2024 ABPI Code of Practice

Changes to the Code clauses

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What has changed?

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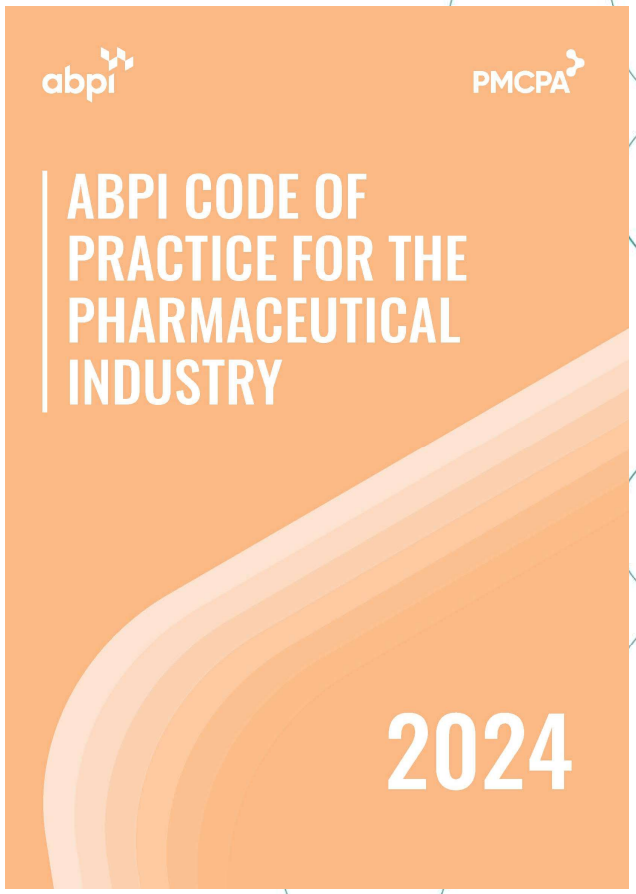
Effective from
1 October 2024



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Key changes to the content

Grey Section – Overarching Requirements

GREY SECTION
OVERARCHING REQUIREMENTS CLAUSES 1–10

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Clause 5 High Standards and Suitability

5.1 Companies must maintain high standards at all times.

5.2 All company personnel must maintain a high standard of ethical conduct in the discharge of their duties and comply with all relevant requirements of the Code.

- A new clause (5.2) to separate the company requirements from the requirements of company personnel
  - Clauses 5.2 to 5.7 are renumbered to 5.3 to 5.8
  - Clause 17.2 of the 2021 Code (relating to the conduct of representatives) has been removed as it is now covered by this broader requirement

- Minor terminology update to the new Clause 5.6 (previously 5.5) in relation to market research

Clause 5 Supplementary Information

Clause 5 High Standards and Suitability

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

Clause 5.1 High Standards

Companies should have policies or similar to clearly communicate corporate standards, expectations and behaviour, and should provide appropriate training.

Clause 5.2 High Standards and Conduct

Companies are responsible under the Code for the acts and omissions of their personnel which come within the scope of the Code, even if they act contrary to the instructions which they have been given.

Company personnel include members of staff, those retained by way of contract and third parties.

Clause 5.3 Suitability

Certain types, styles and methods of communication are unacceptable. These include:

- the display of naked or partially naked people for the purpose of attracting attention to the material or the use of sexual imagery for that purpose
- 'teaser' communication/advertising whereby material is intended to 'tease' the recipient by eliciting an interest in something which will be following or will be available at a later date without providing any actual information about it.

Care should be taken with language, use of abbreviations, etc. and the use of emojis and the like.

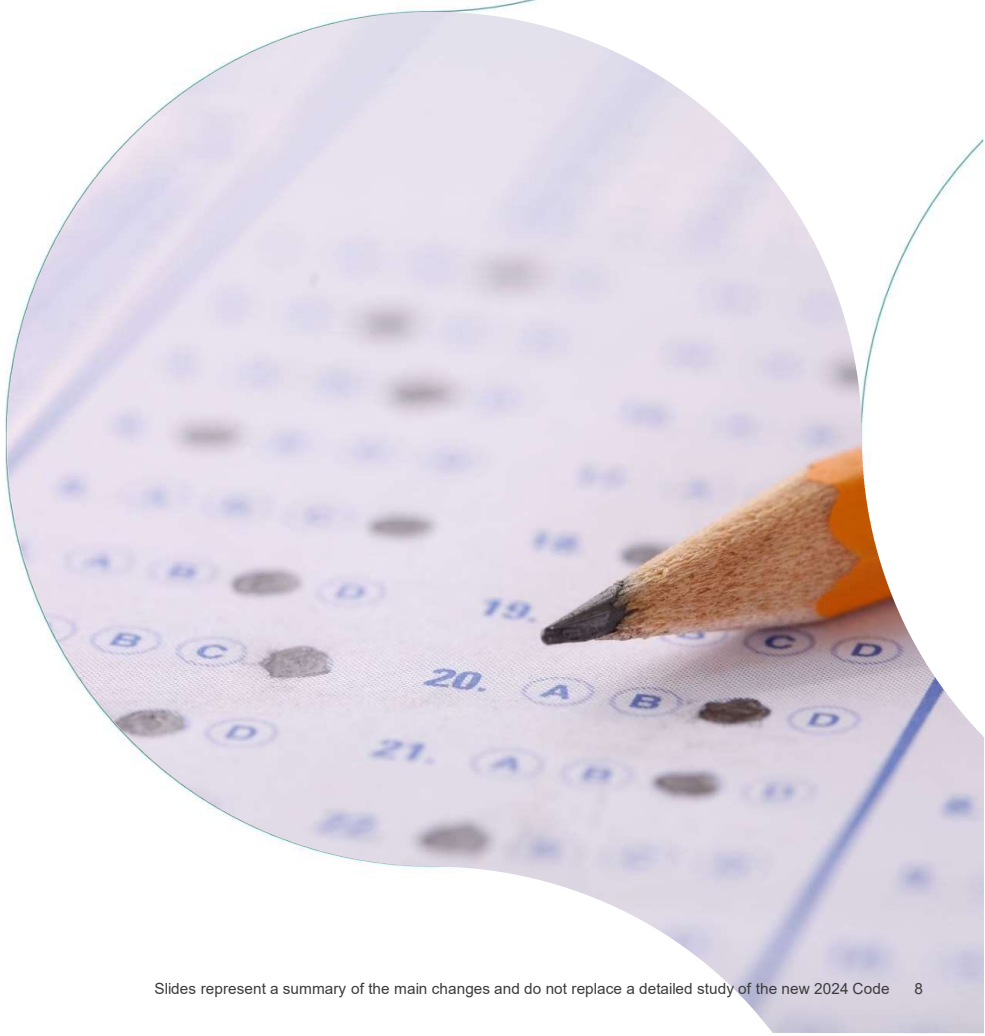
Clause 9.4

- The ABPI examinations have been renamed:

"ABPI Medical Representatives Examination"
is now
"ABPI Advanced Programme for Industry Personnel"

"ABPI Generic Sales Representatives Examination"
is now
"ABPI Intermediate Programme for Industry Personnel"

- Supplementary information about extensions to the time allowed to pass an examination as a result of the COVID-19 pandemic has been replaced by a statement referring to the 2021 Code.



Clause 10.4

10.4 Where a company provides support to an individual health professional or other relevant decision maker to attend an event/meeting there must be a written agreement in place setting out what has been agreed, including the categories of cost such as registration fees, accommodation and/or travel.

Supplementary information:

Clause 10.4 Support for Individual Health Professionals or Other Relevant Decision Makers to Attend Events/Meetings

The rationale for the decision to provide support to an individual health professional or other relevant decision maker to attend an event/meeting should be documented prior to the provision of the support.

- Strengthened Code requirement to increase governance in relation to this high-risk area
- Was previously referred to in the *Guidelines on Company Procedures* but is now a Code requirement

Blue Section – Promotion to Health Professionals and Other Relevant Decision Makers

BLUE SECTION
PROMOTION TO HEALTH PROFESSIONALS AND OTHER RELEVANT DECISION MAKERS CLAUSES 11–17

Clause 11: Marketing Authorisation and Temporary Supply Authorisation	**27**
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Clause 14: Information, Claims and Comparisons	**32**
Clause 15: High Standards, Format and Suitability	**33**
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Clause 17: Representatives	**34**

Clause 12 Prescribing Information and Other Obligatory Information

- The main change to Clause 12 is the option to provide prescribing information via a QR code in printed material and certain digital material
- The 2024 Code now allows for the adverse event reporting statement to be provided in the same manner as prescribing information
- The changes to Clause 12 were developed in consultation with the MHRA

Clause 12.1

12.1 The prescribing information listed in Clause 12.2 must be provided in a clear and legible manner in all promotional material for a medicine except for abbreviated advertisements (see Clause 13). The prescribing information must form part of the promotional material and be positioned for ease of reference.

	Inclusion as text	A clear and prominent QR code	A clear and prominent, direct, single click link	A printed document made available to the recipient and referred to in the material
Printed material	✓	✓		
Posters and exhibition panels at events/meetings	✓	✓		✓

i. In **printed material**, prescribing information must be provided within the promotional material either:

- by inclusion as text, or
- through a clear and prominent Quick Response (QR) code with instructions to scan it for the prescribing information.

The prescribing information for medicines promoted on posters and exhibition panels at events/meetings may alternatively be provided by way of a printed document which is made available at the company stand and this must be referred to on the posters or panels.

Clause 12.1

12.1 The prescribing information listed in Clause 12.2 must be provided in a clear and legible manner in all promotional material for a medicine except for abbreviated advertisements (see Clause 13). The prescribing information must form part of the promotional material and be positioned for ease of reference.

	Inclusion as text	A clear and prominent QR code	A clear and prominent, direct, single click link	A printed document made available to the recipient and referred to in the material
Printed material	✓	✓		
Posters and exhibition panels at events/meetings	✓	✓		✓
Digital material accessed by a recipient on their own device	✓		✓	

ii. In **digital material accessed by a recipient on their own device** (such as emails, advertisements in electronic journals, websites, etc.), the prescribing information must be provided within the promotional material either:

- by inclusion as text, or
- by way of a clear and prominent, direct, single click link.

For webinars and remote detailing viewed by the recipient on their own device, if prescribing information is within the promotional material by way of a clear and prominent, direct, single click link, it must be accessible to the recipient.

Clause 12.1

12.1 The prescribing information listed in Clause 12.2 must be provided in a clear and legible manner in all promotional material for a medicine except for abbreviated advertisements (see Clause 13). The prescribing information must form part of the promotional material and be positioned for ease of reference.

	Inclusion as text	A clear and prominent QR code	A clear and prominent, direct, single click link	A printed document made available to the recipient and referred to in the material
Printed material	✓	✓		
Posters and exhibition panels at events/meetings	✓	✓		✓
Digital material accessed by a recipient on their own device	✓		✓	
Digital material shown to a recipient in person	✓	✓	✓	✓

iii. In **digital material shown to a recipient in person** (such as electronic detail aids on a company device, face-to-face presentations, etc.), the prescribing information must be provided within the promotional material either:

- by inclusion as text, or
- through a clear and prominent QR code with instructions to scan it for the prescribing information, or
- by way of a clear and prominent, direct, single click link which is accessed by the presenter.

The prescribing information may alternatively be provided by way of a printed document made available to the recipient and this must be referred to in the digital material.

Clause 12.1

The prescribing information must form part of the promotional material and be positioned for ease of reference.

	Inclusion as text	A clear and prominent QR code	A clear and prominent, direct, single click link	A printed document made available to the recipient and referred to in the material
Printed material	✓	✓		
Posters and exhibition panels at events/meetings	✓	✓		✓
Digital material accessed by a recipient on their own device	✓		✓	
Digital material shown to a recipient in person	✓	✓	✓	✓

Clause 12 and its supplementary information include specific requirements if prescribing information is provided using a QR code, including that:

- the QR code must be clear and prominent with instructions to scan it for the prescribing information
- where more than one QR code is displayed, it should be clear which medicine each relates to
- each QR code should be of sufficient size, clarity, duration and be positioned to allow it to be easily scanned
- scanning a QR code should directly access the up-to-date version of the prescribing information which can be updated remotely
- two separate personal devices should not be required to view promotional material and scan a QR code on that material

Clause 12.3

12.3 Where not immediately apparent, promotional material must include a clear prominent statement as to where the prescribing information can be found.

- This new clause applies to all promotional material
- This replaces Clause 12.6 of the 2021 Code that just applied to promotional material provided on the internet
- The wording in Clause 12.7 of the 2021 Code referring to printed journal advertisements has moved to the supplementary information for this new clause

Clause 12.6

12.6 All promotional material must include the prominent statement ‘Adverse events should be reported. Reporting forms and information can be found at [website address which links directly to the MHRA Yellow Card site]. Adverse events should also be reported to [relevant pharmaceutical company].’

The adverse event reporting statement must be provided within the promotional material, either by inclusion as text or in the same manner as prescribing information as set out in Clause 12.1.

Where not immediately apparent, promotional material must include a clear prominent statement as to where the adverse event reporting statement can be found.

- The 2024 Code now allows for the adverse event reporting statement to be provided in the same manner as prescribing information
- There is a new requirement that, where not immediately apparent, the material must clearly signpost to where the statement can be found

	Inclusion as text	A clear and prominent QR code	A clear and prominent, direct, single click link	A printed document made available to the recipient and referred to in the material
Printed material	✓	✓		
Posters and exhibition panels at events/meetings	✓	✓		✓
Digital material accessed by a recipient on their own device	✓		✓	
Digital material shown to a recipient in person	✓	✓	✓	✓

Reprints

The supplementary information to Clauses 12.1, 12.6 and 16.5 includes requirements regarding provision of prescribing information and adverse event reporting information in relation to reprints.

Clauses 12.1 and 12.6 Provision of Prescribing Information and Adverse Event Reporting Statement With Reprints

“When providing a reprint of an article about a medicine, it must be accompanied by a document containing the prescribing information and adverse event reporting statement. When providing a digital reprint, this could be provided by way of a clear and prominent, direct, single click link.”

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

GREEN SECTION

INTERACTIONS WITH HEALTH PROFESSIONALS, OTHER RELEVANT DECISION MAKERS AND HEALTHCARE ORGANISATIONS CLAUSES 18–22

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Clause 19.2 Supplementary Information

Clause 19.2 Items for Patient Support

… An ‘inexpensive’ item for patient support means one that has cost the donor company no more than £15, excluding VAT. The perceived value to the health professional and the patient must be similar. …

Clause 20.3

The requirement has been broadened to certification of all collaborative working project initiation documents, not just joint working project initiation documents.

… Material relating to collaborative working must be certified, including the project initiation document and the summary of the collaborative working agreement. …

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

YELLOW SECTION

INTERACTIONS WITH HEALTH PROFESSIONALS, OTHER RELEVANT DECISION MAKERS, HEALTHCARE ORGANISATIONS, PATIENT ORGANISATIONS AND THE PUBLIC, INCLUDING PATIENTS AND JOURNALISTS CLAUSES 23–25

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

PINK SECTION

SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH THE PUBLIC, INCLUDING PATIENTS AND JOURNALISTS, AND PATIENT ORGANISATIONS CLAUSES 26–27

Clause 26: Relations with the Public, Including Patients and Journalists **47**

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Clause 26.3 Supplementary Information

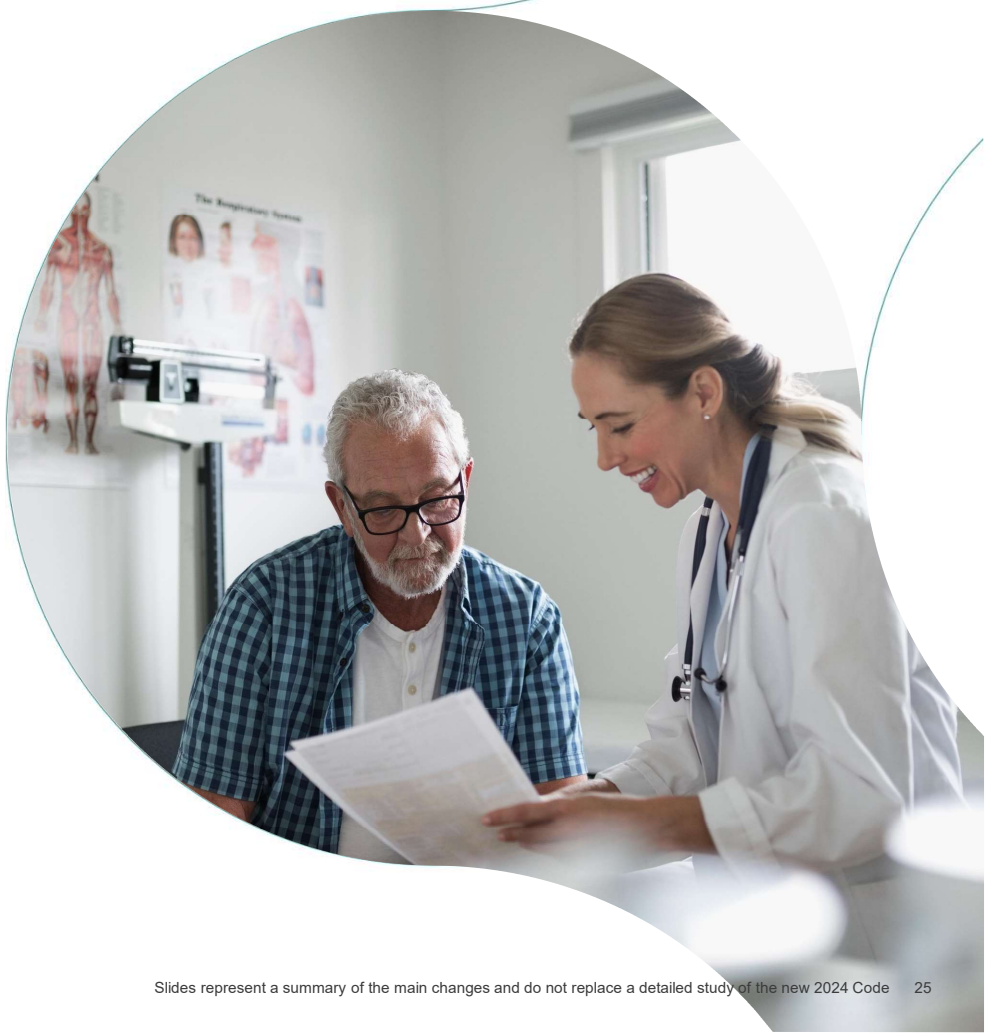
Clause 26.3 Items for Patient Support

An ‘inexpensive’ item for patient support means one that has cost the donor company no more than £15, excluding VAT. The perceived value to the health professional and the patient must be similar. Such items may bear the name of a medicine and/or information about medicines only if such detail is essential for the proper use of the item by patients.

Clause 27 Supplementary Information

Clause 27 Relationships with Patient Organisations

Relationships between pharmaceutical companies and patient organisations are generally covered by the pharmaceutical company providing a donation, grant or sponsorship to the patient organisation or the patient organisation providing a contracted service to the company. In the event that arrangements with the patient organisation do not fall within these categories then the pharmaceutical company needs to satisfy itself that the activity complies with all of the requirements of the Code, including but not limited to Clauses 27 and 29.



Teal Section – Annual Disclosure Requirements

TEAL SECTION
ANNUAL DISCLOSURE REQUIREMENTS CLAUSES 28–31

Clause 28: Annual Disclosure of Transfers of Value to Health Professionals, Other Relevant Decision Makers and Healthcare Organisations **51**

Clause 29: Annual Disclosure of Contracted Services, Donations, Grants and Sponsorship (including in relation to events/meetings) Provided to Patient Organisations **52**

Clause 30: Annual Disclosure of Contracted Services Provided by the Public, Including Patients and Journalists **53**

Clause 31: Timings, Duration and Retention of Disclosure Information **53**

Clause 28 Supplementary Information

- Now explicitly refers to Disclosure UK and its website: www.disclosureuk.org.uk
- Text amended to clarify that the disclosure template is mandatory
- Additional wording

  Clause 28.5 Lawful Basis for Disclosure of Transfers of Value to Individual Health Professionals and Other Relevant Decision Makers

  Companies should seek a lawful basis for individual disclosure and only disclose in aggregate where a lawful basis cannot be obtained.

Clause 29 Supplementary Information

- New supplementary information:

  Clause 29.1 Patient Organisation Disclosure Method

  For transfers of value made in 2024 and publicly disclosed in 2025, and for each calendar year thereafter, companies should submit a link via the relevant Disclosure UK gateway. The link should take visitors from Disclosure UK to patient organisation disclosure information published on the company's website.

Clause 30 Supplementary Information

- New supplementary information:

  Clause 30.1 The Public, Including Patients and Journalists, Disclosure Method

  For transfers of value made in 2024 and publicly disclosed in 2025, and for each calendar year thereafter, companies should submit a link via the relevant Disclosure UK gateway. The link should take visitors from Disclosure UK to the public, including patients and journalists, disclosure information published on the company's website.

Clause 31 Supplementary Information

- New supplementary information:

  Clause 31.1 Disclosure UK Timelines

  Information to be published on Disclosure UK must be submitted in line with the operational timelines of the platform. Details are available at www.disclosureuk.org.uk

Timelines and next steps

1 October 2024:
The 2024 ABPI Code comes into operation

1 October 2024 to 31 December 2024:
During this period, no material or activity will be regarded as being in breach of the Code if it fails to comply with its provisions only because of requirements which this edition of the Code newly introduces.

The new template for disclosure should be used to submit the 2024 data to Disclosure UK by **14.00 GMT Friday, 28 March 2025**.

Companies should:

- Familiarise themselves with the changes to the Code and associated materials
- Encourage relevant staff to view these webinars outlining the changes to the Code
- Update relevant policies and procedures and train staff
- Ensure that materials and activities that do not meet the requirements of the 2024 Code are withdrawn before 1 January 2025

PMCPA

Prescription Medicines Code of Practice Authority

The PMCPA is a division of the ABPI which is a company limited by guarantee registered in England & Wales no 09826787.

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