or third party such a transfer should be disclosed once only, preferably as being a transfer to the health professional or other relevant decision maker.

New Clause Sponsorship to Healthcare Organisations, Institutions, a Third Party Organisation etc.

Supplementary Information
Overarching Requirements

Sponsorship in this context includes registration fees and the costs of accommodation and travel, both inside and outside the UK whether paid directly, indirectly or via a third party organisation. If when providing sponsorship to a healthcare organisation, institution, third party organisation etc in relation to their own event, a company contributes towards the overall cost of subsistence (food and drink) then this must be included in the disclosure of the cost of sponsorship to the healthcare organisation, institution, third party organisation etc.

Marketing Authorization

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3.1 A medicine must not be promoted prior to the grant of the marketing authorization which permits its sale or supply.

3.2 The promotion of a medicine must be in accordance with the terms of its marketing authorization and must not be inconsistent with the particulars listed in its summary of product characteristics.

Prescribing Information and Other Obligatory Information

4.1 The prescribing information listed in Clause 4.2 must be provided in a clear and legible manner in all promotional material for a medicine except for abbreviated advertisements (see Clause 5). The prescribing information must be positioned for ease of reference and must not be presented in a manner such that the reader has to turn the material round in order to read it, for example by providing it diagonally or around the page borders. The prescribing information must form part of the promotional material and must not be separate from it.

4.2 The prescribing information consists of the following:

- the legal classification of the product
- the cost (excluding VAT) of either a specified package of the medicine to which the advertisement relates, or a specified quantity or recommended daily dose, calculated by reference to any specified package of the product, except in the case of advertisements in journals printed in the UK which have more than 15 per cent of their circulation outside the UK and audiovisual advertisements and prescribing information provided in association with them
- and

  i) the name of the medicine (which may be either a brand name or a non-proprietary name)

  ii) a quantitative list of the active ingredients, using approved names where such exist, or other non-proprietary names; alternatively, the non-proprietary name of the product if it is the subject of an accepted monograph

  iii) at least one authorized indication for use consistent with the summary of product characteristics

  iv) a succinct statement of the information in the summary of product characteristics relating to the dosage and method of use relevant to the indications quoted in the advertisement and, where not otherwise obvious, the route of administration

  v) 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 in the summary of product characteristics, together with a statement that prescribers should consult the summary of product characteristics in relation to other adverse reactions

  vi) any warning issued by the Medicines Commission, the Commission on Human Medicines, the Committee on Safety of Medicines or the licensing authority, which is required to be included in advertisements

  vii) the number of the relevant marketing authorization and the name and address of the holder of the authorization or the name and address of the part of the business responsible for its sale or supply

  viii) the date the prescribing information was drawn up or last revised.

The summary of product characteristics may be provided instead of i-viii above.

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If the summary of product characteristics is not used then the information specified above in relation to iv, v, and vi which is required to be included in advertisements, must be placed in such a position in the advertisement that its relationship to the claims and indications for the product can be appreciated by the reader.

4.3 ~~In addition,~~ The non-proprietary name of the medicine or a list of the active ingredients using approved names where such exist must appear immediately adjacent to the most prominent display of the brand name in bold type of a size such that a lower case 'x' is no less than 2mm in height or in type of such a size that the non-proprietary name or list of active ingredients occupies a total area no less than that taken up by the brand name. For electronic advertisements the non-proprietary name of the medicine or the list of active ingredients, as required by Clause 4.3, must appear immediately adjacent to the brand name at its first appearance in a size such that the information is readily readable.

4.4 In ~~the case of~~ digital material such as advertisements in electronic journals, emails, electronic detail aids and suchlike, the prescribing information as required by Clause 4.1 may be provided either:

- by inclusion in the digital material itself, or
- by way of a clear and prominent direct single click link.

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

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

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

4.6 ~~In the case of~~ Promotional material included on the Internet, there must be a clear, prominent statement as to where the prescribing information can be found.

4.7 In ~~the case of~~ a printed journal advertisement where the prescribing information appears on at least one of the pages. The pages where the prescribing information is not visible must include a reference on the outer edge of the page as to where the prescribing information can be found ~~overleaf, at either the beginning or the end of the advertisement, a reference to where it can be found must appear on the outer page of the other page of the advertisement~~ in a type size such that a lower case 'x' is no less than 2mm in height.

4.8 Promotional material other than advertisements appearing in professional publications must include the date on which the promotional material was drawn up or last revised.

4.9 All promotional material must include the prominent statement 'Adverse events should be reported. Reporting forms and information can be found at [website address which links directly to the MHRA Yellow Card site]. Adverse events should also be reported to [relevant pharmaceutical company]'.

4.10 When required by the licensing authority, all promotional material must clearly show an inverted black equilateral triangle to denote that additional monitoring is required in relation to adverse reactions. The symbol should always be black, and its size should normally be not less than 5mm per side but with a smaller size of 3mm per side for A5 size advertisements and a larger size of 7.5mm per side for A3 size advertisements:

- the symbol should appear once and be located adjacent to the most prominent display of the name of the product
- no written explanation of the symbol is necessary.

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Digital communications are also covered by this requirement and the black triangle symbol should be located adjacent to the first mention of the product as this is likely to be considered the most prominent display of the name of the product. The size must be such that it is easily readable. Added from si for clarity

Abbreviated Advertisements

5.1 Abbreviated advertisements are advertisements which are exempt from the requirement to include prescribing information for the advertised medicine, provided that they are limited in size and content as set out in ~~meet with the requirements of~~ this clause.

5.2 Abbreviated advertisements may only appear in professional publications ie publications sent or delivered wholly or mainly to members of the health professions and/or other relevant decision makers. A loose insert in such a publication cannot be an abbreviated advertisement.

Abbreviated advertisements may contain only the information specified in Clauses 5.4, 5.5, 5.6, 5.7 and 5.8.

Abbreviated advertisements are not permitted in audio- visual material or in interactive data systems or on the Internet, including journals on the Internet.

5.3 Abbreviated advertisements must be no larger than 420 square centimetres in size.

5.4 Abbreviated advertisements must provide the following information in a clear and legible manner:

- the name of the medicine (which may be either a brand name or a non-proprietary name)
- the non-proprietary name of the medicine or a list of the active ingredients using approved names where such exist
- at least one indication for use consistent with the summary of product characteristics
- the legal classification of the product
- any warning issued by the Medicines Commission, the Commission on Human Medicines, the Committee on Safety of Medicines or the licensing authority which is required to be included in advertisements
- the name and address of the holder of the marketing authorization or the name and address of the part of the business responsible for its sale or supply
- ~~abbreviated advertisements must include~~ the statement: ' Information about this product, including adverse reactions, precautions, contra-indications and method of use can be found at [the address of the website referred to below] 'and state that prescribers are recommended to consult the summary of product characteristics before prescribing.

The following information must be provided on the website referred to above, either:

(i) the information set out in Clauses 4.2 and 4.3 (except that the non-proprietary name of the medicine or the list of active ingredients, as required by Clause 4.3, must appear immediately adjacent to the most prominent display of the brand name in a size such that the information is readily readable and information about cost as required by Clause 4.2 need not be included on the website where the abbreviated advertisement appears only in journals printed in the UK which have more than 15 per cent of their circulation outside the UK), or

(ii) the summary of product characteristics.

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5.5 ~~In addition,~~ ~~t~~The non-proprietary name of the medicine or a list of the active ingredients using approved names where such exist must appear immediately adjacent to the most prominent display of the brand name in bold type of a size such that a lower case 'x' is no less than 2mm in height or in type of such a size that the non-proprietary name or list of active ingredients occupies a total area no less than that taken up by the brand name.

5.6 ~~In addition,~~ ~~a~~Abbreviated advertisements must include the prominent statement 'Adverse events should be reported. Reporting forms and information can be found at [website address which links directly to the MHRA Yellow Card site]. ~~www.mhra.gov.uk/yellowcard.~~ Adverse events should also be reported to [relevant pharmaceutical company]'.

5.7 When required by the licensing authority, abbreviated advertisements must clearly show an inverted black equilateral triangle to denote that additional monitoring is required in relation to adverse reactions.

It should be borne in mind that abbreviated advertisements must be no larger than 420 square centimetres in size. In abbreviated advertisements of no more than 310.8 square centimetres (A5) each side of the triangle should be no less than 3mm. n abbreviated advertisements larger than A5 (but no larger than 420 square centimetres) each side should be no less than 5mm. Added from si for clarity. The other requirements of Clause 4.10 apply equally to the use of the Black Triangle Symbol on Abbreviated Advertisements.

5.8 Abbreviated advertisements may in addition contain a concise statement consistent with the summary of product characteristics, giving the reason why the medicine is recommended for the indication or indications given.

5.9 Marketing authorization numbers and references must not be included in abbreviated advertisements.

Clause X Information, Claims and Comparisons

7.3 A comparison is only permitted in promotional material if:

- it is not misleading
- medicines or services for the same needs or intended for the same purpose are compared
- one or more material, relevant, substantiable and representative features are compared
- no confusion is created between the medicine advertised and that of a competitor or between the advertiser's trade marks, trade names, other distinguishing marks and those of a competitor
- the trade marks, ~~trade~~ brand names, other distinguishing marks, medicines, services, activities or circumstances of a competitor are not discredited or denigrated
- no unfair advantage is taken of the reputation of a trade mark, trade brand name or other distinguishing marks of a competitor
- medicines or services are not presented as imitations or replicas of goods or services bearing a competitor's trade mark or ~~trade~~ brand name.

7.6 When promotional material refers to published studies, clear references must be given.

7.7 When promotional material refers to data on file, the relevant part of this data must be provided without delay at the request of members of the health professions or other relevant decision makers.

7.10 Promotion must encourage the rational use of a medicine by presenting it objectively and without exaggerating its properties. Exaggerated or all-embracing claims must not be made and superlatives must not be used except for those limited circumstances where they relate to a clear fact about a medicine. Claims should not imply that a medicine or an active ingredient has some special merit, quality or property unless this can be substantiated.

~~6.1 No issue of a print journal may bear advertising for a particular product on more than two pages.~~ Deleted not required

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6.2 None of the individual screens or pages etc of a multi screen/page advertisement ~~Advertisements made up of a number of screens, pages etc~~ must ~~not~~ be false or misleading when read in isolation.

~~6.3 No advertisement taking the form of a loose insert in a print journal may consist of more than a single sheet of a size no larger than the page size of the journal itself, printed on one or both sides.~~ Deleted not required

Clause X High Standards, Format, and Suitability ~~and Causing Offence, Sponsorship~~

9.4 Promotional material must not imitate the devices, copy, slogans or general layout adopted by other companies in a way that is likely to mislead or confuse.

9.5 Promotional material must not include any reference to the Commission on Human Medicines, the Medicines and Healthcare products Regulatory Agency (MHRA) or the licensing authority, unless this is specifically required by the licensing authority.

9.6 Reproductions of official documents must not be used for promotional purposes unless permission has been given in writing by the appropriate body.

9.8 Postcards, other exposed mailings, envelopes or wrappers must not carry matter which might be regarded as advertising to the public, contrary to Clause 26.1.

9.9 The telephone, text messages, email, faxes, automated calling systems and other ~~electronic data~~ digital communications must not be used for promotional purposes, except with the prior permission of the recipient.

12.1 Promotional material and activities must not be disguised.

Clause X Material and Distribution

28.1 Promotional material about prescription only medicines directed to a UK audience which is provided on the Internet must comply with all relevant requirements of the Code.

28.4 A medicine covered by Clause 28.1 may be advertised in a relevant independently produced electronic journal intended for health professionals or other relevant decision makers which can be accessed by members of the public.

11.2 Restraint must be exercised on the frequency of distribution and on the volume of promotional material distributed.

11.3 Mailing lists must be kept up-to-date. Requests to be removed from promotional mailing lists must be complied with promptly and no name may be restored except at the addressee's request or with their permission.

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

Representatives

15.1 Representatives must be given adequate training and have sufficient scientific knowledge to enable them to provide full and accurate information about the medicines which they promote.

15.2 Representatives must ~~at all times~~ maintain a high standard of ethical conduct in the discharge of their duties and ~~must~~ comply with all relevant requirements of the Code.

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15.3 Representatives must not employ any inducement or subterfuge to gain an interview. No fee should be paid or offered for the grant of an interview.

15.4 Representatives must ensure that the frequency, timing and duration of calls on health professionals and other relevant decision makers in hospitals, ~~and~~ the NHS and other organisations, together with the manner in which they are made, do not cause inconvenience. The wishes of individuals on whom representatives ~~wish~~ want to call and the arrangements in force at any particular establishment, must be observed. **When briefing representatives companies should distinguish between expected call rates and expected contact rates.**

15.5 In an interview, or when seeking an appointment for one, representatives must at the outset take reasonable steps to ensure that they do not mislead as to their identity or that of the company they represent.

15.6 Representatives must, without delay, forward any information which they receive in relation to the use of the medicines they promote ~~marketed by their company~~, particularly reports of adverse reactions, ~~transmit forthwith~~ to the scientific service referred to in Clause 25.1 ~~any information which they receive in relation to the use of the medicines which they promote, particularly reports of adverse reactions~~.

15.7 Representatives must be paid a fixed basic salary and any addition proportional to sales of medicines must not constitute an undue proportion of their remuneration.

15.8 Representatives must provide, or have available to provide if requested, a copy of the summary of product characteristics for each medicine which they are to promote.

15.9 Companies must prepare detailed briefing material for medical representatives on the technical aspects of each medicine which they will promote. A copy of such material must be made available to the MHRA and the Prescription Medicines Code of Practice Authority (PMCPA) on request. Briefing material must comply with the relevant requirements of the Code and, in particular, is subject to the certification requirements of Clause 14. Briefing material must not advocate, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code.

15.10 Companies are responsible for the activities of their representatives if these are within the scope of their employment even if they are acting contrary to the instructions which they have been given.

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Clause X Marketing Authorization

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~~ definition of a medicine. Material should clearly state at the outset that the medicine has a conditional marketing authorization.

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

Clause 3 Early Access to Medicines Scheme (EAMS)

Medicines that are approved ~~for~~ under 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 must therefore not be promoted.

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

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

Clause 3 Compassionate Use

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

Clause 3 Promotion at International Events/Meetings

The promotion of medicines at international events/meetings held in the UK may on occasion pose certain problems with regard to medicines or indications for medicines which do not have a marketing authorization in the UK although they are so authorized in another major industrialised country.
The display and provision of promotional material for such medicines is permitted at international events/meetings in the UK provided that the following conditions are met:

- *the event/meeting must be ~~a~~ truly international, ~~meeting~~ of high scientific standing and with a significant proportion of the attendees from countries outside the UK in which the product is licensed*
- *the medicine or indication must be relevant and proportional to the purpose of the event/meeting*
- *promotional material for a medicine or indication that does not have a UK marketing authorization must be clearly and prominently labelled to that effect*
- *in relation to an unlicensed indication, UK approved prescribing information must be readily available for a medicine authorized in the UK even though it will not refer to the unlicensed indication*
- *the names must be given of countries in which the medicine or indication is authorized which must include at least one major developed country and it must be stated that registration conditions differ from country to country*
- *the material is certified in accordance with Clause 14, except that the signatories need certify only that in their belief the material is a fair and truthful presentation of the facts about the medicine.*

Clause 3.2 Unauthorized Indications

The promotion of indications not covered by the marketing authorization for a medicine is prohibited. ~~by this clause.~~

Clause X Prescribing Information and Other Obligatory Information

Clause 4.1 Prescribing Information and Summaries of Product Characteristics

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Each promotional item for a medicine must be able to stand alone. For example, when a ~~'Dear Doctor'~~ promotional letter on a medicine is sent in the same envelope as a brochure about the same medicine, each item has to include the prescribing information. It does not suffice to have the prescribing information on only one of the items. The inclusion of a separate summary of product characteristics is not sufficient to conform with the provisions of this clause.

~~*There may be instances where reproducing the summary of product characteristics will not be an acceptable way to fulfil the requirement for prescribing information. For example, Clause 6.1 limits advertising in journals for a particular product to two pages. The prescribing information must be consistent with the summary of product characteristics for the medicine.*~~

Clause 4.1 Legibility of Prescribing Information

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

Clauses 4.1 and 4.8 Date of Prescribing Information and Promotional Material

If the summary of product characteristics is not used then the date that the prescribing information was last drawn up or last revised must be included (Clause 4.2 viii).

In addition, promotional material (other than journal advertising) must include the date that the material as a whole, ie the copy plus the prescribing information, was drawn up or last revised.

Clause 4.1 Advertisements in Electronic Journals

The first part of an advertisement in an electronic journal, such as the banner, is often the only part of the advertisement that is seen by readers. It must therefore include a clear, prominent statement as to where the prescribing information can be found. This should be in the form of a prominent direct single click link. The first part is often linked to other parts and in such circumstances the linked parts will be considered as one advertisement.

If the first part mentions the product name then this is the most prominent display of the brand name and so the non-proprietary name of the medicine or a list of the active ingredients using approved names where such exist must appear immediately adjacent to it in a size such that the information is easily readable. ~~the most prominent display of the brand name. The size must be such that the information is easily readable.~~ If the product is one that is required to show an inverted black ~~symbol~~ equilateral triangle on its promotional material then ~~the black triangle~~ that symbol must appear adjacent to the product name (see Clause 4.10). The size must be such that it is easily readable. The requirement of Clause 12.1 that promotional material and activities must not be disguised should also be borne in mind.

Clause 4.1 Advertisements for Devices

Where an advertisement relates to the merits of a device used for administering medicines, such as an inhaler, which is supplied containing a variety of medicines, the prescribing information for one only need be given if the advertisement makes no reference to any particular medicine. However, if particular medicines are referred to, then the prescribing information for each must be provided. ~~Full prescribing information must, however, be included in relation to each particular medicine which is referred to~~.

Clause 4.1 Prescribing Information at Exhibitions

The prescribing information for medicines promoted on posters and exhibition panels at events/meetings must either be provided on the posters or panels themselves or must be available at the company stand. If the prescribing information is made available at the company stand, this should be referred to on the posters or panels.

Clause 4.2 Use of the Summary of Product Characteristics

The Code defines prescribing information to consist of three parts, the legal classification, the cost and other elements (listed as i-viii) in Clause 4.2. ~~In certain situations~~ Where space in printed material is not an issue, elements i-viii can be provided by reproducing the summary of product characteristics. ~~However, in some circumstances, elements i-viii will have to be provided either as described in Clause 4.2 or by reproducing the summary of product characteristics. Where there are issues of space on printed material, for example a journal advertisement, then elements i-viii will probably have to be provided as a summary. Where there is no issue of space – perhaps a detail aid, elements i-viii could be provided by reproducing the summary of product characteristics~~. With an electronic

advertisement elements i-viii could be provided by a prominent, direct single click link to the summary of product characteristics (Clause 4.4 and its supplementary information). It would not be acceptable to provide a website address for the summary of product characteristics on ~~a~~ printed ~~journal advertisement~~ material as a means of meeting the requirements to provide elements i-viii.

Clause 4.3 Non-Proprietary Name

'Immediately adjacent to…' means immediately before, immediately after, immediately above or immediately below.
~~It should be noted that in~~ In a promotional letter the most prominent display of the brand name will usually be that in the letter itself, rather than that in prescribing information provided on the reverse of the letter.

Clause 4.4 Use of Links for Prescribing Information

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

Clause 4.5 Prescribing Information on Audio-Visual Material

Where prescribing information is shown in the audio- visual material as part of the recording, it must be of sufficient clarity and duration so that it is easily readable. The prescribing information must be an integral part of the advertisement and must appear with it. It is not acceptable for the advertisement and the prescribing information to be separated by any other material.

Clause 4.8 Date Drawn Up or Last Revised

This is in addition to the requirement in Clause 4.2 that the date of the prescribing information be included.

Clause 4.8 Dates on Loose Inserts

A loose insert is not regarded for this purpose as appearing in the professional publication with which it is sent and must therefore bear the date on which it was drawn up or last revised.

Clause 4.9 Adverse Event Reporting

A telephone number or email address for the relevant department of the company may be included. Text is more likely to be deemed to be prominent if it is presented in a larger type size than that used for the prescribing information.
In the event that the website address required in Clause 4.9 is changed by the Medicines and Healthcare products Regulatory Agency (MHRA), companies must use the new address within one year of the change.

Clause 4.10 Black Triangle Symbol

~~The agreement between the then Committee on Safety of Medicines and the ABPI on the use of the black triangle is that:~~ Deleted

~~The symbol should always be black and its size should normally be not less than 5mm per side but with a smaller size of 3mm per side for A5 size advertisements and a larger size of 7.5mm per side for A3 size advertisements:~~

- *~~the symbol should appear once and be located adjacent to the most prominent display of the name of the product~~*
- *~~no written explanation of the symbol is necessary.~~*

~~Digital communications are also covered by this requirement and the black triangle symbol should be located adjacent to the first mention of the product as this is likely to be considered the most prominent display of the name of the product~~ moved to Clause. *~~The size must be such that it is easily readable.~~* Deleted

~~Summaries of product characteristics and package leaflets are excluded from the definition of 'promotion' in the Code by Clause 1.2. However it should be noted that EU legislation now requires~~ Deleted. *The black triangle symbol ~~to appear~~ is also required on summaries of product characteristics and on package leaflets. The size of the black triangle on these documents has to be*

proportionate to the font size of the subsequent text with a minimum length of 5mm per side. ~~The EU requirements do not apply to promotional material.~~ Obligatory explanatory wording is also required on these documents.

Clause 13 Abbreviates Advertisements

Clause 5.2 Professional Publications

Abbreviated advertisements are largely restricted to journals and other such professional publications sent or delivered wholly or mainly to members of the health professions etc. A promotional mailing or ~~representative~~ leavepiece cannot be an abbreviated advertisement and an abbreviated advertisement cannot appear as part of another promotional item, such as in a brochure consisting of a full advertisement for another of the company's medicines.

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

Clauses 5.4, 5.5, 5.6, 5.7, 5.8 and 5.9 Permitted Information

The contents of abbreviated advertisements are restricted as set out in Clauses 5.4, 5.5, 5.6, 5.7, 5.8 and 5.9 and the following information should not therefore be included in abbreviated advertisements:

- *dosage particulars*
- *details of pack sizes*
- *cost.*

There may be exceptions to the above if the information provided, for example the cost of the medicine or the frequency of its dosage or its availability as a patient pack, is given as the reason why the medicine is recommended for the indication or indications referred to in the advertisement.

Artwork used in abbreviated advertisements must not convey any information about a medicine which is additional to that permitted under Clauses 5.4, 5.5, 5.6, 5.7, 5.8 and 5.9.
Telephone numbers may be included in abbreviated advertisements.

Clause 5.5 Non-Proprietary Name

'Immediately adjacent to…' means immediately before, immediately after, immediately above or immediately below.

Clause 5.6 Adverse Event Reporting

~~A telephone number or email address for the relevant department of the company may be included.~~ Deleted

In the event that the website address given in Clause 5.6 is changed by the MHRA, companies may use a statement incorporating the new address as soon as the change is made and must use the new address within one year of the change.

~~Clause 5.7 Black Triangle Symbol~~

~~The requirements of the supplementary information to 4.10 applies equally to the use of the Black Triangle Symbol on Abbreviated Advertisements~~ Deleted as this is covered in the Clause

Clause X Information, Claims and Comparisons

Clause 7.3 Comparisons

The Code does not preclude the use of other companies' brand names when making comparisons.

Much pharmaceutical advertising contains comparisons with other products and, by the nature of advertising, such comparisons

are usually made to show an advantage of the advertised product over its comparator. Provided that such critical references to another company's products are accurate, balanced, fair etc, and can be substantiated, they are acceptable under the Code. Moved from si to 8.1 as felt this was better here

Clause 7.6 References

~~*Clause 7.6 applies to*~~ *The references referred to are those in* ~~*to*~~ *published material, including the use of quotations, tables, graphs and artwork.*

Clause 7.10 Superlatives

Superlatives are ~~*those*~~ *grammatical expressions which denote the highest quality or degree, such as best, strongest, widest etc. A claim that a product was 'the best' treatment for a particular condition, for example, could not be substantiated as there are too many variables to enable such a sweeping claim to be proven. The use of a superlative is acceptable only if it can be substantiated as a simple statement of fact which can be very clearly demonstrated, such as that a particular medicine is the most widely prescribed in the UK for a certain condition, if this is not presented in a way which misleads as to its significance.*

Clause 7.10 Use of the Words 'The' and 'Unique'

In certain circumstances 'the' can imply a special merit, quality or property for a medicine which is unacceptable under this clause if it cannot be substantiated. For example, a claim that a product is 'The analgesic' implies that it is in effect the best, and might not be acceptable.

Similarly, care needs to be taken with the use of 'unique'. Although 'unique' may sometimes be used to describe some clearly defined special feature of a medicine, often it may simply imply a general superiority. In such instances it is not possible to substantiate the claim as the claim itself is so ill defined.

Clause 7.10 Benefit/Risk Profile

The benefit/risk profile of a medicine must be presented in ~~*promotional campaigns in*~~ *such a way as to comply with the Code. Particular attention should be paid to Clauses 7.2, 7.9 and 7.10.*

Clause X High Standards, Format and Suitability

Clause 9.5 MHRA Drug Safety Update

Where factual safety information given in promotional material is based on advice in the MHRA Drug Safety Update, the information can be referenced to that publication.

~~***Clause 9.8 Reply Paid Cards***~~

~~*Reply paid cards which are intended to be returned to companies through the post and which relate to a prescription only medicine should not bear both the name of the medicine and information as to its usage but may bear one or the other.*~~ Move to Q&A

Clause 9.9 Unsubscribing to Emails

Where permission to use emails for promotional purposes has been given by a recipient, each email sent should inform the recipient as to how to unsubscribe to them.

Clause 9.9 Responding to Emails

An unsolicited enquiry received by email or an unsolicited enquiry received by post which includes an email address can be responded to by email without specific permission, consent to do so being implied in such circumstances. There is no need to inform recipients as to how to unsubscribe to an email response to an enquiry.

Clause 9.9 Remote Detailing

SUPPLEMENTARY INFORMATION
ADDITIONAL REQUIREMENTS FOR THE PROMOTION TO HEALTH PROFESSIONALS / OTHER RELEVANT DECISION MAKERS

When promotion is carried out remotely, such as by telephone call, web chat or other online calls, prior permission from the recipient must be obtained in advance or at the start of the contact or call. In setting up the contact or call, full details must be given of the company the caller will represent, their role and the purpose of the call. Arrangements made to discuss a specific product should be adhered to.

Clause 12.1 Disguised Promotional Material

Promotional material sent in the guise of personal communications, ~~for example by using envelopes or postcards addressed in real or facsimile handwriting~~, is inappropriate. ~~Envelopes must not be used for~~ ~~The dispatch of~~ Promotional material must not imply ~~if they bear words implying~~ that the contents are non-promotional, for example that the contents provide information relating to safety. ~~Similarly, promotional material sent electronically such as emails must not give the impression that it is non-promotional.~~ ~~In addition~~ The identity of the responsible pharmaceutical company must be obvious.

When a company pays for, or otherwise secures or arranges the publication of promotional material in journals, such material must not resemble independent editorial matter. Care must be taken with company sponsored reports of events/meetings and the like to ensure that they are not disguised promotion. Sponsorship must be declared in accordance with Clause 9.10.

Clause X Materials and Distribution

Clause 28.1 Access

Unless access to promotional material about prescription only medicines is limited to health professionals and other relevant decision makers, a pharmaceutical company website or a company sponsored website must provide information for the public as well as promotion to health professionals with the sections for each target audience clearly separated and the intended audience identified. This is to avoid the public needing to access material for health professionals unless they choose to. The MHRA Blue Guide states that the public should not be encouraged to access material which is not intended for them.

Clause 28.4 Advertisements in Electronic Journals

~~It should be noted that the~~ The MHRA Blue Guide states that each page of an advertisement for a prescription only medicine should be clearly labelled as intended for health professionals.

Clause 11.2 Frequency of ~~Mailings~~ Distribution

The style of ~~mailings~~ materials is relevant to their acceptability to doctors and criticism of their frequency is most likely to arise where their informational content is limited.

Emails can only be sent with the prior permission of the recipient.

~~In the first six months following the launch of a new medicine, a health professional may be sent an initial mailing giving detailed information about its use, including, for example, the summary of product characteristics, the public assessment report, the package leaflet and the product monograph, and no more than three other mailings about the medicine.~~

~~No more than eight mailings for a particular medicine may be sent to a health professional in a year.~~

~~Mailings concerned solely with safety issues can be sent in addition to the above as can mailings about price changes which contain no product claims.~~

~~The limitations on frequency of mailings materials do not apply to emails as these can only be sent with the prior permission of the recipient.~~ Deleted no longer required

Clause 10.1 Provision of Reprints

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

SUPPLEMENTARY INFORMATION
ADDITIONAL REQUIREMENTS FOR THE PROMOTION TO HEALTH PROFESSIONALS / OTHER RELEVANT DECISION MAKERS

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

Clause X Representatives

Clause 15 Representatives

All provisions in the Code relating to the need for accuracy, balance, fairness, good taste etc apply equally to oral representations as well as to printed and electronic material. Representatives must not make claims or comparisons which are in any way inaccurate, misleading, disparaging, in poor taste etc, or which are outside the terms of the marketing authorization for the medicine or are inconsistent with the summary of product characteristics. Indications for which the medicine does not have a marketing authorization must not be promoted.

~~*Attention is drawn to the provisions of Clause 9.9 which prohibit the use of the telephone, text messages, email, telemessages and facsimile etc for promotional purposes, except with the prior permission of the recipient.*~~

Clause 15 Contract Representatives

Companies employing or using contract representatives are responsible for their conduct and must ensure that they comply with the provisions of this and all other relevant clauses in the Code, and in particular the training requirements under Clauses 15.1, 16.1 and 16.3.

Clause 15.3 Hospitality and Payments for Events/Meetings

~~*Attention is drawn to the requirements of Clauses 18 and 22 which prohibit the provision of any financial inducement for the purposes of sales promotion and require that any hospitality provided is secondary to the purpose of a meeting, is not out of proportion to the occasion and does not extend beyond members of the health professions or other relevant decision makers.*~~ Deleted

Events/meetings organised for groups of doctors, other health professionals and/or other relevant decision makers which are wholly or mainly of a social or sporting nature are unacceptable.

Representatives organising events/meetings are permitted to provide appropriate hospitality and/or to meet any reasonable, actual costs which may have been incurred. For example, if the ~~refreshments~~ subsistence ie meals (food and drink) has~~ve~~ been organised and paid for

by a medical practice the cost may be reimbursed as long as it is reasonable in relation to what was provided and the ~~refreshments~~ subsistence itself ~~themselves were~~ was appropriate for the occasion.

Donations ~~in lieu~~ instead of hospitality are unacceptable as they are inducements for the purpose of holding an event/meeting. If subsistence is not required at an event/meeting there is no obligation or right to provide some benefit of an equivalent value.

~~*Clause 15.3 Donations to Charities*~~

~~*Donations to charities in return for representatives gaining interviews are prohibited under Clause 15.3.*~~ Deleted move to a Q&A

Clause 15.3 Items Delivered by Representatives

Reply paid cards which refer to representatives delivering items to health professionals or other relevant decision makers should explain that there is no obligation to grant the representative an interview when the items are delivered. This is to avoid the impression that there is such an obligation, which would be contrary to Clause 15.3 which prohibits the use of any inducement or subterfuge to gain an interview.

Clause 15.3 Health Professionals' ~~Codes~~ Standards of Conduct

The General Medical Council, the General Pharmaceutical Council and the ~~Code of the~~ Nursing & Midwifery Council, set out requirements for doctors, pharmacists, pharmacy technicians, nurses and midwives. Further details are given in the supplementary information to Clause ~~18.1 and~~ 22.1.

SUPPLEMENTARY INFORMATION
ADDITIONAL REQUIREMENTS FOR THE PROMOTION TO HEALTH PROFESSIONALS / OTHER RELEVANT DECISION MAKERS

Clause 15.4 Frequency and Manner of Calls on Doctors and Other Prescribers

The number of calls made on ~~a~~ doctors or other prescribers and the intervals between successive visits are relevant to the determination of frequency.

Companies should arrange that intervals between visits do not cause inconvenience. The number of calls made on a doctor or other prescriber by a representative each year should not normally exceed three on average. This does not include the following which may be additional to those three visits:

attendance at group events/meetings, including audio-visual presentations and the like

a visit which is requested by a doctor or other prescriber or a call which is made in order to respond to a specific enquiry

a visit to follow up a report of an adverse reaction.

Representatives must always endeavour to treat prescribers' time with respect and give them no cause to believe that their time might have been wasted. If for any unavoidable reasons, an appointment cannot be kept, the longest possible notice must be given.

When briefing representatives' companies should distinguish clearly between expected call rates and expected contact rates Contacts include those at group events/meetings, visits requested by doctors or other prescribers, visits in response to specific enquiries and visits to follow up adverse reaction reports. Targets must be realistic and not such that representatives breach the Code in order to meet them.

Clause 15.8 Provision of Summary of Product Characteristics

~~The requirement to provide a~~ An electronic copy of the summary of product characteristics can be ~~met by the provision of an electronic~~ provided if the recipient agrees. If discussion on a medicine is initiated by the person or persons on whom a representative calls, the representative is not obliged to have available the information on that medicine referred to in this clause.

Clause 15.9 Briefing Material

The detailed briefing material referred to in this clause ~~consists~~ includes ~~of both~~ the training material used to instruct medical representatives about a medicine and the instructions given to them as to how the product should be promoted.

ADDITIONAL SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH HEALTH PROFESSIONALS, OTHER RELEVANT DECISION MAKERS, HEALTHCARE ORGANISATIONS

Clause X Information, Claims and Comparisons

7.1 Upon reasonable request, a company must promptly provide ~~members of the~~ health professionals and other relevant decision makers with accurate and relevant information about the medicines which the company markets.

7.5 Substantiation for any information, claim or comparison must be provided as soon as possible, and certainly within ten working days, at the request of ~~members of the~~ health professionals or other relevant decision makers. The validity of indications approved in the marketing authorization can be substantiated by provision of the summary of product characteristics.

Clause X Prohibition on Inducements and Inappropriate Payments and the Provision of Items to ~~for Patients~~, Health Professionals ~~and Other Relevant Decision Makers, Agreements to Benefit Patients such as Outcome Agreements and Patient Access Schemes~~

18.1 No gift, pecuniary advantage or benefit may be supplied, offered or promised to ~~members of the~~ health professionals or to other relevant decision makers in connection with the promotion of medicines or as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine, subject to the provisions of Clauses 18.2 and 18.3

18.2 Health professionals may be provided with items which are to be passed on to patients and which are part of a ~~formal~~ patient support programme, the details of which have been appropriately documented and certified in advance as required by Clause 14.3.

The items provided must be inexpensive and directly benefit patient care. They may bear the name of the company providing them but must not be product branded unless the name of the medicine name is essential for the correct use of the item by the patient. Items must not be given out from exhibition stands. They must not be given to administrative staff unless they are to be passed on to a health professional.

~~Medical and Educational Goods and Services~~ added to Donations and Grants

~~19.1 Medical and educational goods and services which enhance patient care, or benefit the NHS and maintain patient care, can be provided subject to the provisions of Clause 18.1. They must not be provided to individuals for their personal benefit. Medical and educational goods and services must not bear the name of any medicine but may bear the name of the company providing them.~~

~~Joint Working~~ added to collaborative working

~~Joint working between one or more pharmaceutical companies and the NHS and others is acceptable provided that this is carried out in a manner compatible with the Code. Joint working must always benefit patients.~~

~~A formal written agreement must be in place and an executive summary of the joint working agreement must be made publicly available before arrangements are implemented.~~

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

Clause X (New Clause and part of 20) Collaborative Working with Organisations

Clause X Collaborative working which either enhances patient care or is for the benefit of patients or alternatively benefits the NHS and, as a minimum, maintains patient care is acceptable providing it is carried out in a manner compatible with the Code. Collaborative working is generally between one or more pharmaceutical companies, healthcare organisations and others.

ADDITIONAL SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH HEALTH PROFESSIONALS, OTHER RELEVANT DECISION MAKERS, HEALTHCARE ORGANISATIONS

Clause X Collaborative working, including its implementation must have and be able to demonstrate the pooling of skills, experience and/or resources from all of the parties involved for the joint development and implementation of patient and/or healthcare centred projects. There must be a shared commitment to successful delivery from all parties and each party must make a significant contribution.

Clause X Collaborative working must:

- enhance patient care or be for the benefit of patients, or alternatively benefit the NHS and, as a minimum maintain patient care
- not constitute an inducement to health professionals or other relevant decision makers to prescribe, supply, recommend, buy or sell a medicine
- be carried out in an open and transparent manner
- be prospective in nature
- be documented with a formal written agreement which is kept on record
- have a summary of the collaborative working agreement publicly available before arrangements are implemented.

Material relating to collaborative working must be certified including the summary of the collaborative working agreement. The collaborative working agreement does not need to be certified. Only the final documents etc for any collaborative working project need be certified. All documents etc used during the development of the project should be of the same standard as certified material but there is no requirement to certify such material. Material used in the delivery of the collaborative working project must also meet the requirements of Clause 14.3, for example educational material for the public or patients which relates to diseases or medicines used during the delivery of collaborative working must be certified.

All collaborative working should adhere to all relevant policies including NHS policies.

(New Clause and part 20) Joint working between one or more pharmaceutical companies and the NHS and others which is patient centred and always benefits patients is an acceptable form of collaborative working providing it is carried out in a manner compatible with Clause X and other relevant requirements of the Code.

It must be clear in the documentation that the project is a joint working project and account must be taken of relevant best practice guidance on joint working between the NHS, the pharmaceutical industry and other relevant commercial organisations.

20.2 Transfers of value made by companies in connection with collaborative working must be publicly disclosed annually.

Provision of Medicines and Samples

17.1 Samples of a product may be provided only to a health professional qualified to prescribe that product. They must not be provided to other relevant decision makers.

17.2 No more than four samples of a particular medicine may be provided to an individual health professional during the course of a year.

Samples of a particular medicine may be provided to a health professional for no longer than two years after that health professional first requested samples of it.

Notwithstanding the above, when a new medicine is marketed which is an extension of an existing product, samples of that new medicine can be provided as above. A 'new medicine' in this context is a product for which a new marketing

authorization has been granted, either following the initial application or following an extension application for a new indication that includes new strengths and/or dosage forms. Extension of a marketing authorization to include additional strengths and/or dosage forms for existing indications or to include additional pack sizes is not regarded as leading to new medicines.

17.3 Samples may only be supplied in response to written requests which have been signed and dated. An electronic signature is acceptable.

17.4 A sample of a medicine must be no larger than the smallest presentation of the medicine on the market in the UK.

17.5 Each sample must be marked 'free medical sample – not for resale' or words to that effect and must be accompanied by a copy of the summary of product characteristics.

17.6 The provision of samples is not permitted for any medicine which contains a substance listed in any of Schedules I, II or IV to the Narcotic Drugs Convention (where the medicine is not a preparation listed in Schedule III to that Convention) or a substance listed in any of Schedules I to IV to the Psychotropic Substances Convention (where the medicine is not a preparation which may be exempted from measures of control in accordance with Paragraphs 2 and 3 of Article 3 of that Convention).

17.7 Companies must have adequate systems of control and accountability for samples which they distribute and for all medicines handled by representatives. Systems must clearly establish, for each health professional, the number of samples supplied in accordance with Clause 17.2.

17.8 Medicines which are sent by post must be packed so as to be reasonably secure against being opened by young children. No unsolicited medicine must be sent through the post.

17.9 Medicines may not be sold or supplied to members of the public for promotional purposes.

17.10 Samples must not be provided simply as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine. Samples must not be given for the sole purpose of treating patients.

Non-Interventional Studies of Marketed Medicines

13.4 Non-interventional studies that are prospective in nature and involve the collection of patient data must be conducted for a scientific purpose. They must comply with the following criteria:

- there must be a written study plan (observational plan/protocol) and written contracts between the health professionals and/or the healthcare organisations, institutes, academic faculties etc where the study will take place and the pharmaceutical company sponsoring the study, which specify the nature of the services to be provided and the payment for those services
- in countries where ethics committees are prepared to review such studies, the study protocol must be submitted to the ethics committee for review
- the company's scientific service must certify the protocol and must supervise the conduct of the study
- the study results must be analysed and summaries must be made available within a reasonable period of time to the company's scientific service, which service shall maintain records of such reports; the summary report should be sent to health professionals who participated in the study. If the study results are important for the assessment of benefit/risk, the summary report should be immediately forwarded to the relevant competent authority
- representatives may only be involved in an administrative capacity and such involvement must be under the supervision of the company's scientific service which will also ensure that the representatives are adequately trained for the role; such involvement must not be linked to the promotion of any medicine.

ADDITIONAL SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH HEALTH PROFESSIONALS, OTHER RELEVANT DECISION MAKERS, HEALTHCARE ORGANISATIONS

To the extent applicable, companies are encouraged to comply with:

- Clause 13.4 for all other types of non-interventional studies, including epidemiological studies and registries and other studies that are retrospective in nature
- Clause 13.3 regarding the publication of the summary details and results of non-interventional studies of marketed medicines in a manner consistent with their parallel obligations with respect to clinical trials.

SUPPLEMENTARY INFORMATION
ADDITIONAL SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH HEALTH PROFESSIONALS, OTHER RELEVANT DECISION MAKERS, HEALTHCARE ORGANISATIONS

~~**Information Claims and Comparisons**~~

~~***Clause 7.5 Data from Clinical Trials***~~

~~*Companies must provide substantiation following a request for it, as set out in Clause 7.5. In addition, when data from a clinical trial is used companies must ensure that where necessary that trial has been registered and the results disclosed in accordance with Clause 13.1. Added to Clause 7.4*~~

Prohibition on Inducements and Inappropriate Payments and the Provision of Items to Health Professionals and Other Relevant Decision Makers

Clause 18.1 Health Professionals' ~~Codes~~ Standards of Conduct
For information on health professionals' ~~codes~~ standards of conduct refer to the supplementary information to 22.1

Clause 18.1 ~~Payments to~~ Contracted Individuals
Any payment to an individual for an activity that is ruled in breach of Clause 12.2 and/or Clause 23 is likely to be viewed as an unacceptable payment and thus in breach of Clause 18.1.

Clause 18.1 Terms of Trade
Measures or trade practices relating to prices, margins and discounts which were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993 are outside the scope of the Code (see Clause 1.2) and are excluded from the provisions of this clause. Other trade practices are subject to the Code. The terms 'prices', 'margins' and 'discounts' are primarily financial terms. Schemes which enable health professionals to obtain personal benefits, for example gift vouchers for high street stores, in relation to the purchase of medicines are unacceptable even if they are presented as alternatives to financial discounts.

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. Transfers of value made in the course of other package deals would need to be disclosed in accordance with Clause 24.

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

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

Clause 18.1 Outcome or Risk Sharing Agreements
Clause 18.1 does not preclude the use of outcome or risk sharing agreements where a full or partial refund of the price paid for a medicine, or some other form of recompense, is due if the outcome of the use of the medicine in a patient fails to meet certain criteria. That is to say its therapeutic effect does not meet expectations. Clear criteria as to when a refund or other recompense would be due must be settled in advance and set out in the agreement. Any refund or recompense must always go to the relevant NHS or other organisation and never to individual health professionals or practices etc.

Clause 18.1 Patient Access Schemes

SUPPLEMENTARY INFORMATION
ADDITIONAL SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH HEALTH PROFESSIONALS, OTHER RELEVANT DECISION MAKERS, HEALTHCARE ORGANISATIONS

Patient access schemes are acceptable in principle under the Code but they must be carried out in conformity with its requirements. The 2014 Pharmaceutical Price Regulation Scheme ~~describes~~ described patient access schemes as schemes proposed by a pharmaceutical company and agreed with the Department of Health (with input from the National Institute for Health and Care Excellence) in order to improve the cost-effectiveness of a medicine and enable patients to receive access to cost-effective innovative medicines. Corresponding arrangements ~~apply~~ applied in the devolved nations.

~~*The outcome of discussions regarding the next Pharmaceutical Price Regulation Scheme will be available in 2019.*~~
The 2019 Voluntary Scheme for Branded Medicines Pricing and Access (VPAS) also refers to the Department, the ABPI and NHS England understanding of the benefits that clinically and cost effective medicines can bring and refers to patient access schemes in relation to commercial flexibilities offered by the health service in England. VPAS states that the scheme represents an opportunity to further expand the commercial flexibility offered by the health service in England.

~~***Clause 18.1 Competitions and Quizzes***~~ moved to meetings in overarching
~~*The use of Competitions, quizzes and suchlike, and the giving of prizes, are unacceptable methods of promotion.*~~
~~*This does not preclude the use at promotional meetings of quizzes which are intended to gauge attendees' knowledge of the subject matter of the meetings, provided that such quizzes are non-promotional in nature and are bona fide genuine tests of skill that recognise the professional standing of the audience and no prizes are offered. To be acceptable a quiz must form part of the meetings formal proceedings. Quizzes must not be conducted from or on exhibition stands. must not be included in any way in the conduct of a quiz*~~

Clause 18.1 Promotional Aids

A promotional aid is defined as a non-monetary ~~gift~~ item ~~made~~ given for a promotional purpose. Promotional aids may be given to health professionals and other relevant decision makers only in accordance with Clause 18.3. Health professionals may, however, be provided with items which are to be passed on to patients in accordance with Clause 18.2.

Literature such as leaflets and booklets ~~and textbooks~~ about medicines and their uses, which is intended for patients, can be provided to health professionals for them to pass on. They are not considered to be promotional aids but they must comply with relevant requirements of the Code, in particular Clause 26 and its supplementary information. A story-book for young patients about a product or a disease could be provided for relevant patients.

Items to be passed on to patients may bear the name of a medicine and/or information about medicines only if such detail is essential for the proper use of the item by patients.
Items for the personal benefit of health professionals or other relevant decision makers must not be offered or provided.

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

Advertisements for prescription medicines must not appear on any items, such as diaries and desk pads, which pharmaceutical companies could not themselves give.

~~***Clause 18.1 DVDs***~~

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

Clause 18.1 ~~Memory Stick~~ Data Storage Devices

Clause 18.1 does not preclude the provision to health professionals and other relevant decision makers of inexpensive data storage devices such as memory sticks and the like ~~memory sticks~~ which bear educational or promotional material compliant with the Code, provided that their storage capacity is commensurate with the amount of data to be stored.

SUPPLEMENTARY INFORMATION
ADDITIONAL SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH HEALTH PROFESSIONALS, OTHER RELEVANT DECISION MAKERS, HEALTHCARE ORGANISATIONS

Clause 18.1 Textbooks

Textbooks must not be given to individual health professionals or other relevant decision makers as promotional aids. In appropriate circumstances independently produced medical/educational publications such as textbooks could be given to these individuals ~~for health professionals~~ to use in accordance with Clause 19.1 ~~Medical and Educational Goods and Services~~ Donations and Grants but they must not be given to individuals.

Clause 18.1 Long Term or Permanent Loan

The requirements of Clause 18.1 cannot be avoided by providing health professionals or practices etc with items on long term or permanent loan. ~~Such items will be regarded as gifts and subject to the requirements of this clause.~~

Clause 18.2 Patient Support Items

Although items which are to be passed on to patients may not be given out from exhibition stands, they may be exhibited and demonstrated on stands and requests for them accepted for later delivery.

Patient support items may be provided to health professionals by representatives during the course of a promotional call and representatives may deliver such items when they are requested by health professionals~~, for example on reply paid cards.~~ Examples of items which might be acceptable include a peak flow meter as part of a scheme for patients to regularly record readings or a pedometer as part of a scheme to encourage exercise~~, perhaps for obese patients.~~

Provided that they have been appropriately documented and certified in advance as required by Clause 14.3, in limited circumstances patient support items which allow patients to gain experience in using their medicines whilst under the supervision of a health professional, may be made available for the use of health professionals even though they are not to be passed on to patients for them to keep. ~~This is where their purpose is to allow patients to gain experience in using their medicines whilst under the supervision of a health professional.~~ Examples include inhalation devices (with no active ingredient) and devices intended to assist patients to learn how to self-inject.

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

Information regarding material and items made available directly to patients is set out in Clause 18.2 and its supplementary information.

~~Clause 18.3 Notebooks, Pens and Pencils~~ moved to meetings in overarching

~~Notebooks, pens and pencils are the only items that can be provided to health professionals and other relevant decision makers for them to keep and then only at~~ bona fide ~~genuine events/meetings. They cannot be provided, for example, by representatives when calling upon health professionals. No individual attendee should receive more than one notebook and one pen or pencil.~~
~~The total cost to the donor company of all such items provided to an individual person attending an event/meeting must not exceed £6, excluding VAT. The perceived value to the recipient must be similar.~~
~~Notebooks, pens and pencils must not be given out from exhibition stands.~~

~~Notebooks, pens and pencils provided at company organised events/meetings may bear the name of the donor company but not the name of any medicine or any information about medicines. etc.~~

~~Notebooks, pens and pencils included in conference bags at third party organised meetings may not bear the names of the donor companies or the name of any medicine or any information about medicines.~~

Collaborative Working

SUPPLEMENTARY INFORMATION
ADDITIONAL SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH HEALTH PROFESSIONALS, OTHER RELEVANT DECISION MAKERS, HEALTHCARE ORGANISATIONS

Clause X ~~Joint Working~~ Collaborative Working

Collaborative working between the pharmaceutical industry, healthcare organisations and others ~~and the NHS~~ must be conducted in an open and transparent manner ~~Joint Working~~ and must either enhance patient care or are for the benefit of patients or alternatively benefit the NHS and ,as a minimum, maintain patient care. It is expected that the arrangements will also benefit the NHS and the pharmaceutical company or companies involved. Treatments when mentioned ~~where applicable~~ must, be in line with nationally accepted clinical guidance where such exists. Collaborative working differs from the situation where pharmaceutical companies provide funds as a grant for a specific event or programme.

~~When considering joint working, companies should take account of the guidance which has been issued by the ABPI and the Department of Health. Joint~~ Collaborative working is acceptable in principle provided that it is carried out in conformity with the Code. Collaborative working ~~In particular it~~ must not constitute an inducement to health professionals or other relevant decision makers to prescribe, supply, recommend, buy, or sell any medicine. It must therefore always be ensured that any and all of the benefits of each collaborative working project do not go to these individuals or their practices. If the collaborative working is a joint working project and there are benefits which are due to the NHS, these must go ~~not to individuals or practices but~~ to an NHS or ~~other~~ similar organisation.

~~A joint working agreement can be based on~~ The use of a particular medicine of a company party to the collaborative working agreement is not prohibited provided all parties are satisfied ~~but only if the requirements below are complied with and only if the parties have are satisfied themselves~~ that the use of the medicine is appropriate and that the requirements for collaborative working are met. ~~will enhance patient care. Goods and services~~

Resources provided by the company required to deliver ~~Goods and services provided by the company as part of~~ the collaborative ~~joint~~ working project ~~agreement~~ must be relevant to the medicines involved and the agreement as a whole must be fair and reasonable. Any resources ~~goods and services~~ provided by the company must themselves contribute to either patientcare or healthcare.

The written agreement ~~must~~ should cover the following points:

- *the name of the ~~joint~~ collaborative working project, the parties to the agreement, the date and the term of the agreement*
- *the expected benefits for patients, the population or user groups, the NHS, ~~and the~~ pharmaceutical company and other organisation(s) as applicable; ~~patient~~ benefits should always be stated first, and ~~patient~~ outcomes should be measured*
- *an outline of the financial arrangements*
- *the roles and responsibilities of the NHS, ~~and~~ the pharmaceutical company and other organisations and how the success of the project will be measured, when and by whom; all aspects of input should be included*
- *the planned publication of any data or outcomes*
- *if a pharmaceutical company enters into a collaborative ~~joint~~ working agreement on the basis that its product is already included in an appropriate place on the local formulary, a clear reference to this should be included in the collaborative working agreement so that all the parties are clear as to what has been agreed*
- *contingency arrangements to cover possible unforeseen circumstances such as changes to summaries of product characteristics and updated clinical guidance; agreements should include a dispute resolution clause and disengagement/exit criteria including an acknowledgement by the parties that the project might need to be amended or stopped if a breach of the Code is ruled*
- *publication by the company of ~~an executive~~ a summary of the collaborative ~~joint~~ working agreement, for example on a clearly defined website or section of a website, such as on the company's or companies' website; the healthcare organisation and other parties involved in the collaboration should also be encouraged to publish this.*
- *Outcomes should be published by all parties within three months of the project's completion, so that other NHS organisations can learn from and potentially replicate the initiative.*

~~Attention is drawn to the certification requirements set out in Clause 14.3 which apply to material relating to collaborative joint working including the project initiation documentation and the executive summary of the collaborative working agreement. Only the final documents etc for any joint collaborative working project need be certified. All documents etc used during the development of the~~

~~*project should be of the same standard as certified material but there is no requirement to certify such materials. The collaborative joint working agreement does not need to be certified.*~~

Collaborative working should be distinguished from straightforward sales where medicines are simply sold and there are no accompanying goods and services etc and from package deals and outcome or risk sharing agreements as defined in the supplementary information to Clause 18.1.

20.1 Joint Working as a Form of Collaborative Working

Joint working as defined by the Department of Health; and first introduced in the Code in 2008 is a form of collaborative working as set out in Clause xx.

The Department of Health defines joint working between the NHS and the pharmaceutical industry as situations where, for the benefit of patients, one or more pharmaceutical companies and the NHS pool skills, experience and/or resources for the joint development and implementation of patient centred projects and share a commitment for successful delivery. Each party must make a significant contribution and the outcomes must be measured. Treatments when mentioned ~~*where applicable*~~*, must, be in line with nationally accepted clinical guidance where such exists.*

In addition to the certification requirements set out in the supplementary information to collaborative working above, the joint working project initiation document must also be certified.

The Department of Health has issued best practice guidance on joint working between the NHS and pharmaceutical industry and other relevant commercial organisations. ~~*The Department of Health and the ABPI have jointly issued Moving beyond sponsorship: interactive toolkit for joint working between the NHS and the pharmaceutical industry.*~~ *The ABPI has produced guidance notes on joint working between pharmaceutical companies and the NHS and others for the benefit of patients with separate guidance for England, Scotland and Wales. When considering joint working companies should take account of the applicable guidance.*

Collaborative working which relies on benefiting the NHS and maintaining patient care will not meet the requirements for a joint working project.

~~*The requirement to make the executive summary for joint working projects public applies to joint working projects started on or after 1 May 2011 or ongoing on that date.*~~

~~*The ABPI has produced guidance notes on joint working between pharmaceutical companies and the NHS and others for the benefit of patients. The ABPI Guidance refers to the requirements of the Code but goes well beyond them*~~

~~*Clause 19.2 is relevant to a joint working agreement between a pharmaceutical company and the NHS which does not involve the use and purchase of any of the company's medicines.*~~

~~*Although the ABPI Guidance is aimed principally at joint working between pharmaceutical companies and the NHS, it also covers joint working conducted though third party service providers and/or with suppliers of private healthcare.*~~

~~*More detail as to the requirements for joint working is provided in the ABPI Guidance which should be consulted when joint working is contemplated.*~~

~~*Joint working should be distinguished from straightforward sales where medicines are simply sold and there are no accompanying goods and services etc and from package deals and outcome or risk sharing agreements as defined in the supplementary information to Clause 18.1.*~~

Clause 20.2 Disclosure

SUPPLEMENTARY INFORMATION
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The information required by Clause 20 as to transfers of value must be publicly disclosed annually, ~~in relation to transfers of value made in 2015 and each calendar year thereafter,~~ giving in each case the financial amount or value and the name of the recipient.

Companies must ensure that the amount spent on ~~joint~~ collaborative working projects is made public irrespective of whether the value is transferred to a healthcare organisation etc or some other funding model is used. Disclosure must be carried out in accordance with Clause 24.

Clause X Medicines and Samples

Clause 17 Samples

A small sample which is provided only for identification or similar purposes and which is not intended to be used in treatment may be provided to any health professional but is otherwise subject to the requirements of Clause 17.

Titration packs, free goods and bonus stock provided to pharmacists and others are not samples. This is because they are not for the purposes described.

Titration packs are packs containing various strengths of a medicine for the purpose of establishing a patient on an effective dose.

The supply of a product which is not a medicine because it does not contain the active ingredient normally present is not regarded as the supply of a sample.

Clause 17 Starter Packs

The provision of starter packs is not permitted. Starterpacks were small packs designed to provide sufficient medicine for a primary care prescriber to initiate treatment in such circumstances as a call out in the night.

Clause 17.3 Sample Requests

This clause does not preclude the provision of a pre-printed sample request form bearing the name of the product for signing and dating by the applicant.

All signed and dated written requests for samples should be retained for not less than one year.

Clause 17.7 Control and Accountability

Companies should ensure that their systems of control, quality and accountability relating to medicines held by representatives cover such matters as the security of delivery to them, the security of medicines held by them, the audit of stocks held by them, including expiry dates, and the return to the companies of medicines no longer to be held by representatives.

Samples distributed by representatives must be handed direct to the health professionals requesting them or persons authorized to receive them on their behalf. The provision of medicines and samples in hospitals must comply with individual hospital requirements.

Non-Interventional Studies

Clause 13.4 Other Studies ~~Covered by Clause 13.2~~

~~Companies are encouraged to comply with Clause 13.4 for all other types of studies covered by Clause 13.2, including~~ All non-interventional studies, including epidemiological studies and registries and other studies that are retrospective in nature. ~~In any case, such studies~~ are subject to Clause 21.

~~Clause 13.4 Approval and Supervision~~

~~The approval and supervision of non-interventional studies are dealt with in Clause 25.2.~~ Deleted covered in 14.3

~~***Clause 13.4 Date of Implementation***~~

~~*Companies must comply with Clause 13.4 in relation to non-interventional studies, that are completed on or after 1 July 2008. Companies are encouraged to comply in relation to studies completed prior to that date.*~~ No longer required

~~***Clause 19.1*** ***Medical and Educational Goods and Services*** ***moved to Donations and Grants section***~~

ADDITIONAL REQUIREMENTS FOR INTERACTIONS WITH HEALTH PROFESSIONALS, OTHER RELEVANT DECISION MAKERS, HEALTHCARE ORGANISATIONS, PATIENT ORGANISATIONS AND PATIENTS

Clause # Donations and Grants

Donations and Grants are funds, benefits in-kind or services freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient organization, institution and the like to provide goods or services to the benefit of the company in return. Donations and grants to individuals is prohibited.

In general donations are physical items, services or benefits in-kind. Grants are the provision of funds. Donations and grants may be offered or requested.

Donations and Grants to healthcare organisations, patient organisations or third party organisations are only allowed if they:

- are made for the purpose of supporting healthcare, scientific research or education
- do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicines Changed from medicinal products
- they are prospective in nature added to ensure it is clear organisations cannot apply retrospectively
- do not bear the name of any medicine - although they may bear the name of the company providing them.

In addition, they must be:

- certified as set out in Clause xxx as this section supports the standards required to help prevent bribery and corruption certification was felt to be important.
- documented and kept on record by the company
- publicly disclosed annually as a donation or grant

Company involvement should be made clear for donations and grants to the extent possible.

In addition, donations and grants made to patient organisations must have a written agreement which must be certified as set out in Clause 27.3.

~~Providing or offering cash, cash equivalents or personal services is also prohibited. For these purposes, personal services are any type of service unrelated to the profession and that confer a personal benefit to the Recipient. Gifts for the personal benefit (such as sporting or entertainment tickets, social courtesy gifts) of health professionals, individuals representing healthcare organisations or patient organisations (either directly or indirectly) are prohibited~~. Moved to Overarching.

Clause # Contracted Services Clause 27.8 incorporated into this clause

23.1 Health professionals, other relevant decision makers or their employers on their behalf, healthcare organisations, patient organisations, individuals representing patient organisations, and members of the public including patients, carers, journalists etc. may be used as consultants and advisors, whether in groups or individually, for services such as speaking at and chairing meetings, involvement in medical/scientific studies, clinical trials, non-interventional studies or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration and/or hospitality.

The arrangements which cover these genuine consultancy or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

- a written contract or agreement must be agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services
- a legitimate need for the services must be clearly identified and documented in advance of requesting the services

and entering into arrangements with the prospective ~~consultants~~ contracted individual(s)

- the criteria for selecting ~~consultants~~ contracted individuals must be directly related to the identified need and the persons responsible for selecting the ~~consultants~~ contracted individuals must have the expertise necessary to evaluate whether the ~~consultants~~ contracted individuals meet those criteria
- the number of ~~consultants~~ contracted individuals retained, and the extent of the service must not be greater than the number reasonably necessary to achieve the identified need
- the contracting company must maintain records concerning, and make appropriate use of, the services provided by ~~consultants~~ contracted individuals
- the hiring of the ~~consultants~~ contracted individuals to provide the relevant service must not be an inducement to prescribe, supply, administer, recommend, buy or sell any medicine
- the remuneration for the services must be reasonable and reflect the fair market value of the services provided. In this regard, token consultancy arrangements must not be used to justify compensating the contracted individual(s). ~~health professionals, other relevant decision makers, patient organisation~~
- in their written contracts or agreements with contracted individuals, companies must include provisions regarding the obligation of the ~~consultants~~ contracted individual to:
  - declare that he/she is a ~~consultants~~ contracted individual to the company whenever he/she writes or speaks in public about a matter that is the subject of the agreement or any other issue relating to that company.
  - Similarly, companies that employ, on a part-time basis, health professionals that are still practising their profession, must ensure that such persons are obliged to declare their employment arrangement with the company whenever they write or speak in public about a matter that is the subject of the employment or any other issue relating to that company.

21. Contracts between companies and health professionals, other relevant decision makers or their employers on their behalf, healthcare organisations, patient organisations, individuals representing patient organisations, and member of the public including patients, carers, journalists etc. under which they provide any type of service to companies are allowed providing such services:

- are provided for the purpose of supporting healthcare, research or education; and
- do not constitute an inducement to recommend and/or, prescribe, purchase, supply, sell or administer a specific medicine.

23.2 Pharmaceutical companies must publicly disclose annually, details of the fees and expenses paid to UK ~~health professionals and other relevant decision makers~~ ~~in the UK~~, individuals , organisations etc for contracted services such as chairing and speaking at meetings, assistance with training and participation in advisory boards etc. Such disclosure includes payments in relation to research and development work, including the conduct of clinical trials.

23.3 In addition to the information required to be made public by Clause 23.2, companies must publicly disclose, annually, details of payments made to ~~consultants~~ contracted individuals in relation to market research (unless the company concerned does not know ~~is not aware~~ of the identities of those participating in the market research).

23.4 Fees, expenses and the like due to ~~consultants~~ contracted individuals/organisations in relation to Clauses 21, 23.2 and 23.3 must be disclosed. ~~whether paid directly to them or to their employers or to healthcare organisations, patient organisations or to companies etc.~~

The relevant disclosure requirements are:

- Fees and expenses paid for contracted services between companies and institutions, organisations or associations of health professionals
- Fees and expenses paid for contracted services to health professionals and other relevant decision makers, or to their employers on their behalf
- The disclosure for contracted services provided by each patient organisation must include:

- The total amount paid per patient organisation per calendar year including a description of the services provided that is sufficiently complete to enable the reader to understand the nature of the services provided without the necessity to divulge confidential information
- Fees and expenses should be disclosed separately.

- The disclosure for contracted services provided by members of the public must include:

  - The total number of members of the public contracted to perform services and the total amount paid to members of the public per calendar year including a description of the services provided that is sufficiently complete to enable the reader to understand the nature of the services provided without the necessity to divulge confidential information.

- In addition, companies should:

  - Fees and expenses should be disclosed separately
  - Companies should provide a breakdown of the total payments to each group of individuals eg journalists, public, patients etc without the necessity to divulge confidential information.

Contracts for UK individuals representing patient organisations should be made with the patient organisation and disclosed against the patient organisation as set out in Clause xx.

~~22.1 si The payment of reasonable honoraria and reimbursement of out of pocket expenses, including travel, for speakers, advisory board members and the providers of other professional services, is permissible. The arrangements for events/meetings must comply with Clause 22.1 with regard to hospitality and venues~~

Relationships with Health Professionals, Other Relevant Decision Makers, Healthcare Organisations, Patient Organisations

27.4 No company may require that it be the sole funder or sponsor of a healthcare organisation or patient organisation or any of its programmes.

27.5 A company must not make public use of a healthcare organisation or patient organisation's logo and/or proprietary material without the organisation's written agreement. In seeking such permission, the specific purpose and the way in which the logo and/or proprietary material will be used must be clearly stated.

27.9 Companies must ensure that ~~their~~ all sponsorship is always clearly acknowledged from the outset The wording of the declaration of sponsorship must be unambiguous and accurately reflect the extent of the company's involvement and influence over the material. ~~nature of the company's involvement.~~

12.2 Market research activities, clinical assessments, post-marketing surveillance and experience programmes, post-authorization studies (including those that are retrospective in nature) and the like must not be disguised promotion. They must be conducted with a primarily scientific or educational purpose.

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Clause X Donations and Grants

Clause 19.1 ~~Medical and Educational Goods and Services~~ Donations and Grants

Clauses 18.1 and 19.1 do not prevent the provision of donations and grants. ~~medical and educational goods and services. In order to comply with the Code such goods and services must be in the interests of patients or benefit the NHS whilst maintaining patient care~~. They must not be provided to individuals ~~for their personal benefit.~~

The requirement in Clause 19.1 that ~~medical and educational goods~~ donations must not bear the name of any medicine does not apply where the ~~goods~~ donation ~~involved consist of~~ is an independently produced textbook~~s~~ or journal~~s~~ which include as part of their texts the names of medicines.

~~The role of medical/generic representatives in relation to the provision of goods and services supplied in accordance with Clauses 18.1 and 19.1 needs to be in accordance with the principles set out below. In this context companies should consider using staff other than medical/generic representatives.~~

Donations as a ~~medical and educational~~ good ~~and~~ or service may bear a corporate name. The involvement of a pharmaceutical company in such activities must be made clear to ~~relevant health professionals and/or other relevant decision makers~~ those receiving a service. In addition the involvement of a pharmaceutical company in any ~~therapy review~~ services~~s~~ should be made clear to patients. Such involvement should also be clear in any associated materials for patients. ~~However, if there are no materials for patients this would be a matter for the relevant health professional. If there are materials for patients the involvement of a pharmaceutical company requirements for declaration of sponsorship set out in~~ Clause 9.10 would apply.~~–~~Companies should be clear regarding the role of staff in the provision of donations and grants, particularly the role of representatives. Companies should consider using staff other than representatives. If companies decide to use representatives in relation to donations and grants, then this should be in accordance with the principles set out below:

~~The following guidance is intended to assist companies in relation to medical and educational goods and services.~~

~~1.~~

i) *The acceptability of the role of ~~medical/generic~~ representatives will depend on the nature of the donation ~~of goods and/~~or grant ~~services goods and services provided~~ and the method of provision*
ii) *Representatives may introduce a donation or grant ~~service~~ by means of a brief description and/or delivering materials but may not instigate a detailed discussion about the donation or grant ~~service~~ at the same time as a call at which products are promoted*
iii) *If ~~medical/generic~~ representatives provide, deliver or demonstrate a donation or grant ~~medical and educational goods and services~~ then this must not be linked in any way to the promotion of products. In order to comply with this stipulation the representative must not carry out both activities at the same call or contact. ~~visit~~.*
iv) *If, during a promotional ~~visit~~ call or contact by a representative, a change in medication to one of the company's products is agreed, the representative may not then offer a donation or grant ~~service such as a therapy review service~~ to facilitate the change in medication. as this would be seen as a way for the company to ensure that the agreed change would in fact be made.*

In addition, companies should consider in relation to donations in the form of a service:

~~v)~~ *The nature of the service provider and the person associated with the provision of the ~~medical and educational goods and/or~~ services~~,~~ is important ie is the service provider an ~~medical/generic representative or is the service provider some other~~ appropriately qualified person, such as a health professional? ~~sponsored registered nurse~~? If the ~~goods and~~ services~~s~~ requires patient contact, for example either directly or by identification of patients from patient records and the like, then ~~medical/generic~~ representatives must not be involved. Only an appropriately qualified person, ~~for example~~ such as a health professional, ~~sponsored registered nurse~~, not employed as a ~~medical/ generic~~ representative, may undertake activities relating to patient contact and/or patient identification. ~~Medical/generic representatives could provide administrative support in relation to the provision of a screening service, but must not be present during the actual screening and must not discuss or help interpret individual clinical findings~~.*

vi) *Neither the company nor its ~~medical/generic~~ representatives may be given access to data/records that could identify, or*

could be linked to, particular patients.
~~Sponsored health professionals should not be involved in the promotion of specific products. Registered nurses, midwives and health visitors are required to comply with the Nursing & Midwifery Council Code – Standards of conduct, performance and ethics for nurses and midwives.~~

vii) Health professionals involved in the delivery of services are required to adhere to all relevant professional standards of conduct (see supplementary information to Clause 22.1). There should be no promotion of specific products by those health professionals.

viii) The remuneration of those not employed as ~~medical/generic~~ representatives but who are engaged to deliver a service, as service providers ~~in relation to the provision of medical and educational goods and services~~, must not be linked to sales in any particular territory or place or to sales of a specific product or products and, in particular, may not include a bonus scheme linked to such sales. Bonus schemes linked to a company's overall national performance, or to the level of service provided, may be acceptable. ~~Companies must ensure that patient confidentiality is maintained at all times and that data protection legislation is complied with.~~

ix) Service providers must operate to detailed written instructions provided by the company. The company must provide the service provider with detailed written instructions. These should be similar to the briefing material for representatives as referred to in Clause 15.9. The written instructions should set out the role of the service provider and should cover patient confidentiality issues. Instructions on how the recipients are to be informed etc should be included. The written instructions must not advocate, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code.

x) Service providers must abide by the principle set out in Clause 15.5 that in an interview, or when seeking an appointment, reasonable steps must be taken to ensure that they do not mislead as to their identity or that of the company they represent.

~~xi)~~ A recipient of a service must be provided with ~~a written protocol~~ sufficient written information to avoid misunderstandings as to what the recipient has agreed. The identity of the sponsoring pharmaceutical company must be given. ~~For example, a general practitioner allowing a sponsored registered nurse access to patient records should be informed in writing of any data to be extracted and the use to which those data will be put.~~

~~xii)~~ Any material designed for use in relation to the provision of a ~~medical and educational good and~~ service must be non-promotional. It is not acceptable for such materials to promote the administration, consumption, prescription, purchase, recommendation, sale, supply or use of the sponsoring company's medicines. Nor is it acceptable for materials to criticise competitor products as this might be seen as promotional. ~~All materials must identify the sponsoring pharmaceutical company.~~ Already covered in the Code

xiii) Material relating to the provision of a ~~medical and educational goods and~~ services, such as internal instructions, external instructions, the written ~~protocol~~ information for recipients and other material, ~~including material relating to therapy reviews, etc~~, must be certified as required by Clause 14.3.

xiv) A copy of the materials must be made available to the PMCPA ~~Prescription Medicines Code of Practice Authority~~ (PMCPA) on request.

xv) Companies are recommended to inform relevant NHS or other organisations of their activities where appropriate. This is particularly recommended where companies are proposing to provide ~~medical and educational~~ a ~~goods and~~ service which would have budgetary implications for the parties involved. ~~For example the provision of a screening service for a limited period might mean that funds would have to be found in the future when company sponsorship stopped. Another example might be the provision of diagnostic or laboratory services and the like, which the relevant organisation would normally be expected to provide.~~

Clause 19.1 Switch and Therapy Review Programmes

Clauses 18.1 and 19.1 prohibit switch services paid for or facilitated directly or indirectly by a pharmaceutical company whereby a patient's medicine is simply changed to another. For example it would be unacceptable if patients on medicine A were changed to medicine B, without any clinical assessment, at the expense of a pharmaceutical company promoting either or both medicines. It would be acceptable for a company to promote a simple switch from one product to another but not to assist a health professional in implementing that switch even by means of a third party. ~~if assistance was by means of a third party such as a sponsored nurse or similar. Such arrangements are seen as companies in effect paying for prescriptions and are unacceptable.~~

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A therapeutic review is different to a switch service. A therapeutic review which aims to ensure that patients receive optimal treatment following a clinical assessment is a legitimate activity for a pharmaceutical company to support and/or assist. The result of such clinical assessments might require, among other things, possible changes of treatment including changes of dose or medicine or cessation of treatment. A genuine therapeutic review should include a comprehensive range of relevant treatment choices, including non-medicinal choices, for the health professional and should not be limited to the medicines of the sponsoring pharmaceutical company. ~~The arrangements for therapeutic review must enhance patient care, or benefit the NHS and maintain patient care, and must otherwise be in accordance with Clause 19.1 and the supplementary information on the provision of medical and educational goods and services.~~ The decision to change or commence treatment must be made for each individual patient by the prescriber and every decision to change an individual patient's treatment must be documented with evidence that it was made on rational grounds.

~~Clause 19.1 Disclosure~~

~~Transfers of value in relation to medical or educational goods and/or services must be publicly disclosed annually in relation to transfers of value made in 2015 and each calendar year thereafter, giving in each case the f inancial amount or value and the name of the recipient. Disclosure must be carried out in accordance with Clause 24.~~

Clause 19.2 Annual Disclosure of Donations and Grants ~~and Benefits in Kind~~

~~Donations and grants to health professionals are prohibited~~. ~~not covered by this clause~~. Company ~~sponsorship~~ support of individuals ~~health professionals~~ to attend events/meetings is covered by Clause 22.

Details of each donation or grant, (transfer of value) must be publicly disclosed annually, giving in each case the financial amount or value and the name of the recipient institution, organisation or association. Companies are also encouraged to ask recipients to make such funding public. Where applicable Fees and agreed expenses should be disclosed separately.
~~The information required by Clause 19.2 must be publicly disclosed in respect of donations, grants and benefits in kind made in 2015 and each calendar year thereafter.~~ Disclosure must be carried out in accordance with Clause 24.

~~Clause 18.1 Donations to Charities~~

~~Donations to charities made by companies in return for health professionals' attendance at company stands at meetings are not unacceptable under this clause provided that the level of donation for each individual is modest, the money is for a reputable charity and any action required of the health professional is not inappropriate. Any donation to a charity must not constitute a payment that would otherwise be unacceptable under the Code. For example, it would not be acceptable for a representative to pay into a practice equipment fund set up as a charity as this would be a financial inducement prohibited under Clause 18.1. Donations to charities in return for representatives gaining interviews are also prohibited under Clause 15.3.~~
~~Any offer by a company of a donation to a charity which is conditional upon some action by a health professional must not place undue pressure on the health professional to fulfil that condition. At all times the provisions of Clauses 2 and 9.1 must be kept in mind.~~

Clause X Contracted Services

Clause 18.1 ~~Payments to~~ Contracted Individuals

The relevant provisions of Clause 22 apply to contracted individuals' attendance at events/meetings. ~~Any payment to an individual for an activity that is ruled in breach of Clause 12.2 and/or Clause 23 is likely to be viewed as an unacceptable payment and thus in breach of Clause 18.1.~~

~~Clause 23 Patient Organisations~~

~~The provision of services to pharmaceutical companies by patient organisations is covered by Clause 27.8.~~

Clause 23.1 ~~The Use of Consultants~~ Contracted Individuals

The requirement that contracts or agreements with ~~consultants~~ contracted individuals must include provisions regarding their obligation to declare the arrangement whenever they write or speak in public ~~applies to contracts entered into or renewed on or after 1 May 2011.~~

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~~*If health professionals or other relevant decision makers attend events in a consultant or advisory capacity the relevant provisions of Clause 22 apply.*~~ Delete as now in overarching requirements

Clause 23.3 Disclosure of Transfers of Value of Market Research

Clause 23.3 relates only to market research using ~~consultants~~ contracted individuals where the pharmaceutical company knows the identity of the ~~consultants~~ contracted individuals. This is because the focus of the requirements concerning transparency is on areas where there are direct relationships between the parties and that is not so where the company does not know the identity of the participants.

Clause 23.2 Annual Disclosure of Transfers of Value to UK Health Professionals and Other Relevant Decision Makers or their Employers on their Behalf

Disclosure must be carried out in accordance with Clause 24.

The information which must be disclosed is the total amount paid in a calendar year to each ~~consultant~~ contracted individual who is a health professional or other relevant decision maker and has provided services. Companies may, of course, give greater detail, for example by giving separate figures for different categories of service.

~~*The information required by Clause 23.2 must be publicly disclosed annually. in respect of the calendar year 2015 and each calendar year thereafter.*~~

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

Fees and ~~agreed~~ expenses should be disclosed separately.

Clause 23.2 Annual Disclosure of Transfers of Value in Relation to Contracted Services Provided by Patient Organisations or Individuals Representing Patient Organisations

Disclosure must be carried out in accordance with Clause X.

A payment to an individual representing a patient organisation should be disclosed as a payment to that patient organisation. This means that the contract should also be with the patient organisation.

The information which must be disclosed is the total amount paid per patient organisation ~~including~~ over the reporting period and a description of the services provided that is sufficiently complete to enable the reader to understand the nature of the services provided without the necessity to divulge confidential information. This information should include contracted services provided by individuals representing patient organisations~~. including those provided by individuals representing patient organisations.~~

Fees and expenses should be disclosed separately.

Clause 23.2 Annual Disclosure of Transfers of Value in Relation to Contracted Services by Members of The Public including Patient, Carers, Journalists etc.

Disclosure must be carried out in accordance with Clause X.

The information which must be disclosed is the total amount paid to members of the public in the UK, including the number of individuals contracted, and a description of the services provided that is sufficiently complete to enable to reader to understand the nature of the services provided without the necessity to divulge confidential information, over the reporting period.

Companies should provide a breakdown of the total payments to each group of individuals eg journalists, public, patients etc without the necessity to divulge confidential information

Fees and expenses should be disclosed separately.

Clause 23.2 Annual Disclosure of Transfers of Value of Research and Development

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

- ~~*non-clinical studies (as defined in the OECD Principles of Good Laboratory Practice)*~~
- ~~*clinical trials (as defined in Directive 2001/20/EC)*~~
- ~~*non-interventional studies that are prospective in nature and involve the collection of data from, or on behalf of individual or groups of health professionals specifically for the study.*~~
- *non-clinical studies (as defined in OECD Principles on Good Laboratory Practice)*
- *clinical trials (as defined in Regulation 536/2014)*
- *non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, health professionals specifically for the study.*

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

Clause X Relationships with Health Professionals, Other relevant Decision Makers, Healthcare Organisations and Patient Organisations

Clause 27.5 Use of Healthcare or Patient Organisation Logos or Material

Even with the organisation's permission the use of its logo or material must not be such as to otherwise breach the Code.

~~***Clause 27.7 Further Information***~~

~~*An indication of the patient organisation's total income and/or the company's support as a percentage of the patient organisation's total income may be given. Neither is obligatory. Companies are encouraged to be prepared to make available up-to-date information about such activities at any time in response to enquiries*~~. Superseded by EFPIA requirements

~~***Clauses 27.7 and 27.8 Transfers of Value to Patient Organisations***~~

~~*Transfers of value to patient organisations made in accordance with Clauses 27.7 and 27.8 are not subject to the requirements relating to transfers of value set out in Clause 24. Clause 24.3 excludes them from its scope.*~~ Superseded by EFPIA requirements

~~***Clause 27.8 Consultancy Services Provided by Patient Organisations***~~

~~*When companies engage patient organisations to provide services under Clause 27.8, the contracts for those services do not need to be certified.*~~ Superseded by EFPIA requirements

~~***Clause 12.2 Non-Interventional Studies of Marketed Medicines***~~

~~*The conduct of non-interventional studies of marketed medicines is dealt with in Clause 13.*~~ Deleted no longer required

Clause 12.2 Market Research

Market research is the collection and analysis of information and must be unbiased and non-promotional. The use to which the statistics or information is put may be promotional. The two phases must be kept distinct.

Attention is drawn to the Legal & Ethical Guidelines for Healthcare Market Research produced by the British Healthcare Business Intelligence Association ~~*in consultation with the ABPI.*~~

Market research material should be examined to ensure that it does not contravene the Code.

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ADDITIONAL REQUIREMENTS FOR INTERACTIONS WITH HEALTH PROFESSIONALS, OTHER RELEVANT DECISION MAKERS, HEALTHCARE ORGANISATIONS, PATIENT ORGANISATIONS AND PATIENTS

Where market research is carried out by an agency on behalf of a pharmaceutical company, the agency must reveal the name of its client to the PMCPA ~~rescription Medicines Code of Practice Authority~~ when ~~the Authority~~ requested it to do so. When commissioning market research, a company must take steps to ensure that its identity would be ~~se~~ made known to the Authority should a request for that information be made.

ADDITIONAL REQUIREMENTS FOR INTERACTIONS WITH THE PUBLIC AND PATIENT ORGANISATIONS

Clause X Relations with the Public ~~and the Media~~ including Patients, Journalists etc

26.1 Prescription only medicines must not be advertised to the public. This prohibition does not apply to vaccination campaigns carried out by companies and approved by the health ministers.

26.2 Information about prescription only medicines which is made available to the public either directly or indirectly must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading with respect to the safety of the product.

Statements must not be made for the purpose of encouraging members of the public to ask their health professional to prescribe a specific prescription only medicine.

Clause 18.2si Items ~~which may be~~ made available to patients, for example by completing a request card enclosed with a medicine, or via a health professional, should be inexpensive, ~~and~~ related to either the condition under treatment or general health, part of a patient support programme and certified in advance as required by Clause 14.2. Care must be taken that any such activity meets all the requirements of the Code and in particular Clause 26.

Clause x ~~No item for use by patients must be given for the purpose of encouraging patients to request a particular medicine.~~ Companies cannot run or sponsor competitions or quizzes for patients if prizes are offered. ~~to individuals. A competition for patients where the prizes were health related and were given to a clinic or similar might be acceptable~~ moved from 18.2 si as it is more appropriate in this section and clause.

26.3 Any material which relates to a medicine and which is intended for patients taking that medicine must include the statement below or a similar one:

> **'Reporting of side effects'** If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at [a website address which links directly to the MHRA Yellow Card site].
>
> By reporting side effects you can help provide more information on the safety of this medicine.'

When the material relates to a medicine which is subject to additional monitoring an inverted black equilateral triangle must be included on it together with the statement below or a similar one:

> 'This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See [a website address which links directly to the MHRA Yellow Card site] for how to report side effects.'

26.4 Requests from individual members of the public for advice on personal medical matters must be refused and the enquirer recommended to consult his or her own doctor or other prescriber or other health professional.

26.5 Companies are responsible for information about their products which is issued by their ~~public relations~~ agencies eg communications, advertising etc.

Clause X Relationships with Patient Organisations

27.1 When pharmaceutical companies ~~can~~ interact with patient organisations or any user organisation such as disability organisations, carer or relative organisations and consumer organisations to support their work, including assistance in the provision of appropriate information to the public, patients and carers companies must:

~~companies interact as set out above they must:~~

- respect the independence of patient organisations
- assure the independence of patient organisations, in terms of their political judgement, policies and activities
- ensure relationships are based on mutual respect, with the views and decisions of each partner having equal value

ADDITIONAL REQUIREMENTS FOR INTERACTIONS WITH THE PUBLIC AND PATIENT ORGANISATIONS

- not promote or request the promotion of a particular prescription only medicine
- ensure the objectives and scope of collaborations are transparent. Financial, ~~and~~ non-financial or in kind support provided by companies must always be clearly acknowledged. ~~Companies welcome broad funding of Patient Organisations from multiple sources~~

27.3 When companies ~~working with patient organisations~~ provide donations, grants or sponsorship (including in relation to events/meetings) to patient organisations as set out ion Clause xx, companies must have ~~in place~~ a written agreement in place for each donation, grant or sponsorship, setting out exactly what has been provided. ~~agreed~~, ~~including funding~~, ~~in relation to every~~ ~~significant~~ ~~activity or ongoing relationship~~

The written agreement must include:

- description of the donation, grant or sponsorship
- objective of the donation, grant or sponsorship. For donations and grants how it will support healthcare, scientific research or education must also be included
- the names of the organisations/ parties involved (pharmaceutical company, patient organisations and any third parties ~~which will be brought in to help~~) and their respective roles ~~of the company and the patient organisation~~
- the type of activity and the nature of the company's contribution (eg donation,~~unrestricted~~ grant, sponsorship of a specific meeting or publication etc)
- ~~the objectives~~
- the time-frame
- the amount of funding and/or a description of ~~significant~~ indirect/non-financial, in kind donation ~~support~~ and the nature of that donation ~~support~~ (eg the donation of ~~public relations~~ agency time or free training courses). Where possible a full breakdown of costs should be included
- a statement that all parties are fully aware the donation, grant or sponsorship must be clearly acknowledged and apparent from the start
- ~~the code or codes of practice which will apply~~
- the signatories to the agreement
- the date of the agreement.

~~The~~ This written agreement must be certified as set out in Clause 14.3. A company must ensure that any materials, activities etc resulting from working with patient organisations are also certified where these are covered by Clause 14.3. Donations, grants and sponsorships (including in relation to events/meetings) must be publicly disclosed annually as set out in Clause 24.

27.2 When ~~working with~~ providing donations, grants or sponsorship (including in relation to events/meetings) to patient organisations, companies must ensure:

- they comply with the prohibition on advertising prescription only medicines to the public
- ~~ensure~~ that the involvement of the company is made clear and that all of the arrangements comply with the Code. This includes the need to declare the provision and the wording of the declaration must accurately reflect the nature of the company's involvement. ~~support,~~ ~~sponsorship~~ (~~Clause 27.9) and the prohibition on advertising prescription only medicines to the public.~~

~~When Member Companies provide financial support, significant indirect support and/or significant non-financial support to patient organisations, they must have in place a written agreement. This must state the amount of funding and also the purpose (e.g. grant, specific event/meeting or publication, etc). It must also include a description of significant indirect support (e.g. the donation of public relations agency's time and the nature of its involvement) and significant non-financial support~~ deleted as covered in the agreement in supp info

27.6 A company must not seek to influence the text of patient organisation material in a manner favourable to its own commercial interests. This does not preclude a company from correcting factual inaccuracies. ~~Companies may contribute to the drafting of the text from a fair and balanced scientific perspective.~~ Moved to supp inf0

New Clause. Partly 27.5 Companies can contract with patient organisations or individuals representing patient

organisations under which they provide any type of service to companies providing these comply with Clause (contracted services). Companies must publicly disclose annually fees and expenses paid to patient organisations as set out in Clause 24. Where companies contract with individuals representing patient organisations to provide services such payment should be disclosed as a payment to the patient organisation

SUPPLEMENTARY INFORMATION
ADDITIONAL REQUIREMENTS FOR INTERACTIONS WITH THE PUBLIC AND PATIENT ORGANISATIONS

Clause X Relations with the Public including Patients, Journalists etc

Clause X (New si) Meetings for or attended by the public

Meetings organised for or attended by members of the public, journalists and patient organisations must comply with Clause 22.

Clause 26.2 Information to the Public

This clause allows for the provision of non-promotional information about prescription only medicines to the public either in response to a direct enquiry from an individual, including enquiries from journalists, or by dissemination of such information via press conferences, press announcements, television and radio reports, public relations activities etc. It also includes reference information made available by companies on their websites or otherwise as a resource for members of the public. and information provided by means of posters distributed for display in surgery waiting rooms etc. Companies should take particular care if they use social media.

Any information so provided must observe the principles set out in this clause; that is, it should be factual, balanced and must not ~~be made for the purpose of~~ encourage~~ing~~ members of the public to ask their doctors or other prescribers to prescribe a specific prescription only medicine. It must not constitute the advertising of prescription only medicines to the public prohibited under Clause 26.1. The provisions of Clause 26.4 must be observed if an enquiry is from an individual member of the public.

Information to the public falls into one of three categories depending on its purpose, how it is supplied and how the public is made aware of the information. ~~Companies should take particular care if they use social media.~~

***Proactive information** is supplied to the public without a direct request. This includes booklets on diseases and/or medicines supplied directly or via a health professional, press releases, briefings, conferences, mailings to patient organisations and disease awareness information. ~~advertising~~.*

***Reference information** is intended to provide a comprehensive up-to-date resource that companies should make available on their websites or by way of a link from their website or by some other means. The primary purpose of reference information is to be a library resource for members of the public giving information relating to prescription only medicines which have marketing authorizations. Such information must not be presented in such a way as to be promotional in nature. Pharmaceutical companies are not obliged to provide reference information but it is considered good practice to provide as a minimum the regulatory information comprising the:*

- *summary of product characteristics (SPC),*
- *the ~~package~~ patient information leaflet which is included in the pack (PIL)*
- *and the public assessment report (PAR) (UK or European) where such a document exists.*

Reference information may also include:

- *~~the~~ registration studies used for marketing authorization applications and variations and*
- *any other studies published or not including those referred to in the SPC, PIL, EPAR or UKPAR or available on clinical trial databases ~~Reference information may also include~~*
- *material supplied for health technology assessments to bodies such as the National Institute for Health and Care Excellence (NICE), the All Wales Medicines Strategy Group (AWMSG) and the Scottish Medicines Consortium (SMC)*
- *medicine guides where available*
- *~~studies (published or not)~~*
- *information about diseases*
- *information about specific medicines. ~~etc.~~ (~~**Reference information** may also include~~,*

Where companies decide to make reference information available this must represent fairly the current body of evidence relating to a medicine and its benefit/risk profile.

***Reactive information** is supplied to the public in response to a direct request and must be limited to that information necessary to respond to the request.*

Public assessment reports (European or UK), summaries of product characteristics and package leaflets may be provided to members of the public on request.

SUPPLEMENTARY INFORMATION
ADDITIONAL REQUIREMENTS FOR INTERACTIONS WITH THE PUBLIC AND PATIENT ORGANISATIONS

The Media: *it is good practice to reference ~~include~~ the summary of product characteristics with a press release or press pack relating to a medicine. Companies should also consider including references to other credible sources of information about a condition or a medicine. Particular care must be taken in responding to approaches from the media to ensure that the provisions of this clause are upheld. Attention is drawn to the Blue Guide Appendix: Reporting to the public on medicines: Advice for journalists and patient organisations produced by the Medicines and Healthcare products Regulatory Agency (MHRA).*

Individuals Prescribed Medicines: *companies may provide members of the health professions with material concerning a medicine with a view to its provision to patients to whom the medicine has already been prescribed. Such material must be factual and non-promotional and clearly state the intended audience.*

Items for patients or for use by patients are covered in Clause 18.2. and its supplementary information.

In the event of a complaint which relates to the provisions of this clause, companies will be asked to provide copies of any information supplied, including copies of any relevant press releases and the like. This information will be assessed to determine whether it fulfils the requirements of this clause.

A company may conduct a disease awareness or public health campaign provided that the purpose is to encourage members of the public to seek treatment for their symptoms while in no way promoting the use of a specific medicine. The use of brand or non-proprietary names and/or restricting the range of treatments described in the campaign might be likely to lead to the use of a specific medicine. Particular care must be taken where the company's product, even though not named, is the only medicine relevant to the disease or symptoms in question.
Information on disease awareness campaigns may be proactive, reactive or reference information depending on the circumstances. Attention is drawn to the Blue Guide Appendix: Disease Awareness Campaigns Guidelines produced by the MHRA. Information about medicines already prescribed for patients may be provided proactively, reactively or as reference information. It could also be supplied to health professionals to pass on to those patients. Such material must be factual, non -promotional and clearly state the intended audience. Reference to the supplementary information to Clause 18.2.

~~*The requirements of Clause 7 relating to information (Clauses 7.2, 7.4, 7.5, 7.8, 7.9, 7.10 and 7.11) also apply to information to the public.*~~
No longer required as this is now covered in overarching requirements
~~*Meetings organised for or attended by members of the public, journalists and patient organisations must comply with Clause 22*~~

Clause 28.5 MHRA Guidance
The MHRA Blue Guide states that the public should not need to access non-UK websites or non-UK parts of websites to obtain basic information about a company's products, such as package leaflets, summaries of product characteristics, public assessment reports and other non-promotional material. It is good practice for each page of a company website to include a statement identifying the intended audience.

Clause 26.2 Financial Information
Information made available in order to inform shareholders, the Stock Exchange and the like by way of annual reports and announcements etc may relate to both existing medicines and those not yet marketed. Such information must be non-promotional, accurate, presented in a factual and balanced way and not misleading, taking into account the information needs of the target audience. ~~Clause 7 shall not apply to such information~~. Business press releases should identify the business importance of the information and should only be aimed at the intended financial and investment audience.

~~*Clause 26.2 Information to Current or Prospective Employees*~~

~~*Information about pharmaceutical companies provided to current or prospective employees may relate to both existing medicines and those not yet marketed. Suh information should be factual and presented in a balanced way.*~~ Move to Q&A

Clause 26.2 ~~Approval~~ Certification of Information
In general information on medicines made available under this clause ~~other than responses from medical information departments or similar to unsolicited enquiries from the public,~~ must be certified in advance as required by Clause14.3.

SUPPLEMENTARY INFORMATION
ADDITIONAL REQUIREMENTS FOR INTERACTIONS WITH THE PUBLIC AND PATIENT ORGANISATIONS

Clause 26.2 Health Technology Assessments

Companies may supply information to relevant patient organisations, the public or patients in relation to forthcoming health technology assessments by public national organisations such as NICE, AWMSG or SMC, provided the information is accurate, not misleading, not promotional in nature and otherwise complies with Clause 26.2.

Clause 18.2 si Items for Patient Support

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

Clause 26.3 Obligatory Wording

The obligatory wording required corresponds to that required for package leaflets by the European Quality Review of Documents Group which updated the requirements in The Human Medicines Regulations 2012. If the suggested wording is not used the same meaning must be conveyed.

In the event that the website address given in Clause 26.3 is changed by the MHRA, companies must use the new address within one year of the change.

Clause 26.3 Black Triangle Symbol

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

Clause 26.4 Requests for Information or Advice on Personal Medical Matters

This clause prohibits the provision of advice on personal medical matters to individual members of the public requesting it ~~The intention behind this prohibition~~ This is to ensure that companies do not intervene in the patient/doctor or patient/prescriber relationship by offering advice or information which properly should be in the domain of the doctor or other prescriber.

Pharmaceutical companies can provide information appropriate to support the use of medicines and enhance patient welfare. Emergency advice, for example action needed in the event of an overdose, can be provided. Other information may also be given, including information on medicines prescribed for the enquirer, provided that it complies with the requirements of Clauses 26.1 and 26.2 and does not impinge on the principle behind this clause. For example, answering requests from members of the public as to whether a particular medicine contains sucrose or some other ~~inactive~~ ingredient, ~~or whether there would be problems associated with drinking alcohol whilst taking the medicine~~ or whether the medicine should be taken before or after a meal, is acceptable. Particular care needs to be taken with regard to enquiries relating to adverse reactions, the indications for a medicine and suchlike.

~~All~~ Requests from members of the public must be handled carefully ~~with great care~~ and a company should refer the enquirer to other sources where appropriate. These might include health professionals, NHS ~~Choices~~ websites, NHS 111, their equivalents in the devolved nations and patient organisations, etc.
A request from a patient for information may in some instances ~~best~~ be more appropriately handled by passing the information to the patient's doctor or other prescriber for discussion with them rather than providing the information direct to the patient concerned. This should not be done without the patient's consent.

Clause X Relationships with Patient Organisations

~~***Clause 27.1 Other Codes and Guidelines***~~

~~*There are other codes and guidelines which cover patient groups, including Charity Commission requirements.*~~

Clause 27.2 Purpose of Materials and Activities

Companies should take into account the purpose of materials and/or activities. The purpose of information supplied to a patient organisation must be made clear. For example, there is a difference between providing information to be supplied to the members of a patient organisation and providing background information to enable a patient organisation to respond to a health technology assessment or similar.

~~***Clause 27.3 Written Agreements***~~ **moved to Clause**

~~*The written agreement must include:*~~

- ~~*the name of the activity*~~

- ~~*the names of the organisations involved (pharmaceutical company, patient organisations and any third parties which will be brought in to help)*~~
- ~~*the type of activity and the nature of the support (eg unrestricted grant, specific meeting or publication etc)*~~
- ~~*the objectives*~~
- ~~*the respective roles of the company and the patient organisation*~~
- ~~*the time frame*~~
- ~~*the amount of funding*~~
- ~~*a description of significant*~~
- ~~*indirect/non-financial, in kind support and the nature of that support (eg the donation of public relations agency time or free training courses)*~~
- ~~*a statement that all parties are fully aware that sponsorship must be clearly acknowledged and apparent from the start*~~
- ~~*the code or codes of practice which will apply*~~
- ~~*the signatories to the agreement*~~
- ~~*the date of the agreement.*~~

~~*The written agreement must be certified as set out in Clause 14.3.*~~

Clause 27.6 Contributing to Patient Organisation Material

At the request of patient organisations companies may contribute to the drafting of patient organisation materials from a fair and balanced and scientific perspective.

ANNUAL DISCLOSURE REQUIREMENTS

Clause X Annual Disclosure of Transfers of Value to Health Professionals, Other Relevant Decision Makers and Healthcare Organisations

24.1 Companies must document and publicly disclose annually certain transfers of value made directly or indirectly to health professionals, other relevant decision makers and healthcare organisations located in Europe. This includes any employee of a pharmaceutical company whose primary occupation is that of a practising health professional. Added instead of being in 24.1 si also in definitions

24.2 The transfers of value covered by Clause 24.1 are:

- ~~joint~~ collaborative working in accordance with Clause 20
- donations and grants ~~and~~ provided to healthcare organisations, institutions or third parties ~~organisations, institutions and associations~~ in accordance with Clauses 19.1 and 19.2
- ~~Contracts~~ fees and expenses paid for contracted services between companies and institutions, organisations ~~and~~ or associations of health professionals in accordance with Clause 21 now contracted services
- ~~sponsorship~~ support of attendance by health professionals and other relevant decision makers at events/meetings whether paid directly, indirectly or via a third party in accordance with Clause 22.5
- fees and expenses paid for contracted services to health professionals and other relevant decision makers, or to their employers on their behalf, ~~in accordance with~~ in relation to Clauses 23.2, 23.3 and 23.4
- Sponsorship including contributions towards the costs of meetings paid to healthcare organisations or to third parties managing events on their behalf, which may include ~~sponsorship~~ support of health professionals not known to the company via the healthcare organisation by way of registration fees, ~~and~~ accommodation and travel.

~~24.3 Clause 24.1 does not apply to transfers of value to patient organisations. These transfers of value are covered by Clauses 27.7 and 27.8.~~ now covered in Code

24.7 Different categories of transfers of value to individual health professionals or other relevant decision makers can be aggregated on a category by category basis, provided that itemised disclosure would be made available upon request to the relevant recipient or the relevant authorities. Payments to healthcare organisations are required to be disclosed on a per activity basis.

24.8 Where a transfer of value is made to an individual health professional or other relevant decision maker indirectly via a healthcare organisation such a transfer should be disclosed once only, preferably as being a transfer to the individual concerned. ~~health professional.~~

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

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

Annual Public Disclosure of Contracted Services, Donations, Grants and Sponsorship Provided to Patient Organisations

Expansion of old Clause 27

Clause xx Companies must make publicly available annually, a list of patient organisations to which it provides donations, grants or sponsorship (including in relation to events/meetings) or with whom it has engaged to provide contracted services over the reporting period. This information must be disclosed on the company website either on a national or European level. Each reporting period shall cover a full calendar year.

ANNUAL DISCLOSURE REQUIREMENTS

Companies must include a note of methodologies used by it in preparing the disclosures and identifying support and contracted services provided.

Clause xx The disclosure for the provision of donations, grants or sponsorship (including in relation to event/meetings) to a patient organisation must include:

i. the monetary value of each financial contribution (grant or sponsorship) to include a description that is sufficiently complete to enable the average reader to understand the nature of that support or the arrangements in accordance with Clauses xxx
ii. the monetary value for each non-financial and/or indirect support (donation), the published information must also include a clear description of each donation that is sufficiently complete to enable the reader to understand the nature of the support or the arrangements. If the non-financial and/or indirect support (donation) cannot be assigned a meaningful monetary value, the published information must describe clearly the non-monetary value that the organisation receives that is sufficiently complete to enable the reader to understand the nature of the support or the arrangements in accordance with Clauses xx

The disclosure for contracted services provided by each patient organisation must include:

- The total amount paid per patient organisation per calendar year including a description of the services provided that is sufficiently complete to enable the average reader to understand the nature of the services provided without the necessity to divulge confidential information
- Fees and expenses should be disclosed separately.

Annual Public Disclosure of Contracted Services Provided by Members of The Public including Patients, Carers, Journalists etc.

New Clauses xx Companies must make publicly available annually details of the fees for contracted services paid to individual patients and members of the public in the UK who are not linked in any way to patient organisations or such individuals outside the UK who provide such a contracted service for a UK company. These services include speaking at meetings, assistance with training, writing articles and/or publications, participating in advisory boards, advising on the design etc of clinical trials, participating in market research where such participation involves remuneration and/or travel.

The disclosure for contracted services provided by members of the public must include:

- The total number of patients contracted to perform services and the total amount paid per calendar year including a description of the services provided that is sufficiently complete to enable the reader to understand the nature of the services provided without the necessity to divulge confidential information
- Fees and expenses should be disclosed separately
- Companies should provide a breakdown of the total payments to each group of individuals eg journalists, public, patients etc without the necessity to divulge confidential information.

Companies must include a note of methodologies used by it in preparing the disclosures and identifying supports and services provided.

Clause X Timings, Duration and Retention of all Disclosure Information

24.4 Disclosures must be made annually in respect of each calendar year. and ~~Disclosure~~ must be in the first six months after the end of the calendar year in which the transfers of value were made.

24.5 The information disclosed must remain in the public domain for at least three years from the time of first disclosure.

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

Supplementary Information
Annual Disclosure Requirements

Clause X Annual Disclosure

Clause 24.1 Consent to Disclosure

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

Clause 24.1 Transfers of Value

~~*The term 'transfer of value' is defined in Clause 1.10.*~~ Now in definitions

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

~~*The term 'health professional' in relation to disclosure of transfers of value also includes any employee of a pharmaceutical company whose primary occupation is that of a practising health professional as defined in Clause 1.4.*~~

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

Clause X Annual Disclosure of Transfers of Value to Health Professionals, Other relevant Decision Makers and Healthcare Organisations

Clause 24.1 Mode of Disclosure for Health Professionals, Other Relevant Decision Makers and Healthcare Organisations

There ~~will be~~ is a central platform for disclosure in the UK which companies must use. The template to be used is available from the Authority's (PMCPA) website www.pmcpa.org.uk.

~~***Clause 24.1 Date of Implementation***~~

~~*The information required by Clause 24.1 must be disclosed in respect of transfers of value made in 2015 and each calendar year thereafter.*~~

Clause 24.2 Further Information

The clauses of the Code noted in Clause 24.2 should be consulted for further information about the requirements. In addition, the requirements of Clauses 22.1 and 22.5 should be borne in mind in relation to ~~sponsorship of~~ meetings.

Clause 24.2 Disclosure of Contributions to Costs Related to Events/Meetings

If when providing sponsorship to a healthcare organisation, institution, third party organisation etc in relation to their own event, a company contributes towards the overall cost of subsistence (food and drink) then this must be included in the disclosure of the cost of the sponsorship to the healthcare organisation, institution, third party etc. Where a company supports individual health professionals or other relevant decision makers (directly or indirectly) to attend events/meetings there is no requirement to disclose subsistence (food and drink) as in Clause x

Clause 24.9 Disclosure of Transfers of Value to Individual Health Professionals and Other Relevant Decision Makers

If an individual health professional or other relevant decision maker receives a number of transfers of value from a company and decides not to agree to disclosure of one or more of those transfers of value, then that company can disclose all of that individual's transfers of value in its aggregate amount

Clause X Annual Disclosure of Contracted Services, Donations, Grants and Sponsorship (including in relation to events/meetings) Provided to Patient Organisations

Clause 27.7 Further Information

An indication of the patient organisation's total income and/or the company's support as a percentage of the patient organisation's total income may be given. Companies are encouraged to be prepared to make available up-to-date information about such activities at any time in response to enquiries.

Supplementary Information
Annual Disclosure Requirements

A template to disclose the information required in relation to patient organisations is available from the PMCPA website www pmcpa.org.uk. The use of this template is optional.

Clause X Annual Disclosure of Contracted Services, Provided by The Public including Patients, Journalists etc

Clause xx (new clause) Disclosure of Contracted Services Provided by Members of the Public
The arrangements for such services should meet the requirements of Clause x [requirements for contracted services]

Disclosure must be in the first six months in the calendar year following that in which the payments were made. The information which must be disclosed is the total amount paid in a calendar year to all the individual patients and members of the public who have provided services. The total number of individuals must be given. The names of the individuals need not be disclosed. Companies may of course give greater detail, for example, by giving separate figures for different categories of service or by providing details of the maximum and minimum payments etc.

A template to disclose the information required in relation to the public etc is available from the PMCPA website www.pmcpa.org.uk. The use of this template is optional

All reasonable steps should be taken by companies to similarly disclose their best estimates of fees paid to UK individuals by overseas affiliates, head offices in the UK or overseas and UK based European offices.

Clause X Timings, Duration and Retention of Disclosure Information

Clause xx (new si) Date of Implementation for Disclosure of Contracted Services to Patients, Carers and The Public including Journalists
The information required by Clause xx must be publicly disclosed in respect of transfers of value made in 2022 and each calendar year thereafter.