PMCPA | Prescription Medicines Code of Practice Authority

PMCPA Guide to the proposed 2021 ABPI Code of Practice for the Pharmaceutical Industry

This PMCPA Guide gives a brief introduction to the proposed 2021 ABPI Code for the Pharmaceutical Industry setting out the major changes some of which are illustrated by graphics/charts at the end of this Guide.

The current 2019 ABPI Code reflects and extends beyond relevant UK law and ensures that the ABPI meets its commitments to implement other codes, such as the IFPMA and EFPIA Codes. This approach has been maintained when drafting the proposed 2021 ABPI Code.

It is not possible to list each and every change. The proposed 2021 ABPI Code supplied as part of the consultation includes the new clause numbers as well as references to the corresponding clause numbers (or supplementary information) in the 2019 ABPI Code. For those who would like more detailed information the PMCPA will publish working documents on its website (www.pmcpa.org.uk) to provide more background including a presentation. When responding to the consultation please concentrate on the content of the Code and consider the supporting materials in that context.

Every effort has been made to ensure that the proposed 2021 ABPI Code is of a high standard. In addition to commenting on substantive matters, we also welcome the identification of every error or inconsistency however trivial it might seem.

If you have any questions or queries about the proposed ABPI Code, please do not hesitate to contact the PMCPA.

A Background

The PMCPA was mandated by the ABPI Board at the end of 2019 to produce the proposed 2021 ABPI Code of Practice. The ABPI Board agreed in early June that the proposed 2021 ABPI Code should be issued for consultation. The ABPI Code has been updated to:

1 Reflect the structure of the 2019 EFPIA Code of Practice which is a consolidation of the three EFPIA Codes, namely:

- EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals
- EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations and
- EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations.

The objectives of the EFPIA consolidation were to simplify, clarify, harmonise and remove repetition and this led to consequential and other changes. As a member of EFPIA, the ABPI is required to implement the EFPIA Code. The proposed 2021 ABPI Code reflects the 2019 EFPIA Code.

2 Address the three themes identified by the Code Working Group and endorsed by the ABPI Board, which are:

i) further develop principles
ii) ensure the Code is accessible
iii) future proofing the Code where possible.

3 Incorporate regular updates resulting from cases considered etc.

Together the resultant changes provide a new look and approach. The key changes are set out below. It will take all those who use the Code time to become familiar with its new layout and content particularly as a number of sections of the Code might be relevant to an activity/material and the need to always cross refer to the definitions. This document and other supporting materials are intended to support those reviewing the Code during the consultation and implementing the new 2021 Code once it is agreed.

B High Level Overview of Proposed 2021 ABPI Code of Practice

1 Structure

Reflecting a similar structure to the 2019 EFPIA Code, the clauses of the proposed 2021 ABPI Code are set out in six sections, each colour coded to support navigation as follows:

Code Section Title	Colour
Overarching Requirements	Grey
Promotion to Health Professionals and Other Relevant Decision Makers	Blue
Interactions with Health Professionals, Other Relevant Decision Makers and Healthcare Organisations	Green
Interactions with Health Professionals, Other Relevant Decision Makers, Healthcare Organisations, Patient Organisations and The Public including Patients, Journalists etc	Yellow
Interactions with The Public including Patients, Journalists etc and Patient Organisations	Pink
Annual Disclosure Requirements	Teal

As a consequence, allocation of clauses from the 2019 ABPI Code into the relevant section of the proposed 2021 ABPI Code has seen some clauses:

- split between more than one section
- duplicated as they are required to be in more than one section
- updated to reflect EFPIA requirements
- updated to future proof the Code or improve clarity, or
- deleted as they are no longer required.

Some of the duplication of clauses in the proposed 2021 ABPI Code is seen as essential to support understanding of the requirements, particularly during the transition to the new format. This will be reviewed during the development of subsequent codes. Clauses 3.1, 12.1, 15.1, 24.1 and 26.1 of the 2019 ABPI Code have been duplicated.

The supplementary information is essential for the delivery of proportionate regulation and to give appropriate additional information to that contained in the relevant clause. As with the clauses similar work has been carried out on the supplementary information in the 2019 ABPI Code and so in the proposed 2021 ABPI Code some has been:

- deleted as it is no longer required (or moved to Q&A)
- split between more than one section
- duplicated where necessary
- updated as needed to reflect the relevant clause, or
- included in the relevant clause.

In the final version of the 2021 Code the supplementary information will be published adjacent to the relevant clause (as in the 2019 ABPI Code) but is currently positioned at the end of each section in the proposed 2021 ABPI Code.

2 ABPI Principles

Principles and an overview of self regulation were first introduced in the 2019 Code. The principles, amended and developed further by the ABPI, are now based on the EFPIA principles which were introduced in the 2019 EFPIA Code and also take account of the IFPMA Ethos. There are now four primary principles: Patients, Integrity, Transparency and Respect. The overview of self regulation will be included in the introduction to the 2021 ABPI Code.

3 Accessibility

The new structure of the proposed 2021 Code is similar to that of the 2019 EFPIA Code and as such introduces an overarching section as well as sections relating to specific stakeholders. These changes in structure aim to improve understanding, usability and navigation.

The updated PMCPA website, launched in December 2019, provided a new platform and format for the interactive Code with improved functionality which has been welcomed. Once approved an interactive version of the 2021 ABPI Code will also be available on this platform. The interactive Code works on many devices, including mobile phones, and will help users find relevant sections of the Code, associated cases and relevant Q&A. This will improve understanding and support good compliance decisions. A PDF of the Code will also be available. As in the 2019 ABPI Code, when finalised the supplementary information will be positioned alongside the relevant clause.

4 Future Proofing

The language used in the Code has been updated to improve clarity, to help future proof the Code and to assist in the transition to the new format. This includes making it clear that the requirements of the Code apply to all types of communication and interaction including those via digital channels. It is the content, target audience, use and reach of a platform which are important factors not the channel *per se*.

C Overview of Sections of the Code

A visual of the sections of the Code and how they interrelate can be found in Appendix 2.

1 Overarching Requirements (Grey Section)

This is a pivotal section of the proposed 2021 ABPI Code. It sets out requirements which need to be considered in relation to all activities, materials, interactions, relationships etc in scope of the Code. It provides umbrella requirements under which companies should work, for example it includes definitions, obligations, responsibilities as well as quality standards.

2 Promotion to Health Professionals and Other Relevant Decision Makers (Blue Section)

The requirements in this section have had few amendments compared with the similar requirements in the 2019 ABPI Code.

3 Interactions with Health professionals, Other Relevant Decision Makers and Healthcare Organisations (Green Section)

This section includes requirements for collaborative working (which includes joint working) and the provision of medicines and samples. It also includes the prohibition of inducements.

4 Interactions with Health Professionals, Other Relevant Decision Makers, Healthcare Organisations, Patient Organisations and the Public including Patients and Journalists (Yellow Section)

The harmonisation of the EFPIA codes means that requirements for certain activities which previously only applied when companies interacted with certain groups, now apply more broadly. Patient organisations and individuals representing patient organisations are now incorporated in many areas of the Code such as donations and grants, sponsorship (including events/meetings) which previously only referred to health professionals, other relevant decision makers, healthcare organisations etc. Similarly, health professionals, other relevant decision makers and healthcare organisations have been incorporated into areas of the Code which previously only referred to patient organisations. Members of the public etc are now also included in the requirements for contracted services.

5 Interactions with the Public including Patients, Journalists etc and Patient Organisations (Pink Section)

This section includes areas which apply solely to these groups and therefore cannot be included in other sections such as the provision of information to the public, patients and the media, and specific requirements for relationships with patient organisations.

6 Annual Disclosure (Teal Section)

This section includes the proposal for disclosing Code related contracted services provided by members of the public etc and the introduction of a methodological note for this disclosure and for patient organisation disclosures.

D Proposed changes to the 2019 ABPI Code

Given the extent of the changes it is not possible to list each and every change and the reason for that change as in previous consultations. Many of the changes are as a result of the incorporation of the EFPIA Code updates, the change in the format, new definitions etc.

i) Changes as a consequence of the 2019 EFPIA Code

1 Definitions are an important component to understanding the requirements of the EFPIA Code. These have been adopted and together with other definitions from the 2019 ABPI Code have been incorporated into the proposed 2021 ABPI Code. These are key clauses of the proposed 2021 ABPI Code and should be referred to when using the subsequent sections. A few new definitions are Donations and Grants, Events (which includes meetings), Sponsorship and Support.

2 Donations and Grants have been included in detail, expanded to apply to patient organisations and will replace what were medical educational goods and services (MEGS) in the 2019 ABPI Code. MEGS can be still be provided as either Donations or Grants.

3 Patient Organisations and individuals representing patient organisations have been incorporated into certain general requirements covering a range of stakeholders (rather than their own separate requirements), these are:

- Donations and Grants
- Sponsorship of organisations in relation to Events and Meetings and other activities
  - Contracted Services
  - Disclosure.

ii) Other Changes

1 Collaborative Working with healthcare organisations (and others) has been introduced as a means of recognising that there might be some projects which cannot show a direct benefit to patients and thus could not be Joint Working as defined by the Department of Health and set out in the 2019 Code, Clause 20. 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. Joint Working must continue to be patient centred and always benefit patients and is thus now an example of collaborative working. Some of the previous language for MEGS (2019 Code, Clause 19) has been adapted.

2 The introduction of collaborative working is to better accommodate the range of activities companies may wish to undertake.

3 A proposal such that where members of the public (patients, journalists etc) provide contracted services similar to those provided by health professionals etc covered in the 2019 ABPI Code, Clause 23, then these are also covered by the proposed 2021 ABPI Code.

4 A proposal to update Annual Disclosure requirements to include an additional requirement to disclose in aggregate payments to members of the public not representing a patient organisation to include patients, journalists etc. This was thought to be a needed disclosure particularly following the publication of the EFPIA guidance 'Working together with patients – Principles for remunerating patients, patient organisation representatives and carers for work undertaken with the pharmaceutical industry'.

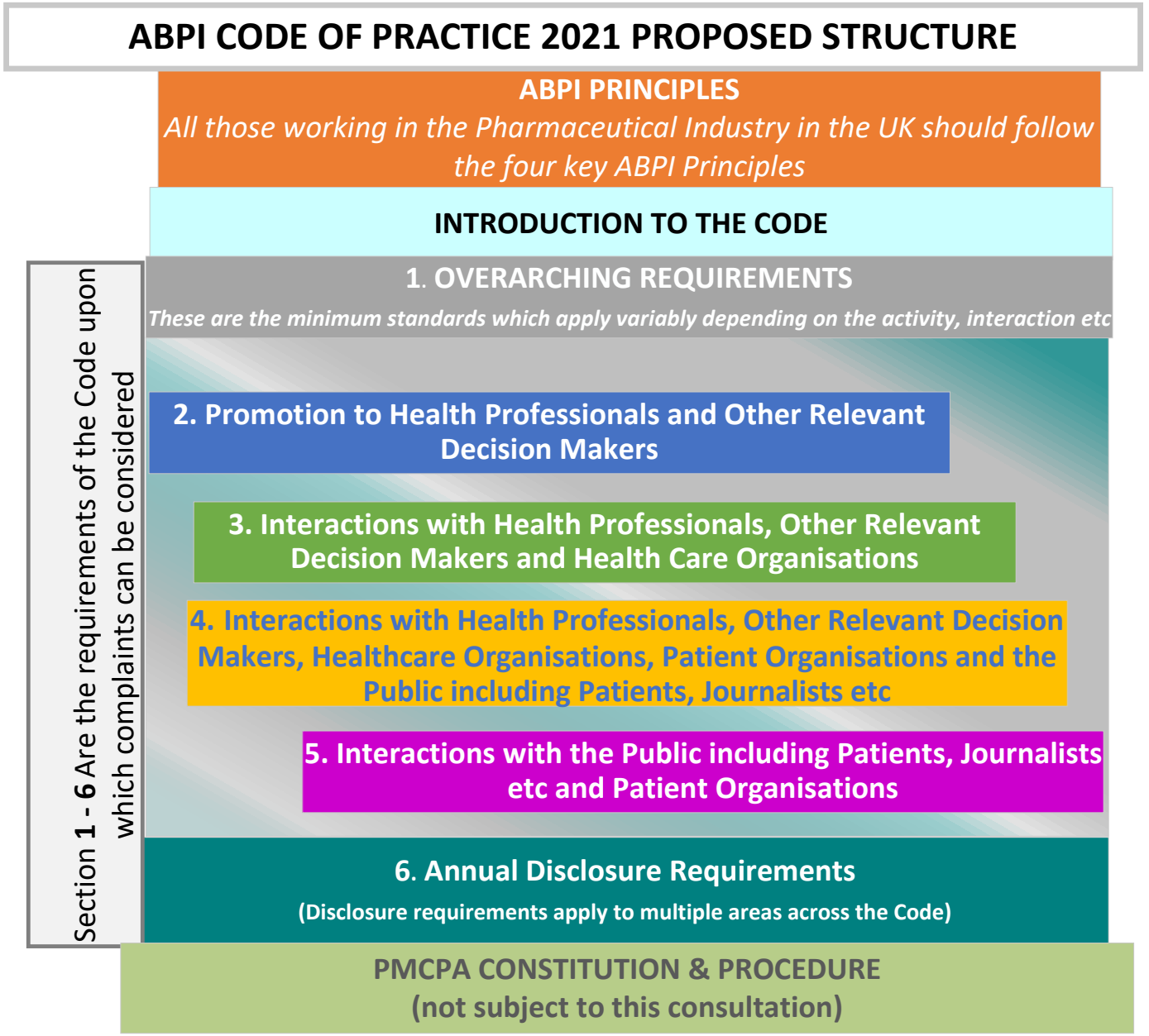
5 An optional template has been developed which companies can use to fulfil the obligation to disclose payments to patient organisations and members of the public etc.

6 The wording on the obligatory template has been updated to reflect the new clause numbers and to reflect the introduction of collaborative working.

E How to use the Code

The new format will support either an audience-led or activity-led approach (see below for a schematic relating to audience). A number of sections of the Code, including the Overarching Requirements (Grey Section), will apply to either approach.

Prescription Medicines Code of Practice Authority 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT
Tel: 020 7747 8880 **Fax:** 020 7747 8881 **Email:** info@pmcpa.org.uk **www.pmcpa.org.uk**



Prescription Medicines Code of Practice Authority 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT
Tel: 020 7747 8880 **Fax:** 020 7747 8881 **Email:** info@pmcpa.org.uk **www.pmcpa.org.uk**

Brief overview of 2019 EFPIA Code and 2021 ABPI Code Structure

2019 EFPIA CODE

- DEFINITIONS
- PREAMBLE
- INTRODUCTION
- SCOPE OF THE EFPIA CODE
- APPLICABILITY OF THE EFPIA CODE

CHAPTER 1 PROMOTION OF POM TO HCPs
- Article 1 Marketing authorization
- Article 2 Information to be made available
- Article 3 Promotion and its substantiation
- Article 4 Use of quotations in Promotion
- Article 5 Acceptability of Promotion
- Article 6 Distribution of Promotion
- Article 7 Transparency of Promotion
- Article 8 Promotional information provided during international Events
- Article 9 Personal medical matters

CHAPTER 2 INTERACTIONS WITH HCPs, HCOs AND POs
- Article 10 Events and hospitality
- Article 11 Prohibition of Gifts
- Article 12 Donations and Grants to HCOs and POs
- Article 13 Contribution to Cost of Events and Sponsorship
- Article 14 Member Company funding
- Article 15 Contracted services

CHAPTER 3 SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH HCPs AND HCOs
- Article 16 Medical education
- Article 17 Informational or Educational Materials, and Items of Medical Utility
- Article 18 Non-Interventional Studies
- Article 19 Medical Samples
- Article 20 Member Company Staff

CHAPTER 4 SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH POs
- Article 21 Interactions with POs

CHAPTER 5 DISCLOSURE OF TRANSFERS OF VALUE FROM MEMBER COMPANIES
- Article 22 Disclosure of ToVs to HCPs & HCOs and POs
- Article 23 Disclosure of ToVs to HCPs and HCOs
- Article 24 Disclosure of support and services provided to POs

CHAPTER 6 PROCEDURAL REQUIREMENTS

PROPOSED 2021 ABPI CODE STRUCTURE

PAGE	NEW CLAUSE #	Section	2019 Code Clauses
		Introduction to the Code	
Page 2		ABPI PRINCIPLES	
Grey Section		Overarching Requirements	
Page 3	Clause 1	Scope of Code Definition of Certain Terms	Clauses 1.1 & 28.2 Clause 1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1.8, 1.9, 1.10, 13.2, 17si, 23.2si, 24.1si, 27.1 (collaborative working, contribution to costs related to events, events, patient organisation representative, sponsorship, support, third party)
Page 6	Clause 2	Upholding Confidence in the Industry	Clause 2
Page 6	Clause 3	Obligations	Clauses 1.11, 1.12, 3.1, 12.1, 26.1 & 29
Page 6	Clause 4	Responsibilities	Clauses 13.1, 13.3, 24.1, 25.1, 25.2, 27.7 & 27.8
Page 7	Clauses 5 - 10	Quality Standards High Standards and Suitability Clauses 5 Information, Claims and Comparisons Clauses 6 Use of Quotations Clauses 7 Certification and Examination Clauses 8 Training Clauses 9 Events, Meetings and Hospitality Clauses 10	Clauses 7.2, 7.4, 7.8, 7.9, 7.11, 8.1, 8.2, 9.1, 9.2, 9.3, 9.7, 9.10, 10.2, 10.3, 11.1, 14.1, 14.2, 14.3, 14.4, 14.5, 14.6, 15.1, 16.1, 16.2, 16.3, 16.4, 18.1si, 18.3, 18.3si, 22.1, 22.2, 22.3, 22.4, 22.5 & 28.6
Blue Section		Promotion to Health Professionals/ Other Relevant Decision Makers	
Page 23	Clause 11	Marketing Authorisation	Clause 3.1, 3.2
Page 23	Clause 12	Prescribing Information and Other Obligatory information	Clause 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.8, 4.9, 4.10
Page 24	Clause 13	Abbreviated Advertisements	Clause 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9
Page 26	Clause 14	Information, Claims and Comparisons	Clause 6.2, 7.3, 7.6, 7.7, 7.10
Page 26	Clause 15	High Standards, Format and Causing Offence	Clause 9.4, 9.5, 9.6, 9.8, 9.9, 12.1
Page 26	Clause 16	Material and Distribution	Clause 10.1, 11.2, 11.3, 28.1, 28.4
Page 27	Clause 17	Representatives	Clause 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	
Page 35	Clause 18	Information, Claims and Comparisons	Clause 7.1, 7.5
Page 35	Clause 19	Prohibition on Inducements and Inappropriate Payments and the Provision of Items to Health Professionals	Clause 18.1, 18.2
Page 35	Clause 20	Collaborative Working	Clause 20
Page 36	Clause 21	Provision of Medicines and Samples	Clause 17.1, 17.2, 17.2, 17.3, 17.4, 17.5, 17.6, 17.7, 17.8, 17.9, 17.10
Page 37	Clause 22	Non-Interventional Studies of Marketed Medicines	Clause 13.4
Yellow Section		Interactions with Health Professionals, Other Relevant Decision Makers, Healthcare Organisations, Patient Organisations and The Public including Patients, Journalist etc	
Page 43	Clause 23	Donations and Grants	MEGS in the form of Donations and Grants in Clause 19.1, 19.2,
Page 43	Clause 24	Contracted Services	Clause 21, 23.1, 23.2, 23.3, 23.4, (27.8 incorporated)
Page 45	Clause 25	Relationships with Health Professionals, Other Relevant Decision Makers, Healthcare Organisations and Patient Organisations	Clause 27.4, 27.5, 27.9, 12.2
Pink Section		Interactions with The Public including Patients, Journalists etc and Patient Organisations	
Page 50	Clause 26	Relations with the Public including Patients, Journalists etc	Clause 18.2si, 26.1, 26.2, 26.3, 26.4, 26.5
Page 50	Clause 27	Relationships with Patient Organisations	Clause 27.1, 27.2, 27.3, 27.6
Teal Section		Annual Disclosure Requirements	
Page 55	Clause 28	Annual Disclosure of Transfers of Value to Health Professionals, Other Relevant Decision Makers, Healthcare Organisations	Clause 24.1, 24.2, 24.7, 24.8, 24.9, 24.10
Page 55	Clause 29	Annual Public Disclosure of Contracted Services, Donations, Grants and Sponsorship provided to Patient Organisations	EFPIA Requirement
Page 56	Clause 30	Annual Public Disclosure of Contracted Services Provided by The Public including Patients, Journalists etc	EFPIA Requirement
Page 56	Clause 31	Timings, Duration and Retention of Disclosure	Clause 24.4, 24.5, 24.6
		CONSTITUTION AND PROCEDURE	

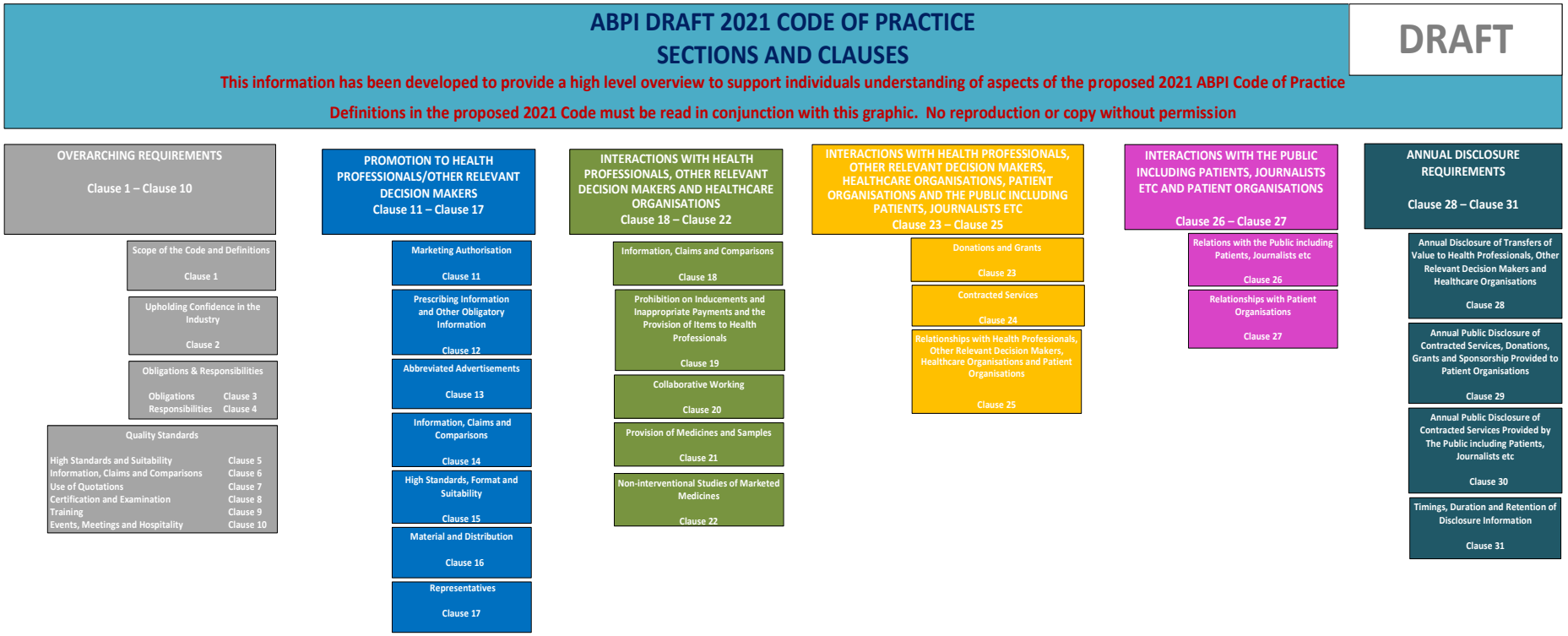
Prescription Medicines Code of Practice Authority 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT
Tel: 020 7747 8880 **Fax:** 020 7747 8881 **Email:** info@pmcpa.org.uk **www.pmcpa.org.uk**

APPENDIX CONTENTS

APPENDIX CONTENTS

Prescription Medicines Code of Practice Authority 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT
Tel: 020 7747 8880 **Fax:** 020 7747 8881 **Email:** info@pmcpa.org.uk **www.pmcpa.org.uk**

APPENDIX 1– Overview of Sections with Clause Names and Numbers



Prescription Medicines Code of Practice Authority 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT
Tel: 020 7747 8880 **Fax:** 020 7747 8881 **Email:** info@pmcpa.org.uk **www.pmcpa.org.uk**

APPENDIX 2– Overview of Activities

2021 Draft ABPI Code - Activities by Organisation / Individuals

This information has been developed to provide a high level overview to support individuals understanding of aspects of the proposed 2021 ABPI Code of Practice

Definitions in the proposed 2021 Code must be read in conjunction with this graphic

DRAFT

Health Professional (HCP) or Other Relevant Decision Maker (ORDM)

- Support for HCP/ORDM attendance at events/meetings
- Promotion to Health Professionals and Other Relevant Decision Makers
- Medicines and Samples
- Contracted Services

Healthcare Organisation (HCO), Institution or Third Party Organisation

- Sponsorship of an activity (including events/meetings or material) –
- Collaborative Working
- Non-Interventional Studies
- Donations and Grants
- Contracted Services

Patient Organisations

- Sponsorship of an activity (including events/meetings or material)
- Donations and Grants
- Contracted Services
- Interactions with Members of the Public including Patients, Journalists etc and Patient Organisations

The Public Including Patients, Journalists etc

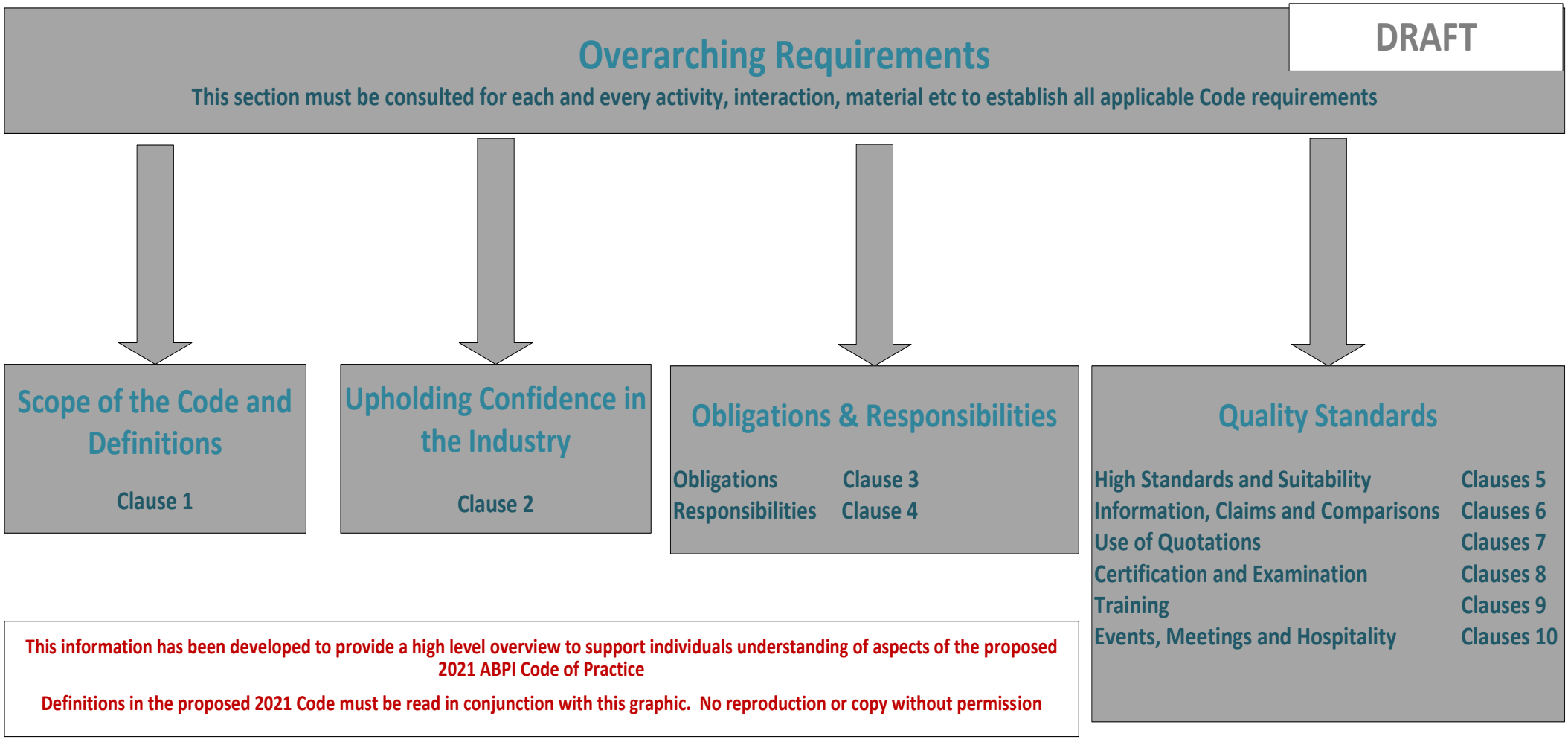
- Events/Meetings and Hospitality
- Contracted Services
- Interactions with the Public including Patients, Journalists etc and Patient Organisations

Overarching Requirements Section must be consulted

- Annual Disclosure
- Annual Disclosure
  - Medicines and Samples are not subject to the requirements for the disclosure of transfers of value
- Annual Disclosure
- Annual Disclosure

Prescription Medicines Code of Practice Authority 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT
Tel: 020 7747 8880 **Fax:** 020 7747 8881 **Email:** info@pmcpa.org.uk **www.pmcpa.org.uk**

APPENDIX 3 –Overarching Requirements



Prescription Medicines Code of Practice Authority 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT
Tel: 020 7747 8880 **Fax:** 020 7747 8881 **Email:** info@pmcpa.org.uk **www.pmcpa.org.uk**

APPENDIX 4 – Obligations and Responsibilities within Overarching Requirements

Obligations Clause 3

Clause 3 Obligations

3.1 (3.1) A medicine must not be promoted prior to the grant of the marketing authorization 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 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 (New Clause) Gifts for personal benefit (such as sporting or entertainment tickets, social courtesy gifts) are prohibited and must not be given, either directly or indirectly, to any individual health professionals, other relevant decision makers or individuals associated with healthcare organisations or patient organisations.

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.

Responsibilities Clause 4

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 also have a scientific service to deal with the approval and supervision of non-interventional studies. This scientific service must include a registered medical practitioner, or a pharmacist registered in the UK, who will be responsible for the oversight of non-interventional studies (including the review of any responsibilities relating to such studies, particularly those given to 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 & 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 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, carers, journalists etc 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.

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.

Prescription Medicines Code of Practice Authority 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT
Tel: 020 7747 8880 **Fax:** 020 7747 8881 **Email:** info@pmcpa.org.uk **www.pmcpa.org.uk**

APPENDIX 5 – Certification and Examination

DRAFT

<table>
<tr><th colspan="4">Proposed 2021 ABPI Code of Practice</th></tr>
<tr><th colspan="3">Certification (Clause 8)
(names must be notified to the MHRA and PMCPA)</th><th>Examination</th></tr>
<tr><td colspan="2">HCP Signatory
Note: The HCP Signatory may also carry out the role of the AQP Signatory and the AQP
Note: the HCP signatory 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.</td><td>HCP Signatory or Appropriately Qualified Person Signatory (AQP Signatory)</td><td>HCP Signatory or Appropriately Qualified Person (AQP)</td></tr>
<tr><td>Promotional (Clause 8.1)</td><td>Non-Promotional (Clause 8.3)</td><td>(Clause 8.2)</td><td rowspan="2">• the final form of printed materials prior to use, such materials will have been electronically certified prior to printing
• arrangements for UK meetings
• corporate advertising
• financial information to inform shareholders, the Stock Exchange and the like
• press releases
• written responses from medical information departments or similar to unsolicited enquiries from the public etc.
• market research materials</td></tr>
<tr><td>• All Promotional material</td><td>• 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 described in Clause 20 and its supplementary information
• material and items relating to a patient support programme whether provided directly to patients or to health professionals to be passed on to patients as described in Clause 19.2 and 26.3 and associated supplementary information
• donations and grants including relevant internal company and service provider instructions, as described in Clause 23.2 and the written agreement for donations and grants to patient organisations
• protocols relating to non-interventional studies.</td><td>• all events/meetings involving travel outside the UK (unless the company's only involvement is to support a speaker to present at a meeting)</td></tr>
<tr><td colspan="3">Note: Appropriately Qualified Person Signatory (AQP signatory): 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, 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.

The names of the nominated AQP signatory must be notified in advance to the MHRA and to the PMCPA. Changes in the names of nominees must be promptly notified.
Last updated 110620</td><td>Note: Some companies may choose to certify these materials
It is for companies to decide how Examination is performed and who has the experience and expertise to be the AQP for each category. The names of the AQPs nominated for Examination <u>do not</u> need to be notified to the MHRA or the PMCPA.</td></tr>
</table>

Prescription Medicines Code of Practice Authority 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT
Tel: 020 7747 8880 **Fax:** 020 7747 8881 **Email:** info@pmcpa.org.uk **www.pmcpa.org.uk**

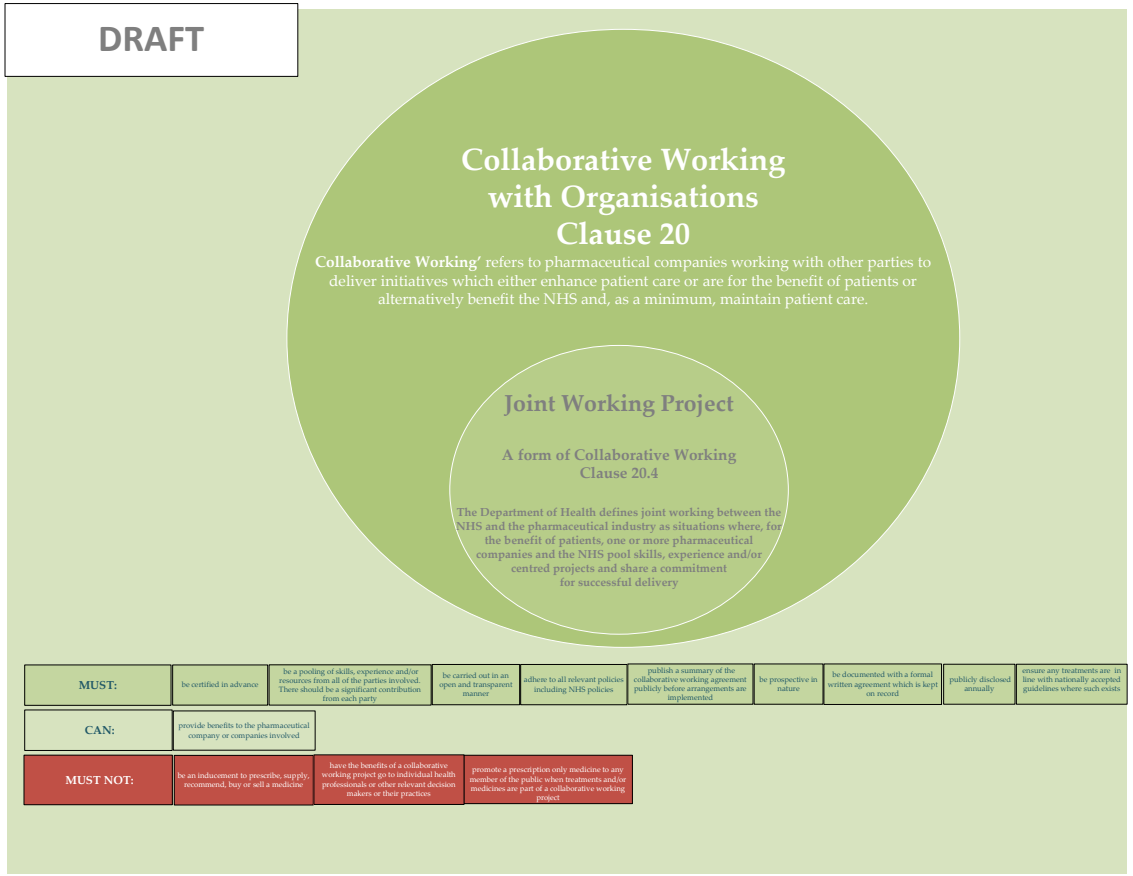
The Prescription Medicines Code of Practice Authority (PMCPA) was established by The Association of the British Pharmaceutical Industry (ABPI) to operate the ABPI Code of Practice for the Pharmaceutical Industry independently of the ABPI. The PMCPA is a division of the ABPI which is a company limited by guarantee registered in England & Wales no 09826787, registered office 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT.

APPENDIX 6 – Collaborative Working with Organisations

Collaborative Working with Healthcare Organisations, Institutions and Third Party Organisation Providers

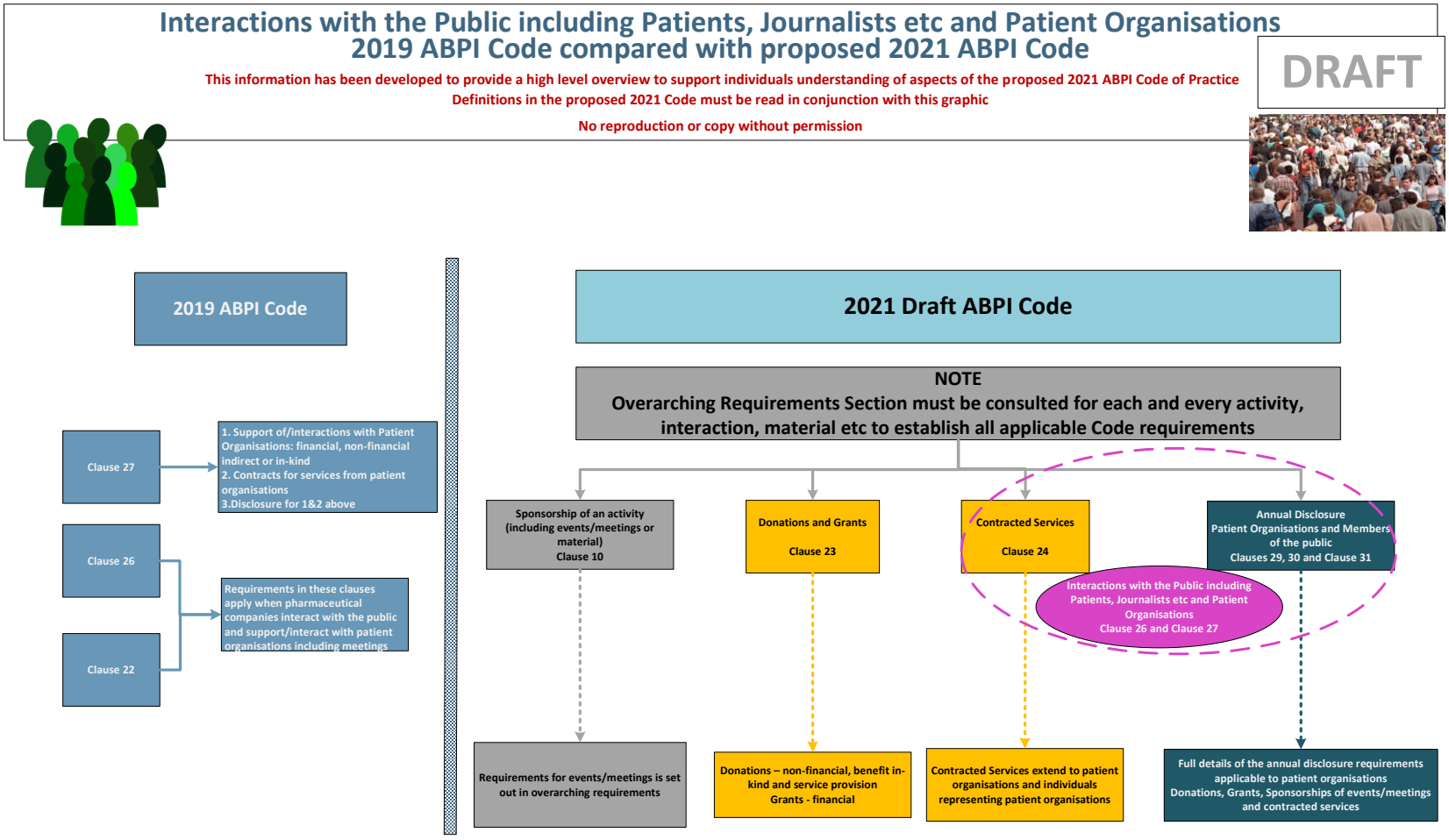
This information has been developed to provide a high level overview to support individuals understanding of aspects of the proposed 2021 ABPI Code of Practice

Definitions in the proposed 2021 Code must be read in conjunction with this graphic



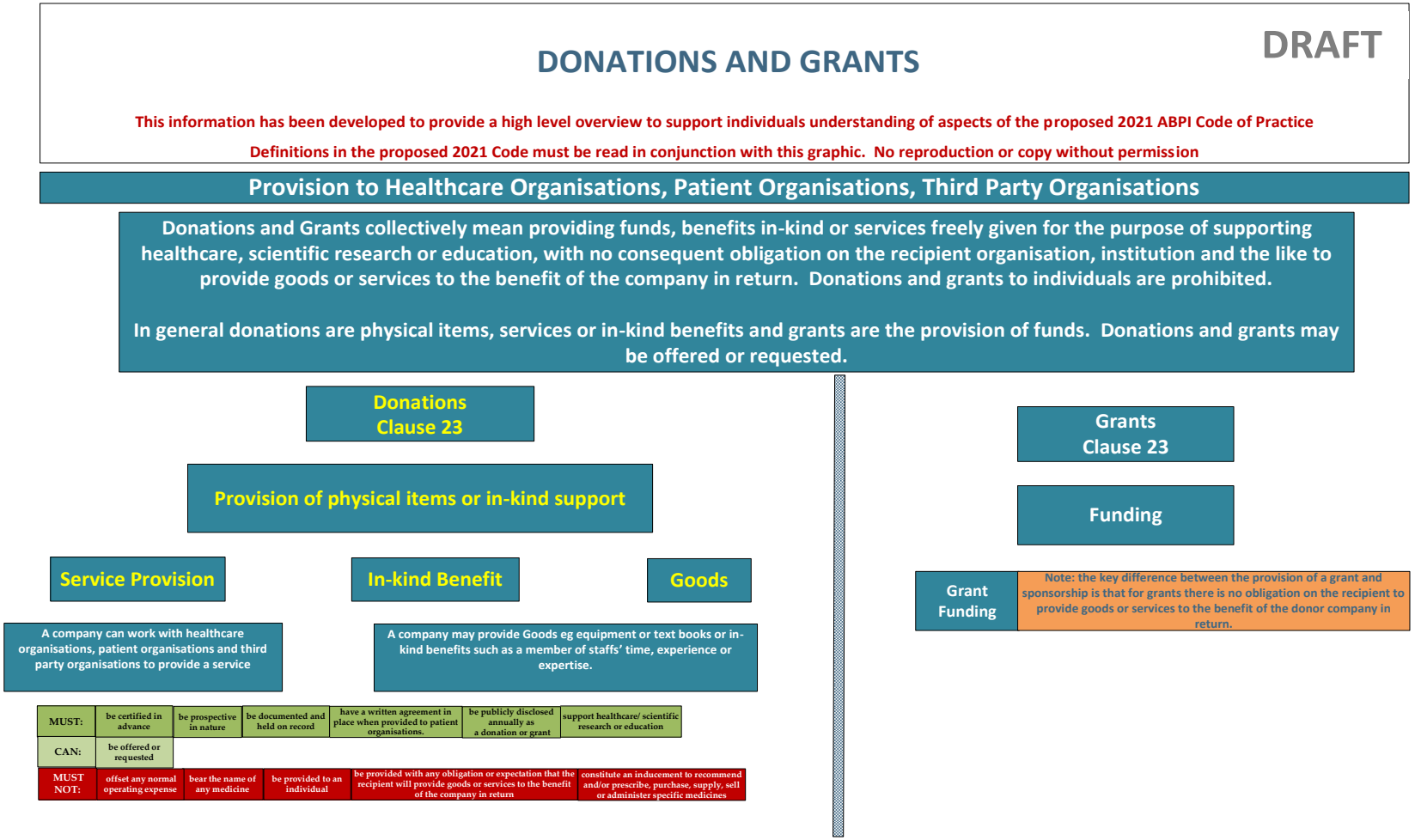
Prescription Medicines Code of Practice Authority 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT
Tel: 020 7747 8880 **Fax:** 020 7747 8881 **Email:** info@pmcpa.org.uk **www.pmcpa.org.uk**

APPENDIX 7 – Integration of The Public and Patient Organisation



Prescription Medicines Code of Practice Authority 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT
Tel: 020 7747 8880 **Fax:** 020 7747 8881 **Email:** info@pmcpa.org.uk **www.pmcpa.org.uk**

APPENDIX 8 – Donations and Grants



Prescription Medicines Code of Practice Authority 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT
Tel: 020 7747 8880 **Fax:** 020 7747 8881 **Email:** info@pmcpa.org.uk **www.pmcpa.org.uk**

APPENDIX 9 - Sponsorship vs Support

SPONSORSHIP TO ORGANISATIONS AND SUPPORT TO INDIVIDUAL HEALTH PROFESSIONALS AND OTHER RELEVANT DECISION MAKERS

This information has been developed to provide a high level overview to support individuals understanding of aspects of the proposed 2021 ABPI Code of Practice
Definitions in the proposed 2021 Code must be read in conjunction with this graphic. No reproduction or copy without permission

DRAFT

Provision of financial contribution in whole or in part whether paid directly, in-directly or through a third party

SPONSORSHIP

SUPPORT

Provision of financial contribution in whole or in part whether paid directly, in-directly or through a third party

Defined term - 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 third party organisation.

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

Note: Contracts for individuals representing patient organisations to attend events/meetings should be carried out as sponsorship and made with the patient organisation and disclosed against the patient organisation

Note: the key differences between the provision of sponsorship and support is that support is the contribution in whole or in part to events/meetings for individual health professionals or other relevant decision makers

Prescription Medicines Code of Practice Authority 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT
Tel: 020 7747 8880 **Fax:** 020 7747 8881 **Email:** info@pmcpa.org.uk **www.pmcpa.org.uk**

APPENDIX 10 - Optional Disclosure Template for Patient Organisations and The Public

ABPI CODE OF PRACTICE 2021
OPTIONAL DISCLOSURE TEMPLATE FOR PATIENT ORGANISATIONS (POs) AND THE PUBLIC

LAST UPDATED 100620

Companies must include a note of methodologies used in preparing the disclosures

1. Annual Disclosure of Support Provided to Patient Organisations and Contracted Services Provided by Individuals Representing Patients Organisations

Patient Organisation Name (add additional table for each Patient Organisation)	Country	Types of the Support or Services Provided		Monetary Value of Financial Support and of Invoiced costs	Description of Support [1]	Non-monetary Benefit for PO [2]	Optional Indication of Patient Organisation's Total Income and/or the Company's Support as a Percentage	Fees for Services/ Expenses
		Financial Support	Grants add a line for each Grant			Not applicable		Not applicable
			Sponsorship of Meetings add a line for each sponsorship					
			Other Sponsorships add a line for each sponsorship					
		Non-financial support	Donations add a line for each donation					
		Contracted services (Fees and expenses should be disclosed separately)	Fees	Not applicable		Not applicable		
			Out of pocket/ expenses					

2. Annual Disclosure of Contracted Services Provide by The Public

	Number of Members of the Public / Journalists Contracted	Country	Contracted Services Provided		Monetary Value of Financial Support and of Invoiced costs	Description of Support [1]	Non-monetary Benefit for PO [2]	Optional Indication of Patient Organisation's Total Income and/or the Company's Support as a Percentage	Fees for Services/ Expenses
Members of the Public			Contracted services (Fees and expenses should be disclosed separately) add a line for each different service provided	Fees	Not applicable		Not applicable	Not applicable	
				Out of pocket expenses					
Journalists			Contracted services (Fees and expenses should be disclosed separately) add a line for each different service provided	Fees					
				Out of pocket expenses					

1. Add a clear description which is sufficiently complete to enable the reader to understand the nature of each support or services provided

2. For example, employee hours or company's facilities offered to support a Patient Organisation activity