

ABPI CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY

2021



ABPI CODE OF PRACTICE
for the
PHARMACEUTICAL INDUSTRY 2021

together with the

PRESCRIPTION MEDICINES
CODE OF PRACTICE AUTHORITY
Constitution and Procedure

PMCPA | Prescription Medicines
Code of Practice Authority

This edition of the Code of Practice comes into operation on 1 July 2021. There is no transition period other than for companies wishing to continue with ongoing Medical and Educational Goods and Services where there is a transition period until 31 December 2021 as set out in the supplementary information to Clause 23. The template for disclosure agreed for the 2021 Code should be used to submit the 2021 data to Disclosure UK in 2022.

THE PRESCRIPTION MEDICINES CODE OF PRACTICE AUTHORITY

The Prescription Medicines Code of Practice Authority (PMCPA) was established by the Association of the British Pharmaceutical Industry (ABPI) in 1993 to operate the Code of Practice for the Pharmaceutical Industry independently of the Association itself.

Complaints should be submitted to the Director of the Prescription Medicines Code of Practice Authority, 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT, telephone 020 7747 8880, email complaints@pmcpa.org.uk.

Complaints made under the Code are considered by the Code of Practice Panel and, where required, by the Code of Practice Appeal Board. Reports on cases are published by the Authority and are available on request and on the Authority's website www.pmcpa.org.uk.

The PMCPA is a division of the ABPI which is a company limited by guarantee registered in England and Wales, No 09826787. Registered office: 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT.

Contents

2021 CODE AND 2019 CODE CLAUSES COMPARED

..... 04

ABPI PRINCIPLES

..... 05

ABPI CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY INTRODUCTION

..... 06

GREY SECTION – OVERARCHING REQUIREMENTS

CLAUSES 1–10

Clause 1: Scope of the Code and Definition of Certain Terms..... 08

Obligations and Responsibilities

Clause 2: Upholding Confidence in the Industry 11

Clause 3: Obligations 11

Clause 4: Responsibilities 13

Quality Standards

Clause 5: High Standards and Suitability..... 14

Clause 6: Information, Claims, Comparisons and Disparagement 14

Clause 7: Use of Quotations 16

Clause 8: Certification and Examination 16

Clause 9: Training 18

Clause 10: Events/Meetings and Hospitality 20

BLUE SECTION – PROMOTION TO HEALTH PROFESSIONALS AND OTHER RELEVANT DECISION MAKERS

CLAUSES 11–17

Clause 11: Marketing Authorisation and Temporary Supply Authorisation 24

Clause 12: Prescribing Information and Other Obligatory Information 25

Clause 13: Abbreviated Advertisements..... 27

Clause 14: Information, Claims and Comparisons 29

Clause 15: High Standards, Format and Suitability 30

Clause 16: Material and Distribution..... 30

Clause 17: Representatives 31

GREEN SECTION – INTERACTIONS WITH HEALTH PROFESSIONALS, OTHER RELEVANT DECISION MAKERS AND HEALTHCARE ORGANISATIONS

CLAUSES 18–22

Clause 18: Information, Claims and Comparisons 33

Clause 19: Prohibition on Inducements and Inappropriate Payments and the Provision of Items to Health Professionals and Other Relevant Decision Makers..... 33

Clause 20: Collaborative Working with Organisations..... 35

Clause 21: Provision of Medicines and Samples 37

Clause 22: Non-Interventional Studies of Marketed Medicines .. 38

YELLOW SECTION – INTERACTIONS WITH HEALTH PROFESSIONALS, OTHER RELEVANT DECISION MAKERS, HEALTHCARE ORGANISATIONS, PATIENT ORGANISATIONS AND THE PUBLIC, INCLUDING PATIENTS AND JOURNALISTS

CLAUSES 23–25

Clause 23: Donations and Grants..... 39

Clause 24: Contracted Services 41

Clause 25: Relationships with Health Professionals, Other Relevant Decision Makers, Healthcare Organisations and Patient Organisations 43

PINK SECTION – SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH THE PUBLIC, INCLUDING PATIENTS AND JOURNALISTS, AND PATIENT ORGANISATIONS

CLAUSES 26–27

Clause 26: Relations with the Public, Including Patients and Journalists..... 44

Clause 27: Relationships with Patient Organisations 47

TEAL SECTION – ANNUAL DISCLOSURE REQUIREMENTS

CLAUSES 28–31

Clause 28: Annual Disclosure of Transfers of Value to Health Professionals, Other Relevant Decision Makers and Healthcare Organisations 48

Clause 29: Annual Disclosure of Contracted Services, Donations, Grants and Sponsorship (including in relation to events/meetings) Provided to Patient Organisations 49

Clause 30: Annual Disclosure of Contracted Services Provided by the Public, Including Patients and Journalists 49

Clause 31: Timings, Duration and Retention of Disclosure Information..... 50

PRESCRIPTION MEDICINES CODE OF PRACTICE AUTHORITY CONSTITUTION AND PROCEDURE

..... 51

GUIDELINES ON COMPANY PROCEDURES RELATING TO THE ABPI CODE OF PRACTICE

..... 64

LEGISLATION, OTHER CODES AND GUIDELINES

..... 65

In the Code of Practice, guidance on the interpretation of the Code appears as supplementary information to the text against a pale coloured background.

2021 CODE AND 2019 CODE CLAUSES COMPARED

The table below provides a comparison of the 2021 Code clauses to the relevant 2019 Code clauses, to support familiarisation with the changes. The numbers in brackets beside each clause or supplementary information throughout the 2021 Code are those from the 2019 Code.

2021 Code Clauses	2019 Code Clauses
Grey Section – Overarching Requirements	
Clause 1	Scope of the Code and Definition of Certain Terms <i>Obligations and Responsibilities</i>
	1.1, 28.2, 1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1.8, 1.9, 1.10, 13.2, 17 SI, 23.2 SI, 24.1 SI, 27.1
Clause 2	Upholding Confidence in the Industry
	2
Clause 3	Obligations
	1.11, 1.12, 3.1, 12.1, 26.1, 29
Clause 4	Responsibilities
	13.1, 13.3, 24.1, 25.1, 25.2, 26.5, 27.7, 27.8
	<i>Quality Standards</i>
Clause 5	High Standards and Suitability
	9.1, 9.2, 9.3, 9.7, 9.10, 11.1, 28.6
Clause 6	Information, Claims, Comparisons and Disparagement
	7.2, 7.4, 7.8, 7.9, 7.11, 8.1, 8.2
Clause 7	Use of Quotations
	10.2, 10.3
Clause 8	Certification and Examination
	14.1, 14.2, 14.3, 14.4, 14.5, 14.6
Clause 9	Training
	15.1, 16.1, 16.2, 16.3, 16.4
Clause 10	Events/Meetings and Hospitality
	18.1 SI, 18.3, 18.3 SI, 22.1, 22.1 SI, 22.2, 22.3, 22.4, 22.5, 24.2, 27.3
Blue Section – Promotion to Health Professionals and Other Relevant Decision Makers	
Clause 11	Marketing Authorisation and Temporary Supply Authorisation
	3.1, 3.2
Clause 12	Prescribing Information and Other Obligatory Information
	4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 4.10
Clause 13	Abbreviated Advertisements
	5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9
Clause 14	Information, Claims and Comparisons
	6.2, 7.3, 7.6, 7.7, 7.10
Clause 15	High Standards, Format and Suitability
	9.4, 9.5, 9.6, 9.8, 9.9, 12.1
Clause 16	Material and Distribution
	10.1, 11.2, 11.3, 28.1, 28.4
Clause 17	Representatives
	15.1, 15.2, 15.3, 15.4, 15.5, 15.6, 15.7, 15.8, 15.9, 15.10
Green Section – Interactions with Health Professionals, Other Relevant Decision Makers and Healthcare Organisations	
Clause 18	Information, Claims and Comparisons
	7.1, 7.5
Clause 19	Prohibition on Inducements and Inappropriate Payments and the Provision of Items to Health Professionals and Other Relevant Decision Makers
	18.1, 18.2
Clause 20	Collaborative Working with Organisations
	20, 24.2
Clause 21	Provision of Medicines and Samples
	17.1, 17.2, 17.3, 17.4, 17.5, 17.6, 17.7, 17.8, 17.9, 17.10
Clause 22	Non-Interventional Studies of Marketed Medicines
	13.4
Yellow Section – Interactions with Health Professionals, Other Relevant Decision Makers, Healthcare Organisations, Patient Organisations and the Public, Including Patients and Journalists	
Clause 23	Donations and Grants
	MEGS in the form of Donations and Grants in 19.1, 19.2
Clause 24	Contracted Services
	21, 23.1, 23.2, 23.3, 23.4 (27.8 incorporated)
Clause 25	Relationships with Health Professionals, Other Relevant Decision Makers, Healthcare Organisations and Patient Organisations
	27.4, 27.5, 27.9, 12.2
Pink Section – Specific Requirements for Interactions with the Public, Including Patients and Journalists, and Patient Organisations	
Clause 26	Relations with the Public, Including Patients and Journalists
	18.2 SI, 26.1, 26.2, 26.3, 26.4
Clause 27	Relationships with Patient Organisations
	27.1, 27.2, 27.3, 27.5, 27.6
Teal Section – Annual Disclosure Requirements	
Clause 28	Annual Disclosure of Transfers of Value to Health Professionals, Other Relevant Decision Makers and Healthcare Organisations
	24.1, 24.2, 24.7, 24.8, 24.9, 24.10
Clause 29	Annual Public Disclosure of Contracted Services, Donations, Grants and Sponsorship Provided to Patient Organisations
	EFPIA Requirement, 27.7, 27.8
Clause 30	Annual Public Disclosure of Contracted Services Provided by the Public, Including Patients and Journalists
	ABPI Requirement
Clause 31	Timings, Duration and Retention of Disclosure Information
	24.4, 24.5, 24.6

ABPI PRINCIPLES

The following principles for pharmaceutical companies are seen by the ABPI as key to how we operate as an industry and build trust and enhance our reputation. Companies are expected to implement and work to embed these into their organisation.

Patients are at the heart of our industry. We aspire to ensure that everything we do will ultimately benefit patients. Our primary contribution to society is to research and develop high quality medicines and to encourage their appropriate and rational use. Patient safety is paramount.

Ethical relationships with stakeholders are critical to our mission of helping patients, guiding the appropriate use of our medicines and ensuring the appropriate and timely exchange of scientific information.

An important guide for such ethical relationships is adherence to the ABPI Code of Practice which, among other things, sets the standards and drives an ethical culture in the industry. This is delivered through self-regulation. Our industry, and the individuals within it, are committed to supporting that culture, working within both the letter and the spirit of the ABPI Code and all relevant laws and regulations.

In adhering to the ABPI Code, we follow four key principles:

Principles developed by the ABPI	Some examples of how we demonstrate the principle in our behaviour
<p>1. We are committed to benefiting PATIENTS and ensuring patient safety by operating in a professional, ethical and transparent manner to ensure the appropriate and rational use of medicines and to support the provision of high quality healthcare. All interactions with patients and other stakeholders must comply with all applicable laws and regulations.</p>	<ul style="list-style-type: none"> • We promote only within the terms of the marketing authorisation. • We do not advertise prescription only medicines to the public (other than vaccination campaigns approved by the health ministers). • While our activities can encourage members of the public to seek treatment, they must not promote the use of a specific prescription only medicine. • We ensure that all information is accurate, fair and balanced. • We act promptly when advised of adverse events and encourage the use of the MHRA Yellow Card Scheme to support patient safety.
<p>2. We act with INTEGRITY and commit to engaging in relationships which are responsible, professional, ethical and transparent. We ensure that all our communications are appropriate, accurate, factual, fair, balanced, up-to-date, not misleading, capable of substantiation and reflect the available evidence, and that all other activities are appropriate and reasonable and of the highest standards.</p>	<ul style="list-style-type: none"> • We are accountable for the activities of both our staff and third party providers. • We do not offer any improper payments, benefits, inducements, or anything of value to influence actions or decisions, obtain or retain business, or otherwise secure any improper advantage, either directly or indirectly, to any individual, organisation or stakeholder.
<p>3. We are committed to ensuring that TRANSPARENCY is respected. We are open about our activities and interactions with all stakeholders and encourage our stakeholders to act with the same openness.</p>	<ul style="list-style-type: none"> • We disclose certain transfers of value to health professionals, other relevant decision makers, healthcare organisations, institutions etc and payments made to patient organisations and the public, including patients and journalists. • We publish details of ongoing and completed clinical trials via relevant databases and registries. • We do not disguise promotion. • Company involvement in all materials and activities is made clear from the outset.
<p>4. We interact with all our stakeholders with RESPECT. We are committed to approaching our stakeholders in an open and constructive manner and with mutual respect.</p>	<ul style="list-style-type: none"> • We recognise and seek to balance the needs of patients, health professionals and the public, taking into account the environment within which the industry operates and the statutory controls governing medicines. • We value the importance of independent decision-making by all those we interact with.

ABPI CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY INTRODUCTION

Promoting Appropriate Use of Medicines

The pharmaceutical industry in the United Kingdom is committed to benefiting patients by operating in a professional, ethical and transparent manner to ensure the appropriate use of medicines and support the provision of high quality healthcare. This commitment applies to all with whom the industry interacts. To demonstrate this commitment over 60 years ago, in October 1958, the Association of the British Pharmaceutical Industry (ABPI), which represents the UK industry, decided that certain activities should be covered in detail and thus agreed the first ABPI Code of Practice. The Code covers the promotion of medicines for prescribing to both health professionals and other relevant decision makers. It also includes requirements for interactions with health professionals. In addition, it sets standards for the provision of information about prescription only medicines to the public and patients, including patient organisations.

In addition to the Code, there is extensive UK and European law relating to the promotion of medicines. Following the UK departure from the EU, certain European law still applies in the UK, for example, in Northern Ireland. The Code reflects and extends beyond the relevant UK law.

The aim of the Code is to ensure that the promotion of medicines to health professionals and other relevant decision makers is carried out within a robust framework to support high quality patient care. As well as covering promotional material, it controls samples, meetings, promotional aids, outcome or risk sharing agreements, patient access schemes, collaborative working between the industry and healthcare organisations, including joint working between the pharmaceutical industry and the NHS, the conduct of non-interventional studies, the use of health professionals and other relevant decision makers as consultants and transfers of value to health professionals, other relevant decision makers and healthcare organisations. The Code also sets standards relating to the provision of information to patients and the public as well as relationships with patient organisations. The industry considers that provided the requirements of the Code are met, working with patients and patient organisations can bring significant public health benefits. These requirements also apply to working with all user groups, such as disability associations, relative and carer associations and consumer associations. There are disclosure requirements for interactions with patient organisations and contracted services by patient organisations and individuals representing patient organisations and certain contracted services provided by members of the public, including patients and journalists.

In summary, companies must ensure that their materials are appropriate, factual, fair and capable of substantiation and that all other activities are appropriate and reasonable.

Ensuring High Standards

The detailed provisions in the Code are to ensure that pharmaceutical companies operate in a responsible, ethical and professional manner. Whilst the industry has a legitimate right to promote medicines to health professionals, the Code recognises

and seeks to achieve a balance between the needs of patients, health professionals and the public, bearing in mind the political and social environment within which the industry operates and the statutory controls governing medicines. The availability of accurate, up-to-date information is vital to the safety of patients and the appropriate use of medicines. Pharmaceutical companies must ensure that enquiries about their medicines are answered appropriately in a timely manner.

Strong support is given to the Code by the industry with all companies devoting considerable resources to ensure that their activities comply with it. Any complaint made against a company under the Code is regarded as a serious matter both by that company and by the industry as a whole. Sanctions are applied against a company ruled in breach of the Code.

Companies must ensure that all relevant personnel are appropriately trained in the requirements of the Code and must have robust operating procedures under which all materials and activities covered by the Code are reviewed to ensure compliance both with the Code and with the appropriate legal requirements.

The Code incorporates the principles set out in:

- the International Federation of Pharmaceutical Manufacturers and Associations' (IFPMA) Code of Practice
- the European Federation of Pharmaceutical Industries and Associations' (EFPIA) Code of Practice
- the World Health Organisation's Ethical Criteria for Medicinal Drug Promotion
- Directive 2001/83/EC on the Community Code relating to medicinal products for human use, as amended by Directive 2004/27/EC
- the Human Medicines Regulations 2012 (2012 No. 1916), as amended.

The Code covers the industry's activities only. However, those interacting with industry as individuals or organisations also have a responsibility to ensure that their interactions comply with relevant legal requirements and are asked to follow the Code where relevant and not make requests that are not in accordance with the Code. Most of those interacting with the industry, other than patients, are covered by a selection of professional codes and guidance. For example, the General Medical Council Ethics guidance for doctors, the General Pharmaceutical Council's Standards for pharmacy professionals and the Nursing & Midwifery Council's professional standards of practice and behaviour for nurses and midwives.

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'.

Patient organisations are likely to be covered by Charity Commission rules as well as their own codes. The pharmaceutical industry takes note of all relevant codes and guidance as well as the ABPI Code.

Transparency

The industry recognises that transparency is an important means of building and maintaining confidence. The operation of the Code, including the complaints procedure, is a demonstration of the industry's commitment to transparency as are the requirement to declare pharmaceutical company involvement in activities and materials and the publication of detailed reports of cases considered under the Code. The industry's global agreement to disclose certain clinical trial data is another example of the industry's commitment to transparency. Companies also have to publish the summary details and results of non-interventional studies as well as the monetary value of certain support to patient organisations.

Other transparency changes, effective in 2012 and 2013, included disclosure of the total amount of fees paid to consultants for certain services and the total amounts paid to sponsor attendance at meetings organised by third parties. As set out in the 2014 Code, starting in 2015 transparency was extended in relation to disclosure of fees and sponsorship provided to health professionals, other relevant decision makers and healthcare organisations, including naming the recipients in many instances.

The Code requires disclosure of donations, grants and sponsorship to patient organisations and when contracting with patient organisations or individuals representing patient organisations to provide services for companies. Certain contracted services provided by the public, including patients and journalists, will also now be disclosed on an annual basis; this will start with 2022 data to be disclosed by 30 June 2023.

Sanctions

In each case where a breach of the Code is ruled, the company concerned must give an undertaking that the practice in question has ceased forthwith and that all possible steps have been taken to avoid a similar breach in the future. An undertaking must be accompanied by details of the action taken to implement the ruling. At the conclusion of a case, a detailed case report is published.

Additional sanctions are imposed in serious cases. These can include:

- the audit of a company's procedures to comply with the Code, followed by the possibility of a requirement for the pre-vetting of future material
- recovery of material from those to whom it has been given
- the issue of a corrective statement
- a public reprimand
- advertising in the medical, pharmaceutical and nursing press of brief details of cases in which companies were ruled in breach of Clause 2 of the Code, were required to issue a corrective statement or were the subject of a public reprimand
- suspension or expulsion from the ABPI.

Monitoring of Activities and Guidance

The Prescription Medicines Code of Practice Authority (PMCPA) arranges for advertising and meetings to be regularly monitored.

The PMCPA also provides informal guidance about the Code and its operation.

Promoting Health

The commitment of the pharmaceutical industry to bringing high quality and effective medicines and vaccines to patients supports the UK's health and economy.

Pharmaceutical companies invest over £4.5bn a year in researching and developing new products, for the benefit of patients.

The Association of the British Pharmaceutical Industry and its Code of Practice

The Association of the British Pharmaceutical Industry exists to make the UK the best place in the world to research, develop and use new medicines. It represents companies of all sizes which invest in discovering the medicines of the future.

The ABPI represents companies which supply more than 80% of all branded medicines used by the NHS and are researching and developing the majority of the current medicines pipeline.

The Code has been regularly revised since its inception in 1958 and is drawn up in consultation with the British Medical Association, the Royal Pharmaceutical Society, the Royal College of Nursing, the Medicines and Healthcare products Regulatory Agency of the Department of Health, the Competition and Markets Authority and the Serious Fraud Office. Anyone is welcome to send suggestions for amendments or additions to the Code to the PMCPA.

It is a condition of membership of the ABPI to abide by the Code in both the spirit and the letter. The Code applies to both members and affiliate members of the ABPI. Companies which are not members of the ABPI may give their formal agreement to abide by the Code and accept the jurisdiction of the PMCPA, and over sixty have done so. Thus the Code is accepted by virtually all pharmaceutical companies operating in the UK.

Administering the Code of Practice

The Code is administered by the PMCPA, which is responsible for the provision of advice, guidance and training on the Code as well as for the complaints procedure. The PMCPA operates independently of the ABPI itself. The relationship between the PMCPA and the ABPI is set out in a protocol of agreement. Financial information about the PMCPA is published in its annual report.

PMCPA publications can all be found on its website, www.pmcpa.org.uk, or are supplied on request.

Complaints under the Code are considered by the Code of Practice Panel and, where required, by the Code of Practice Appeal Board. Reports on completed cases are published by the PMCPA on its website. The PMCPA also publishes a list of ongoing cases on its website.

How to Complain

Complaints should be submitted to the Director of the Prescription Medicines Code of Practice Authority, 7th Floor, Southside, 105 Victoria Street, London, SW1E 6QT, telephone: 020 7747 8880, email: complaints@pmcpa.org.uk.

Overarching Requirements

CLAUSE 1 SCOPE OF THE CODE AND DEFINITION OF CERTAIN TERMS

Clause 1

Scope of the Code and Definition of Certain Terms

- 1.1** (1.1) This Code applies to the promotion of medicines to members of the United Kingdom (UK) health professions and to other relevant decision makers. For the purposes of the application of the Code, the UK includes the Channel Islands and the Isle of Man. 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 (OTC) medicines to members of the health professions when the object of that promotion is to encourage their purchase by members of the public.
- 1.2** (28.2) Information or promotional material about medicines which is placed on the internet outside the UK will be regarded as coming within the scope of the Code, if it was placed there by:
- a UK company/with a UK company's authority, or
 - 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.
- 1.3** 'Collaborative working' refers to pharmaceutical companies working with other organisations to deliver initiatives which either enhance patient care or are for the benefit of patients or alternatively benefit the National Health Service (NHS) and, as a minimum, maintain patient care. Further details are given in Clause 20.
- 1.4** 'Contribution to costs related to events' in relation to the disclosure of transfers of value means providing or covering the costs of travel, accommodation and/or registration fees to support the attendance of an individual to an event organised or created by a company and/or independent organisation. When providing sponsorship of events/meetings to organisations, associations etc such contributions may include costs for subsistence (food and drink).
- 1.5** '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 pharmaceutical company in return. Donations and grants to individuals are prohibited.
- In general, donations are physical items, services or benefits-in-kind which may be offered or requested. Grants are the provision of funds.
- 1.6** (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).
- 1.7** '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 (further examples can be found in the supplementary information to Clause 10.1).
- 1.8** (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.
- 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.
- 1.9** (1.4) 'Health professional' includes any member of the medical, dental, pharmacy or nursing profession and any other person who in the course of their professional activities may administer, prescribe, purchase, recommend or supply a medicine. In relation to the annual disclosure of transfers of value (Clause 28), the term also includes any employee of a pharmaceutical company whose primary occupation is that of a practising health professional.
- 1.10** 'Hospitality' is limited to travel, subsistence (food and drink), accommodation and genuine registration fees extended in connection with events/meetings.
- 1.11** (1.3) 'Medicine' means any branded or unbranded medicine intended for use in humans which requires a marketing authorisation.
- 1.12** (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 authorisation. 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.

- 1.13** (1.5) **'Other relevant decision maker'** particularly includes someone 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 is not a health professional.
- 1.14** (1.6) **'Over-the-counter medicine'** (OTC) means a medicine or particular pack of medicine which is primarily advertised to the public for use in self-medication.
- 1.15** (27.1) **'Patient organisation'** means an organisation mainly comprising of patients and/or caregivers or any user organisation such as a disability organisation, carer or relative organisation and consumer organisation that represents and/or supports the needs of patients and/or caregivers.
- 1.16** **'Individuals representing patient organisations'** means a person who is mandated to represent and express the views of a patient organisation.
- 1.17** (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
 - the sponsorship of scientific events/meetings, including payment of travelling and accommodation expenses in connection therewith
 - all other promotion.
- 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 direct or indirect reference to specific medicines.
- 1.18** (1.8) **'Promotional aid'** means a non-monetary item given for a promotional purpose. Promotional aids may be given to health professionals and other relevant decision makers only in accordance with Clause 10.4. Health professionals may, however, be provided with items which are to be passed on to patients in accordance with Clause 19.2.
- 1.19** (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.
- 1.20** (23.2 SI) **'Research and development transfers of value'** means, for the purposes of disclosure, transfers of value to health professionals or healthcare organisations related to the planning or conduct of:
- i. non-clinical studies (as defined in the 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.
- 1.21** (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.
- 1.22** A company can provide sponsorship for an activity to certain organisations. **'Sponsorship'** means a contribution, financial or otherwise, in whole or in part provided by or on behalf of a company, towards an activity (including an event/meeting or material) performed, organised, created etc by a healthcare organisation, patient organisation or other independent organisation.

1.23 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 or in part, whether paid directly or indirectly to individual health professionals or other relevant decision makers to attend events/meetings.

1.24 'Third party' means a legal person/entity or individual that represents a company or interacts with other parties on behalf of a company or relating to a company's medicine, 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.

1.25 (1.10) '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 OTC medicines
- ordinary course purchases and sales of medicines by and between a company and a health professional or a healthcare organisation
- samples of medicines provided in accordance with Clause 21
- transfers of value provided in accordance with Clauses 10.4, 10.5 and 19.2
- subsistence provided to health professionals and other relevant decision makers in accordance with Clause 10.1.

Clause 1 Supplementary Information

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 on applicability of codes can be found in the supplementary information to Clause 3.4.

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 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 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 included in the pack (PIL) (excluded from the definition of promotion in Clause 1.17) is used for a promotional purpose, then it would come within the scope of the Code.

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 authorisation.

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 authorisation for the product.

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 OTC 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 OTC medicines aimed wholly or mainly at persons qualified to prescribe or supply and people

working for them, 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 Clause 5.6.

Clause 1.17 (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 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 look like promotional material.

Clause 1.17 (1.2) Terms of Trade

See supplementary information to Clause 19.1.

Clause 1.17 (1.2) Price Lists for Unlicensed Medicines

Price lists 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 1.17 (1.2) Risk Minimisation Plans and Material

As part of the marketing authorisation 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 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.

Overarching Requirements

CLAUSES 2-4 OBLIGATIONS AND RESPONSIBILITIES

Clause 2

Upholding Confidence in the Industry

Activities or materials must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry.

Clause 2 Supplementary Information

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 authorisation, 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.

Clause 3

Obligations

- 3.1** (3.1) A medicine must not be promoted prior to the grant of the marketing authorisation which permits its sale or supply.
- 3.2** (26.1) Prescription only medicines must not be advertised to the public. This prohibition does not apply to vaccination and other campaigns carried out by companies and approved by the health ministers.
- 3.3** (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.
- 3.4** (1.11) Companies must comply with all applicable codes, laws and regulations to which they are subject.
- 3.5** 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 professional, other relevant decision maker or individual associated with a healthcare organisation or patient organisation.

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

- 3.6** (12.1) Materials and activities must not be disguised promotion.
- 3.7** (1.12) Each company must appoint a senior employee to be responsible for ensuring that the company meets the requirements of the Code.

Clause 3 Supplementary Information

Clause 3.1 (3) Marketing Authorisation

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 (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, so 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.

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

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

The information provided must not:

- vi. 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
- vii. include mock up drafts of either summaries of product characteristics or package leaflets.

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

Clauses 3.1 and 3.2 (New) Temporary Authorisation for Sale or Supply without a Marketing Authorisation

In response to certain types of public health emergency, under UK law, the licensing authority may temporarily authorise the sale or supply of a medicine without a marketing authorisation. This might apply to medicines without UK marketing authorisations or indications without UK marketing authorisations. The campaign must be approved by the health ministers and all other relevant requirements of the Code will apply. In relation to advertising to health professionals and other relevant decision makers, further information is given in Clause 11.3 and its supplementary information. In relation to advertising to the public, further information is given in Clause 26.1 and its supplementary information. Companies should contact the Medicines and Healthcare products Regulatory Agency (MHRA) for information regarding approval of materials and activities.

Clause 3.2 (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 over-the-counter (OTC) medicines to the public for self-medication purposes is covered by the Consumer Code of the Proprietary Association of Great Britain (PAGB).

Clause 3.4 (1.11) Applicability of Codes

Compliance with all applicable codes, laws and regulations to which a pharmaceutical company is subject is particularly relevant when activities/materials involve more than one country or when a 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 European Federation of Pharmaceutical Industries and Associations (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.

The term 'company' 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 the EFPIA Code as referred to in the supplementary information to Clause 10.7.

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 1.17, for example, joint ventures or licensees, comply with the Code.

Clause 3.7 (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 4

Responsibilities

- 4.1** (25.1) Companies must have a scientific service to compile and collate all information received from any source about the medicines which they market.
- 4.2** (25.2) Companies must 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 representatives) and certification of the protocol.
- 4.3** (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 as set out in Clause 28. This includes any employee of a pharmaceutical company whose primary occupation is that of a practising health professional.

- 4.4** (27.7 and 27.8) Companies must document and publicly disclose annually donations and grants whether financial, non-financial or a benefit-in-kind, and sponsorship (including in relation to events/meetings) made to patient organisations.

Fees and expenses for the provision of contracted services, including those performed by individuals representing patient organisations, which should be paid to patient organisations must also be publicly disclosed annually as set out in Clause 29.

- 4.5** (New Clause) Companies must document and publicly disclose annually fees and expenses made to individual members of the public, including patients and journalists, for the provision of contracted services performed as set out in Clause 30.
- 4.6** (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. Companies must include on the home page of their website information as to where details of their clinical trials can be found.
- 4.7** (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.
- 4.8** (26.5) Companies are responsible for information about their products which is issued by their agencies, eg communications, advertising etc.

Clause 4 Supplementary Information

Clauses 4.1 and 4.2 (25.1 and 25.2) Scientific Service

Companies can have one scientific service in charge of both responsibilities or separate services with clearly delineated duties.

Clause 4.6 (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 www.ifpma.org/resource-centre/clinical-trials-position-papers/.

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.

Overarching Requirements

CLAUSES 5-10 QUALITY STANDARDS

Clause 5

High Standards and Suitability

- 5.1** (9.1) High standards must be maintained at all times.
- 5.2** (9.2) All material and activities must recognise the special nature of medicines and respect the professional standing or otherwise of the audience to which they are directed and must not be likely to cause offence.
- 5.3** (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.
- 5.4** (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.
- 5.5** (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 other involvement, must clearly indicate the role of that pharmaceutical company.
- The only exception to this is market research material if it is such that the name of the company involved is not required to be stated; then the material must state that it is sponsored by a pharmaceutical company.
- 5.6** (11.1) Material should only be provided or made available to those groups of people whose need for or interest in it can reasonably be assumed. Material should be tailored to the audience to whom it is directed.
- 5.7** (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.

Clause 5 Supplementary Information

Clauses 5.1 and 5.2 (9.1 and 9.2) High Standards and Suitability

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

It follows, therefore, that certain types, styles and methods of communication, even where they might be acceptable for 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' communication/advertising whereby 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 use of emojis and the like.

Clause 5.5 (9.10) Declaration of Involvement

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 5.7 (28.6) Sites Linked via Company Sites

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

Clause 6

Information, Claims, Comparisons and Disparagement

Clauses 14 and 18 may also be relevant.

- 6.1** (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 recipients to form their own opinion of the therapeutic value of the medicine.

- 6.2** (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 Clauses 14.3 and 18.2. 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 4.6.

- 6.3** (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.
- 6.4** (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.
- 6.5** (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.
- 6.6** (8.1) The medicines, products and activities of other pharmaceutical companies must not be disparaged.
- 6.7** (8.2) The health professions and the clinical and scientific opinions of health professionals must not be disparaged.

Clause 6 Supplementary Information

Clauses 14 and 18 may also be relevant.

Clause 6.1 (7) General

The application of this clause is not limited to information or claims of a medical or scientific nature. It includes, among other things, information or claims relating to pricing and market share.

It should be borne in mind that claims in 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 6.1 (7.2) 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
- **data derived from in vitro studies, studies in healthy volunteers and in animals** must not be used in a way that 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
- **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.** Any claim involving the economic evaluation of a medicine must be borne out by the data available and not exaggerate its significance. To be acceptable as the basis of claims, the assumptions made in an economic evaluation must be clinically appropriate and consistent with the marketing authorisation
- **emerging clinical or scientific opinions** which have not been resolved in favour of one generally accepted viewpoint must be referred to in a balanced manner
- **hanging comparisons** whereby a medicine is described as being better or stronger or suchlike without stating that with which it is compared must not be made
- **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
- **statistical information, claims and comparisons** must have a sound statistical basis. 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 material, it must have been subjected to statistical appraisal.

Clause 6.3 (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 authorised 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 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 14.2). 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 6.4 (7.9) Use of the Word 'Safe'

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

Clause 7**Use of Quotations**

- 7.1** (10.2) Quotations from medical and scientific literature or from personal communications must be faithfully reproduced, accurately reflect the meaning and current views of the author and otherwise comply with the Code. The precise source of the quotation must be identified.
- 7.2** (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.

Clause 7 Supplementary Information**Clause 7.1 (10.2) Quotations**

Any quotation chosen by a company for use in 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 6.4 to state without qualification 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.

If there is any doubt as to the current view of an author, companies should check with the author prior to its use.

Clause 8**Certification and Examination**

- 8.1** (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.

- 8.2** (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 8.1 or by an appropriately qualified person signatory (AQP signatory). That person does not need to be either a registered medical practitioner or a pharmacist registered in the UK.
- 8.3** (14.3) The following must be certified in advance in a manner similar to that provided for by Clause 8.1:
- 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 collaborative working as described in Clause 20 and its supplementary information
 - material and items for patient support whether provided directly to patients or to health professionals to be passed on to patients as described in Clauses 19.2, 26.3 and associated supplementary information
 - the written agreement for donations and grants, including where relevant internal company and service provider instructions as described in Clause 23 and its supplementary information
 - (25.2) protocols relating to non-interventional studies.
- 8.4** (14.4) The names of those nominated as signatories as set out in Clauses 8.1 and 8.2, together with their qualifications, must be notified in advance to the Advertising Standards and Outreach Unit, Vigilance and Risk Management of Medicines Division of the Medicines and Healthcare products Regulatory Agency (MHRA), and to the Prescription Medicines Code of Practice Authority (PMCPA). Changes in the names of nominees must be promptly notified.
- 8.5** (14.5) The certificate for promotional material must certify that the signatory has examined the final form of the material to ensure that in their belief it is:
- in accordance with the requirements of the relevant regulations relating to advertising and this Code
 - not inconsistent with the marketing authorisation and the summary of product characteristics
 - a fair and truthful presentation of the facts about the medicine.

The certificate for material covered by Clause 8.3 above must certify that the signatory has examined the final form of the material to ensure that in their 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 and that, in their belief, they are in accordance with the relevant regulations relating to advertising and the Code.

- 8.6** (14.6) Companies must preserve certificates. 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 must preserve certificates and the relevant accompanying information for not less than three years after the final use of the material or the date of the event/meeting and produce them on request from the MHRA or the PMCPA.

Clause 8 Supplementary Information

Clause 8.1 (14.1) Certification

An acceptable way to comply with Clause 8.1 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 8.6.

All promotional material must be certified in this way, including audio and audiovisual material, promotional material on databases, interactive data systems and the internet and relevant representatives' briefing materials. Promotional aids must also be certified – 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.

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 the item has been examined and signed 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 and both must be preserved as they form the certification of the item. The examination of the printed form can be carried out by a signatory, an appropriately qualified person signatory (AQP signatory) or an appropriately qualified person (AQP).

In certifying audio and audiovisual material and promotional material on databases, interactive systems and the internet, companies must ensure that a written transcript of the

material is 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.

See also the supplementary information to Clause 11 regarding the certification of promotional material to be used at international conferences.

Clause 8.1 (14.1) Certifying 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 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 8.1 (14.1) 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 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.

Clause 8.1 (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.

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 and the PMCPA 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 8.2 (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 to go to events/meetings outside the UK. Clauses 24, 28, 29, 30 and 31 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 8.2 (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 8.2 (14.2) 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 is appropriately qualified to certify events/meetings involving travel outside the UK (AQP signatory), account should be taken of relevant experience both within and 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.

Clauses 8.1 and 8.2 Appropriately Qualified Persons

It is possible for a company to have different individuals who would act as an AQP for examination depending on their skill sets and the material and activities etc being examined. For example, an individual with proof reading skills could examine and sign the final form of printed material which has been certified electronically as set out in the supplementary information to Clause 8.1. It is unlikely that this AQP would also have the necessary skills to examine market research material to ensure it does not contravene the Code as set out under the supplementary information to Clause 8.3.

Clause 8.3 (14.3) Examination of Other Material

Material issued by companies which is not required to be certified under the Code should be examined by a signatory or an AQP, who needs not be a signatory, to ensure that it does not contravene the Code or the relevant statutory requirements. Such material might include 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.

Clause 8.4 (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. The PMCPA can be notified by completing the nominated signatory form which can be found at www.pmcpa.org.uk. The names and qualifications to be sent to the MHRA and PMCPA are those of the registered medical practitioner or the pharmacist registered in the UK or, if the product is for dental use only, a UK registered dentist as set out in Clause 8.1 and the AQP signatory as set out in Clause 8.2.

Clause 8.6 (14.6) Retention of Documentation

The MHRA is entitled to request details 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 8.6 is applicable. There is further information in the MHRA Blue Guide.

Clause 9 Training

- 9.1** (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.
- 9.2** (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.
- 9.3** (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.
- 9.4** (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 or its equivalent 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 at the level of a Diploma (equivalent to at least 480 hours Total Qualification Time).

An appropriate examination for generic sales representatives is one that requires a broad understanding

of body systems and the structure and function of the NHS and of the pharmaceutical industry. Such an examination must be at the level of a Certificate (equivalent to at least 330 hours Total Qualification Time).

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 which covers similar content and learning material as the corresponding ABPI examination.

- 9.5** (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.

Clause 9 Supplementary Information

Clause 9.1 (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 9.4 (16.3) Representatives 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 of, among other things, 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.*

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 representatives must take an appropriate examination within one year of their change of duties and pass it within two years.

Clause 9.4 (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 9.4 (16.3) Information from Examination Provider

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

Clause 9.4 (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.

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.

Clause 9.4 (New) Extensions to the Time Allowed to Pass an Examination as a Result of the COVID-19 Pandemic

In addition to the information for extensions set out above, further arrangements were put in place as the ABPI examination was not available between 13 March 2020 and 30 September 2020 due to the impact of the COVID-19 pandemic, and as a consequence, certain representatives could not meet the time periods for taking and/or passing the examination as required by the Code. Extensions have been granted during 2020 when requested. Everyone's circumstances are different and will need to be taken into account. Companies should make every effort to comply with the spirit of the Code and ensure that representatives take and pass the appropriate examination as soon as possible.

An examination is now available online. In order to assist, the following arrangements for all affected representatives were put in place in late 2020 and are set out below.

Representatives who started work as a representative for the first time from 1 July 2020

For representatives who were employed as a representative for the first time from 1 July 2020, the time periods as set out in the Code will apply.

Representatives who worked as representatives during 2019 and have continued to work as representatives in 2020

For those representatives working as such in 2019 and whose one year or two year time periods include any time between 13 March 2020 and 31 October 2020, these eight months will not count towards their time period for taking and passing the examination. Representatives making use of these additional eight months do not need to contact the PMCPA for an extension but must ensure that their employers are informed and a record is kept.

Representatives who started their first role as a representative between 1 January 2020 and 30 June 2020

For representatives who were employed as a representative in their first role anytime from 1 January 2020 to 30 June 2020, the relevant months they worked when the examination was not available will not count towards their time period. For example, a representative starting in January 2020 will have eight months to add to the time period to take the examination for the first time, ie they must take the examination by September 2021 and pass it by September 2022. A representative starting in February or March 2020 will also have eight months to add to the time period to take the examination for the first time. A representative starting in April 2020 will have seven months to add to their time period, and a representative starting in June 2020 will have five months to add to their time period. A representative starting in such a role for the first time in July 2020 will not have an extension in relation to the cancellation of the examination. Representatives making use of these additional months do not need to contact the PMCPA for an extension but must ensure that their employers are informed and a record is kept.

Representatives who were previously employed as a representative and who returned to such a role in anytime between 1 January and 31 October 2020 following a gap in service (for example, due to a change of role, career break, parental leave)

For representatives who have been employed as a representative and returned to work as a representative in 2020 (perhaps after a career break, maternity leave, etc), including during the time the examination was not available (between 13 March 2020 and 30 September 2020), then the relevant months they worked when the examination was not available will not count towards their time period for taking and passing the examination. For example, a representative restarting such work in January 2020 will have eight months to add to their time period, a representative restarting in April 2020 will have seven months to add to their time period and a representative restarting in September 2020 will have

two months to add to their time period. Representatives who returned to work in 2020 anytime after 31 October will not have an extension in relation to the cancellation of the examination. Representatives making use of these additional months do not need to contact the PMCPA for an extension but must ensure that their employers are informed and a record is kept.

Extensions in addition to those set out above

There may be some representatives who might need longer extensions than those referred to above. This is most likely to apply to those whose time periods completed around February/March 2020. Applications should be made to the PMCPA in the usual way.

Clause 10 Events/Meetings and Hospitality

10.1 (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. This may include support of health professionals not known to the company via a healthcare organisation by way of registration fees, accommodation and travel.

Companies must not provide hospitality to health professionals, other relevant decision makers etc except in association with scientific meetings, promotional meetings, scientific congresses 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 and not the associated hospitality or venue
- the content must be appropriate and relevant to attendees
- 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 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 and must be appropriate and not out of proportion to the occasion (see Clause 10.7)
- companies must not sponsor, support or organise entertainment (such as sporting or leisure activities, etc)
- any hospitality provided must not extend to an accompanying 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), similar hospitality may be provided for an accompanying person.

10.2 (New Clause, previously 22.1 SI) No payment may be offered or paid to individuals to compensate merely for the time spent in attending events/meetings.

10.3 (New Clause and part of Clause 27.3) Sponsorship of patient organisations (including individuals representing patient organisations to attend events/meetings) must have a written agreement in place setting out what has been agreed including, where possible, a breakdown of agreed costs. (The requirements for the written agreement are set out in Clause 27.2.)

10.4 (18.3) Attendees of company organised events/meetings may be provided with inexpensive pens, pencils and notepads when required for use at those events/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 or pencil or one notepad.

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.

10.5 (18.3 SI) Pens/pencils and notepads provided in conference bags at independently organised meetings must not include the name of the donor company, 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.

10.6 (18.1 SI) Quizzes which are intended to gauge attendees' understanding of the subject matter of a meeting are acceptable provided that such quizzes are non-promotional and genuine tests of skill or knowledge; they must respect the professional standing or otherwise of the audience and no prizes can be 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.

The use of competitions, quizzes and suchlike are unacceptable methods of promotion.

10.7 (22.2) The cost of any subsistence (food and drink) provided must not exceed £75 per person, excluding VAT and gratuities.

10.8 (22.3) Payments may not be made to doctors, groups of doctors, or to other prescribers, either directly or indirectly, for rental for rooms to be used for events/meetings.

10.9 (22.4) When events/meetings are sponsored by pharmaceutical companies, that fact must be disclosed in all the material 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.

10.10 (22.5) Companies must publicly disclose annually financial details of support of UK health professionals and other relevant decision makers in relation to attendance at events/meetings.

10.11 (New Clause and part of Clause 24.2) Companies must publicly disclose annually financial details for contributions to costs related to events/meetings (sponsorship) paid to healthcare organisations, patient organisations or organisations managing an event/meeting on their behalf. This may include support of health professionals not known to the company via the healthcare organisation by way of registration fees, accommodation and travel.

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 29.

Clause 10 Supplementary Information

Clause 10.1 (22.1) Events/Meetings and Hospitality

In determining whether 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.

Clause 10.1 (22.1) Types of Events/Meetings

Events/meetings range from small lunchtime audiovisual 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 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.

Clause 10.1 (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.

Clause 10.1 (22.1) Events/Meetings Organised by Affiliates Outside the UK

Companies should remind their affiliates outside the UK that the ABPI Code 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 10.1 (22.1) Certification and Examination of Events/Meetings

Pharmaceutical companies must ensure that all events/meetings which are planned are 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 certified as set out in Clause 8.2.

Clause 10.1 (22.1) Health Professionals' 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 10.1 (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 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 10.4 (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.

Clause 10.7 (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 10.1 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 the EFPIA Code. In such circumstances, the limits in the host country code would apply. Information can be found at www.efpia.eu.

Clause 10.8 (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 10.9 (22.4) Sponsorship and Reports of Events/Meetings

Attention is drawn to Clause 5.5 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.

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 10.10 (22.5) 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 28.

The information required by Clause 10.10 must be publicly disclosed annually in respect of support for attendance at events/meetings whether paid directly, indirectly or via another party. Support in this context includes registration fees and the costs of accommodation and travel, both inside and outside the UK.

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 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 other party, such a transfer should be disclosed once only, preferably as being a transfer to the health professional or other relevant decision maker.

Clause 10.11 (New) Sponsorship to Healthcare Organisations, Institutions and other Organisations

Disclosure of this information must be carried out in accordance with Clause 28.

Sponsorship in this context includes registration fees and the costs of accommodation and travel, both inside and outside the UK, whether paid directly or indirectly. If, when providing sponsorship to a healthcare organisation, institution or other organisation 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 or other organisation.

Promotion to Health Professionals and Other Relevant Decision Makers

CLAUSES 11–17

Clause 11

Marketing Authorisation and Temporary Supply Authorisation

- 11.1** (3.1) A medicine must not be promoted prior to the grant of the marketing authorisation which permits its sale or supply subject to the provisions of Clause 11.3 below.
- 11.2** (3.2) The promotion of a medicine must be in accordance with the terms of its marketing authorisation and must not be inconsistent with the particulars listed in its summary of product characteristics subject to the provisions of Clause 11.3 below.
- 11.3** (New Clause) A medicine with a temporary supply authorisation must not be promoted unless it is part of a campaign that has been approved by the health ministers.

Clause 11 Supplementary Information

Clause 11.1 (3) Conditional Marketing Authorisation

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

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

Clause 11.1 (3) Early Access to Medicines Scheme (EAMS)

Medicines that are approved under the EAMS meet one of the following two conditions. Either the medicine does not have a marketing authorisation or the medicine has a marketing authorisation but no licence for the specific indication. Medicines or indications that are approved for EAMS must therefore not be promoted.

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

Clause 11.1 (3) Compassionate Use

Companies 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 the medicine does not have a relevant marketing authorisation, then it cannot be promoted.

Clause 11.1 (3) Promotion at International Events/Meetings

Promotion 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 authorisation in the UK although they are so authorised 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 truly international, 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 authorisation 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 authorised 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 authorised 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 8, 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 11.2 (3.2) Unauthorised Indications

The promotion of indications not covered by the marketing authorisation for a medicine is prohibited.

Clause 11.3 (New) Temporary Authorisation for Sale or Supply Without a Marketing Authorisation

In response to certain types of public health emergency, under UK law, the licensing authority may temporarily authorise the sale or supply of a medicine without a marketing authorisation. This might apply to medicines without UK marketing authorisations or indications without UK marketing authorisations. The campaign must be approved by the health ministers, and all relevant requirements of the Code will apply. If there is no marketing authorisation, then the requirement for inclusion of the marketing authorisation number in the prescribing information will not apply. The name and address of the holder of the temporary authorisation or the business name and address of the part of the holder's business that is responsible for its sale or supply must be given in addition to the name and address of the marketing authorisation holder where there is one. Companies should contact the MHRA for information regarding approval of materials and activities.

Clause 12

Prescribing Information and Other Obligatory Information

12.1 (4.1) The prescribing information listed in Clause 12.2 must be provided in a clear and legible manner in all promotional material for a medicine except for abbreviated advertisements (see Clause 13). 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.

12.2 (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 authorised 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 authorisation and the name and address of the holder of the authorisation 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.

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.

12.3 (4.3) 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 12.3, must appear immediately adjacent to the brand name at its first appearance in a size such that the information is easily readable.

12.4 (4.4) In digital material such as advertisements in electronic journals, emails, electronic detail aids and suchlike, the prescribing information as required by Clause 12.1 may be provided either:

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

12.5 (4.5) In audiovisual material and in interactive data systems, the prescribing information may be provided either:

- by way of a document which is made available to all persons to whom the material is shown or sent, or
- by inclusion on the audiovisual 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.

12.6 (4.6) Promotional material provided on the internet must include a clear prominent statement as to where the prescribing information can be found.

12.7 (4.7) In a printed journal advertisement the prescribing information must appear 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 in a type size such that a lower case 'x' is no less than 2mm in height.

12.8 (4.8) Promotional material other than advertisements in professional publications must include the date on which the promotional material was created or last revised.

12.9 (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]'.¹

12.10 (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.

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 noticed.

Clause 12 Supplementary Information

Clause 12 Arrangements for Changes to the Marketing Authorisation Number and the Marketing Authorisation Holder Name and Address Following Changes Resulting from the UK Leaving the EU

For the period from 1 January 2021 until 1 January 2023, a complaint that the prescribing information for a previously centrally approved medicine does not have the new marketing authorisation number or any new marketing authorisation holder's name and address as required by Clause 12.2 (vii) will not be considered to be in breach of that clause and potentially any other relevant clause provided that:

- other changes to the prescribing information have not been needed
- the prescribing information includes the previous information about the marketing authorisation number and
- any new marketing authorisation holder can be contacted via the address given in the prescribing information.

This will also apply to medicines (other than those centrally approved) if the marketing authorisation numbers and marketing authorisation holder name and address are changed from 1 January 2021 as a result of the departure of the UK from the EU.

Clause 12.1 (4.1) Prescribing Information and Summaries of Product Characteristics

Each promotional item for a medicine must be able to stand alone. For example, when a 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.

Clause 12.1 (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.

Clause 12.1 (4.1) Prescribing Information on Printed Material and Reference to Online Current Regulatory Documents

In addition to including prescribing information, companies are encouraged to include references on printed materials to an online resource where the current regulatory documents for each medicine promoted can be found.

Clauses 12.1 and 12.8 (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 12.2 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 created or last revised.

Clause 12.1 (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. If the product is one that is required to show an inverted black equilateral triangle on its promotional material then that symbol must appear adjacent to the product name (see Clause 12.10). The size must be such that it would not be easily overlooked. The requirement of Clause 15.6 that promotional material and activities must not be disguised should also be borne in mind.

Clause 12.1 (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.

Clause 12.1 (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 12.2 (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 12.2. Where space in printed material is not an issue, elements i-viii can 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 12.4 and its supplementary information). It would not be acceptable to provide a website address for the summary of product characteristics on printed material as a means of meeting the requirements to provide elements i-viii.

Clause 12.3 (4.3) Non-Proprietary Name

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

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 12.4 (4.4) Use of Links for Prescribing Information

When digital material includes 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 12.5 (4.5) Prescribing Information on Audiovisual Material

Where prescribing information is shown on audiovisual 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 promotional content and must appear with it. It is not acceptable for the promotional content and the prescribing information to be separated by any other material.

Clause 12.8 (4.8) Date Created or Last Revised

This is in addition to the requirement in Clause 12.2 that the date of the prescribing information be included.

Clause 12.8 (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 created or last revised.

Clause 12.9 (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 12.9 is changed by the Medicines and Healthcare products Regulatory Agency (MHRA), companies must use the new address within one year of the change.

Clause 12.10 (4.10) Black Triangle Symbol

The black triangle symbol 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. Obligatory explanatory wording is also required on these documents.

Clause 13

Abbreviated Advertisements

13.1 (5.1) Abbreviated advertisements 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 this clause.

13.2 (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 13.4, 13.5, 13.6, 13.7 and 13.8.

Abbreviated advertisements are not permitted in audiovisual material or in interactive data systems or on the internet, including journals on the internet.

13.3 (5.3) Abbreviated advertisements must be no larger than 420 square centimetres in size.

13.4 (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 marketing authorisation holder or the name and address of the part of the business responsible for the medicine's sale or supply
- 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 website referred to above must provide either:

- the information set out in Clauses 12.2 and 12.3 (except that the non-proprietary name of the medicine or the list of active ingredients, as required by Clause 12.3, must appear immediately adjacent to the most prominent display of the brand name in a size such that the information is easily readable and information about cost, as required by Clause 12.2, 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
- the summary of product characteristics.

13.5 (5.5) 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.

13.6 (5.6) 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]. Adverse events should also be reported to [relevant pharmaceutical company]':

13.7 (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. In abbreviated advertisements larger than A5 (but no larger than 420 square centimetres) each side should be no less than 5mm. The other relevant requirements of Clause 12.10 apply equally to the use of the black triangle symbol on abbreviated advertisements.

13.8 (5.8) Abbreviated advertisements may 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.

13.9 (5.9) Marketing authorisation numbers and references must not be included in abbreviated advertisements.

Clause 13 Supplementary Information

Clause 13.2 (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 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.

The prescribing information must be made available for any advertisement for a medicine appearing on audiovisual material or in an interactive data system or on the internet, including online journals, as such advertisements cannot be deemed abbreviated advertisements.

Clauses 13.4, 13.5, 13.6, 13.7, 13.8 and 13.9 (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 13.4, 13.5, 13.6, 13.7, 13.8 and 13.9 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 13.4, 13.5, 13.6, 13.7, 13.8 and 13.9.

Telephone numbers may be included in abbreviated advertisements.

Clause 13.5 (5.5) Non-Proprietary Name

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

Clause 13.6 (5.6) Adverse Event Reporting

In the event that the website address given in Clause 13.6 is changed by the MHRA, companies must use the new address within one year of the change.

Clause 14 Information, Claims and Comparisons

Clauses 6 and 18 may also be relevant.

- 14.1** (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 trademarks, brand names, other distinguishing marks and those of a competitor
 - the trademarks, 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 trademark, 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 trademark or brand name.
- 14.2** (7.6) When promotional material refers to published studies, clear references must be given.
- 14.3** (7.7) When promotional material refers to data on file, the relevant part of that data must be provided as soon as possible, and certainly within ten working days, in response to a request from a health professional or other relevant decision maker.
- 14.4** (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.
- 14.5** (6.2) None of the individual screens or pages etc of a multi screen/page advertisement must be false or misleading when read in isolation.

Clause 14 Supplementary Information

Clauses 6 and 18 may also be relevant.

Clause 14.1 (7.3) Comparisons

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

Comparisons with other products 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.

Clause 14.2 (7.6) References

The references referred to are those to published material, including the use of quotations, tables, graphs and artwork.

Clause 14.4 (7.10) Superlatives

Superlatives are 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, provided that this is not presented in a way which misleads as to its significance.

Clause 14.4 (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 14.4 (7.10) Benefit/Risk Profile

The benefit/risk profile of a medicine must be presented in such a way as to comply with the Code. Particular attention should also be paid to Clauses 6.1 and 6.4.

Clause 15

High Standards, Format and Suitability

- 15.1** (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.
- 15.2** (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.
- 15.3** (9.6) Reproductions of official documents must not be used for promotional purposes unless permission has been given in writing by the appropriate body.
- 15.4** (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.
- 15.5** (9.9) The telephone, text messages, email, faxes, automated calling systems and other digital communications must not be used for promotional purposes, except with the prior permission of the recipient.
- 15.6** (12.1) Promotional material and activities must not be disguised.

Clause 15 Supplementary Information

Clause 15.2 (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 15.5 (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 from such emails.

Clause 15.5 (9.9) Responding to Emails

An unsolicited enquiry 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 15.5 (9.9) Remote Detailing

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 15.6 (12.1) Disguised Promotional Material

Promotional material sent in the guise of personal communications is inappropriate. Promotional material must not imply that the contents are non-promotional, for example, that the contents provide information relating to safety. 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 5.5.

Clause 16

Material and Distribution

- 16.1** (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.
- 16.2** (28.4) A medicine covered by Clause 16.1 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.
- 16.3** (11.2) Restraint must be exercised on the frequency of distribution and on the volume of promotional material distributed.
- 16.4** (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.
- 16.5** (10.1) Reprints of articles in journals must not be provided proactively unless the articles have been peer reviewed.

Clause 16 Supplementary Information

Clause 16.1 (28.1) Website 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 16.2 (28.4) Advertisements in Electronic Journals

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 16.3 (11.2) Frequency of Distribution

The style of materials is relevant to their acceptability and criticism of their frequency is most likely to arise when their informational content is limited.

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

Clause 16.5 (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 Clauses 12.1 and 12.2.

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

**Clause 17
Representatives**

- 17.1** (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.
- 17.2** (15.2) Representatives must maintain a high standard of ethical conduct in the discharge of their duties and comply with all relevant requirements of the Code.
- 17.3** (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.
- 17.4** (15.4) Representatives must ensure that the frequency, timing and duration of calls on health professionals and other relevant decision makers in hospitals, 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 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.
- 17.5** (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.
- 17.6** (15.6) Representatives must, without delay, forward any information which they receive in relation to the use of their company's medicines, particularly reports of adverse reactions, to the scientific service referred to in Clause 4.1.
- 17.7** (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.
- 17.8** (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.
- 17.9** (15.9) Representatives' briefing material must comply with the relevant requirements of the Code and, in particular, is subject to the certification requirements of Clause 8.

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. 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 Medicines Healthcare products Regulatory Agency (MHRA) and the PMCPA on request.

- 17.10** (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.

Clause 17 Supplementary Information

Clause 17 (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 authorisation for the medicine or are inconsistent with the summary of product characteristics. Indications for which the medicine does not have a marketing authorisation must not be promoted.

Clause 17 (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 Clause 9.

Clause 17.3 (15.3) Hospitality and Payments for Events/Meetings

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 subsistence (food and drink) has 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 subsistence itself was appropriate for the occasion. The requirements of Clause 10 apply.

Donations 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 17.3 (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 17.3, which prohibits the use of any inducement or subterfuge to gain an interview.

Clause 17.3 (15.3) Health Professionals' Standards of Conduct

The General Medical Council, the General Pharmaceutical Council and 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 10.1.

Clause 17.4 (15.4) Frequency and Manner of Calls on Doctors and Other Prescribers

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

Companies should arrange that the frequency of visits does 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 audiovisual 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' and others' 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 17.8 (15.8) Provision of the Summary of Product Characteristics

An electronic copy of the summary of product characteristics can be provided. 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 17.9 (15.9) Briefing Material

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

Interactions with Health Professionals, Other Relevant Decision Makers and Healthcare Organisations

CLAUSES 18–22

Clause 18 Information, Claims and Comparisons

Clauses 6 and 14 may also be relevant.

- 18.1** (7.1) Upon reasonable request, a company must promptly provide health professionals and other relevant decision makers with accurate and relevant information about the medicines which the company markets.
- 18.2** (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 health professionals or other relevant decision makers. The validity of indications approved in the marketing authorisation can be substantiated by provision of the summary of product characteristics.

Clause 19 Prohibition on Inducements and Inappropriate Payments and the Provision of Items to Health Professionals and Other Relevant Decision Makers

- 19.1** (18.1) No gift, pecuniary advantage or benefit may be supplied, offered or promised to 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 10.4 and 19.2.
- 19.2** (18.2) Health professionals may be provided with materials and items for patient support which are to be passed on to patients, the details of which must be appropriately documented and certified in advance as required by Clause 8.3.

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 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.

Clause 19 Supplementary Information

Clause 19.1 (18.1) Health Professionals' Standards of Conduct

For information on health professionals' standards of conduct refer to the supplementary information to Clause 10.1.

Clause 19.1 (18.1) Payments to Contracted Individuals

Any payment to an individual for an activity that is ruled in breach of Clause 24 and/or Clause 25.4 is likely to be viewed as an unacceptable payment and thus in breach of Clause 19.1.

Clause 19.1 (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 1.17) 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 19.1 (18.1) Package Deals

Clause 19.1 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. Transfers of value made in the course of these package deals would need to be disclosed in accordance with Clause 28. The transaction as a whole must be fair and reasonable and the associated benefits must be relevant to the medicine involved.

Clause 1.25 exempts package deals solely relating to ordinary course purchases and sales of medicines from the requirement to disclose transfers of value.

Companies can provide genetic testing or other biomarkers/specific testing in relation to the rational use 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 19.1 (18.1) Outcome or Risk Sharing Agreements

Clause 19.1 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 19.1 (18.1) Patient Access Schemes

Patient access schemes are acceptable in principle under the Code but they must be carried out in a manner compatible with its requirements.

The 2014 Pharmaceutical Price Regulation Scheme 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 applied in the devolved nations.

The 2019 Voluntary Scheme for Branded Medicines Pricing and Access (VPAS) also refers to the Department of Health and Social Services, 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. The governments of Scotland, Wales and Northern Ireland may agree similar arrangements.

Clause 19.1 (18.1) Promotional Aids

A promotional aid is defined as a non-monetary item given for a promotional purpose. Promotional aids may be given to health professionals and other relevant decision makers only in accordance with Clause 10.4. Health professionals may, however, be provided with items which are to be passed on to patients in accordance with Clause 19.2.

Items for the personal benefit of health professionals or other relevant decision makers must not be offered or provided.

Coffee mugs, stationery, computer accessories, diaries, calendars and the like and items for use in the home or car are not acceptable. 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. Toys and puzzles intended for children to play with while waiting must not be provided.

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

Literature such as leaflets and booklets 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 the 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.

Clause 19.1 (18.1) Data Storage Devices

Clause 19.1 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 which bear educational or promotional material compliant with the Code, provided that their storage capacity is commensurate with the amount of data to be provided.

Clause 19.1 (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 for health professionals and other relevant decision makers to use in accordance with Clause 23.1, Donations and Grants, but they must not be given to individuals.

Clause 19.1 (18.1) Long Term or Permanent Loan

The requirements of Clause 23 cannot be avoided by providing health professionals or practices etc with items on long term or permanent loan.

Clause 19.2 (18.2) Items for Patient Support

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.

Items for patient support 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. 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.

Provided that they have been appropriately documented and certified in advance as required by Clause 8.3, items for patient support 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. 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 26 and its supplementary information.

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

- 20.1** 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 other organisations. Joint working is a limited form of collaborative working as set out in Clause 20.4.
- 20.2** 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.
- 20.3** In addition to Clause 20.2, 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 8.3, 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.

- 20.4** (New Clause and part of Clause 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 20 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.

- 20.5** (24.2) Transfers of value made by companies in connection with collaborative working must be publicly disclosed annually.

Clause 20 Supplementary Information

Clause 20 Medical and Educational Goods and Services which Comply with Clause 19 of the 2019 ABPI Code, Including their Transition under the 2021 ABPI Code
Medical and educational goods and services (MEGS) provided under Clause 19 of the 2019 Code are likely to fall under donations in Clause 23 or collaborative working in Clause 20 of the 2021 Code. Companies wishing to continue with ongoing MEGS from 1 July 2021 can do so until 31 December 2021 under the 2021 Code without the need for them to be reclassified as either a donation or collaborative working and comply with any new requirements as a result of this change. Thus there is a six month transition period for MEGS.

If the collaborative working involves services, then the supplementary information to Clause 23 Donations and Grants should be considered.

Clause 20 Collaborative Working with Organisations
Collaborative working between the pharmaceutical industry, healthcare organisations and others must be conducted in an open and transparent manner and must either enhance patient care or be 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, must be in line with nationally accepted clinical guidance where such exists. Collaborative working differs from the situation where pharmaceutical companies provide funds in the form of a grant for a specific event or programme.

Collaborative working between the pharmaceutical industry, healthcare organisations and others may, in addition, involve working with a patient organisation. In such circumstances, the arrangements for the patient organisation involvement must comply with Clause 27 and is likely to be a contracted service, as set out in Clause 27.5.

Collaborative working is acceptable in principle provided that it is carried out in a manner compatible with the Code. Collaborative working 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 none of the benefits of any collaborative working project 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 to an NHS or similar organisation.

The use of a particular medicine of a company party to a collaborative working agreement is not prohibited provided all parties are satisfied that the use of the medicine is appropriate and that the requirements for collaborative working are met.

Resources provided by the company to deliver the collaborative working project must be relevant and the agreement as a whole must be fair and reasonable. Any resources provided by the company must themselves contribute to either patient care or healthcare.

The written agreement should cover the following points:

- the name of the 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, pharmaceutical company and other organisation(s) as applicable; benefits should always be stated first, and outcomes should be measured
- an outline of the financial arrangements
- the roles and responsibilities of the NHS, 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 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 a summary of the collaborative working agreement, for example, on a clearly defined website or section of a website, such as on the company's or companies' websites; the healthcare organisation(s) and other parties involved in the collaboration should also be encouraged to publish this
- outcomes should be published by all parties as soon as possible and usually within six months of the project's completion, so that other NHS organisations and others can learn from and potentially replicate the initiative.
Companies should publish the outcomes on their websites.

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 19.1.

Clause 20.4 (20) 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 20.

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, must be in line with nationally accepted clinical guidance where such exists.

In addition to the certification requirements set out in Clause 20.3, 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 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.

Clause 20.5 (24.2) Disclosure

The information required by Clause 20.5 as to transfers of value must be publicly disclosed annually, giving in each case the financial amount or value and the name of the recipient.

Companies must ensure that the amount spent on 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 28.

Clause 21

Provision of Medicines and Samples

- 21.1** (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.
- 21.2** (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 authorisation 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 authorisation to include additional strengths and/or dosage forms for existing indications or to include additional pack sizes is not regarded as leading to a new medicine.
- 21.3** (17.3) Samples may only be supplied in response to written requests which have been signed and dated. An electronic signature is acceptable. All signed and dated written requests for samples should be retained for not less than one year.
- 21.4** (17.4) A sample of a medicine must be no larger than the smallest presentation of the medicine on the market in the UK.
- 21.5** (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.
- 21.6** (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).
- 21.7** (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 21.2.
- 21.8** (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.
- 21.9** (17.9) Medicines may not be sold or supplied to members of the public for promotional purposes.

- 21.10** (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.

Clause 21 Supplementary Information

Clause 21.1 (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 21.

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 in Clause 1.21.

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 21.1 (17) Starter Packs

The provision of starter packs is not permitted. Starter packs 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 21.3 (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.

Clause 21.7 (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 authorised to receive them on their behalf. The provision of medicines and samples in hospitals must comply with individual hospital requirements.

Clause 22

Non-Interventional Studies of Marketed Medicines

- 22.1** (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
 - any remuneration must be reasonable and reflect the fair market value of the work
 - the study must not constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine
 - the company's scientific service must certify the protocol and supervise the conduct of the study
 - the study results must be analysed and summaries made available within a reasonable period of time to the company's scientific service, which 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 supervised by 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.

22.2 To the extent applicable, companies are encouraged to comply with Clause 22.1 for all other types of non-interventional studies, including epidemiological studies and registries and other studies that are retrospective in nature.

22.3 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, as set out in Clause 4.6.

Clause 22 Supplementary Information

Clause 22 (13.4) Other Studies

All non-interventional studies, including epidemiological studies and registries and other studies that are retrospective in nature are subject to Clause 24.3.

Interactions with Health Professionals, Other Relevant Decision Makers, Healthcare Organisations, Patient Organisations and the Public, Including Patients and Journalists

CLAUSES 23–25

Clause 23

Donations and Grants

23.1 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 organisation, institution and the like to provide goods or services to the benefit of the pharmaceutical company in return. Donations and grants to individuals are prohibited.

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

23.2 (19.1 and 19.2) Donations and grants to healthcare organisations, patient organisations or other 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
- are prospective in nature
- do not bear the name of any medicine – although they may bear the name of the company providing them.

In addition:

- there must be a written agreement in place for each donation or grant. The arrangements for the written agreement for donations and grants to patient organisations are set out in Clause 27.2 and for other organisations in the supplementary information to Clause 23.2
- the written agreement, and where relevant, internal company and service provider instructions must be certified in advance as set out in Clause 8.3
- all information relating to the donation or grant should be kept on record by the company
- donations and grants must be publicly disclosed annually as set out in Clauses 28 and 29.

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

Clause 23 Supplementary Information

Clause 23 Medical and Educational Goods and Services which Comply with Clause 19 of the 2019 ABPI Code, Including their Transition under the 2021 ABPI Code

Medical and educational goods and services (MEGS) provided under Clause 19 of the 2019 Code are likely to fall under donations in Clause 23 or collaborative working in Clause 20 of the 2021 Code. Companies wishing to continue with ongoing MEGS from 1 July 2021 can do so until 31 December 2021 under the 2021 Code without the need for them to be reclassified as either a donation or as collaborative working and comply with any new requirements as a result of this change. Thus there is a six month transition period for MEGS.

Clause 23 (19.1) Donations and Grants

Clause 19.1 does not prevent the provision of donations and grants. They must not be provided to individuals.

The requirement in Clause 23.2 that donations must not bear the name of any medicine does not apply where the donation is an independently produced textbook or journal which includes as part of its texts the names of medicines.

Donations as a good or service may bear a corporate name. The involvement of a pharmaceutical company in such activities must be made clear to those receiving a service. In addition, the involvement of a pharmaceutical company in any services should be made clear to patients. Such involvement should also be clear in any associated materials for patients. Clause 5.5 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 acceptability of the role of representatives will depend on the nature of the donation or grant and the method of provision*
- representatives may introduce a donation or no more than a call for grant applications by means of a brief description and/or delivering materials but may not*

instigate a detailed discussion about the donation or grant at the same time as a call or contact at which products are promoted

- iii. if representatives provide, deliver or demonstrate a donation or grant, then this must not be linked in any way to the promotion of products. In order to comply with this, the representative must not carry out both activities at the same call or contact
- iv. if, during a promotional 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 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 the following 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 service is important, ie is the service provider a suitably qualified person, such as a health professional? If the service requires patient contact, for example, either directly or by identification of patients from patient records and the like, then representatives must not be involved. Only a suitably qualified person, such as a health professional, not employed as a representative, may undertake activities relating to patient contact and/or patient identification
- vi. neither the company nor its representatives may be given access to data/records that could identify, or could be linked to, particular patients
- 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 10.1). There should be no promotion of specific products by those health professionals
- viii. the remuneration of those not employed as representatives but who are engaged to deliver a service as service providers 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
- ix. service providers must operate to detailed written instructions provided by the company. These should be similar to the briefing material for representatives as referred to in Clause 17.9. 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 17.5 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 sponsoring pharmaceutical company
- xi. a recipient of a service must be provided with sufficient written information to avoid misunderstandings as to what the recipient has agreed. The identity of the sponsoring pharmaceutical company must be given
- xii. any material designed for use in relation to the provision of a 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
- xiii. material relating to the provision of a service, such as internal instructions, external instructions, the written information for recipients and other material, must be certified as required by Clause 8.3
- xiv. a copy of the materials must be made available to the 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 a service which would have budgetary implications for the parties involved.

Clause 23 (19.1) Switch and Therapy Review Programmes

Clauses 19.1 and 23.1 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.

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 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 23.2 Written Agreements

Clause 27.2 sets out the arrangements for patient organisations. The written agreement for donations and grants to other organisations should include:

- description of the donation or grant
- objective of the donation or grant. How it will support healthcare, scientific research or education must also be included
- the names of the organisations/parties involved and their respective roles
- the type of activity and the nature of the company's contribution
- the time frame
- the amount of funding and/or a description of indirect/non-financial, in-kind donation and the nature of that donation. Where possible a full breakdown of costs should be included
- a statement that all parties are fully aware that the donation or grant must be clearly acknowledged and apparent from the start
- the signatories to the agreement
- the date of the agreement.

Clause 23.2 (19.2) Annual Disclosure of Donations and Grants

Company support of individuals to attend events/meetings is covered by Clause 10.

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 expenses should be disclosed separately. Disclosure must be carried out in accordance with Clauses 28 and 29.

**Clause 24
Contracted Services**

24.1 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 and journalists, 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 or training services, writing articles and/or publications, participation at advisory board meetings, and participation in market research where such participation may involve remuneration and/or hospitality.

24.2 (23.1 and 27.8) The arrangements which cover 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
- the criteria for selection must be directly related to the identified need and the persons responsible for selection must have the expertise necessary to evaluate whether the particular contracted individuals and/or organisations meet those criteria
- the number of contracted individuals and/or organisations 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
- the hiring of the contracted party 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. Token consultancy arrangements must not be used to justify compensating the contracted party
- in their written contracts or agreements, companies must include provisions regarding the obligation of the individual to:
 - declare that they are a contracted individual to the company whenever they write or speak 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 who 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.

24.3 (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 members of the public, including patients and journalists under which they provide any type of service (not otherwise covered by the Code) 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.

24.4 (23.2) Pharmaceutical companies must publicly disclose annually details of the fees and expenses paid to 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.

24.5 (23.3) In addition to the information required to be made public by Clause 24.4, companies must publicly disclose annually details of payments made to contracted individuals in relation to market research (unless the company concerned does not know the identities of those participating in the market research).

24.6 (23.4 and part of Clause 27.8) Fees, expenses and the like due to contracted individuals/organisations in relation to Clauses 24.3, 24.4 and 24.5 must be disclosed.

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, including patients and journalists, must include:
 - the total number of members of the public contracted to perform services, the total amount paid to members of the public per calendar year and a description of the types of 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
 - a breakdown of the total payments to each group of individuals, ie the public, patients and journalists, without the necessity to divulge confidential information.

In addition, companies should disclose fees and expenses separately.

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 29.

Clause 24 Supplementary Information

Clause 24.1 Contracted Services with Members of the Public, Including Patients and Journalists

Only certain services provided by members of the public, including patients and journalists, are covered by the Code; others are clearly outside the scope of the Code. The services covered by the Code generally relate to healthcare,

disease or medicine. Providing advice with regard to the design of clinical trials would be an included contracted service whereas being a participant in a clinical trial would not.

The transparency of contracted services with members of the public, including patients and journalists, is the next step in evolving disclosures made by pharmaceutical companies. The arrangements are similar to those used when disclosure for health professionals was introduced. The introduction of requirements for contracted services with the public, including patients and journalists, was thought necessary following publication of the EFPIA document 'Working together with patients – principles for remunerating patients, patient organisation representatives and carers for work undertaken with the pharmaceutical industry' in June 2019.

Clause 24.1 (23.1) Contracted Individuals

The relevant provisions of Clause 10 apply to contracted individuals' attendance at events/meetings.

Clause 24.5 (23.3) Annual Disclosure of Transfers of Value of Market Research

Clause 24.5 relates only to market research using contracted individuals where the pharmaceutical company knows the identity of the 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 24.6 (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 28.

The information which must be disclosed is the total amount paid in a calendar year to each 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 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 expenses should be disclosed separately.

Clause 24.6 (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 29.

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 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.

Fees and expenses should be disclosed separately.

Clause 24.6 (23.2) Annual Disclosure of Transfers of Value in Relation to Contracted Services by Members of the Public, Including Patients and Journalists

Disclosure must be carried out in accordance with Clauses 30 and 31.

The information which must be disclosed is the total amount paid to members of the UK public over the reporting period, including the number of individuals contracted and a description of the types of 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.

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

Fees and expenses should be disclosed separately.

Clause 24.6 (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:

- i. non-clinical studies (as defined in the 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.

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

Clause 25

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

- 25.1** (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.
- 25.2** (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.
- 25.3** (27.9) Companies must ensure that all sponsorship is 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.
- 25.4** (12.2) Market research activities, clinical assessments, post-marketing surveillance and experience programmes, post-authorisation 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.

Clause 25 Supplementary Information

Clause 25.2 (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 25.4 (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.

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

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 when requested to do so. When commissioning market research, a company must take steps to ensure that its identity would be made known to the PMCPA should a request for that information be made.

Specific Requirements for Interactions with the Public, Including Patients and Journalists, and Patient Organisations

CLAUSES 26–27

Clause 26

Relations with the Public, Including Patients and Journalists

- 26.1** (26.1) Prescription only medicines must not be advertised to the public. This prohibition does not apply to vaccination and other campaigns carried out by companies and approved by the health ministers.
- 26.2** (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.

- 26.3** (18.2 SI) Items for patient support made available to patients, for example, by completing a request card enclosed with a medicine, should be inexpensive, related to either the condition under treatment or general health, and must be appropriately documented and certified in advance as required by Clause 8.3. Care must be taken that any such activity meets all the requirements of the Code and in particular Clause 26.4.

Companies cannot run or sponsor competitions or quizzes for patients if prizes are offered.

- 26.4** (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.'

- 26.5** (26.4) Requests from individual members of the public for advice on personal medical matters must be refused and the enquirer recommended to consult their own doctor, or other prescriber or other health professional.

Clause 26 Supplementary Information

Attention is drawn to other relevant clauses of the Code, in particular, the quality standards Clauses 5 to 10, including meetings organised for or attended by members of the public, patients, journalists and patient organisations which must comply with Clause 10.

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.

Clause 26.1 (New) Vaccination and Other Campaigns Approved by the Health Ministers

Further information regarding temporary supply authorisations is given in the supplementary information to Clauses 3.1 and 3.2. Where the campaign for the public is approved by the health ministers all other relevant requirements of the Code will apply. In addition, such campaigns should include a general reference to the reporting of side effects as it is unlikely that the requirements of Clause 26.4 will apply as the relevant material is not intended for patients taking a particular medicine.

Clause 26.2 (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 encourage 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 26.5 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.

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.

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 authorisations. 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 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:

- registration studies used for marketing authorisation 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
- 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
- information about diseases
- information about specific medicines.

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.

The Media: It is good practice to reference 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: 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 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 Clauses 19.2 and 26.3 and their supplementary information.

Disease Awareness or Public Health Campaigns can be conducted by a company 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 Campaign Guidelines produced by the MHRA.

Further information is available in Clauses 19.2 and 26.3 and its supplementary information.

Clause 26.2 (28.1) Website Access

A pharmaceutical company website or a company sponsored website providing information for the public as well as promotion to health professionals must have 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 26.2 (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 (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. 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 (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. Such information must be factual and presented in a balanced way.

Clause 26.2 (26.2) Certification of Information

In general, information on medicines made available under this clause must be certified in advance as required by Clause 8.3. There are exceptions such as for responses from medical information departments or similar to unsolicited enquiries from the public, which should be examined as set out in the supplementary information to Clause 8.3.

Clause 26.2 (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, AWMMSG or SMC, provided the information is accurate, not misleading, not promotional in nature and otherwise complies with Clause 26.2.

Clause 26.3 (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. Such items 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.

Clause 26.4 (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 26.4 is changed by the MHRA, companies must use the new address within one year of the change.

Clause 26.4 (26.3) Black Triangle Symbol

Details of the black triangle symbol can be found in the supplementary information to Clause 12.10.

Clause 26.5 (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. 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 ingredient, 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.

Requests from members of the public must be handled carefully and a company should refer the enquirer to other sources where appropriate. These might include health professionals, NHS websites, NHS 111, their equivalents in the devolved nations and patient organisations etc.

A request from a patient for information may in some instances 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 27

Relationships with Patient Organisations

27.1 (27.1) When pharmaceutical companies interact with patient organisations or any user organisations such as disability organisations, carer or relative organisations and consumer organisations, companies must:

- respect the independence of the organisations
- assure the independence of the 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
- not promote or request the promotion of a particular prescription only medicine
- ensure the objectives and scope are transparent and support provided by companies must always be clearly acknowledged.

27.2 (27.3) When companies provide donations, grants or sponsorship (including in relation to events/meetings) to patient organisations as set out in Clauses 23.2 and 10, companies must have a written agreement in place for each donation, grant or sponsorship setting out exactly what has been provided.

The written agreement must include:

- a description of the donation, grant or sponsorship
- the objective of the donation, grant or sponsorship, including how it will support healthcare, scientific research or education
- the names of the organisations/parties involved (pharmaceutical company, patient organisations and any other parties) and their respective roles
- the type of activity and the nature of the company's contribution (eg donation, grant, sponsorship of a specific meeting or publication etc)
- the time frame
- the amount of funding and/or a description of indirect/non-financial, in-kind donation and the nature of that donation (eg the donation of agency time or free training courses). Where possible, a full breakdown of costs should be included
- a statement that all parties are fully aware that the donation, grant or sponsorship must be clearly acknowledged and apparent from the start
- the signatories to the agreement
- the date of the agreement.

This written agreement must be certified as set out in Clause 8.3. A company must ensure that any materials, activities etc resulting from working with patient organisations are also certified where these are covered in Clause 8.3.

Donations, grants and sponsorships (including in relation to events/meetings) must be publicly disclosed annually as set out in Clause 29.

27.3 (27.2) When 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
- 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.

27.4 (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.

27.5 (New Clause and part of Clause 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 24. Companies must publicly disclose annually fees and expenses paid to patient organisations as set out in Clause 29. In their written contracts with patient organisations, companies are strongly encouraged to include provisions regarding an obligation of the patient organisations to declare that they have provided paid services to the company whenever those concerned write or speak in public about a matter that is the subject of the agreement or any other issue relating to that company.

Where companies contract with individuals representing patient organisations to provide services, such contracts should be made with the patient organisation, and payment should be disclosed as a payment to the patient organisation.

Clause 27 Supplementary Information

Clause 27.3 (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 27.4 (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

CLAUSES 28–31

Clause 28

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

28.1 (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.

28.2 (24.2) The transfers of value covered by Clause 28.1 are:

- collaborative working, including joint working, in accordance with Clause 20
- donations and grants provided to healthcare organisations, institutions and other organisations in accordance with Clause 23
- fees and expenses paid for contracted services between companies and institutions, organisations or associations of health professionals, in accordance with Clause 24.6
- support of attendance by health professionals and other relevant decision makers at events/meetings whether paid directly, indirectly or via another party in accordance with Clause 10.10
- fees and expenses paid for contracted services to health professionals and other relevant decision makers, or to their employers on their behalf, in relation to Clause 24.6
- sponsorship, including contributions to costs related to events/meetings paid to healthcare organisations or to organisations managing events on their behalf, which may include support of health professionals not known to the company via the healthcare organisation by way of registration fees, accommodation and travel, in accordance with Clause 10.11.

28.3 (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.

28.4 (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.

28.5 (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.

28.6 (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.

Clauses 28, 29 and 30 Supplementary Information

(24.1) Lawful 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.

(24.1) Transfers of Value

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 28 Supplementary Information

Clause 28.1 (24.1) Mode of Disclosure for Health Professionals, Other Relevant Decision Makers and Healthcare Organisations

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

Clause 28.2 (24.2) Further Information

The clauses of the Code noted in Clause 28.2 should be consulted for further information about the requirements. In addition, the requirements of Clauses 10.1 and 10.10 should be borne in mind in relation to meetings.

Clause 28.2 (24.2) Disclosure of Contributions to Costs Related to Events/Meetings

If when providing sponsorship to a healthcare organisation, institution, other 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, other organisation 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 10.1.

Clause 28.5 (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 29
Annual Disclosure of Contracted Services, Donations, Grants and Sponsorship (including in relation to events/meetings) Provided to Patient Organisations**

29.1 (New Clause) 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.

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

29.2 (New Clause and part of Clauses 27.7 and 27.8) The disclosure for the provision of donations, grants or sponsorship (including in relation to events/meetings) to a patient organisation must include:

- the monetary value of each financial contribution (grant or sponsorship) to include a description that is sufficiently complete to enable the reader to understand the nature of that support or the arrangements in accordance with Clauses 23 and 10
- 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 Clause 23.

The disclosure for contracted services provided by each patient organisation, in accordance with Clause 24, 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.

Clause 29 Supplementary Information

Clause 29.1 (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.

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 30
Annual Disclosure of Contracted Services Provided by the Public, Including Patients and Journalists**

30.1 (New Clause) Companies must make publicly available annually details of the fees for certain contracted services paid to members of the UK public, including patients and journalists. 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 and participating in market research where such participation involves remuneration and/or travel.

The disclosure for contracted services provided by members of the public, in accordance with Clause 24, must include:

- the total number of members of the public, including patients and journalists contracted to perform services and the total amount paid per calendar year, and a description of the types of 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
- companies should provide a breakdown of the total payments to each group of individuals, ie the public, patients and journalists without the necessity to divulge confidential information
- fees and expenses should be disclosed separately.

Each company must include a note summarising the methodologies used by it in preparing the disclosures and identifying support and services provided.

Clause 30 Supplementary Information

Clause 30 (New) Disclosure of Contracted Services Provided by the Public, Including Patients and Journalists

The arrangements for such services should meet the requirements of Clause 24.

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 the public, including individual patients, journalists 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 31

Timings, Duration and Retention of Disclosure Information

- 31.1** (24.4) Disclosures must be made annually in respect of each calendar year and must be in the first six months after the end of the calendar year in which the transfers of value/ payments were made.
- 31.2** (24.5) The information disclosed must remain in the public domain for at least three years from the time of first disclosure.
- 31.3** (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.

Clause 31 Supplementary Information

Clause 31.1 (New) Date of Implementation for Disclosure of Contracted Services Provided by the Public, Including Patients and Journalists

The information required by Clause 30 must be publicly disclosed annually in respect of transfers of value made in 2022 and each calendar year thereafter.

PRESCRIPTION MEDICINES CODE OF PRACTICE AUTHORITY CONSTITUTION AND PROCEDURE

Introduction	52
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STRUCTURE AND RESPONSIBILITIES

1 Prescription Medicines Code of Practice Authority	53
2 Code of Practice Panel – Constitution and Procedure	53
3 Code of Practice Appeal Board – Constitution	53
4 Code of Practice Appeal Board – Procedure	55

COMPLAINTS PROCEDURE

5 Action on Complaints	56
6 Complaints Arising from Media Criticism	57
7 Code of Practice Panel – Rulings	57
8 Code of Practice Panel – Reports to the Code of Practice Appeal Board	59
9 Action on Complaints about Safety from the Medicines and Healthcare products Regulatory Agency	59
10 Code of Practice Appeal Board – Rulings	59
11 Reports to the Code of Practice Appeal Board	60
12 Code of Practice Appeal Board – Reports to the ABPI Board	60
13 Case Reports	61

GENERAL PROVISIONS

14 Time Periods for Responding to Matters under the Code	62
15 Withdrawal of Complaints and Notices of Appeal	62
16 Code of Practice Levy and Charges	62
17 Scrutiny	62
18 Provision of Advice and Assistance with Conciliation	63
19 Amendments to the Code of Practice and Constitution and Procedure	63
20 Annual Report	63

Introduction to the PMCPA Constitution and Procedure

OPERATIVE ON 1 JANUARY 2019

The Code of Practice for the Pharmaceutical Industry is administered by the Prescription Medicines Code of Practice Authority. The Authority is responsible for the provision of advice, guidance and training on the Code as well as for the complaints procedure. It is also responsible for arranging for conciliation between companies when requested to do so and for arranging for the scrutiny of advertising and meetings on a regular basis.

The Authority is not an investigatory body as such. It asks the respondent company for a complete response and may ask the parties to a case for further information in order to clarify the issues. It is essentially an adversarial process in which the evidence to be taken into account comes from the complainant and the respondent company, though the Authority can seek evidence from third parties where necessary. A complainant has the burden of proving their complaint on the balance of probabilities. The system is designed so that both parties can participate fully in the process. Although anonymous complaints are accepted, it is preferable if complainants from outside the industry provide a name, contact details and relevant information about their interests in the matter of complaint. The names of individuals complaining from outside the pharmaceutical industry are kept confidential. In exceptional cases it may be necessary for a company to know the identity of the complainant so that the matter can be properly investigated. Even in these instances, the name of the complainant is only disclosed with the complainant's permission.

All complaints are judged on the evidence provided by the parties. The weight to be attached to any evidence may be adversely affected if the source is anonymous and thus in some instances it will not be possible for such a complaint to proceed.

Complaints made under the Code are considered by the Code of Practice Panel and, where required, by the Code of Practice Appeal Board. Reports on cases are published by the Authority and are available on request and on the Authority's website www.pmcpa.org.uk.

Complaints should be submitted to the Director of the Prescription Medicines Code of Practice Authority, 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT, telephone 020-7747 8880, email complaints@pmcpa.org.uk.

Structure and Responsibilities

1 Prescription Medicines Code of Practice Authority

- 1.1** The Prescription Medicines Code of Practice Authority (the 'Authority') is responsible for the administration of the Code of Practice for the Pharmaceutical Industry (the 'Code') including the provision of advice, guidance and training on the Code. It is also responsible for arranging for conciliation between companies when requested to do so and for arranging for the scrutiny of advertising and meetings on a regular basis.
- 1.2** The Authority also administers the complaints procedure by which complaints made under the Code are considered by the Code of Practice Panel (the 'Panel') and, where required, by the Code of Practice Appeal Board (the 'Appeal Board').
- 1.3** The Authority is appointed by and reports to the Board of the Association of the British Pharmaceutical Industry (ABPI) (the 'ABPI Board') and consists of the Director, Deputy Director and two Managers.

Notwithstanding the above, the Director reports to the Appeal Board for guidance on the interpretation of the Code and the operation of the complaints procedure and to the President of the ABPI (or, at the President's discretion, the Vice President of the ABPI) for administrative purposes.

In the absence of the Director, the Deputy Director is authorized to act on his/her behalf. In the absence of the Director and Deputy Director, one of the Managers is authorized to act on the Director's behalf.

- 1.4** To facilitate the complaints procedure by ensuring that the requisite information is available, the Director may request copies of any relevant material from a pharmaceutical company, including copies of the certificates authorizing any such material and copies of relevant briefing material for representatives.
- 1.5** The Director may consult the Appeal Board upon any matter concerning the Code or its administration.

2 Code of Practice Panel – Constitution and Procedure

- 2.1** The Panel consists of the members of the Authority and meets as business requires to consider complaints made under the Code.

The member of the Authority who acted as case preparation manager for a particular case must not participate when the Panel considers it or be present when it does so.

The parties have no right to appear or be represented before the Panel.

- 2.2** Two members of the Authority form a quorum for a meeting of the Panel. Decisions are made by majority voting. The Director or, in his/her absence, the Deputy Director or, in his/her absence, one of the Managers, acts as Chair of the Panel and has both an original and a casting vote.

If necessary the Director or in his/her absence the Deputy Director, may co-opt an appropriate person to be a member of the Panel. The Director should seek the agreement of the Chair of the Appeal Board prior to any co-option. The list of persons approved for co-option is drawn up following procedures similar to those in place for appointing the Authority.

Rulings are made on the basis that a complainant has the burden of proving their complaint on the balance of probabilities.

- 2.3** The Director may obtain expert assistance in any field. Expert advisors who are consulted may be invited to attend a meeting of the Panel but have no voting rights.

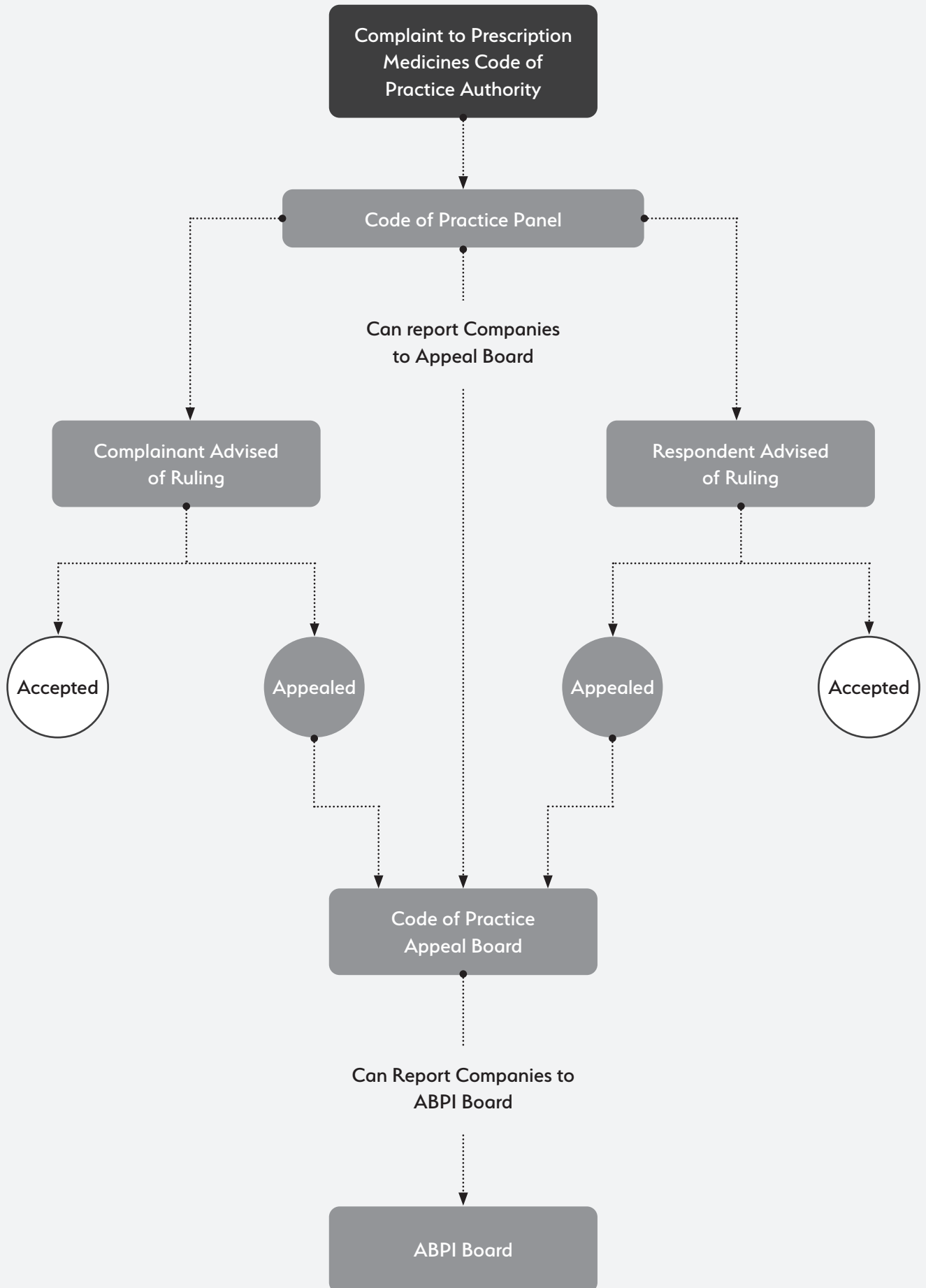
3 Code of Practice Appeal Board – Constitution

- 3.1** Vacancies for independent members of the Appeal Board, including the Chair, are advertised in appropriate journals and/or the national press.

The Appeal Board and its Chair are appointed by the ABPI Board. The appointment of independent members to the Appeal Board, including the Chair, is made following consultation with the Medicines and Healthcare products Regulatory Agency.

- 3.2** The Appeal Board comprises:

- an independent, legally qualified Chair
- three independent registered medical practitioners appointed following consultation with the British Medical Association, one with recent experience as a general practitioner and one with recent experience as a hospital consultant treating patients
- one independent registered pharmacist appointed following consultation with the Royal Pharmaceutical Society



- one independent registered nurse prescriber appointed following consultation with the Royal College of Nursing
- one independent member representative of the interests of patients
- one member from an independent body involved in providing information on medicines
- one independent lay member
- four registered medical practitioners who are medical directors or senior executives of pharmaceutical companies
- four directors or senior executives of pharmaceutical companies.

One of the members from pharmaceutical companies may be retired, provided that the initial appointment is made within one year of the date of retirement.

- 3.3** The Chair of the Appeal Board is appointed for a term of five years which may be renewed.

Members of the Appeal Board are each appointed for a term of three years. Members may be reappointed but may serve for no more than two consecutive terms. In exceptional circumstances the Chair may nominate a member who has served two terms for reappointment for a third term. A member of the Appeal Board who has served two or, following the Chair's nomination, three consecutive terms of service is eligible for reappointment after a minimum interval of one year.

- 3.4** The Director is responsible for providing appropriate administrative support to the Appeal Board including the provision of case papers.

The Director, Deputy Director and the two Managers of the Authority may be present as observers at a meeting of the Appeal Board during the consideration of an appeal or a report under Paragraph 11 below only at the invitation of the Chair and with the agreement of the party or parties involved in the appeal or report in question.

4 Code of Practice Appeal Board – Procedure

- 4.1** The Appeal Board meets as business requires to consider appeals under the Code and any other matter which relates to the Code. The Appeal Board receives reports on all complaints which have been submitted under the Code and details of the action taken on them.

- 4.2** The Chair and seven members of the Appeal Board constitute a quorum. Four of those present, in addition to the Chair, must be independent members, at least one of whom must be a registered medical practitioner, and there must also be present three members from pharmaceutical companies, at least one of whom must be a registered medical practitioner.

For the consideration of any particular case, or a report under Paragraph 11 below, independent members, including the Chair, must be in a majority.

In the event that a quorum cannot be attained for the consideration of a case because of the number of members barred under Paragraph 4.4 below, or for any other reason, the Chair may co-opt appropriate persons who are former

members of the Appeal Board, or who are on a list of persons approved for co-option to the Appeal Board, so as to enable a quorum to be achieved. The list of persons approved for co-option is drawn up following procedures similar to those for appointing members of the Appeal Board. No one may be co-opted in relation to any case in which he/she has acted as a referee in accordance with Paragraphs 5.1, 5.2, 5.3, 7.2, 7.4, 7.5 and 7.6 below.

- 4.3** Decisions are made by majority voting. The Chair has both an original and a casting vote.

Rulings are made on the basis that a complainant has the burden of proving their complaint on the balance of probabilities.

- 4.4** If a member of the Appeal Board is concerned in a case either as complainant or respondent, that member does not receive copies of the papers circulated in connection with the case and is required to withdraw from the Appeal Board during its consideration.

The complainant and the respondent are advised in advance of the membership of the Appeal Board, including potential co-optees, and asked if they have any objections to particular members and the grounds for such objections. Any member in respect of whom there are valid objections must withdraw from the Appeal Board during consideration of the case. The Chair determines whether objections are valid.

Members of the Appeal Board must declare any other interest in a case prior to its consideration. Having consulted the representatives of the parties (if present), the Chair determines whether it is appropriate for a particular member to remain for the consideration of the case.

- 4.5** The Chair may obtain expert assistance in any field. Expert advisors may be invited to attend a meeting of the Appeal Board but have no voting rights.

- 4.6** When an appeal is considered by the Appeal Board, both the complainant and the respondent company are entitled to appear or be represented.

The first presentation in relation to a ruling which is appealed is made by the appellant.

A company may not be represented before the Appeal Board by a representative who is also a member of the Appeal Board except with the consent of the Chair. Such consent may be given only if the member of the Appeal Board can satisfy the Chair that no other person within his/her company can properly represent it in the case in question.

- 4.7** Where an appeal is brought which is concerned with an issue of fact between a complainant and the company concerned which cannot be properly resolved without the oral evidence of the persons directly involved, the Chair may invite such persons to attend and give evidence.

Complaints Procedure

5 Action on Complaints

5.1 When the Director receives information from which it appears that a company (being either a member of the ABPI or a company which, although not a member, has agreed to comply with the Code and accept the jurisdiction of the Authority) may have contravened the Code, the Director must assign a member of the Authority (who may be the Director) to be the case preparation manager to process the matter and, if appropriate, prepare case papers for the Panel.

The case preparation manager must not divulge to other members of the Authority details of matters being processed until the formal case papers are provided to the Panel for consideration as provided for in Paragraph 5.5 below.

The Director is responsible for ensuring that the preparation of a case and the adjudication of it are carried out by different members of the Authority and must take steps to make certain that this separation is maintained in the event of absences of those involved.

The Director may delegate to a case preparation manager one or more of his/her responsibilities under this Constitution and Procedure when he/she considers it appropriate and necessary to do so.

The case preparation manager:

- determines whether a case should go before the Panel
- may invite evidence from third parties when considered to be appropriate even though the primary responsibility for the provision of evidence lies with the parties to a case
- may delay processing a complaint if the facts are essentially similar to those before an external forum, such as an employment tribunal; this does not apply to matters before the Medicines and Healthcare products Regulatory Agency
- may amalgamate a complaint with an ongoing complaint or complaints where two or more complaints are based on essentially the same evidence.

When a complaint is delayed or amalgamated, as above, the complainant may appeal against the delay or amalgamation to an independent referee identified by the Director and the Chair of the Appeal Board, for example a former independent member of the Appeal Board, for his/her determination which is final.

5.2 The managing director or chief executive or equivalent of the company concerned is requested to provide a complete response to the matters of complaint.

To assist companies in ensuring that a complete response is submitted the case preparation manager may suggest relevant supporting material to be supplied. It is nonetheless the responsibility of the respondent to ensure that a full response is submitted. If the complainant is not a pharmaceutical company, the case preparation manager may suggest the clauses of the Code to be addressed.

If a complaint is received about a company other than one of those referred to in Paragraph 5.1 above, it is invited by the case preparation manager to agree to comply with the Code and accept the jurisdiction of the Authority (unless it has previously declined to do so). In the absence of such agreement, the complaint is not proceeded with and the complainant is advised to refer the matter to the Medicines and Healthcare products Regulatory Agency.

Unless the information is disclosed in the complaint, a complainant other than a pharmaceutical company is asked whether or not they have any commercial, financial or other interest in the matter of complaint or in the company concerned, such as whether the complainant is an employee or ex-employee, or in a competitor.

Such interests will be disclosed to the respondent company and will normally be included in the case report.

If a complaint concerns a matter closely similar to one which has been the subject of a previous adjudication, it may be allowed to proceed at the discretion of the Director if new evidence is adduced by the complainant or if the passage of time or a change in circumstances raises doubts as to whether the same decision would be made in respect of the current complaint. The Director should normally allow a complaint to proceed if it covers matters similar to those in a decision of the Panel where no breach of the Code was ruled and which was not the subject of appeal to the Appeal Board.

If a complainant does not accept a decision of the Director that a complaint should not be proceeded with because a similar complaint has been adjudicated upon previously and nothing has changed in the meantime, then the matter is referred to an independent referee identified by the Director and the Chair of the Appeal Board, for example a former independent member of the Appeal Board, for his/her determination which is final.

If, in the view of the Director, a complaint does not show that there may have been a breach of the Code, the complainant will be so advised. If the complainant does not accept that view, the matter is referred to an independent referee identified by the Director and the Chair of the Appeal Board, for example a former independent member of the Appeal Board, for his/her determination which is final.

- 5.3** When the complaint is from a pharmaceutical company, the complaint must be signed or authorized in writing by the company's managing director or chief executive or equivalent and must state those clauses of the Code which are alleged to have been breached.

A complaint from a pharmaceutical company will be accepted only if the Director is satisfied that the company concerned has previously informed the company alleged to have breached the Code that it proposed to make a formal complaint and offered inter-company dialogue at a senior level in an attempt to resolve the matter, but that this offer was refused or dialogue proved unsuccessful. A formal statement detailing the actions taken must be provided. This requirement does not apply where the allegation is that a company has failed to comply with an undertaking that it has given and is in breach of Clause 29 of the 2019 Code (Clause 3.3 of the 2021 Code).

If, in the view of the Director, that condition has not been met, the complainant shall be so advised. If the complainant does not accept that view, the matter is referred to an independent referee identified by the Director and the Chair of the Appeal Board, for example a former independent member of the Appeal Board, for his/her determination which is final.

Attention is drawn to the availability of conciliation prior to making a complaint as referred to in Paragraph 18.2 below. Information about conciliation is available from the Director.

- 5.4** Upon receipt of a complaint, the company concerned has ten working days in which to submit its comments in writing.
- 5.5** When the respondent company's response is received, the case preparation manager must determine whether there is a *prima facie* case to answer under the Code. If, in the view of the case preparation manager, no *prima facie* case has been established, the complainant and the respondent company are so advised. If the complainant does not accept that view, the matter is referred to the Code of Practice Panel to determine whether or not there has been a breach of the Code. If the complainant submits further evidence, then the respondent company shall be invited to comment on that further evidence before the matter is referred to the Panel.
- 5.6** When a company advises the Authority that it may have breached the Code, the Director will treat the matter as a complaint. The company's response is invited. The case preparation manager may suggest the clauses of the Code to be addressed. When the response is received the procedure under Paragraph 5.5 above will be followed.
- 5.7** The parties must be notified that a case has been referred to the Panel.

6 Complaints Arising from Media Criticism

- 6.1** When it appears to the Director from media reports (other than letters to the editor of a publication) that a company may have breached the Code, the matter is treated as a complaint.

The author of the article, or the editor where no author is named, is treated as the complainant.

The author, or editor, is asked if they want to be involved in the case and whether they have any additional information to submit. The consequences of not being involved (no right of appeal and no right to comment on a respondent's appeal or the proposed text of the case report) must be explained in writing. If the author or editor declines involvement, this is stated in the case report.

- 6.2** A published letter from which it appears that a company may have breached the Code is dealt with as a complaint with the author being treated as the complainant. The procedure set out in Paragraph 6.1 above will be followed.

7 Code of Practice Panel – Rulings

- 7.1** Where the Panel rules that there is a breach of the Code, the complainant and the respondent company are so advised in writing and are given the reasons for the decision.

If the material or activity at issue is considered by the Panel to be likely to prejudice public health and/or patient safety, and/or it represents a serious breach of the Code, the Panel must decide whether, if there is subsequently an appeal by the respondent company, it would be required to suspend the use of the material or activity pending the final outcome of the case. If suspension would be required, the company must be so notified when it is advised of the Panel's ruling of a breach of the Code.

The respondent company has five working days to provide a written undertaking that the activity or use of the material in question and any similar material (if not already discontinued or no longer in use) will cease forthwith and that all possible steps will be taken to avoid a similar breach of the Code in the future. This undertaking must be signed by the managing director or chief executive or equivalent of the company or with his/her authority and must be accompanied by details of the actions taken by the company to implement the undertaking, including the date on which the material was finally used or appeared and/or the last date on which the activity took place.

In exceptional circumstances, an extension in the time allowed in which to respond may be granted at the discretion of the Director in accordance with Paragraph 14 below.

The company must also pay within twenty working days an administrative charge based on the number of matters ruled in breach of the Code.

- 7.2** Where the Panel rules that there is no breach of the Code, the complainant and the respondent company are so advised in writing and are given the reasons for the decision. Where the complaint is from a pharmaceutical company, the complainant must pay within twenty working days an administrative charge based on the number of matters alleged and ruled not to be in breach of the Code.

When advised of the outcome, the complainant will be sent a copy of the comments and enclosures submitted by the respondent company in relation to the complaint. If the respondent company objects to this because it regards part of the material as being confidential, and the matter cannot be settled by the Director, then it will be referred to an independent referee identified by the Director and the Chair of the Appeal Board, for example a former independent member of the Appeal Board, for his/her determination which is final.

- 7.3** The complainant or the respondent company may appeal against a ruling of the Panel to the Appeal Board. Appeals must be accompanied by reasons as to why the Panel's ruling is not accepted. These reasons will be circulated to the Appeal Board.

Notice of appeal must be given within five working days of notification of the Panel's ruling and the appeal must be lodged within ten days of notification of the Panel's ruling.

If the Panel has so required in accordance with Paragraph 7.1 above, where the respondent company gives notice of appeal it must, within five working days of notification of the Panel's ruling, suspend the use of the promotional material or activity at issue, pending the final outcome of the case, and must notify the Authority that such action has been taken.

If the respondent company accepts one or more of the Panel's rulings of breaches of the Code, but appeals one or more other such rulings, then within five working days of notification of the Panel's rulings it must provide the undertaking required by Paragraph 7.1 above in respect of the ruling or rulings which it is not appealing.

In exceptional circumstances, an extension in the time allowed in which to respond may be granted at the discretion of the Director in accordance with Paragraph 14 below.

- 7.4** Where an appeal is lodged by the complainant, the respondent company has five working days to comment on the reasons given by the complainant for the appeal and these comments will be circulated to the Appeal Board.

The complainant has five working days to comment on the respondent company's comments upon the reasons given by the complainant for the appeal and these comments will be circulated to the respondent company and the Appeal Board.

Relevant material previously submitted to the Panel is provided to the Appeal Board. All additional material which the complainant and the respondent company want the Appeal Board to consider must be submitted in writing with the appeal, with the respondent company's comments on the reasons given by the complainant for the appeal or with the complainant's comments on the respondent company's comments on the reasons given by the complainant for the appeal. No new material may be introduced when the appeal is heard by the Appeal Board.

In the event that the respondent company objects to certain of its comments being made available to the complainant on the grounds of confidentiality, and the matter cannot be settled by the Director, then it will be referred to an independent referee identified by the Director and the Chair of the Appeal Board, for example a former independent member of the Appeal Board, who will determine whether those particular comments can be included in the evidence which goes before the Appeal Board. The referee's decision is final.

- 7.5** Where an appeal is lodged by the respondent company, the complainant has five working days to comment on the reasons given by the respondent company for the appeal and these comments will be circulated to the respondent company and the Appeal Board.

Relevant material previously submitted to the Panel is provided to the Appeal Board. All additional material which the complainant and the respondent company want the Appeal Board to consider must be submitted in writing with the appeal or with the complainant's comments on the reasons given by the respondent company for the appeal. No new material may be introduced when the appeal is heard by the Appeal Board.

In the event that the respondent company objects to certain details of its appeal being made available to the complainant on the grounds of confidentiality, and the matter cannot be settled by the Director, then it will be referred to an independent referee identified by the Director and the Chair of the Appeal Board, for example a former independent member of the Appeal Board, who will determine whether those particular details can be included in the evidence which goes before the Appeal Board. The referee's decision is final.

Where an appeal is lodged by the respondent company, the complainant is sent a copy of the initial comments and enclosures submitted by the respondent company in relation to the complaint. If the respondent company objects to this because it regards part of the material as being confidential, and the matter cannot be settled by the Director, then it will be referred to an independent referee identified by the Director and the Chair of the Appeal Board, for example a former independent member of the Appeal Board, for his/her determination which is final.

- 7.6** Where the Panel rules no breach of the Code because it considers the matter of complaint is not within the scope of the Code the complainant and the respondent company are so advised in writing.

When advised of the outcome, the complainant will be sent a copy of the comments and enclosures submitted by the respondent company in relation to the complaint. If the respondent company objects to this because it regards part of the material as being confidential, and the matter cannot be settled by the Director, then it will be referred to an independent referee identified by the Director and the Chair

of the Appeal Board, for example a former independent member of the Appeal Board, for his/her determination which is final.

The complainant may appeal against the Panel's ruling to an independent referee identified by the Director and the Chair of the Appeal Board, for example a former independent member of the Appeal Board, for his/her determination which is final. An appeal must be accompanied by reasons as to why the Panel's ruling is not accepted. These reasons will be provided to the referee. The appeal must be lodged within ten working days of notification of the ruling of the Panel.

The respondent company has five working days to comment on the reasons given by the complainant for the appeal and these comments will be provided to the referee.

The complainant has five working days to comment on the respondent company's comments upon the reasons given by the complainant for the appeal and these comments will be provided to the respondent company and the referee.

In the event that the respondent company objects to certain of its comments being made available to the complainant on the grounds of confidentiality, and the matter cannot be settled by the Director, then the referee must decide whether he/she can take those comments into consideration when making his/her determination.

In such an appeal, the referee must consider no more than whether or not the matter of complaint is within the scope of the Code.

If the referee determines that the matter is not within the scope of the Code the complainant and the respondent company are so advised in writing.

If the referee determines that the matter is within the scope of the Code the complainant and the respondent company are so advised in writing. The case is referred back to the Panel for it to be considered on its merits and the procedure in Paragraph 5.5 above will be followed.

No administrative charges apply in relation to proceedings under Paragraph 7.6 and there will be no case reports.

8 Code of Practice Panel – Reports to the Code of Practice Appeal Board

8.1 Failure to comply with the procedures set out in Paragraphs 5 and 7 above will be reported to the Appeal Board.

8.2 The Panel may also report to the Appeal Board any company whose conduct in relation to the Code, or in relation to a particular case before it, or because it repeatedly breaches the Code such that it raises concerns about the company's procedures, warrants consideration by the Appeal Board. Such a report to the Appeal Board may be made notwithstanding the fact that a company has provided an undertaking requested by the Panel.

9 Action on Complaints about Safety from the Medicines and Healthcare products Regulatory Agency

9.1 In the event of the Medicines and Healthcare products Regulatory Agency making a complaint which relates to the safety or proper use of a medicine, and requesting that an advertisement be withdrawn, the respondent company has five working days to respond with its comments.

9.2 If the Panel upholds the complaint, the company is required to suspend the advertisement or practice forthwith pending the final outcome of the case.

10 Code of Practice Appeal Board – Rulings

10.1 Where the Appeal Board rules that there is no breach of the Code, the complainant and the respondent company are so advised in writing and are given the reasons for the decision.

Where a complainant pharmaceutical company appeals and the Appeal Board upholds the ruling that there is no breach of the Code, the complainant pharmaceutical company must pay within twenty working days an administrative charge based on the number of matters taken to appeal on which no breach is ruled.

Where a respondent company appeals and the Appeal Board rules that there is no breach of the Code, the complainant pharmaceutical company must pay within twenty working days an administrative charge based on the number of matters taken to appeal on which no breach is ruled.

10.2 Where the Appeal Board rules that there is a breach of the Code, the respondent company is so advised in writing and is given the reasons for the decision. The respondent company then has five working days to provide a written undertaking providing relevant information as specified in Paragraph 7.1 above.

The company must also pay within twenty working days an administrative charge based on the number of matters ruled in breach of the Code.

10.3 Where the Appeal Board rules that there is a breach of the Code, it may require the company to take steps to recover items given in connection with the promotion of a medicine or non-promotional items provided to health professionals and members of the public and the like. Written details of the action taken must be provided to the Appeal Board.

10.4 Where the Appeal Board rules that there is a breach of the Code, it may require an audit of the company's procedures in relation to the Code to be carried out by the Authority and, following that audit, decide whether to impose requirements on the company concerned to improve its procedures in relation to the Code. These could include a further audit and/or a requirement that promotional material be submitted to the Authority for pre-vetting for a specified period. The Authority must arrange for material

submitted for pre-vetting to be examined for compliance with the Code but it cannot approve such material. All of the costs of pre-vetting must be met by the company concerned.

The Appeal Board may also require an audit if a company repeatedly breaches the Code.

10.5 Where the Appeal Board rules that there is a breach of the Code, it may reprimand the company and publish details of that reprimand.

10.6 Where the Appeal Board rules that there is a breach of the Code, it may require the company to issue a corrective statement. Details of the proposed content and mode and timing of dissemination of the corrective statement must be provided to the Appeal Board for approval prior to use.

11 Reports to the Code of Practice Appeal Board

11.1 Where the Panel reports a company to the Appeal Board under the provisions of Paragraphs 8.1 and 8.2 above, or where the Panel reports the failure of a company to comply with the procedure set out in Paragraph 9 above, or where the Authority reports the failure of a company to comply with the procedures set out in Paragraph 10 above, the procedures set out below shall apply. These procedures also apply if the Appeal Board, having received a report on a case completed at the Panel level, in accordance with Paragraph 4.1 above, considers that additional sanctions may be appropriate.

11.2 The company concerned is provided with a copy of the report prior to its consideration and is entitled to have a representative or representatives appear before the Appeal Board to state the company's case.

A company may not be represented before the Appeal Board by a representative who is also a member of the Appeal Board except with the consent of the Chair. Such consent may be given only if the member of the Appeal Board can satisfy the Chair that no other person within his/her company can properly represent it in the matter in question.

11.3 The Appeal Board may:

- reprimand the company and publish details of that reprimand
- require an audit of the company's procedures in relation to the Code to be carried out by the Authority and, following that audit, decide whether to impose requirements on the company concerned to improve its procedures in relation to the Code; these could include a further audit and/or a requirement that promotional material be submitted to the Authority for pre-vetting for a specified period; the Authority must arrange for material submitted for pre-vetting to be examined for compliance with the Code but it cannot approve such material; all of the costs of pre-vetting must be met by the company concerned

- require the company to issue a corrective statement; details of the proposed content and mode and timing of dissemination of the corrective statement must be provided to the Appeal Board for approval prior to use
- require the company to take steps to recover items given in connection with the promotion of a medicine or non-promotional items provided to health professionals and members of the public and the like; written details of the action taken must be provided to the Appeal Board.

11.4 Where a company not in membership of the ABPI fails to comply with the procedures set out in Paragraphs 5, 7, 9 or 10 above and indicates that it no longer wishes to accept the jurisdiction of the Authority, the Appeal Board may decide to remove the company from the list of non member companies which have agreed to comply with the Code and advise the Medicines and Healthcare products Regulatory Agency that responsibility for that company under the Code can no longer be accepted.

The ABPI Board must be advised that such action has been taken.

12 Code of Practice Appeal Board – Reports to the ABPI Board

12.1 Where the Appeal Board considers that the conduct of a company in relation to the Code or a particular case before it warrants such action, it may report the company to the ABPI Board. Such a report may be made notwithstanding the fact that the company has provided an undertaking requested by either the Panel or the Appeal Board.

12.2 Where such a report is made to the ABPI Board, the ABPI Board may suspend or expel the company from the ABPI.

In the case of a company not in membership of the ABPI, the ABPI Board may remove the company from the list of non member companies which have agreed to comply with the Code and advise the Medicines and Healthcare products Regulatory Agency that responsibility for that company under the Code can no longer be accepted.

To assist it in deciding whether to suspend or expel a company or, in the case of a company not in membership of the ABPI, to remove the company from the list of non member companies which have agreed to comply with the Code, the ABPI Board may require an audit of the company's procedures in relation to the Code to be carried out by the Authority.

12.3 If a member of the ABPI Board is concerned in a case which has led to the report, as either complainant or respondent, that member does not receive a copy of the report and is required to withdraw from the ABPI Board during its consideration.

The company concerned is advised in advance of the membership of the ABPI Board and asked if it has any objections to particular members and the grounds for such

objections. Any member in respect of whom there are valid objections must withdraw from the ABPI Board during consideration of the report. The President (or Chair of the ABPI Board in the absence of the President) determines whether objections are valid.

Members of the ABPI Board must declare any other interest in a report prior to its consideration. Having consulted the company representative(s) (if present), the President (or Chair of the ABPI Board in the absence of the President) determines whether it is appropriate for a particular member to remain for the consideration of the report.

- 12.4** Where a report is made to the ABPI Board under Paragraph 12.1 above, the company concerned is provided with a copy of the report prior to its consideration and is entitled to have a representative or representatives appear before the ABPI Board to state the company's case.

13 Case Reports

- 13.1** At the conclusion of any case under the Code, the complainant is advised of the outcome and a report is published summarising the details of the case.

- 13.2** The respondent company and the medicine concerned are named in the report.

In a case where the complaint was initiated by a company or by an organisation or official body, that company or organisation or official body is named in the report. The information given must not, however, be such as to identify any individual.

Where expert assistance has been obtained by either the Panel or the Appeal Board, the report will include the name and qualifications of the expert concerned.

Where a company has been required to issue a corrective statement, the report will reproduce its text and provide details of how the corrective statement was disseminated.

- 13.3** A copy of the report on a case is sent to both the complainant and the respondent company prior to publication. Any amendments to the report suggested by these parties are considered by the Director, consulting with the other party where appropriate. If either party does not accept the Director's decision as to whether or not a report should be amended, the matter is referred to the Chair of the Appeal Board for his/her decision which is final.
- 13.4** Copies of all case reports are submitted to the Appeal Board prior to publication. Copies of the reports are sent to the ABPI Board for information following publication.
- 13.5** Full case reports in printed form are published each quarter by the Authority.

Copies of the reports are sent to the Medicines and Healthcare products Regulatory Agency, the Competition and Markets Authority, the Serious Fraud Office, the British

Medical Association, the Royal Pharmaceutical Society, the Royal College of Nursing and the Editors of the BMJ, The Pharmaceutical Journal and the Nursing Standard. Copies are also available to anyone on request.

- 13.6** In addition to the printed reports, full case reports appear on the Authority's website. The website also carries brief details of all complaints which are currently under consideration but not yet resolved and the texts and modes of dissemination of any corrective statements that companies have been required to issue during the previous twelve months. The Authority's website also carries interim case reports in respect of cases where publication of the final report is delayed because either the Appeal Board or the ABPI Board has required an audit of the respondent company's procedures in relation to the Code.

Access to the Authority's website is unrestricted.

- 13.7** Following publication of the relevant case reports, the Authority advertises in the medical, pharmaceutical and nursing press brief details of cases in which companies were ruled in breach of Clause 2 of the Code, were required to issue a corrective statement or were the subject of a public reprimand. Such advertisements also appear on the Authority's website. The companies concerned are required to contribute to the cost of the press advertisements.

General Provisions

14 Time Periods for Responding to Matters under the Code

The number of working days within which companies or complainants must respond to enquiries etc from the Authority, as referred to in the above procedures, is counted from the date of receipt of the notification in question.

An extension in time to respond to such notifications may be granted at the discretion of the Director.

15 Withdrawal of Complaints and Notices of Appeal

15.1 A complaint may be withdrawn by a complainant with the consent of the respondent company up until such time as the respondent company's comments on the complaint have been received by the Authority, but not thereafter.

15.2 Notice of appeal may be withdrawn by a complainant with the consent of the respondent company at any time but if notice is given by a complainant company after the papers relating to its appeal have been circulated to the Appeal Board, then the higher administrative charge will be payable.

15.3 Notice of appeal may be withdrawn by a respondent company at any time but if notice is given after the papers relating to its appeal have been circulated to the Appeal Board, then the higher administrative charge will be payable.

16 Code of Practice Levy and Charges

16.1 An annual Code of Practice levy is paid by members of the ABPI. The levy together with the administrative charges referred to in Paragraphs 7 and 10 above, the charges for audits carried out in accordance with Paragraphs 10.4, 11.3 and 12.2 above and the contributions to the cost of press advertisements referred to in Paragraph 13.7 above are determined by the ABPI Board subject to approval at a General Meeting of the ABPI by a simple majority of those present and voting.

16.2 Administrative charges are payable only by pharmaceutical companies and companies are liable for such charges whether they are members of the ABPI or not.

There are two levels of administrative charge.

The lower level is payable by a company which accepts either a ruling of the Panel that it was in breach of the Code or a rejection by the Panel of its allegation against another company. The lower level is also payable by a complainant company if a ruling of the Panel that there was a breach of the Code is subsequently overturned by the Appeal Board and by a respondent company if a ruling of the Panel that there was no breach of the Code is subsequently overturned by the Appeal Board.

The higher level is paid by a company which unsuccessfully appeals a ruling of the Panel.

16.3 Where two or more companies are ruled in breach of the Code in relation to a matter involving co-promotion, each company will be separately liable to pay any administrative charge which is payable.

16.4 Where a company advises the Authority that it may have breached the Code, and it is subsequently ruled in breach, any administrative charge payable will be one half of that which would otherwise have been due.

16.5 The number of administrative charges which apply in a case is determined by the Director. If a company does not agree with the Director's decision, the matter is referred to the Chair of the Appeal Board for his/her decision which is final.

16.6 Failure to pay any of the charges provided for by this paragraph must be reported by the Director to the Appeal Board or the ABPI Board as appropriate.

17 Scrutiny

17.1 The Authority arranges for the scrutiny of samples of advertisements, detail aids, leavepieces, other promotional items and meetings on a continuing basis in relation to the requirements of the Code.

Members of the Authority must not carry out scrutiny.

To facilitate such scrutiny, the Director may request relevant material from pharmaceutical companies, including copies of the certificates authorizing such material, and companies must respond to such requests within ten working days.

17.2 Where a possible breach of the Code is identified under this procedure by the scrutineer, the company concerned is requested to comment in writing within ten working days of receipt of the notification.

17.3 If the company accepts that there is a breach of the Code, the company is requested to provide an undertaking providing the information specified in Paragraph 7.1 above. No administrative charge will be payable in these circumstances and there will be no case report on the matter in question.

17.4 If the company does not accept that there is a breach of the Code and, having considered the company's comments, the scrutineer decides that there is no case to answer under the Code, then the procedure is brought to a close. There will be no case report on the matter in question.

17.5 If the company does not accept that there is a breach of the Code but, having considered the company's comments, the scrutineer considers that a case has been established, the matter will be dealt with as a complaint.

18 Provision of Advice and Assistance with Conciliation

- 18.1** The Authority is willing and able to provide informal guidance and advice in relation to the requirements of the Code and, where appropriate, may seek the views of the Appeal Board.
- 18.2** Companies wishing to seek the assistance of a conciliator with the view to reaching agreement on inter-company differences about promotion may contact the Director for advice and assistance.

19 Amendments to the Code of Practice and Constitution and Procedure

- 19.1** The Code and this Constitution and Procedure may be amended by a simple majority of those present and voting at a General Meeting of the ABPI.

Notwithstanding the above, where a proposal to amend the Code or this Constitution and Procedure arises solely from the ABPI's obligation to comply with any code promulgated by the European Federation of Pharmaceutical Industries and Associations (EFPIA), then the ABPI Board may decide that formal approval at an ABPI General Meeting is not necessary. ABPI member companies must nonetheless be consulted in relation to the proposed texts of the changes.

- 19.2** The views of the Authority and the Appeal Board must be sought on any proposal to amend the Code or this Constitution and Procedure. The views of the Medicines and Healthcare products Regulatory Agency, the Competition and Markets Authority, the Serious Fraud Office, the British Medical Association, the Royal Pharmaceutical Society and the Royal College of Nursing must also be invited.

Notwithstanding the above, where the ABPI Board has decided, in accordance with Paragraph 19.1 above, that formal approval of the proposal at an ABPI General Meeting is not necessary, then the bodies referred to above need only be informed of the changes which are to be made.

- 19.3** The Authority and the Appeal Board may, in the light of their experience, make recommendations for amendment of the Code and this Constitution and Procedure.

20 Annual Report

An annual report of the Authority is published each year with the approval of the Appeal Board. This report includes details of the work of the Authority, the Panel and the Appeal Board during the year and provides a list of all companies ruled in breach of the Code during the year which specifically identifies those ruled to have breached Clause 2.

GUIDELINES ON COMPANY PROCEDURES RELATING TO THE ABPI CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY

It is important for companies to have policies and standard operating procedures (SOPs) to communicate corporate standards, expectations and behaviour. These might be a mixture of global, regional and local SOPs. Company documents should support compliance, ensure consistency, manage risk and provide a platform for continuous improvement. It should be clear and apparent to all staff which requirements are relevant to their role. These policies and SOPs are minimum requirements which should be adapted to fit the arrangements at a particular company. The introduction of the new ABPI Principles should also be reflected where appropriate. The PMCPA will not adjudicate on the ABPI Principles.

Companies' Code related policies and procedures should be in line with the ABPI Code requirements, but of course, companies are fully entitled to have policies and procedures that impose higher standards than the ABPI Code. The ABPI Code reflects and extends beyond relevant UK legislation and ensures that the ABPI meets its commitments to implement other codes, such as the IFPMA and EFPIA Codes.

The guidelines, which are published on the PMCPA website, are regarded as best practice and should be adapted to fit in with the arrangements at any particular company. Paragraphs 10.4, 11.3 and 12.2 of the Constitution and Procedure for the PMCPA variously authorise the Code of Practice Appeal Board or the ABPI Board to require an audit of a company's procedures in relation to the ABPI Code to be carried out by the PMCPA. During such audits, the PMCPA will review a company's policies and SOPs and their implementation, including but not limited to those relating to the Code. A company's website may also be reviewed and should be up-to-date and accurate at all times. It is likely that an audit would also include a discussion about the company's implementation of the ABPI Principles.

The guidelines do not cover all aspects of the Code and are thus no substitute for a detailed study of the Code as a whole, including the supplementary information.

LEGISLATION, OTHER CODES AND GUIDELINES

Legislation

The Human Medicines Regulations 2012 as amended
2012 No. 1916

The Human Medicines (Amendment) (No. 2) Regulations
2014 No. 1878

The Consumer Protection from Unfair Trading Regulations 2008
2008 No. 1277

Directive 2001/83/EC on the Community Code relating to
medicinal products for human use, as amended by Directive
2004/27/EC

Bribery Act 2010

Data Protection Act 2018

Other Codes

International

IFPMA Code of Practice (International Federation of
Pharmaceutical Manufacturers and Associations)

EFPIA Code of Practice (European Federation of Pharmaceutical
Industries and Associations)

WHO Ethical Criteria for Medicinal Drug Promotion, Geneva 1988
(World Health Organisation)

IPCAA International Healthcare Congress Guidelines
(International Pharmaceutical Congress Advisory Association)

United Kingdom

The UK Code of Non-broadcast Advertising and Direct &
Promotional Marketing (Committee of Advertising Practice/
Advertising Standards Authority)

Codes of Practice for Advertising Over-the-Counter Medicines
– the PAGB Consumer Code and the PAGB Professional Code
(Proprietary Association of Great Britain – PAGB)

BMA 'Medical ethics today' (British Medical Association)

General Medical Council 'Ethical guidance for doctors'

General Pharmaceutical Council 'Standards
for pharmacy professionals'

Nursing & Midwifery Council 'Professional standards of behaviour
for nurses, midwives and nursing associates'

NHS England Standards of Business Conduct Policy, 2019

NHS Managing Conflicts of Interest: Revised statutory guidance
for CCGs [Clinical Commissioning Groups] 2017

Joint Statement from the chief executives of statutory regulators
of health and care professionals

Guidelines

Advertising and Promotion of Medicines in the UK (2020) – The
Blue Guide (Medicines and Healthcare products Regulatory
Agency). It includes Disease Awareness Campaign Guidelines
and Medicines which are promoted for use during pregnancy –
Guidance for the pharmaceutical industry

Best practice guidance on joint working between the NHS and
the pharmaceutical industry and other relevant commercial
organisations (Department of Health)

Moving beyond sponsorship: interactive toolkit for joint working
between the NHS and the pharmaceutical industry (Department
of Health/ABPI)

ABPI Guidance notes on joint working between pharmaceutical
companies and the NHS and others for the benefit of patients,
March 2009

Joint Position on the Disclosure of Clinical Trial Information
via Clinical Trial Registries and Databases 2009
(www.ifpma.org/resources/position-papers)

Joint Position on the Publication of Clinical Trial Results
in the Scientific Literature 2010
(www.ifpma.org/resources/position-papers)

The Legal & Ethical Guidelines for Healthcare Market Research
(British Healthcare Business Intelligence Association)

PMCPA GUIDANCE is available at www.pmcpa.org.uk

