PMCPA | Prescription Medicines Code of Practice Authority

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

This document provides a brief introduction to the agreed 2021 ABPI Code of Practice for the Pharmaceutical Industry setting out the major changes and those made following the consultation, 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 legislation and ensures that the ABPI meets its commitments to implement other codes, such as the IFPMA and EFPIA Codes. This approach has been maintained for the 2021 ABPI Code.

Given the extent of the changes in the 2021 ABPI Code, including its format, it is not possible to list each and every change. The 2021 ABPI Code includes the new clause numbers as well as references to the corresponding clause numbers (or supplementary information) in the 2019 ABPI Code.

The changes to the Code were made using a development strategy agreed in advance by the ABPI Board with a format similar to that used for the 2019 EFPIA Code of Practice. The development strategy (in order of priority) was to:

- Add as Q&A
- Add as guidance (including updates to guidelines on company procedures relating to the Code, published in the Code booklet)
- Add to the supplementary information
- In exceptional circumstances add to the Code.

Following the responses to the consultation held over summer 2020, the ABPI/PMCPA Decision Group discussed the general approach and agreed the proposals for the ABPI Board to consider on 14 December. The ABPI dealt with the comments on the ABPI Principles. The PMCPA action on comments generally fell into 4 categories:

- Update to the Code, either in clause or supplementary information
- Require PMCPA to develop Q&A or guidance
- PMCPA response as the comment was a question rather than a comment on the proposed Code
- No action needed.

The ABPI Board agreed that the proposals be forwarded to ABPI member companies for approval at a general meeting of the ABPI on 12 January 2021. The new Code was agreed at that meeting and will come into operation on 1 July 2021.

If you have any questions or queries, about this document or the agreed 2021 Code generally 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 2020 the version issued for the consultation (19 June – 11 September 2020). Following the consultation, further discussions and other developments, an updated version was produced and on 14 December the ABPI Board agreed that it be sent to members for approval. The 2021 Code was approved on 12 January 2021. 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 2021 ABPI Code reflects the 2019 EFPIA Code. (See page 8.)

2 Address the three themes identified by the Code Working Group (an ABPI Group which started work in March 2019) and endorsed by the ABPI Board, which are:

- further develop principles
- ensure the Code is accessible
- future proof the Code where possible.

3 Incorporate regular updates resulting from cases considered etc.

Together the resultant changes provided the new look and approach. The key changes are set out below. It will take 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 Overarching Requirements including the definitions. This document and other materials are intended to support those reviewing and implementing the new 2021 Code.

B High Level Overview of 2021 ABPI Code of Practice

1 Structure

Reflecting a similar structure to the 2019 EFPIA Code, the clauses of the 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 and Journalists	Yellow
Specific Requirements for Interactions with The Public including Patients and Journalists 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 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 2021 ABPI Code is seen as essential to support understanding of the requirements, particularly during the transition to the new format. This was reviewed following the consultation and 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 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 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 ABPI Principles: Patients, Integrity, Transparency and Respect. The overview of self-regulation will be included in the introduction to the 2021 ABPI Code.

Following the consultation expectations about the implementation of the ABPI Principles have been added. Minor changes have been made to some of the principles.

The PMCPA will continue to make rulings based on the requirements of the Code and will not adjudicate on the principles.

3 Accessibility

The new structure of the 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. 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, the 2021 Code will be set out with two columns a page and 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 who they apply to can be found in Appendices 1 and 2 below.

1 Overarching Requirements (Grey Section)

This is a pivotal section and 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. (See Appendix 3 below.)

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. (See Appendices 5 and 9 below).

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. (See Appendices 7 and 9 below.)

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

This section includes areas which apply solely to these groups such as the provision of information to the public, patients and the media, and specific requirements for relationships with patient organisations; they therefore cannot be included in other sections. (See Appendix 6 below.)

6 Annual Disclosure Requirements (Teal Section)

This section includes the requirement to disclose 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. (See Appendix 10 below.)

D Proposed changes to the 2019 ABPI Code and updates following the consultation

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.

Around 1000 comments were received as part of the consultation and these have been carefully considered using a similar approach to that set out above. It was clear that much work was undertaken to provide appropriate challenge and comment on the proposed Code.

The ABPI dealt with the comments on the ABPI Principles. The PMCPA discussed the comments with the ABPI/PMCPA Decision Group and a general approach was agreed.

In addition, changes to UK legislation had to be considered and incorporated into the 2021Code.

Webinars were held over the summer during the consultation period (mid June 2020 to September). Discussions were held with various companies as well as the Compliance Network and the ABPI company medical directors.

Full details are given on the attached presentation and copy of the 2021 Code (which provides the changes following the consultation in track change). The main changes are highlighted below.

- **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) and Sponsorship and Support. (See Appendices 7 and 8 below). Changes have been made following the consultation.

2 Donations and Grants have been included in detail, expanded to apply to patient organisations and will replace what were medical and educational goods and services (MEGS) in the 2019 ABPI Code. MEGS can be still be provided as either Donations or Grants. Some MEGS might be considered to meet the requirements for collaborative working. Changes have been made following the consultation.

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.

4 In general working with patient organisations should be carried out as a contracted service.

- **Other changes**

5 Collaborative working with healthcare organisations (and others) has been introduced as a means of recognising that there might be some projects which are not carried out with the NHS or 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 with Organisations 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. Changes have been made following the consultation.

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

7 Members of the public (including patients and journalists) who provide contracted services similar to those provided by health professionals etc, covered in Clause 23 of the 2019 ABPI Code, are now also covered by the 2021 ABPI Code, Clause 24. Changes have been made following the consultation including that the services which need to be disclosed generally relate to healthcare, disease or medicine.

8 Annual Disclosure requirements have been amended following a proposed additional requirement to disclose in aggregate payments to members of the public including patients, individual patients not representing a patient organisation and journalists. 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'. Changes have been made following the consultation.

9 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. (See Appendix 11 below).

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

- **Updates as a result of the consultation**

These are set out on the accompanying slides and some details are given above **(Other changes)** and below (**Updates as a result of developments since the consultation).** All the updates are set out on the track change copy of the 2021 Code.

- **Updates as a result of developments since the consultation**

  The changes with regard to Brexit and the temporary supply authorisations (points 11 and 12 below) have not been the subject of consultation but they are designed to ensure that companies following new UK law and MHRA guidance in relation to specific requirements are not in breach of the Code. The change regarding extensions to the time to pass the examination did not need to be consulted upon as it is within the current arrangements where the Director has discretion (2019 Code, supplementary information to Clause 16.3 Time Allowed to Pass an Examination).

11 **Brexit**

The new UK legislation regarding changes to marketing authorisations, introduction of GB and NI licences, UK licences and EU licences will mean that new marketing authorisation numbers and possibly new marketing authorisation holder addresses will be needed. Company materials will need to be updated as soon as possible but a transition in certain circumstances will be introduced.

(An exception to the 2019 ABPI Code will also be needed and materials are currently being developed and discussed with the MHRA).

It is possible that further changes might be needed. A place holder has been included in the 2021 Code in the supplementary information to Clause 12.

12 **Coronavirus and influenza amendment regulations 2020 (temporary supply)**

Changes are included in relation to the new above legislation which requires materials to be approved by health ministers (both materials for health professionals etc and for public). The changes can be found in Clauses 3.1, 3.2, 11 and 26.1.

(An exception to the 2019 Code will also be needed and has been agreed following discussion with the MHRA).

13 **Extensions to examination**

An additional extension for the period that the ABPI examination for representatives was not available (8 months) has been set out in the supplementary information to Clause 9.4.

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.

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

2021 ABPI CODE STRUCTURE

PAGE		
Page 1	ABPI PRINCIPLES	
	2021 Code Clauses	2019 Code Clauses
Grey Section	OVERARCHING REQUIREMENTS	
Page 2	Clause 1 - Scope of the Code and Definition of Certain Terms	Clauses 1.1 & 28.2 Clauses 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
Page 5	*Obligations and Responsibilities* Clause 2 - Upholding Confidence in the Industry Clause 3 - Obligations Clause 4 - Responsibilities	Clause 2 Clauses 1.11, 1.12, 3.1, 12.1, 26.1 & 29 Clauses 13.1, 13.3, 24.1, 25.1, 25.2, 26.5, 27.7 & 27.8
Page 6	*Quality Standards* Clause 5 - High Standards and Suitability Clause 6 - Information, Claims, Comparisons and Disparagement Clause 7 - Use of Quotations Clause 8 - Certification and Examination Clause 9 - Training Clause 10 - Events/Meetings and Hospitality	Clauses 9.1, 9.2, 9.3, 9.7, 9.10 Clauses 7.2, 7.4, 7.8, 7.9, 7.11, 8.1, 8.2 Clauses 10.2, 10.3 Clauses 14.1, 14.2, 14.3, 14.4, 14.5, 14.6 Clauses 15.1, 16.1, 16.2, 16.3, 16.4 Clauses 18.1si, 18.3, 18.3si, 22.1, 22.1si, 22.2, 22.3, 22.4, 22.5 & 24.2
Blue Section	Promotion to Health Professionals and Other Relevant Decision Makers	
Page 24	Clause 11 - Marketing Authorisation	Clauses 3.1, 3.2
Page 24	Clause 12 - Prescribing Information and Other Obligatory information	Clauses 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.8, 4.9, 4.10
Page 26	Clause 13 - Abbreviated Advertisements	Clauses 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9
Page 27	Clause 14 - Information, Claims and Comparisons	Clauses 6.2, 7.3, 7.6, 7.7, 7.10
Page 27	Clause 15 - High Standards, Format and Suitability	Clauses 9.4, 9.5, 9.6, 9.8, 9.9, 12.1
Page 28	Clause 16 - Material and Distribution	Clauses 10.1, 11.2, 11.3, 28.1, 28.4
Page 28	Clause 17 - Representatives	Clauses 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 37	Clause 18 - Information, Claims and Comparisons	Clauses 7.1, 7.5
Page 37	Clause 19 - Prohibition on Inducements and Inappropriate Payments and the Provision of Items to Health Professionals and Other Relevant Decision Makers	Clauses 18.1, 18.2
Page 37	Clause 20 - Collaborative Working with Organisations	Clause 20
Page 38	Clause 21 - Provision of Medicines and Samples	Clauses 17.1, 17.2, 17.3, 17.4, 17.5, 17.6, 17.7, 17.8, 17.9, 17.10
Page 39	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 and Journalist	
Page 45	Clause 23 - Donations and Grants	Clauses 19.1, 19.2,
Page 45	Clause 24 - Contracted Services	Clauses 21, 23.1, 23.2, 23.3, 23.4, (27.8 incorporated)
Page 47	Clause 25 - Relationships with Health Professionals, Other Relevant Decision Makers, Healthcare Organisations and Patient Organisations	Clauses 27.4, 27.5, 27.9, 12.2
Pink Section	Specific Requirements for Interactions with the Public, including Patients and Journalists, and Patient Organisations	
Page 53	Clause 26 - Relations with the Public including Patients and Journalists	Clauses 18.2si, 26.1, 26.2, 26.3, 26.4, 26.5
Page 53	Clause 27 - Relationships with Patient Organisations	Clauses 27.1, 27.2, 27.3, 27.5, 27.6
Teal Section	Annual Disclosure Requirements	
Page 59	Clause 28 - Annual Disclosure of Transfers of Value to Health Professionals, Other Relevant Decision Makers, Healthcare Organisations	Clauses 24.1, 24.2, 24.7, 24.8, 24.9, 24.10
Page 59	Clause 29 - Annual Public Disclosure of Contracted Services, Donations, Grants and Sponsorship (including in relation to events/meetings) provided to Patient Organisations	EFPIA Requirement
Page 60	Clause 30 - Annual Public Disclosure of Contracted Services Provided by the Public including Patients and Journalists	ABPI Requirement
Page 60	Timings, Duration and Retention of Disclosure Information	Clauses 24.4, 24.5, 24.6

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**

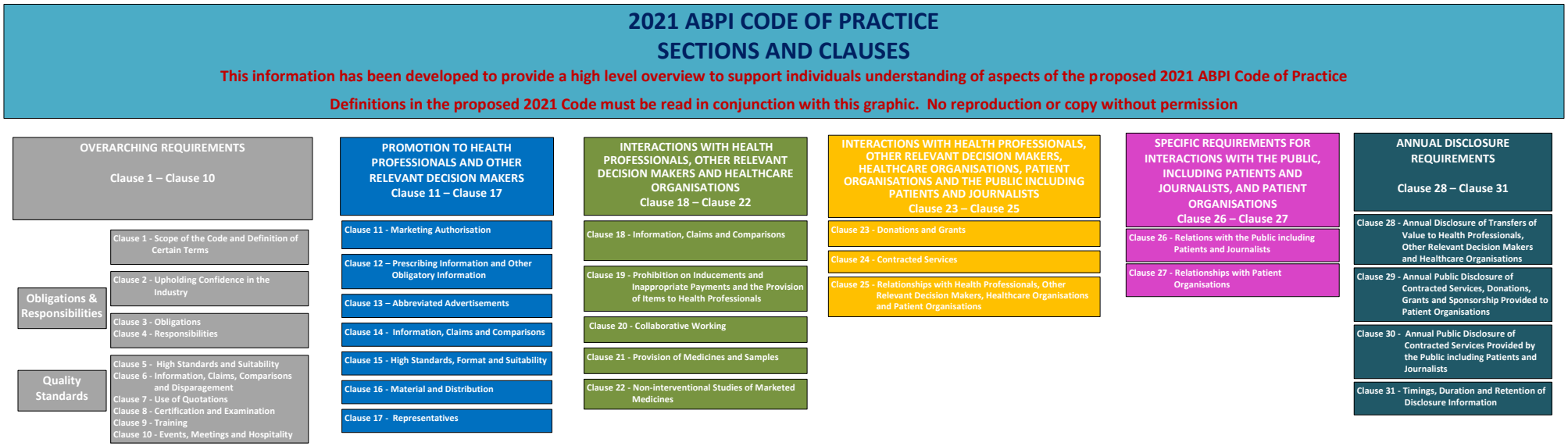
APPENDICIES

The Appendices have been developed to provide a high-level overview to support individuals understanding of the 2021 ABPI Code of Practice

Definitions in the 2021 Code must be read in conjunction with the graphics

APPENDIX CONTENTS

APPENDIX 1 – Overview of Sections with Titles and Clause 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 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 2021 ABPI Code of Practice

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

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 Other Organisation

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

Patient Organisations

- Sponsorship (including events/meetings or material)
- Donations and Grants
- Contracted Services
- Specific requirements for Interactions with the Public, including Patients and Journalists, and Patient Organisations

The Public Including Patients and Journalists

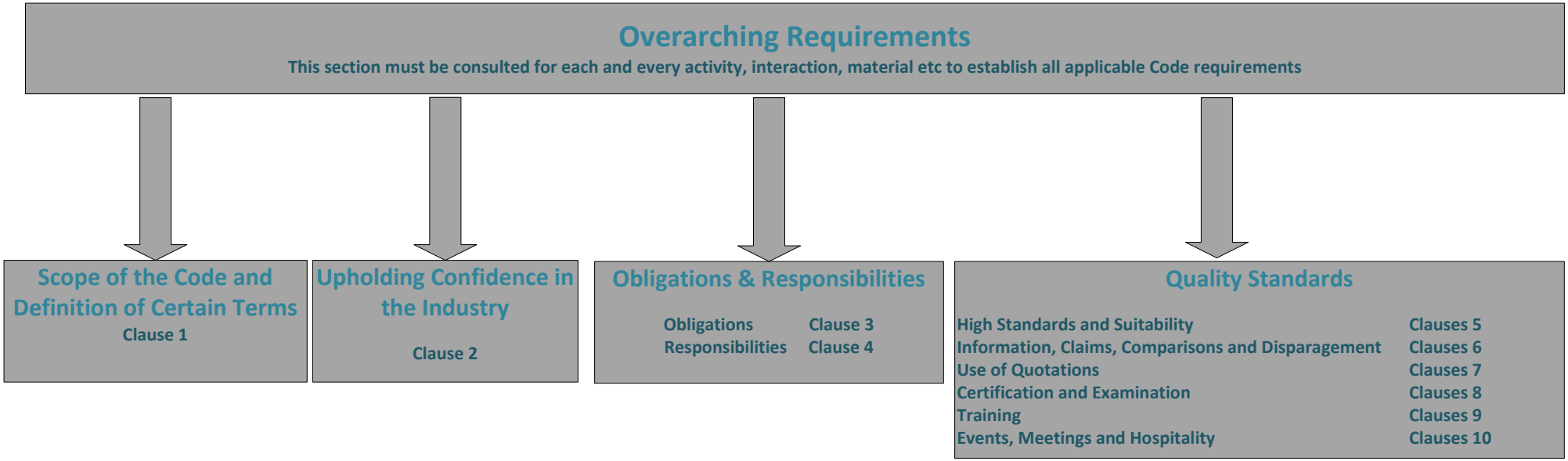
- Events/Meetings and Hospitality
- Contracted Services
- Specific Requirements for Interactions with the Public, including Patients and Journalists and Patient Organisations

Overarching Requirements Section must be consulted

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

<table>
<tr><th colspan="4">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>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
• 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.
Clauses 8.1 and 8.2 Appropriately Qualified Persons
It is possible for a company to have different individuals who would act as an appropriately qualified persons (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.
Last updated 25.11.20</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>

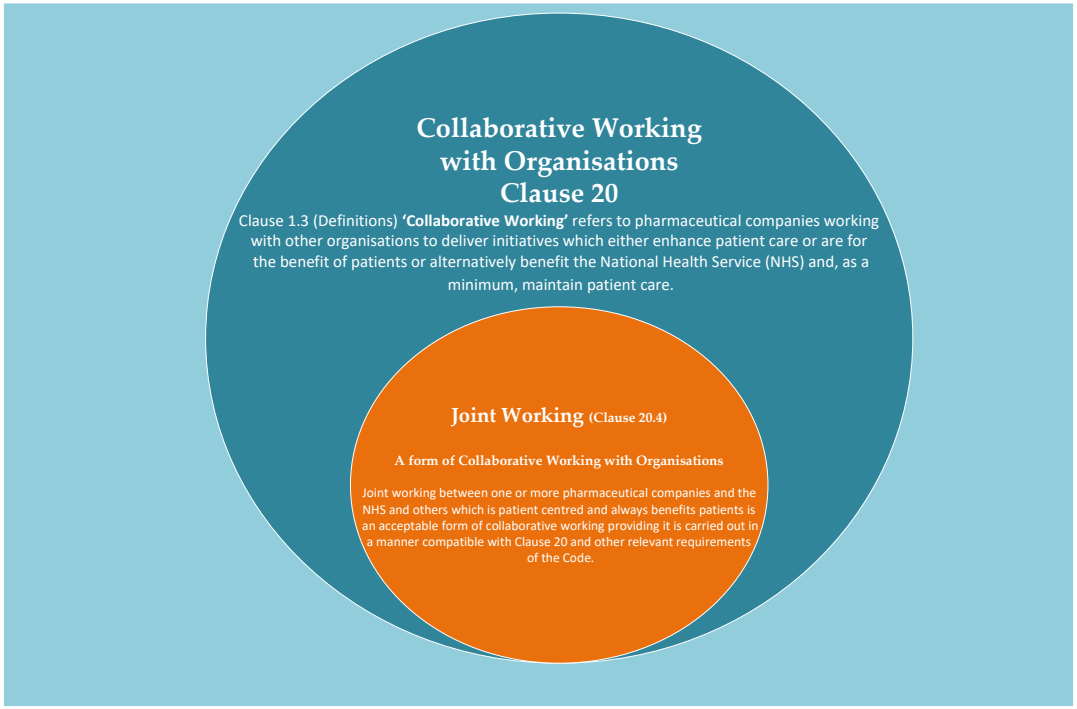
This information has been developed to provide a high-level overview to support individuals understanding of aspects of the 2021 ABPI Code of Practice
Definitions in the 2021 Code must be read in conjunction with this graphic.

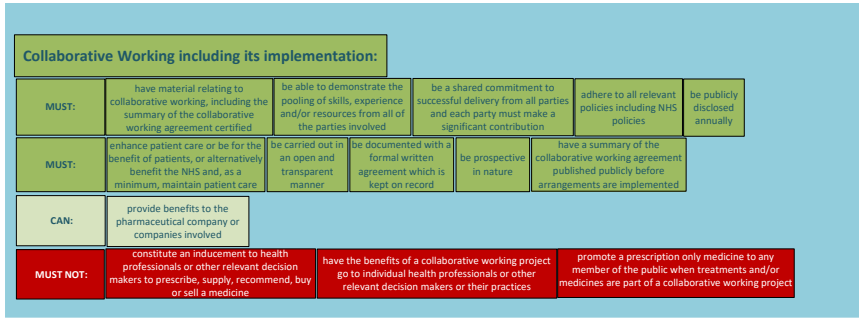
Prescription Medicines Code of Practice Authority 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT
Tel: 020 7747 8880 **Fax:** 020 7747 8881 **Email:** info@pmcpa.org.uk **www.pmcpa.org.uk**

APPENDIX 5 – Collaborative Working with Organisations

Collaborative Working with Organisations

This information has been developed to provide a high level overview to support individuals understanding of aspects of the 2021 ABPI Code of Practice.
Definitions in the 2021 Code must be read in conjunction with this graphic.





Joint Working is defined in the DH Joint Working Guidance and Joint Working Toolkit 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 to successful delivery.

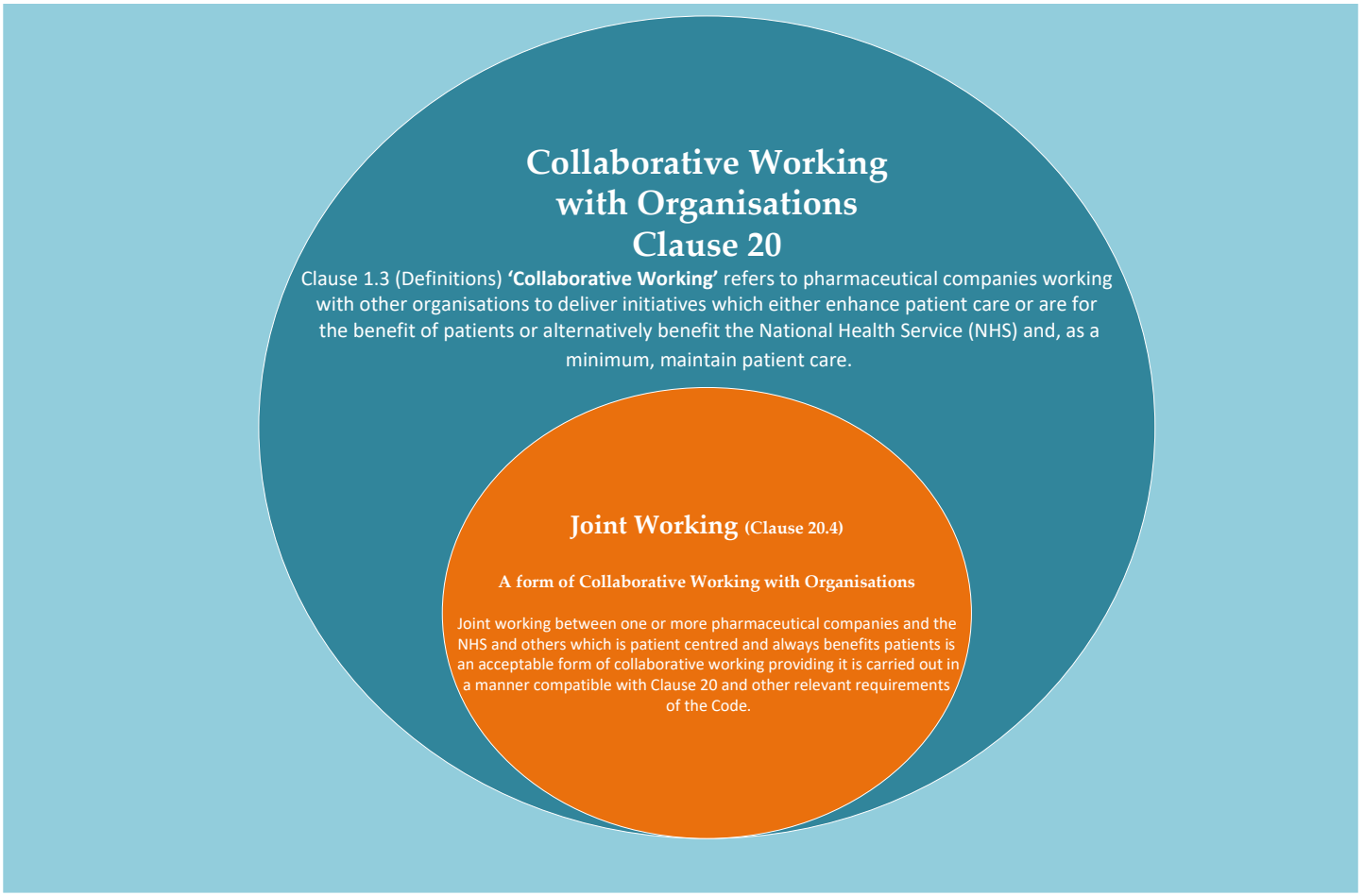
ABPI Guidance notes states: The key requirements from this definition are two-fold:
(i) the Joint Working project must be focused on benefits to patients; and
(ii) there must be a "pooling" of resources between the pharmaceutical company or companies and the NHS organisation(s) involved. Each party must, therefore, make a significant contribution to the joint working project to avoid the arrangement being construed as merely a gift, benefit in kind, donation or some other non-promotional/ commercial practice. Resources may come in various forms, including people, expertise, equipment, communication channels, information technology, and finance.
In addition, given the significant governance and administrative requirements involved in setting up proper joint working arrangements, it is likely that most joint working projects will be of a significant size and duration – as a guideline, generally involving resources (manpower, materials, funding etc) in the region of £15,000 - £20,000 and lasting 6 months or more. Ideas for Joint Working projects can arise from either party, hence pharmaceutical companies (as well as NHS organisations) can pro-actively propose ideas for joint working.

Reference - ABPI Guidance notes on Joint Working between pharmaceutical companies and the NHS and others for the benefit of patients. March 2009

APPENDIX 5 – Collaborative Working with Organisations

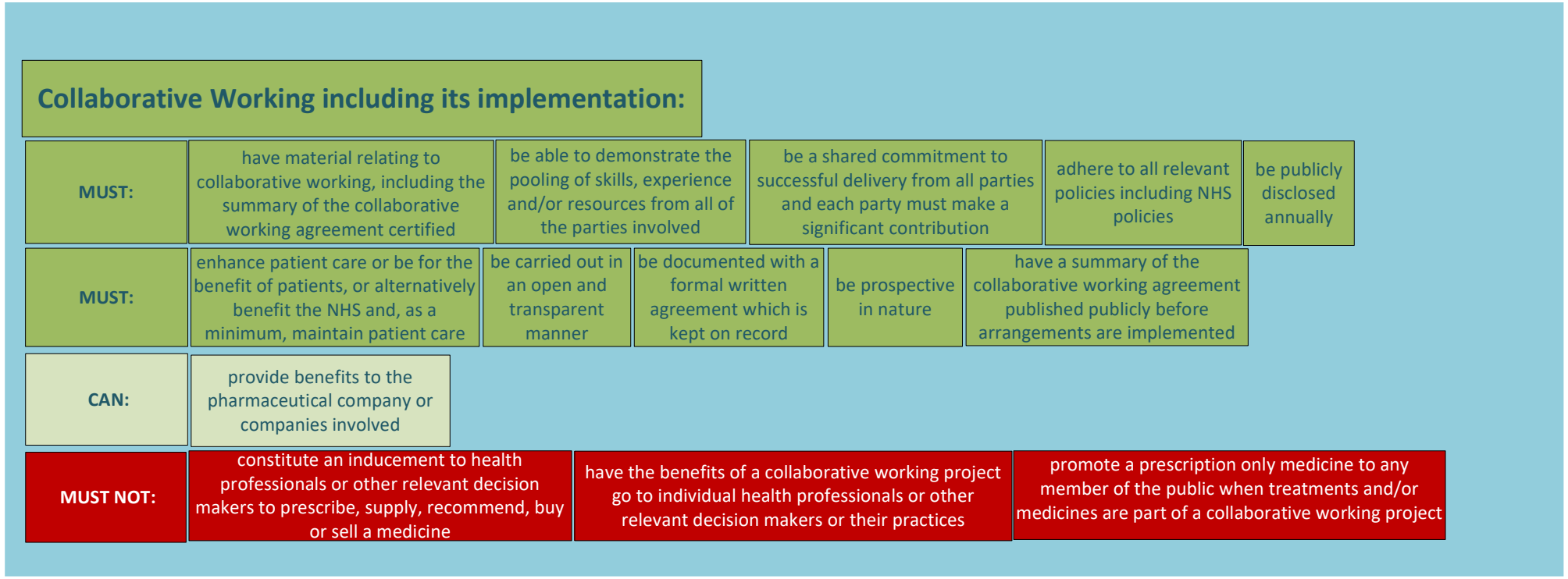
Collaborative Working with Organisations

This information has been developed to provide a high level overview to support individuals understanding of aspects of the 2021 ABPI Code of Practice. Definitions in the 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 5 – Collaborative Working with Organisations



APPENDIX 5 – Collaborative Working with Organisations

Joint Working is defined in the DH Joint Working Guidance and Joint Working Toolkit 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 to successful delivery.

ABPI Guidance notes states: The key requirements from this definition are two-fold:
(i) the Joint Working project must be focused on benefits to patients; and
(ii) there must be a "pooling" of resources between the pharmaceutical company or companies and the NHS organisation(s) involved. Each party must, therefore, make a significant contribution to the joint working project to avoid the arrangement being construed as merely a gift, benefit in kind, donation or some other non-promotional/ commercial practice. Resources may come in various forms, including people, expertise, equipment, communication channels, information technology, and finance.
In addition, given the significant governance and administrative requirements involved in setting up proper joint working arrangements, it is likely that most joint working projects will be of a significant size and duration – as a guideline, generally involving resources (manpower, materials, funding etc) in the region of £15,000 - £20,000 and lasting 6 months or more. Ideas for Joint Working projects can arise from either party, hence pharmaceutical companies (as well as NHS organisations) can pro-actively propose ideas for joint working.

Reference - ABPI Guidance notes on Joint Working between pharmaceutical companies and the NHS and others for the benefit of patients. March 2009

APPENDIX 6 – Integration of The Public including Patients and Journalists and Patient Organisations

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

2019 ABPI Code compared with 2021 ABPI Code

This information has been developed to provide a high level overview to support individuals understanding of aspects of the 2021 ABPI Code of Practice
Definitions in the 2021 Code must be read in conjunction with this graphic

2019 ABPI Code

2021 Draft ABPI Code

Clause 27 → 1. Support of/interactions with Patient Organisations: financial, non-financial indirect or in-kind
2. Contracts for services from patient organisations
3.Disclosure for 1&2 above

Clause 26 → Requirements in these clauses apply when pharmaceutical companies interact with the public and support/interact with patient organisations including meetings

Clause 22 → Requirements in these clauses apply when pharmaceutical companies interact with the public and support/interact with patient organisations including meetings

Overarching Requirements Clauses 1 - 10

Requirements for contribution to costs relating to events/meetings, sponsorship and other requirements which would apply to patient organisations and the public are set out in the overarching requirements

Donations and Grants Clause 23

Note: Donations and Grants are not applicable to members of the public including patients or journalists

Donations – non-financial, benefit in-kind and service provision
Grants – financial
Donations and Grants can be offered or requested (the offer can be the call for grant applications or similar)

Contracted Services Clause 24

Contracted Services extend to patient organisations, individuals representing patient organisations and the public including patients and journalists.

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 is not.

Specific Requirements for Interactions with the Public including Patients and Journalists and Patient Organisations Clause 26 and Clause 27

Details of the standards applicable to patient organisations (including individuals representing patient organisations Clause 27.5) and the public including patients and journalists

Annual Disclosure Requirements

Patient Organisations and the Public including Patient and Journalist Clauses 29, 30 and Clause 31

Full details of the annual disclosure requirements applicable to patient organisations and the public including patients and journalists

NOTE
Overarching Requirements section must be consulted for each and every activity, interaction, material etc to establish all applicable Code 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 7 – Donations and Grants

DONATIONS AND GRANTS

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

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

Provision to Healthcare Organisations, Patient Organisations or Other Organisations

Clause 1.5 (Definitions) **'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. Grants are the provision of funds. Donations and grants may be offered or requested. **Note: offer with respect to grants can, for example, be the call for grant applications**

Donations

Clause 23

Service Provision, physical items or in-kind support

Service Provision

A company can work with healthcare organisations, patient organisations and other organisations to provide a service

Physical Items

In-kind Benefit

A company may provide Goods eg equipment or text books or in-kind benefits such as a member of staffs' time, experience or expertise

Grants

Clause 23

Funding

Grant Funding

Note: the key difference between the provision of a grant and sponsorship is that for grants there is no obligation on the recipient to provide goods or services to the benefit of the donor company in return.

MUST:	support healthcare/ scientific research or education	be certified in advance	be prospective in nature	have a written agreement (for each donation or grant)	be documented and held on record	be publicly disclosed annually as a donation or grant	have the company involvement made clear to the extent possible
CAN:	be offered or requested Note: offer with respect to grants can, for example, be the call for grant applications	bear the name of the company providing them					
MUST NOT:	offset any normal operating expense	bear the name of any medicine	be provided to an individual	be provided with any obligation or expectation that the recipient will provide goods or services to the benefit of the company in return	constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicines		

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 2021 ABPI Code. Companies wishing to continue with ongoing MEGS from 1 July 2021 can do so until 31 December 2021 under the 2021 ABPI 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.

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 – Sponsorship and 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 2021 ABPI Code of Practice
Definitions in the 2021 Code must be read in conjunction with this graphic.

Contribution to Costs Related to Events

Clause 1.4 (Definitions) '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).

SUPPORT

Clause 1.23 (Definitions) 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.

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

SPONSORSHIP

Clause 1.22 (Definitions) 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.

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

OTHER FORMS OF SPONSORSHIP

Clause 1.22 (Definitions) 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.

Note: Companies can provide sponsorship towards an activity other than an event/meeting

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 – Service Provision

SERVICE PROVISION

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

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

Companies can provide services to the NHS and other organisations. These may be provided through a Donation or Collaborative Working, the following is to aid companies decide which is the most appropriate manner to deliver such services.

Donation must:

- support healthcare/ scientific research or education
- be provided without any obligation or expectation that the recipient will provide goods or services to the benefit of the company in return
- must not bear the name of any medicine

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
- be able to demonstrate the pooling of skills, experience and/or resources from all of the parties involved
- be a shared commitment to successful delivery from all parties and each party must make a significant contribution
- have a summary of the collaborative working agreement published publicly before arrangements are implemented
- provide benefits to the pharmaceutical company or companies involved

For both Donations and Collaborative Working companies should consider the information set out in the supplementary information to Clause 23 with respect to the provision of services
AND

MUST:	be certified in advance	be prospective in nature	be documented with a formal written agreement which is kept on record	be carried out in an open and transparent manner	have the company involvement made clear to the extent possible	publicly disclosed annually
CAN:	be offered or requested Note: offer with respect to grants can, for example, be the call for grant applications	bear the name of the company providing them				
MUST NOT:	offset any normal operating expense	be provided to an individual	Constitute an inducement to health professionals or other relevant decision makers to prescribe, supply, recommend, buy or sell a medicine	promote a prescription only medicine to any member of the public when treatments and/or medicines are part of a collaborative working project		

Note: 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 2021 ABPI Code. Companies wishing to continue with ongoing MEGS from 1 July 2021 can do so until 31 December 2021 under the 2021 ABPI 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.

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**

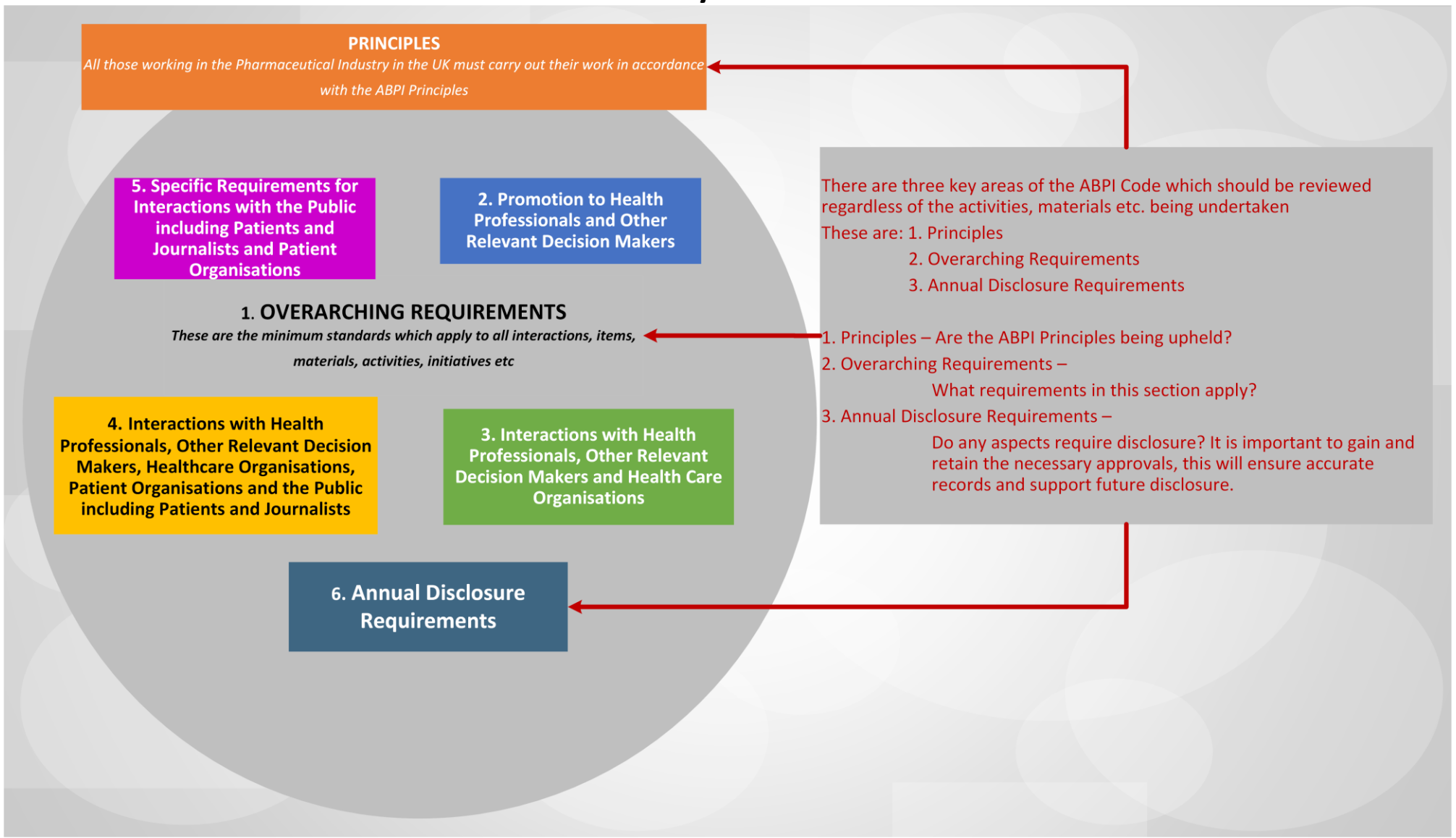
APPENDIX 10 Optional Disclosure Template for Patient Organisations and the Public including Patient and Journalists

LAST UPDATED 251120	Companies must include a note of methodologies used in preparing the disclosures										
	Patient Organisation Name	Country	Types of the Support or Services Provided								
			Financial Support			Non-financial support	Contracted services (Fees and expenses should be disclosed separately)				
			Grants add a line for each Grant	Sponsorship of Meetings add a line for each sponsorship	Other Sponsorships add a line for each sponsorship	Donations add a line for each donation	Fees	Out of pocket/ expenses	Non-monetary Benefit for PO [2]	Optional Indication of Patient Organisation's Total Income and/or the Company's Support as a Percentage	Description of Services
Patient Organisation (add additional table for each Patient Organisation)											
Members of the Public	Description of Services [1]	Add additional lines as required					N/A	N/A	N/A	N/A	
	Description of Services [1]	Add additional lines as required					N/A	N/A	N/A	N/A	
	Aggregate amount attributable to transfers of value to such Recipients								N/A	N/A	N/A
	Number of Recipients in aggregate disclosure								N/A	N/A	N/A
Patients	Description of Services [1]	Add additional lines as required					N/A	N/A	N/A	N/A	
	Description of Services [1]	Add additional lines as required					N/A	N/A	N/A	N/A	
	Aggregate amount attributable to transfers of value to such Recipients								N/A	N/A	N/A
	Number of Recipients in aggregate disclosure								N/A	N/A	N/A
Journalists	Description of Services [1]	Add additional lines as required					N/A	N/A	N/A	N/A	
	Description of Services [1]	Add additional lines as required					N/A	N/A	N/A	N/A	
	Aggregate amount attributable to transfers of value to such Recipients								N/A	N/A	N/A
	Number of Recipients in aggregate disclosure								N/A	N/A	N/A

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

APPENDIX 11 – Sections of the 2021 ABPI Code including Areas of Key Consideration



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**