PMCPA | Prescription Medicines Code of Practice Authority

2021 ABPI Code of Practice for the Pharmaceutical Industry as agreed at ABPI General Meeting 12 January 2021

www.pmcpa.org.uk

Documents for technical release

- Clean copy of 2021 Code (clauses, supplementary information and ABPI Principles) to come into operation on 1 July 2021
- Track change copy showing changes following the consultation
- PMCPA Guide to the 2021 Code
- Slides summarising the main changes including the outcome of the consultation and other updates
- Mandatory template for disclosure to reflect 2021 Code requirements
- New optional template for disclosure of transfers of value to patient organisations and the public including patients and journalists

Contents of presentation

- History and Approach taken
- Other developments relevant to 2019 Code and 2021 Code
- Further work required
- What will companies need to consider?
- Details of outcome of the consultation and action taken
- What has changed following the consultation?
- Summary of changes to the 2019 Code

History and background

- PMCPA mandated by the ABPI Board at the end of 2019 to produce the 2021 Code
- ABPI Board received regular updates on the work and agreed in June 2020 the version for consultation (19 June – 11 September 2020). Medical directors and compliance network etc also received regular updates
- ABPI Code updated to:
  - Reflect the structure of the 2019 EFPIA Code of Practice The objectives of the EFPIA consolidation were to simplify, clarify, harmonise and remove repetition
  - 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:
    - Further develop principles
    - Ensure the Code is accessible
    - Future proof where possible
  - Incorporate regular updates resulting from cases considered etc

Approach Taken

- **Changes to the Code made using the ABPI Board agreed Code development strategy (in order of priority)**
  - Add as Q & A
  - Add as guidance (including updates to guidelines on company procedures relating to the Code (published in the Code booklet)
  - Add in the supplementary information
  - In exceptional circumstances add to the Code (substantive changes arising from the outcome of the consultation in summer 2020 would require further consultation before being included)

Approach Taken

- **ABPI/PMCPA Decision Group finalised recommendations to the ABPI Board**
  - Regular discussions on approaches to be taken
  - Agreed changes as set out in documents for ABPI Board meeting 14 December
  - ABPI dealt with comments on ABPI Principles
  - PMCPA dealt with comments on Code which 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 is a question not comment
    - No action needed

History and background

- ABPI Board agreed the proposals for circulation to ABPI member companies (December 2020) including changes needed due to other developments (new UK legislation and guidance from the MHRA) which are enabling and have not been the subject of consultation
- ABPI members agreed the 2021 Code on 12 January 2021
- 2021 Code to come into operation on 1 July 2021
- No transition period – other than for medical and educational goods and services as set out in the supplementary information to Clause 23
- Technical release on PMPCA website in January

Other Developments Relevant to 2019 Code and 2021 Code

- **Brexit updates – work in progress (place holder in 2021 Code)**

  New UK legislation re changes to marketing authorisations, introduction of GB and NI licences, UK licences and EU licences. New marketing authorisation numbers and possibly new marketing authorisation holder addresses will be needed, materials to be updated as soon as possible to reflect the new numbers and addresses but transition introduced by MHRA. Proposed changes to 2021 Code and/or supplementary information still to be finalised and will follow. Position regarding 2019 Code to be finalised

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

  Changes to the 2021 Code cover the new regulations. Position regarding 2019 Code finalised and to be published shortly (information already provided to companies with temporary supply authorisations)

- **Extensions to representatives' examination**

  Additional extension set out for clarity in supplementary information to Clause 9.4 of the 2021 Code to cover the period when the ABPI examination was not available (8 months)

Further work required includes

- Guidelines on company procedures relating to the Code
- Guidance documents and Q and A
- Amendments to the Constitution & Procedure (which will require consultation)
- Introduction to the Code to be updated
- Communications plan for 2021 Code launch (July 2021)
- Training materials
- Website update and 2021 Interactive Code development

What will companies need to consider?

- Proposing a contact for the roll out and implementation
- Update relevant policies and procedures
- Training on Code and related policies and procedures
- Implementation of ABPI Principles, including reinforcing the importance and privilege of self regulation to staff
- How the ABPI and PMCPA can support eg
  - PMCPA topic led webinars
  - communications plan
  - tool kit to include: key messages for use with health professionals, patient organisations and journalists

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Details of outcome of consultation and action taken

Feedback from Consultation

- Thank you to all who provided in-depth feedback
- Clear much work was undertaken to provide appropriate challenge and comment
- In addition, patient organisations and many anonymous contributors have provided comment and insights
- Feedback invaluable in ensuring the Code is as robust as possible
- 1,000+ comments took over 8 weeks to read and discuss, review and amend proposed Code where appropriate
- Regular updates and discussion with various groups including Compliance Network and medical directors

Summary of Respondents

Respondent	Total	Percent
Pharmaceutical company (one response per company)	49	64.47%
• ABPI Member Companies • Non-member Companies • ABPI • Unknown	33 7 1 8	N/A
Healthcare professional	1	1.32%
NHS employee	3	3.95%
Other healthcare industry employee	1	1.32%
Patient organisation	5	6.58%
Patient	0	0.00%
Professional body (e.g. royal colleges)	3	3.95%
Regulatory organisation	0	0.00%
Consultancy/agency	10	13.16%
General Public	0	0.00%
Other	5	6.58%
MHRA submitted to PMCPA directly	1	Received by PMCPA; not included in percentage calculation
Appeal Board	1	

Number of responses by clause etc

Question	Number of valid Responses
ABPI Principles - Principles	37
General comments on this section - Your comments (optional)	24
Scope of the Code and Definition of Certain Terms - Clause 1 GREY SECTION	39
Obligations and Responsibilities - Clause 2 Upholding Confidence in the Industry (optional)	7
Obligations and Responsibilities - Clause 3 Obligations (optional)	11
Obligations and Responsibilities - Clause 4 Responsibilities (optional)	21
Quality Standards - Clause 5 Quality standards	20
Quality Standards - Clause 6 Information, claims and comparisons	11
Quality Standards - Clause 7 Use of Quotations	1
Quality Standards - Clause 8 Certification and Examination (optional)	37
Quality Standards - Clause 9 Training (optional)	9
Quality Standards - Clause 10 Events/Meetings and Hospitality (optional)	24
General comments on this section - Your comments (optional)	8
Scope of the Code and Definition of Certain Terms - Supplementary information to Clause 1	11
Obligations and Responsibilities - Supplementary information to Clause 2 Upholding Confidence in the Industry (optional)	0
Obligations and Responsibilities - Supplementary information to Clause 3 Obligations (optional)	8
Obligations and Responsibilities - Supplementary information to Clause 4 Responsibilities (optional)	2
Quality Standards - Supplementary information to Clause 5 High Standards and Suitability	7
Quality Standards - Supplementary information to Clause 6 Information Claims and Comparisons (optional)	7
Quality Standards - Supplementary information to Clause 7 Use of Quotations (optional)	2
Quality Standards - Supplementary information to Clause 8 Certification and Examination (optional)	31
Quality Standards - Supplementary information to Clause 9 Training (optional)	4
Quality Standards - Supplementary information to Clause 10 Events/Meetings and Hospitality (optional)	16

Question	Number of valid Responses
General comments on this section - Your comments (optional) BLUE SECTION	9
Clause 11 Marketing Authorisation	4
Clause 12 Prescribing Information and Other Obligatory Information	24
Clause 13 Abbreviated Advertisements	7
Clause 14 Information, Claims and Comparisons	7
Clause 15 High Standards, Format and Suitability	8
Clause 16 Material and Distribution	10
Clause 17 Representatives	13
General comments on this section - Your comments (optional) Blue Section	5
Supplementary information to Clause 11 Marketing Authorisation	8
Supplementary information to Clause 12 Prescribing Information and Other Obligatory Information	9
Supplementary information to Clause 13 Abbreviated Advertisements	0
Supplementary information to Clause 14 Information, Claims and Comparisons	2
Supplementary information to Clause 15 High Standards, Format and Suitability	4
Supplementary information to Clause 16 Material and Distribution	10
Supplementary information to Clause 17 Representatives	9

Question	Number of valid Responses
General comments on this section - Your comments (optional) GREEN SECTION	7
Clause 18 Information, Claims and Comparisons	4
Clause 19 Prohibition on Inducements and Inappropriate Payments and the Provision of Items to Health Professionals and other Relevant Decision Makers	8
Clause 20 Collaborative Working with Organisations - Collaborative working	35
Clause 21 Provision of Medicines and Samples	9
Clause 22 Non-Interventional Studies of Marketed Medicines	16
Supplementary information to Clause 18 Information, Claims and Comparisons	0
Supplementary information to Clause 19 Prohibition on Inducements and Inappropriate Payments and the Provision of Items to Health Professionals and other Relevant Decision Makers	11
Supplementary information to Clause 20 Collaborative Working with Organisations - Collaborative working	16
Supplementary information to Clause 21 Provision of Medicines and Samples	2
Supplementary information to Clause 22 Non-Interventional Studies of Marketed Medicines	16
General comments on this section - Your comments (optional) YELLOW SECTION	14
Clause 23 Donations and Grants - Donations and grants	30
Clause 24 Contracted Services - Contracted services	27
Clause 25 Relationships with Health Professionals, Other Relevant Decision Makers, Healthcare Organisations and Patient Organisations	11
General comments on this section - Your comments (optional)	4
Supplementary information to Clause 23 Donations and Grants	13
Supplementary information to Clause 24 Contracted Services	9
Supplementary information to Clause 25 Relationships with Health Professionals, Other Relevant Decision Makers, Healthcare Organisations and Patient Organisations	6

Question	Number of valid Responses
General comments on this section - Your comments (optional)	10
Clause 26 Relations with the Public including Patients, Journalists etc	15
Clause 27 Relationships with Patient Organisations	14
General comments on this section - Your comments (optional)	2
Supplementary information to Clause 26 Relations with the Public including Patients, Journalists etc	11
Supplementary information to Clause 27 Relationships with Patient Organisations	2
General comments on this section - Your comments (optional)	11
Clause 28 Annual Disclosure of Transfers of Value to Health Professionals, Other Relevant Decision Makers and Healthcare Organisations	13
Clause 29 Annual Disclosure of Contracted Services, Donations, Grants and Sponsorship (including in relation to events/meetings) Provided to Patient Organisations	9
Clause 30 Annual Disclosure of Contracted Services Provided by the Public including Patients, Journalists etc	22
Clause 31 Timings, Duration and Retention of Disclosure Information	2
Supplementary information to Clause 28, 29 and 30 Annual Disclosure	3
Supplementary information to Clause 28 Annual Disclosure of Transfers of Value to Health Professionals, Other Relevant Decision Makers and Healthcare Organisations	3
Supplementary information to Clause 29 Annual Disclosure of Contracted Services, Donations, Grants and Sponsorship (including in relation to events/meetings) Provided to Patient Organisations	0
Supplementary information to Clause 30 Annual Disclosure of Contracted Services Provided by the Public including Patients, Journalists etc	5
Supplementary information to Clause 31 Timings, Duration and Retention of Disclosure Information	0

Question	Number of valid Responses
Please give us your comments on the structure of the proposed Code - Your comments (optional)	39
What works well? Please provide an explanation for your views. - Your comments (optional)	25
What works less well? Please provide an explanation for your views - Your comments (optional)	24
Does the new Collaborative Working with Organisations section work? Do you have any suggestion on how this could be improved? If so, please provide details to help understanding and discussions following the consultation. - Your comments (optional)	28
Is it clear that Joint Working is part of Collaborative Working? Do you think an agreement should be included as a requirement in the Code for sponsorships and support? Appropriate arrangements are already required to enable the disclosure of sponsorship and support as a transfer of value. - Your comments (optional)	29
A written agreement is required when providing donations or grants to patient organisations, yet for healthcare organisations etc donations and grants must be documented and held on record. Again, appropriate arrangements are already required to enable the disclosure of donations and grants. Should an agreement be added as a requirement which would cover both current obligations? - Your comments (optional)	34
Are there any areas which are unclear? If so, please provide details - Your comments (optional)	22
Please provide any other feedback on the proposed Code changes - Your comments (optional)	25

Note: number of responses does not equal number of comments. Most responses to clauses etc have multiple comments

Themes identified from consultation include:

- PMCPA webinars welcomed as the start of the conversation
  - 4 webinars held over summer 2020 with over 100 attendees at each
- Most of the comments are for more detail to be added to the Code rather than less
- Need to improve understanding, including reasons for the wording, particularly where it reflects UK law, EFPIA Code etc

Themes identified from consultation include:

- Format and definitions generally welcome.
  - Some concern regarding the definition of grants and donations ('offer' and the general examples for each provided in clause)
  - changes to company SOPs, policies etc
  - Many comments regarding the continued use of the term 'Europe', (ABPI will remain a member of EFPIA and part of the European continent)

- Collaborative working seen as a positive addition. Request for examples to improve understanding of the differences between collaborative working and joint working

Themes identified from consultation include:

- Duplication of clauses; concern at the potential for companies to be found in breach of two clauses for the same issue eg Clauses 3.1 and 11.1

- Disclosure of certain payments to the public including patients and journalists. Comments that this goes beyond EFPIA requirements, not necessary, large amount of work.

- Certification queries: regarding registered medical practitioners, appropriately qualified people, what needs to be certified eg non interventional studies, patient organisation contract, representatives' briefings etc

- Materials - asked to remove the difference between print and digital, the two-page limit for journal advertising was taken out, now being asked to reinstate and add detailed references to digital

- Medical and Educational Goods and Services (MEGS) transition and future

MHRA Comments

Code

- Volume of communications with health professionals
- Homecare for unlicensed medicines

Constitution and Procedure/Guidelines on Company Procedures

- Internal audit standards
- Monitoring activities

Next steps for PMCPA following the MHRA comments

- Meeting with MHRA to discuss these points and actions taken
    - Clause 3 to include early access to medicine scheme (EAMS), prescribing information, risk management materials, Brexit transition, information to the public, etc

- Discuss homecare with ABPI

What has changed following the Consultation?

- Changes made following the consultation are shown on a track change copy of the 2021 Code
- Place holders added where further changes are needed

ABPI Principles – main change following consultation

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

What has changed following the consultation?

- **General**
  - More cross references, more supplementary information, correction of typographical errors, repetition, gender neutral language, updates to ensure consistency between clauses and supplementary information
- **Clause 1 Definitions**
  - Use of ‘third party’ changed, confusion between third party acting for a company and those independent parties (applies in other clauses, eg Clause 10.5, Clause 10.11 which now refers to a patient organisation)
  - Slight amendment to definition of patient organisation representative
  - Amendment to excluded transfers of value, to add back in the reference to subsistence provided to health professionals etc (omitted in error)

What has changed following the consultation?

- **Clause 3 Obligations (also Clauses 11 and 26)**
  - Coronavirus amendment regulations in relation to temporary supply of medicines for public health emergencies. Promotion of such medicines to the health professionals and other relevant decision makers need such campaigns approved by health ministers.
  - Advertising to public of such campaigns also need approval by health ministers

What has changed following the consultation?

- **Clause 4 Responsibilities**
  - Amendment to Clause 4.5 (and others) to refer to disclosure of fees and expenses to individual members of the public including patients and journalists (deleted carers and etc)
  - Moved the supplementary information regarding details of clinical trials to be included on the home page into Clause 4.6
  - Moved Clause 26.6 re responsibility for material issued by third party agencies to new Clause 4.8
- **Clause 5 High Standards and Suitability**:
  - Clarified wording regarding market research studies when it is such that it does not need to identify the company (there are circumstances when the company will have to be identified due to GDPR)

What has changed following the consultation?

- **Clause 8 Certification and Examination**
  - Written agreements to be required for all donations and grants and to be certified
  - Items for patient support replaces patient support programmes (also Clause 19.2 prohibition on inducements)
  - Removal of reference to designated alternative signatories
  - Language in Clause 8.5 to be consistent in use of ‘examined’
  - Supplementary information to Clause 8.1 make it clear that the proof check can be done by a signatory, an appropriately qualified person (AQP) signatory or an AQP
  - New supplementary information to Clauses 8.1, 8.2 regarding AQP which might be different people depending on the role

What has changed following the consultation?

- **Clause 8 Certification and Examination**
  - Supplementary information to Clause 8.3 Examination to make it clear that press releases (and other materials) which cover matters in Clause 8.3 to be certified, others to be examined
  - Supplementary information to Clause 8.6 to include information from MHRA Blue Guide
- **Clause 9 Training**
  - additional supplementary information re examination and impact of Covid on timescales, additional extension included for clarity
- **Clause 10 Events/Meetings Hospitality**
  - additional references to make it clear sponsor/support can include for health professionals not known to the company
  - Make it clear that it is one notebook plus one pen or pencil

What has been changed following the consultation?

- **Clause 17 Representatives**
  - Clause 17.6 in relation to forwarding information about their company's medicines not limited to the medicines they promote, particularly reports of adverse reactions (reflects existing pharmacovigilance requirements)
  - The order of Clause 17.9, briefing material must comply with the Code to come before requirement to provide

What has been changed following the consultation?

- **Clause 19 Prohibition on inducements etc**
  - Supplementary information to Clause 19.1 package deals, switch wording to say package deals disclosed and then the exemption solely for ordinary course purchases
  - Supplementary information to Clause 19.1 Promotional Aids, reordered and removed the reference to when the brand name can be used as that is in Clause 19.2.
  - Supplementary information to Clause 19.1 Textbooks reworded to make it clear that they cannot be given to individuals but can be given to organisations for health professionals/other relevant decision makers to use

What has been changed following the consultation?

- **Clause 19 Prohibition on inducements etc continued**
  - Clause 19.2 and supplementary information patient support items changed to items for patient support (not using references to patient support programmes in 2021 Code).
  - Supplementary information Patient Access schemes added reference to devolved nations re VPAS (Voluntary Scheme for Branded Medicines Pricing and Access)

What has been changed following the consultation?

- **Clause 20 Collaborative Working**
  - Added to Clause 20.1 that Joint Working is a form of collaborative working
  - Supplementary information reworded regarding publication of outcomes of collaborative working, as soon as possible and usually within six months of the project's completion. Publication on the company website.
  - Supplementary information includes new reference to service provision in Clause 23 and transition arrangements for medical and educational goods and services
  - Supplementary information includes more information about the arrangements when collaborative working also involves patient organisations

What has been changed following the consultation?

- **Clause 21 Samples**
  - Supplementary information regarding retention of sample requests moved to the clause

- **Clause 22 Non interventional studie**s
  - Clause 22.2 separated the two bullets into two clauses so a new Clause 22.3 regarding publication of the summary details and results

What has been changed following the consultation?

- **Clause 23 Donations and Grants**
  - Clause 23.1 changed to read ‘In general donations are physical items, services or benefits in-kind which can be offered or requested. Grants are the provision of funds’.
  - Written agreements required for all donations and grants not just those for patient organisations
  - Supplementary information amended to give further explanation about the offer of a donation or grant (call for grant applications), including the role of representatives
  - Supplementary information amended to refer to medical and educational goods and services (MEGS) under the 2019 Code may fall under either donations or collaborative working. Added an extra 6 months for companies transitioning ongoing MEGS to donations or possibly collaborative working (also added to the supplementary information to Clause 20)

What has been changed following the consultation?

- **Clause 24 Contracted services**
  - Clause 24.1 Remove references to carers and etc so only members of the public including patients and journalists are covered. Writing articles and/or publications added. Changed to participation ***may*** involve remuneration and/or hospitality.
  - Clause 24.2 amended to be clear that it applies to individuals and organisations
  - Clause 24.6 in relation to the public reordered slightly
  - Supplementary information to Clause 24.1 added to give more explanation about the services provide by the public, including patients and journalists (carers and etc deleted) which are required to be disclosed – generally healthcare, disease or medicine. Added a reference to the EFPIA document.

What has been changed following the consultation?

Clauses 26 and 27 Specific requirements for interactions with the public, including patients, journalists and patient organisations

- **Clause 26.1 Advertising to the Public**
  - Reference to exemption for vaccination campaigns approved by the health ministers in Clause 26.1 amended to add a reference to other campaigns
  - New supplementary information to Clause 26.1 added to include reference to temporary supply authorisations
- **Clause 26.2 Information to the Public including patients and journalists**
  - Supplementary information to Clause 16.1 about website access added to supplementary information to Clause 26.2
  - Supplementary information re individuals prescribed medicines reordered
  - Supplementary information re to current or prospective employees from 2019 Code added back

What has been changed following the consultation?

- Clauses 26 and 27 Specific requirements for interactions with the public, including patients, journalists and patient organisations

- **Clause 27 Patient organisations**
  - Clause 27.1 removed ‘to support their work, including assistance in the provision of appropriate information to the public, patients and carers’ as donations and grants are covered in Clause 23. These are general principles for working for patient organisations.

Responses to Additional Questions asked during the Consultation

Question	Number of Responses	Summary of Responses	
Is it clear that Joint Working is part of Collaborative Working?	29	**Yes** **No** **More detail required**	**25** **0** **4**
Do you think an agreement should be included as a requirement in the Code for sponsorships and support?	29	**Yes** **No** **Question not answered**	**22** **2** **5**
Outcome - Added to the Guidelines on Company Procedures Relating to the Code of Practice. A consultation is required to establish the full impact on representative meetings.			
A written agreement is required when providing donations or grants to patient organisations, yet for healthcare organisations etc donations and grants must be documented and held on record?	34	**Yes** **No** **Answer unclear**	**25** **3** **6**
Outcome - This has been added to the 2021 Code			

What else has been changed?

- Optional template for disclosure of information for patient organisations and the public including patients and journalists updated
- Graphics updated and additional graphic added (provided as appendices to the PMCPA Guide)

What has not been changed following the consultation?

- Suggestions which need consultation before implementation (other than updates to reflect new UK law and MHRA guidance which is enabling and not restricting)
- The addition to the supplementary information to Clause 8.1 to reflect the current Q and A that the registered medical practitioner should be capable of being registered in the UK without the need for additional tests of medical/clinical knowledge
- Certification of non interventional studies (needed for consistency with EFPIA)

Ongoing and emerging further work on Code includes

- Brexit and Covid
- Prescribing information changes (to discuss with MHRA changes to UK law)
- Risk Management Materials
- EAMS
- Exemption to Clause 8.2 independent speaker, this is confusing and should be taken out
- Remove reference to CD Roms, USB sticks
- APEC (Appropriate Prescribing Ethics and Code, ABPI group) work in 2021 on virtual ways of working, information for patients, industry approach to homecare may lead to changes to the Code

Summary of agreed changes to the 2019 Code

Update of presentation provided with the consultation documents to summarise all the changes (ie those in June 2020, those following the consultation and those arising from changes to UK law or MHRA guidance)

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.

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 new definitions are Donations and Grants, Events (which includes meetings) Sponsorship and Support.

- Donations and Grants replace medical educational goods and services (MEGS) in the 2019 ABPI Code and have been expanded to include patient organisations. MEGS can still be provided as either Donations or Grants or possibly as Collaborative Working.

Changes as a consequence of the 2019 EFPIA Code

- Patient Organisations and/or individuals representing patient organisations are 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 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 including patients and journalists provide services similar to those already covered in the Code (2019 Code, Clause 23 Use of Consultants) have been incorporated. The services generally relate to healthcare, disease or medicine.

Other Changes

- Additional requirement to disclose payments for contracted services paid to members of the public (not representing a patient organisation) to include patients and journalists 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 requirement for a note summarising the methodologies used in preparing the disclosure.

- An optional template is available for companies to use to disclose payments to patient organisations and members of the public.

OVERARCHING REQUIREMENTS

GREY SECTION
CLAUSES 1 - 10

Scope of the Code and Definitions
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, individuals representing patient organisations, third party, sponsorship and support).

Obligations and Responsibilities
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
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 Clause 11.1 and 11.2 of 2021 Code (Blue Section, promotion))
- Brings together
  - prohibition on promoting a medicine without a marketing authorisation
  - prohibition on promoting a prescription only medicine to the public (plus exclusion for approved vaccination and other campaigns)
  - 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
Clause 3
Obligations
Grey Section

Main changes

- Additional reference in the supplementary information to products with temporary authorisations for sale or supply without a marketing authorisation

Obligations and Responsibilities
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
  - responsibility for information about products issued by agencies.

Quality Standards
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
Clause 6
Information, Claims, Comparisons and Disparagement
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
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
Clause 8
Certification and Examination
Grey Section

Main changes compared with 2019 Code Clause 14

- More information about examination of material
- Requirement for certification of the written agreement for donations and grants
- 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 in the PMCPA Guide

Quality Standards
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
- Details about the extensions to the time allowed to pass the examination as a result of the pandemic added to the supplementary information

Quality Standards
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
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 Clause 10.1
  - prohibition on compensating merely for time attending meetings, 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 can be found in the PMCPA Guide

PROMOTION TO HEALTH PROFESSIONALS AND OTHER RELEVANT DECISION MAKERS

BLUE SECTION
CLAUSES 11 - 17

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

- Brings together
  - Marketing Authorisation - Clause 11
  - Prescribing Information - Clause 12
  - Abbreviated Advertisements - Clause 13
  - Information, Claims and Comparison - 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.

Marketing Authorisation and Temporary Supply Authorisation Clause 11 Blue Section

Main changes compared with 2019 Code Clause 3

- Additional requirement that a medicine with a temporary supply authorisation must not be promoted unless it is part of a campaign that has been approved by the health ministers. Explanation added to the supplementary information

Prescribing Information and Other Obligatory Information
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.
- Place holder in the supplementary information for the transition arrangements for marketing authorisation numbers and possible some addresses following the end of the transition period for leaving the EU

Further work

This (and 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
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 and Other Relevant Decision Makers
Clauses 15 – 17
Blue Section

- Brings together
  - High Standards, Format and Suitability - 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 - 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 - Clause 17

Representatives
Clause 17
Blue Section

Main changes compared with 2019 Code Clause 15

- Additional requirement that representatives must forward any information about the use of their company's medicine to the scientific service (not just those they promote)
- Reordering of the requirements for representatives' briefing material

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

GREEN SECTION
CLAUSES 18 - 22

Information, Claims and Comparisons
Clause 18
Green Section

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

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

Clause 19

Green Section

- Brings together
  - prohibition on gifts and inducements
  - requirements for materials and items for patient support supplied to health professionals to pass on to patients.

Collaborative Working with Organisations
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 (MEGS) and Joint Working. MEGS which comply with the 2019 Code can continue until 31 December 2021 without the need for them to be reclassified as either a donation or collaborative working and comply with any new requirements.

Schematic setting out Collaborative Working with Healthcare Organisations and others can be found in the PMPCA Guide

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

- 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 AND JOURNALISTS

YELLOW SECTION
CLAUSES 23 - 25

Donations and Grants
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 pharmaceutical company in return. Prohibited to individuals
- Requirement for a written agreement which must be certified
- Medical and educational goods and services replaced by donations and grants or possibly collaborative working.

Schematic setting out the requirements for donations and grants can be found in the PMCPA Guide

Contracted Services
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
- Requirement for disclosure for fee for Code related service payments to individual members of the public including patients and journalists for certain services, (in general those related to healthcare, diseases, medicines) 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
Clause 25
Yellow Section

Main changes compared with 2019 Code Clauses 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 without prior agreement

and also includes requirements

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

SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH THE PUBLIC INCLUDING PATIENTS AND JOURNALISTS AND PATIENT ORGANISATIONS

PINK SECTION
CLAUSES 26 - 27

Relations with the Public including Patients and Journalists
Clause 26
Pink Section

Main changes compared with 2019 Code Clause 26

- Additional reference to medicines with a temporary supply authorisation in relation to vaccination and other campaigns carried out by pharmaceutical companies and approved by the health ministers
- Additional reference to items for patient support
- Prizes for patient competitions no longer allowed
- Reordering of supplementary information to Clause 26.2.

A schematic setting out the requirements for the public and patient organisations can be found in the PMCPA Guide

Relationships with Patient Organisations
Clause 27
Pink Section

Main changes compared with 2019 Code Clause 27

- Additional reference to individuals representing patient organisations and the need for the contract to be with the patient organisation
- Removal of reference to supporting the work of patient organisations including the assistance of the provision of appropriate information to the public, patients and carers.

A schematic setting out the requirements for the public and patient organisations can be found in the PMCPA Guide

ANNUAL DISCLOSURE REQUIREMENTS

TEAL SECTION
CLAUSES 28 - 31

Annual Disclosure Requirements
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 transfers of value to health professionals, other relevant decision makers and healthcare organisations 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 Clause 29
- Timings, Duration and Retention of Disclosure Information - Clause 31.

Disclosure of Contracted Services Provided by The Public including Patients and Journalists
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 in the PMCPA Guide