PMCPA | Prescription Medicines Code of Practice Authority

Proposed 2021 ABPI Code and next steps

Monday 15 June 2020

www.pmcpa.org.uk

Agenda

- Overview
- Changes in brief
- What would help you
- What the PMCPA needs from you
- Timelines
- Further information and next steps

Overview

The PMCPA mandated by the ABPI Board at the end of 2019 has produced a proposed 2021 ABPI Code of Practice to:

- Reflect a similar structure to that of the 2019 EFPIA Code of Practice and implement the updates
- Address the three themes identified by the Code Working Group (CWG) which have been discussed with various ABPI groups (including Appropriate Prescribing, Ethics and Code (APEC)) and endorsed by the ABPI Board, which are:
  - further develop ABPI principles
  - ensure the Code is accessible
  - future proofing where possible.
- Include regular updates resulting from cases considered etc

Overview

- Final decisions on the content of the proposed Code were made by the ABPI/PMCPA decision group. CWG and APEC have provided feedback and comment.
- Unlike previous consultations it is not possible to list each change. Many of the changes are as a result of the new format or the EFPIA Code updates including new definitions.
- The proposed Code needs input from you all. It is important that you use your experience, and your company's experience to provide detailed comments.
- We have done our best to balance all the comments, inputs, requirements etc however we need to know if the proposals work in practice.

Overview

Allocating the 2019 Code clauses into the relevant section of the proposed 2021 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.

The supplementary information is essential for the delivery of proportionate regulation and to give appropriate additional information. Similar work has been carried out and some has been:

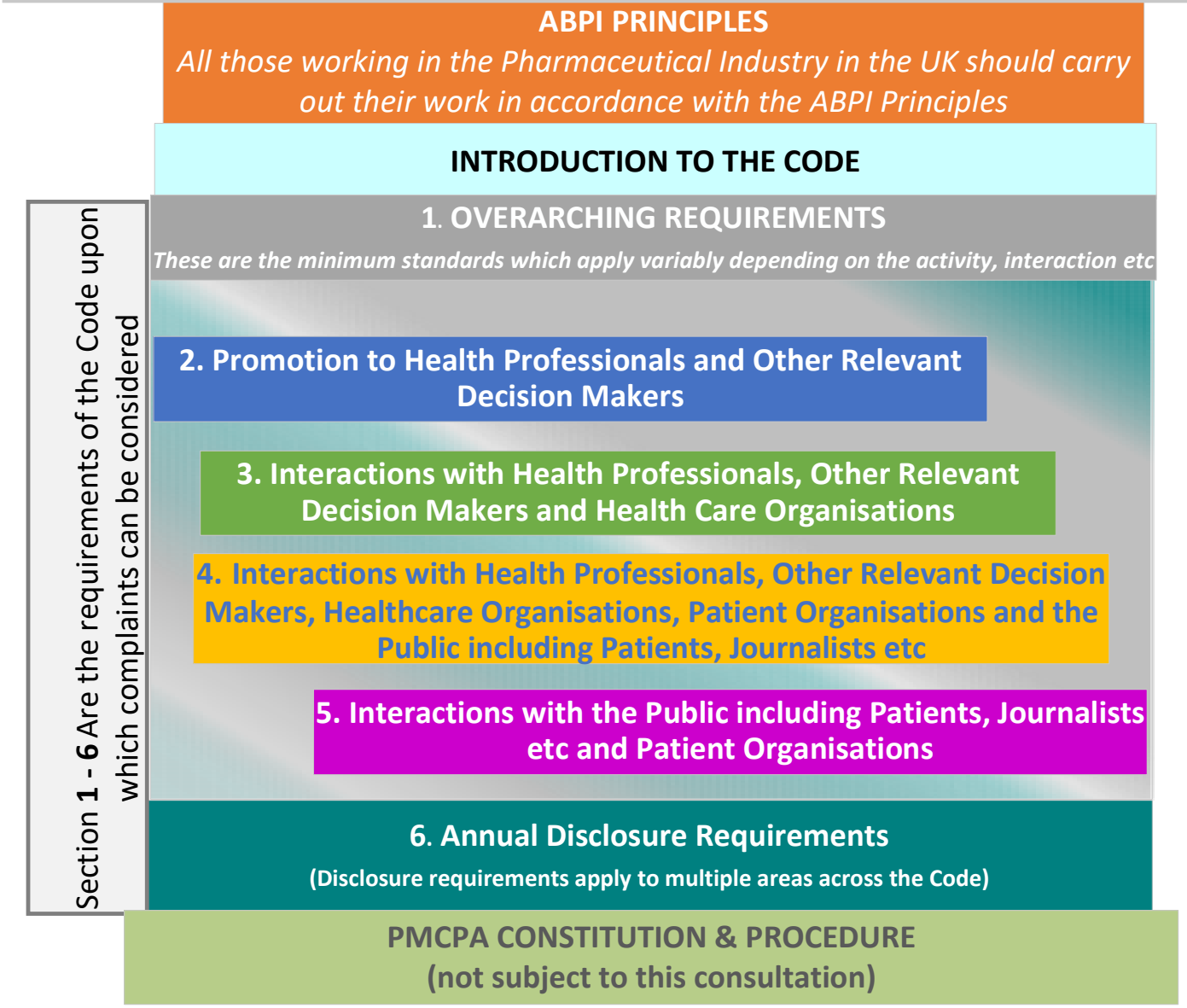
- deleted as it is no longer required (or moved to Q & A)
- split between more than one section
- duplicated where necessary
- updated as needed to reflect the clause or
- included in the clause.

What has changed?

- Six sections (grey, blue, green yellow, pink, teal)
- New descriptions for sub sections eg obligations and responsibilities, quality standards
- Audience/activity focussed
- More consistency between requirements for interactions with different stakeholders
- More consistency and alignment with the deletion of many references to print, to ensure it is clear digital activity is included as a platform of communication
- 31 Clauses (two more)
  - Duplicated Clauses 3.1, 12.1, 15.1, 24.1 and 26.1 of the 2019 Code – some duplication is to help transition
- Less supplementary information
- Better language
- Different arrangements for transitioning to the new Code
- A plan for further work, including on prescribing information.

		Introduction to the Code	
Page 2		ABPI PRINCIPLES	
PAGE	NEW CLAUSE #	Section	2019 Code Clauses
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	

ABPI CODE OF PRACTICE 2021 PROPOSED STRUCTURE



ABPI Principles

ABPI Principles will not be subject to rulings

Principle Developed by the ABPI	Some examples of how we demonstrate the principle in our behaviour
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.	We promote only within the terms of the marketing authorization 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 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.
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, reflect the available evidence and that all other activities are appropriate and reasonable and of the highest standards.	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.
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.	We disclose certain transfers of value to health professionals, other relevant decision makers, healthcare organisations, institutions, third parties etc and payments made to patient organisations, patients, journalists etc. 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.
4. We interact with all our stakeholders with **RESPECT**. We are committed to approach our stakeholders in an open and constructive manner and with mutual respect.	We recognise and seek to balance the needs of patients, health professionals and the public, bearing in mind 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.

Changes as a consequence of the 2019 EFPIA Code

- EFPIA Definitions have been adopted or amended bearing in mind definitions used in the ABPI Code. Definitions are key and should be referred to when using the Code. A few key definitions are Donations and Grants, Events (which includes meetings) Sponsorship and Support.

- Donations and Grants will replace medical educational goods and services (MEGS) in the current ABPI Code and have been expanded to include patient organisations. MEGS can still be provided as either Donations or Grants.

Changes as a consequence of the 2019 EFPIA Code

- Patient Organisations and/or individuals representing patient organisations have been incorporated into relevant Code activities including:
  - Donations and Grants
  - Sponsorship of organisations in relation to Events and Meetings and other activities
  - Contracted Services (previously Use of Consultants)
  - Disclosure which includes a requirement for a note summarising the methodologies used in preparing the disclosure.

Other Changes

- Collaborative Working with organisations has been introduced as a means of recognising that there might be some projects which cannot show a direct benefit to patient care and thus could not be Joint Working as defined in the 2019 Code.
  - 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 now an example of a type of collaborative working.
  - Some of the previous language for MEGS (2019 Code, Clause 19) has been adapted.

  This change is to better reflect activities companies wish to undertake. It means changes to the mandatory disclosure template.

Other Changes

- Contracted services requirements where members of the public (patients, journalists etc) provide services similar to those already covered in the Code (2019 Code, Clause 23 Use of Consultants) have been incorporated.

Other Changes

- Proposal for an additional requirement to disclose payments for contracted services paid to members of the public (not representing a patient organisation) to include patients, journalists etc from 2022 (to be disclosed in 2023). This was added 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.' There is also a proposal to require a note summarising the methodologies used in preparing the disclosure.

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

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Overarching Requirements

This section must be consulted for each and every activity, interaction, material etc to establish all applicable Code requirements

Scope of the Code and Definitions

Clause 1

Upholding Confidence in the Industry

Clause 2

Obligations & Responsibilities

Obligations	Clause 3
Responsibilities	Clause 4

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

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

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

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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.

ABPI DRAFT 2021 CODE OF PRACTICE
SECTIONS AND CLAUSES

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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

OVERARCHING REQUIREMENTS

Clause 1 – Clause 10

- Scope of the Code and Definitions — Clause 1
- Upholding Confidence in the Industry — Clause 2
- Obligations & Responsibilities
  - Obligations — Clause 3
  - Responsibilities — Clause 4
- Quality Standards
  - High Standards and Suitability — Clause 5
  - Information, Claims and Comparisons — Clause 6
  - Use of Quotations — Clause 7
  - Certification and Examination — Clause 8
  - Training — Clause 9
  - Events, Meetings and Hospitality — Clause 10

PROMOTION TO HEALTH PROFESSIONALS/OTHER RELEVANT DECISION MAKERS

Clause 11 – Clause 17

- Marketing Authorisation — Clause 11
- Prescribing Information and Other Obligatory Information — Clause 12
- Abbreviated Advertisements — Clause 13
- Information, Claims and Comparisons — Clause 14
- High Standards, Format and Suitability — Clause 15
- Material and Distribution — Clause 16
- Representatives — Clause 17

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

Clause 18 – Clause 22

- Information, Claims and Comparisons — Clause 18
- Prohibition on Inducements and Inappropriate Payments and the Provision of Items to Health Professionals — Clause 19
- Collaborative Working — Clause 20
- Provision of Medicines and Samples — Clause 21
- Non-interventional Studies of Marketed Medicines — Clause 22

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

Clause 23 – Clause 25

- Donations and Grants — Clause 23
- Contracted Services — Clause 24
- Relationships with Health Professionals, Other Relevant Decision Makers, Healthcare Organisations and Patient Organisations — Clause 25

INTERACTIONS WITH THE PUBLIC INCLUDING PATIENTS, JOURNALISTS ETC AND PATIENT ORGANISATIONS

Clause 26 – Clause 27

- Relations with the Public including Patients, Journalists etc — Clause 26
- Relationships with Patient Organisations — Clause 27

ANNUAL DISCLOSURE REQUIREMENTS

Clause 28 – Clause 31

- Annual Disclosure of Transfers of Value to Health Professionals, Other Relevant Decision Makers and Healthcare Organisations — Clause 28
- Annual Public Disclosure of Contracted Services, Donations, Grants and Sponsorship Provided to Patient Organisations — Clause 29
- Annual Public Disclosure of Contracted Services Provided by The Public including Patients, Journalists etc — Clause 30
- Timings, Duration and Retention of Disclosure Information — Clause 31

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

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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

Material to be made available for the consultation

- PMCPA will put copies of the documents, which will be on the ABPI consultation portal, on its website :
  - proposed 2021 ABPI Code
  - proposed mandatory template (HCPs, ORDMs and HCOs)
  - proposed optional template (patient organisations and members of the public)
  - PMCPA Guide to the proposed 2021 ABPI Code

- PMCPA will also put additional documents to support the consultation on its website:
  - presentation to help explain the changes
  - Draft 2019 ABPI Code marked up with the requirements of UK law, IFPMA and current EFPIA three codes
  - EFPIA Working Together With Patients
  - Draft working document of the proposed 2021 Code providing more detailed information about where the content is from (to be available shortly).

What would help you (and us)?

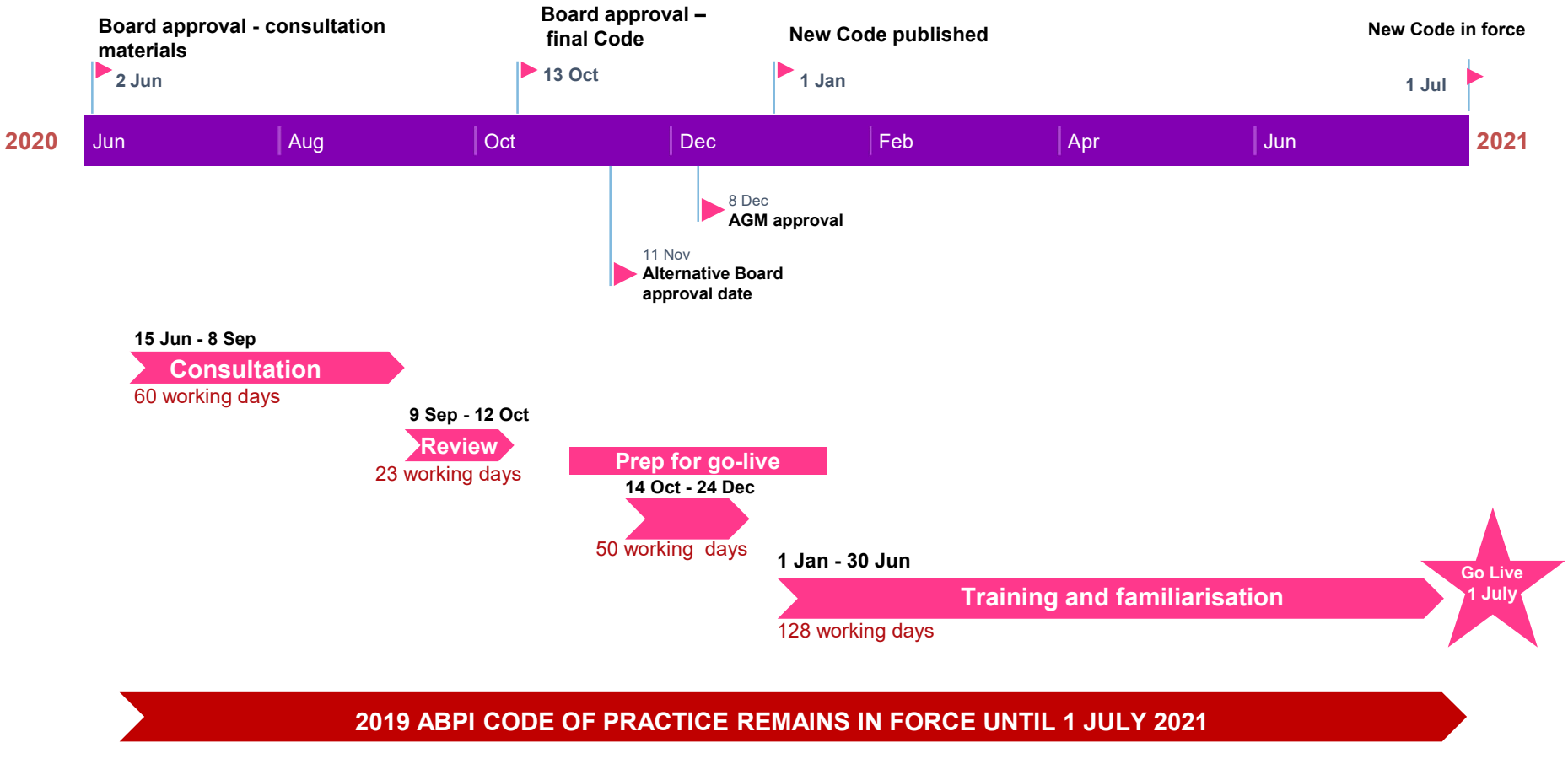
- PMCPA would welcome discussions and views on various topics for example:
  - collaborative working - does this work? is it clear that joint working is a kind of collaborative working?
  - substantiation – should it be provided to anyone who asks?
  - should an agreement be required in the Code for sponsorships and support? (in addition to the requirement for appropriate arrangements to enable the disclosure of sponsorship and support as a transfer of value)
  - should the requirements for a written agreement when providing donations or grants to patient organisations be extended to healthcare organisations? (currently donations and grants must be documented and held on record and appropriate arrangements are required to enable the disclosure of donations and grants)
  - training and support.

Let us know what else we should cover

Please ….

- Fully engage with the consultation. Stress test the proposed 2021 Code with activities you are currently undertaking and are thinking about doing. Does is work for your organisation?
- Think about what can be improved
- Does it work for virtual activities and interactions as well as face to face?
- Consider the impact on your company policies, SOPs
- Remember the timelines

Timeline for Consultation on the Proposed 2021 ABPI Code of Practice



BACKGROUND SLIDES (NOT PRESENTED ON 15 JUNE)

OVERARCHING REQUIREMENTS

GREY SECTION
CLAUSES 1 - 10

Scope of the Code and Definitions
Proposed Clause 1
Definition of Certain Terms
Grey Section

Main changes compared with 2019 Code

- Update of some existing definitions and new ones added (collaborative working, contributions to costs related to events, donations and grants, events, hospitality, patient organisation representative, third party, sponsorship and support).

Obligations and Responsibilities
Proposed Clause 2
Upholding Confidence in the Industry
Grey Section

Main changes compared with 2019 Code

- Deletion of reference to promotion in 2019 Clause 2:

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

Obligations and Responsibilities
Proposed Clause 3
Obligations
Grey Section

Main changes

- Separation and partial duplication of Clause 3 in 2019 Code (both 3.1 and 3.2 in 2019 Code also included in proposed Clause 11.1 and 11.2 (Blue Section, promotion)
- Brings together
  - prohibition on promoting a medicine without a MA
  - prohibition on promoting a POM to the public
  - requirement to comply with an undertaking
  - requirement to comply with applicable codes, laws and regulations
  - prohibition on personal gifts
  - requirement for materials and activities not to be disguised
  - senior employee to be responsible.

Obligations and Responsibilities
Proposed Clause 4
Responsibilities
Grey Section

- Brings together
  - requirement and role of scientific service
  - disclosure requirements including:
    - certain transfers of value to health professionals, other relevant decision makers and healthcare organisations
    - donations, grants and sponsorship, and fees and expenses paid for contracted services to patient organisations
    - fees and expenses for contracted services made to members of the public.
  - disclosure of details of clinical trials
  - publication of summary details and results of non-interventional studies.

Quality Standards
Proposed Clause 5
High Standards and Suitability
Grey Section

- Brings together
  - requirement for high standards
  - requirements for recognising the special nature of medicine and the standing of the audience
  - use of photographs of health professionals
  - prohibition on extremes of format
  - requirement to declare sponsorship
  - requirement to tailor material to the audience
  - need to be clear when leaving company website.

Quality Standards
Proposed Clause 6
Information, Claims and Comparisons
Grey Section

- Brings together
  - requirements that claims etc are accurate, balanced, fair, objective and unambiguous, up to date, reflect all the evidence, not mislead etc
  - requirement that claims etc are capable of substantiation
  - requirements for artwork to conform with the Code etc, referenced
  - requirements for information, claims etc about adverse events
  - use of the word ‘new’
  - prohibitions on disparaging other companies’ medicines, professional opinions etc.

Quality Standards
Proposed Clause 7
Use of Quotations
Grey Section

- Keeps together
  - requirement for quotations to comply with the Code
  - the need for permission to use quotations from a private occasion.

Quality Standards
Proposed Clause 8
Certification and Examination
Grey Section

Main changes compared with 2019 Code Clause 14

- More information about examination of material
- More information about role of Appropriately Qualified Person ‘AQP’
- Requirement to certify donations and grants (these now replace medical and educational goods and services).

Table setting out certification and examination requirements can be found on slide 55.

Quality Standards
Proposed Clause 9
Training
Grey Section

Main changes compared with 2019 Code Clause 16

- Reference to Total Qualification Time 480 hours for diploma and 330 hours for certificate
- Will be kept under review re impact of social distancing requirements.

Quality Standards
Proposed Clause 10
Events/Meetings and Hospitality
Grey Section

Main changes compared with 2019 Code Clause 22

- Definition of events applies
- Requirements apply to all meetings companies organise. This includes those with patient organisations (previously only as a cross reference from 2019 Code Clause 26.2 supplementary information), journalists etc.

(continued)

Quality Standards
Proposed Clause 10
Events/Meetings and Hospitality
Grey Section

Main changes compared with 2019 Code Clause 22 (continued)

- current supplementary information added to clause
  - regarding criteria for meetings added to proposed Clause 10.1
  - prohibition on compensating merely for time attending meetings, proposed Clause 10.2
  - provision of pens, pencils and notepads
  - quizzes
  - contracts for sponsorship of individuals representing patient organisations to attend an event/meeting should be made with the patient organisation and disclosed against the patient organisation.

Schematic setting out the difference between sponsorship and support on slide 56

PROMOTION TO HEALTH PROFESSIONALS / OTHER RELEVANT DECISION MAKERS

BLUE SECTION
CLAUSES 11 - 17

Promotion to Health Professionals/Other Relevant Decision Makers Proposed Clauses 11 – 14 Overview Blue Section

- Brings together
  - Marketing Authorization - proposed Clause 11
  - Prescribing Information - proposed Clause 12
  - Abbreviated Advertisements - proposed Clause 13
  - Information, Claims and Comparison - proposed Clause 14
    - Comparisons, use of published studies, references when referring to published studies, data on file, encourage rational use, no exaggerated all-embracing claims, limited use of superlatives etc, need to ensure multi screen/page advertisement is not misleading.

Prescribing Information and Other Obligatory Information Proposed Clause 12 Blue Section

Main changes compared with 2019 Code Clause 4

- Addition to the supplementary information to encourage references on printed material to a resource where the current regulatory documents for each medicine promoted can be found.

Further work

This (and proposed Clause 13, Abbreviated Advertisements) is an area which will be discussed with the MHRA in relation to changes in UK law.

Information, Claims and Comparisons
Proposed Clause 14
Blue Section

Main changes compared with 2019 Code Clause 6.1

- Limitation on number of pages in print journal removed – covered by general requirement for restraint on the volume and frequency of promotion.

Promotion to Health Professionals/Other Relevant Decision Makers Proposed Clauses 15 – 17 Blue Section

- Brings together
  - High Standards, Format and Suitability - proposed Clause 15
    - Not imitating others' device, copy, slogans, no reference to Commission on Human Medicines etc, prior permission for reproducing official documents
  - Material and Distribution proposed - proposed Clause 16
    - Promotional material about POMs to a UK audience on the Internet to comply with all relevant requirements of the Code, advertising in an independent electronic journal intended for health professionals, restraint on frequency and volume of distribution (limits for mailings deleted from supplementary information), mailing lists up-to-date, use of reprints..
  - Representatives - proposed Clause 17.

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

GREEN SECTION
CLAUSES 18 - 22

Interactions with Health Professionals, Other Relevant Decision Makers and Healthcare Organisations
Proposed Clause 18
Green Section

Information, Claims and Comparisons - proposed Clause 18

- Brings together
  - requirement to provide information to health professionals and other relevant decision makers about marketed medicines
  - requirement to provide substantiation on request.

Interactions with Health Professionals, Other Relevant Decision Makers and Healthcare Organisations
Proposed Clause 19
Green Section

Prohibition on Inducements and Inappropriate Payments and the Provision of Items to Health Professionals - proposed Clause 19

- Brings together
  - prohibition on gifts and inducements
  - requirement for materials and items to be passed to patients as part of a patient support programme.

Interactions with Health Professionals, Other Relevant Decision Makers and Healthcare Organisations
Proposed Clause 20
Green Section

Main changes compared with 2019 Code Clause 20

- Introduction of collaborative working with organisations, with Joint Working being a type of collaborative working
- Collaborative working must either:

  enhance patient care or be for the benefit of patients

  or alternatively

  benefit the NHS and, as a minimum, maintain patient care
- Joint Working as defined by Department of Health remains

Based on requirements for Medical and Educational Goods and Services and Joint Working.

Schematic setting out Collaborative Working with Healthcare Organisations and others can be found on slide 57

Interactions with Health Professionals, Other Relevant Decision Makers and Healthcare Organisations
Proposed Clauses 21 – 22
Green Section

- Provision of Medicines and Samples - proposed Clause 21
- Non-interventional studies of Market Medicines - proposed Clause 22.

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

YELLOW SECTION
CLAUSES 23 - 25

Donations and Grants
Proposed Clause 23
Yellow Section

Main changes compared with 2019 Code Clause 19

- Donations and grants which are funds, benefits in-kind or services freely given for the purpose of supporting healthcare, scientific research or education with no obligation on the recipient to provide goods or services to the benefit of the company in return. Prohibited to individuals
- Medical and educational goods and services replaced by donations and grants.

Schematic setting out the requirements for donations and grants can be found on slide 58

Contracted Services
Proposed Clause 24
Yellow Section

Main changes compared with 2019 Code Clauses 23, 27.8

- Contracted services, brings together requirements for fees for services for a wider audience
- Proposes a requirement for disclosure for fee for Code related service payments to individual members of the public etc to include total number, total amount paid per calendar year and a description of the services (similar to when disclosure for health professionals was introduced).

Relationships with health professionals, Other relevant Decision makers, Healthcare Organisations and Patient Organisations Proposed Clause 25 Yellow Section

Main changes compared with 2019 Code 27.3, 27.4,27.9, 12.2

Extends existing requirements for relationships with patient organisations to relationships with health professionals, other relevant decision makers, and healthcare organisations and *vice versa* such that no company can

- require it is a sole funder or sponsor of an HCO or PO
- make public use of HCO or PO logo and proprietary material

and also includes requirements

- to clearly acknowledge sponsorship
- that market research, clinical assessments post-marketing surveillance must not be disguised promotion.

INTERACTIONS WITH THE PUBLIC INCLUDING PATIENTS, JOURNALISTS ETC AND PATIENT ORGANISATIONS

PINK SECTION
CLAUSES 26 - 27

Interactions with The Public including Patients, Journalists etc and Patient Organisations
Proposed Clauses 26 – 27
Pink Section

Main changes compared with 2019 Code

Relations with the Public including Patients, Journalists etc - proposed Clause 26 with the addition of a reference to patient support items

Proposes that prizes for patient competitions no longer allowed.

Relationships with Patient Organisations - proposed Clause 27 with the addition of references to individuals representing patient organisations and the need for the contract to be with the patient organisation.

A schematic setting out the requirements for the public and patient organisations can be found on slide 59

ANNUAL DISCLOSURE REQUIREMENTS

TEAL SECTION
CLAUSES 28 - 31

Annual Disclosure Requirements Proposed Clauses 24 – 31 Teal Section

Main changes compared with 2019 Code Clause 24

- Brings together all the requirements for disclosure to be by the end of June after the end of the calendar year in which the payments were made
- Disclosure of ToV to health professionals, other relevant decision makers and healthcare organisations proposed Clause 28
- Disclosure of contracted services, donations, grants and sponsorship provided to patient organisations has an additional reference to individuals representing patient organisations and the need for the contract to be with the patient organisation proposed Clause 29
- Timings, Duration and Retention of Disclosure Information - proposed Clause 31.

Annual Disclosure Requirements
Disclosure of Contracted Services Provided by The Public including Patients, Journalist etc
Proposed Clause 30
Teal Section

- Introduction of requirements for contracted individuals (who are not linked in anyway to a patient organisation) and who provide contracted services to a UK company. Services include speaking at meetings, assistance with training, writing articles, participating in advisory boards, advising on design etc of clinical trials, participation in market research where such participation involves remuneration and/or travel.
- Disclosure must include
  - total number, total amount paid, description of services
  - fees and expenses disclosed separately
  - should include a breakdown to each group eg patients, public, journalists etc
- Methodological note required and optional template proposed

Copy of the optional disclosure template can be found on slide 60

Proposed 2021 ABPI Code of Practice

Certification (Clause 8)
(names must be notified to the MHRA and PMCPA)

Examination

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.

HCP Signatory or Appropriately Qualified Person Signatory (AQP Signatory)

HCP Signatory or Appropriately Qualified Person (AQP)

Promotional (Clause 8.1)	**Non-Promotional (Clause 8.3)**	**(Clause 8.2)**	
• All Promotional material	• 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.	• all events/meetings involving travel outside the UK (unless the company's only involvement is to support a speaker to present at a meeting)	• 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

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

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 **do not** need to be notified to the MHRA or the PMCPA.

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.

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

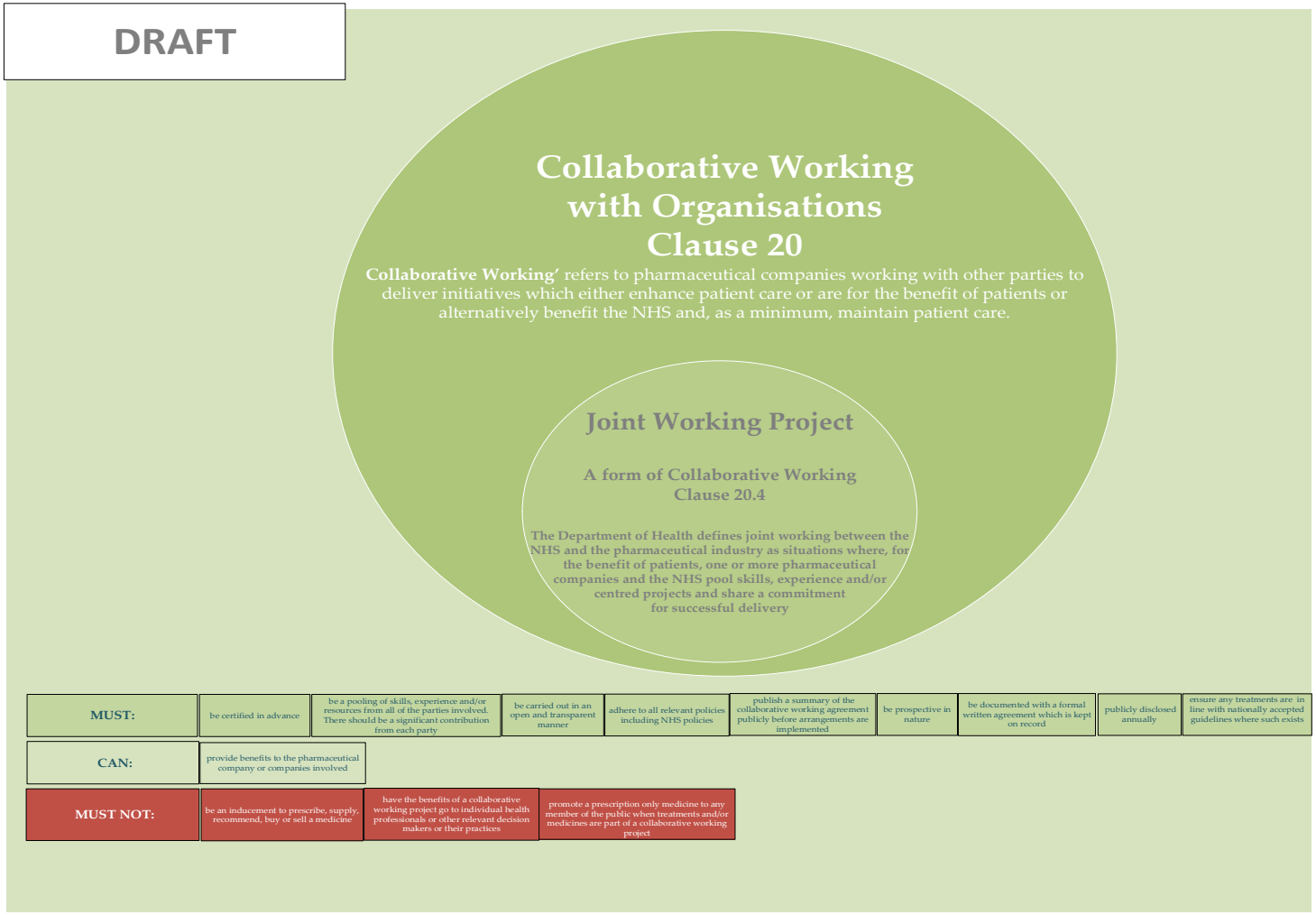
Note: the key differences between the provision of sponsorship and support is that support is the contribution in whole or in part to events/meetings for individual health professionals or other relevant decision makers

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

DRAFT



DONATIONS AND GRANTS

DRAFT

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

Provision to Healthcare Organisations, Patient Organisations, Third Party Organisations

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

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

Donations Clause 23

Provision of physical items or in-kind support

Service Provision

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

In-kind Benefit

Goods

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

MUST:	be certified in advance	be prospective in nature	be documented and held on record	have a written agreement in place when provided to patient organisations.	be publicly disclosed annually as a donation or grant	support healthcare/ scientific research or education
CAN:	be offered or requested					
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	

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.

Interactions with the Public including Patients, Journalists etc and Patient Organisations
2019 ABPI Code compared with proposed 2021 ABPI Code

DRAFT

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

2019 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

2021 Draft ABPI Code

NOTE
Overarching Requirements Section must be consulted for each and every activity, interaction, material etc to establish all applicable Code requirements

- Sponsorship of an activity (including events/meetings or material) Clause 10 → Requirements for events/meetings is set out in overarching requirements
- Donations and Grants Clause 23 → Donations – non-financial, benefit in-kind and service provision; Grants - financial
- Contracted Services Clause 24 → Contracted Services extend to patient organisations and individuals representing patient organisations
- Annual Disclosure Patient Organisations and Members of the public Clauses 29, 30 and Clause 31 → Full details of the annual disclosure requirements applicable to patient organisations Donations, Grants, Sponsorships of events/meetings and contracted services

Interactions with the Public including Patients, Journalists etc and Patient Organisations Clause 26 and Clause 27

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