CHANGES TO THE 2021 ABPI CODE

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The Update to the 2021 ABPI Code of Practice for the Pharmaceutical Industry

Proposals to develop the ABPI Code were developed by the PMCPA in collaboration with Code Working Groups. The significant changes to Clause 12, including the introduction of QR codes to access Prescribing Information on certain promotional materials, were developed by a cross-functional project team comprising MHRA, ABPI, PMCPA and member companies.

A public consultation on proposals to update the ABPI Code was undertaken for a twelve week period between December 2023 and February 2024. All of the responses were reviewed by the PMCPA. Multiple comments were received on the Code and Constitution and Procedure that were not associated with the topics being consulted on.

The ABPI Board agreed there is a need to ensure that important changes proposed within the consultation are delivered on, while also ensuring that momentum is maintained to assess other potential changes. Some comments received require more extensive consideration and the PMCPA cannot address all feedback in the timescales planned for the 2024 Code launch. A phased approach is being taken to assess, in particular, proposals which were not supported during public consultation and require revisiting, and responses received that were not associated with the topics being consulted upon. These will be assessed for either a future Code update, or the development of guidance.

There are also minor updates to the mandatory disclosure template. There is a minor update to Note M to change ‘sponsorship’ to ‘transfers of value’ to give companies the option to use the associated column to disclose transfers of value to healthcare organisations that cannot be disclosed elsewhere on the template and provide an explanation in the methodological note. There is also an update to the coloured key to make clear where companies should and should not enter data.

The proposals to amend the ABPI Code take into account the need to ensure that the ABPI Code reflects UK law and incorporates requirements from the IFPMA and EFPIA Codes.

This document is designed to be used in conjunction with the 2024 ABPI Code and does not replace a detailed study of the new Code. It details the following:

- A table describing the main changes to the Code clauses.
- A summary of proposed changes that were consulted upon that were not taken forward for the 2024 Code
- An explanation of the changes to Clause 12 and its revision post public consultation.

Please note that the **2024 Code comes into operation on 1 October 2024**. During the period 1 October 2024 to 31 December 2024, 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. **From 1 January 2025**, all materials/activities must comply with the 2024 Code. There are separate timelines for the new requirement for Disclosure UK gateway links (see table below).

Changes to the 2021 ABPI Code

The table below describes the main changes to the Code clauses. New wording is highlighted in red and underlined, removed wording is highlighted in blue with a strikethrough. The changes to Clause 12 are described separately, at the end of this document. The changes to the Constitution and Procedure have been described in a separate document. The table does not include general/house-keeping updates to the Code, e.g., PMCPA address change, which are briefly summarised beneath the table. **This document does not replace a detailed study of the new 2024 Code.**

Proposals for clause amendments that went to public consultation that were not taken forward for the 2024 Code are summarised beneath the table.

Mandatory disclosure template

The template for disclosure agreed for the 2024 Code should be used to submit the 2024 data to Disclosure UK in 2025. The minor changes to the mandatory disclosure template include:

- The Code year updated from '2021' to '2024'
- In the notes section below the main template, cell C46 [Note M: (M)] has had the word 'Sponsorship' replaced with 'Transfers of value'. This change is to give companies the option to use the column associated with Note M to disclose transfers of value to healthcare organisations that cannot be disclosed elsewhere on the template and provide an explanation in the methodological note.
- Below the notes section, in cells A52-C52, grey has been added to the key to make clear that it means 'do not enter data'

Table of main Clause changes (minus Clause 12) that went to consultation and decision following consultation

Clause	Proposed amends that went out to public consultation	Rational for change and decision following public consultation	Final wording for 2024 Code
Clause 5.1	Companies must maintain high standards ~~must be maintained~~ at all times.	To emphasise the requirement for companies to ensure high standards are maintained – supported by the addition of supplementary information and a new clause to separate the company requirements versus the requirements of company employees. Amendment accepted as per consultation.	Companies must maintain high standards ~~must be maintained~~ at all times.

General Clause 5 Supplementary Information (SI)	**Clause~~s~~ ~~5.1 and 5.2~~ 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. **Clauses 5.1 ~~and 5.2~~ High Standards** Companies must have policies and standard operating procedures (SOPs) to clearly communicate corporate standards, expectations, and behaviour, and provide training in this regard. ~~It follows, therefore, that certain types, styles and methods of communication, even where they might be acceptable for products other than medicines, 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.~~	Restructuring of some of the supplementary information to better reflect the clause numbers. High standards and suitability are applicable to the whole of Clause 5. Some of the deleted text has moved to a new Clause 5.3 Suitability subheading. The amends support the update to Clause 5.1 to include the requirements companies should have in place to deliver their compliance programme – aligned with the guidelines on company procedures published on PMCPA website and referred to in the Code. Amended Clause 5.1 High Standards SI following feedback that companies may not have both policies and SOPs, and that corporate standards might be communicated in other formal company documents.	**Clause~~s~~ ~~5.1 and 5.2~~ 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. **Clauses 5.1 ~~and 5.2~~ High Standards** Companies should have policies or similar to clearly communicate corporate standards, expectations and behaviour, and should provide appropriate training. ~~It follows, therefore, that certain types, styles and methods of communication, even where they might be acceptable for products other than medicines, 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.~~

New Clause 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.	Aligns the requirements for all employees to maintain a high standard of ethical conduct in the discharge of their duties and comply with all relevant requirements of the Code in the same way as the requirements for representatives in Clause 17.2 of the 2021 Code. Amendment accepted as per consultation. Feedback received that Clause 17.2 should now be deleted as representatives are covered by this broader requirement. (see change below).	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.
New Clause 5.2 SI	**Clause 5.2 High Standards of Ethical Conduct** Companies are responsible for the actions of their personnel, if such actions are within the scope of the Code, even if they are acting contrary to the instructions which they have been given. Company personnel includes those retained by way of contract and third parties.	Strengthens the expectations upon companies regarding contracted personnel and third parties. Amendment following consultation to standardise with the wording in Clause 1.24. Feedback received that Clause 17.10 should now be deleted, as it's covered by this new wording, and to ensure consistent wording is used throughout the Code on this matter (see change below).	**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 SI	**Clause 5.3 Suitability** It follows from the supplementary information above, therefore, that 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	Restructuring of Clause 5 SI for reasons referred to above. Removal of 'even where they might be acceptable for products other than medicines' to reflect changing times in relation to all advertising. Slight amendment to remove 'It follows from the supplementary information above, therefore, that …' due to changes to the structure of the SI.	**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.		• '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 5.6 (previously Clause 5.5)	Material relating to medicines and their uses, whether promotional or not, and information relating to human health or diseases which is sponsored by a pharmaceutical company or in which a pharmaceutical company has any other involvement, must clearly indicate the role of that pharmaceutical company. The only exception to this is market research material if it is such that the name of the company involved is not required to be stated; then the material must state that it is ~~sponsored~~ commissioned by a pharmaceutical company.	Update to reflect that market research is not sponsored by a company under the definition of Sponsorship in Clause 1.22. The research is commissioned by the company. Amendment accepted as per consultation.	Material relating to medicines and their uses, whether promotional or not, and information relating to human health or diseases which is sponsored by a pharmaceutical company or in which a pharmaceutical company has any other involvement, must clearly indicate the role of that pharmaceutical company. The only exception to this is market research material if it is such that the name of the company involved is not required to be stated; then the material must state that it is ~~sponsored~~ commissioned by a pharmaceutical company.

Clause 9.4 (fourth paragraph)	**Change was not in public consultation**	This amendment was not in the public consultation documents as the PMCPA were informed of the change in the examination names following consultation.	An appropriate examination can be either the relevant ABPI examination (advanced or intermediate programme for industry personnel ~~for medical or generic sales representatives~~) or an examination of at least the same standard which covers similar content and learning material as the corresponding ABPI examination.
Clause 9.4 SI	**Change was not in public consultation**	This amendment was not in the public consultation documents as the PMCPA were informed of the change in the examination names following consultation.	**Clause 9.4 ~~(16.3)~~ Representatives Examinations** The ABPI offers two examinations, and further details can be obtained from the ABPI. Examinations may also be offered by other providers. A company using an examination provider other than the ABPI must be able to demonstrate that its examinations are at least equivalent to those offered by the ABPI. The syllabus studied should be mapped to and meet the requirements in the published ABPI standards. The assessment must be under invigilated examination conditions. The **ABPI Advanced Programme for Industry Personnel** (previously called **ABPI Medical Representatives Examination)** is appropriate for representatives whose duties comprise or include one or both of: • calling upon doctors and/or dentists and/or other prescribers • the promotion of medicines on the basis of, among other things, their particular therapeutic properties. The **ABPI Intermediate Programme for Industry Personnel** (previously called **ABPI Generic Sales Representatives Examination)** is appropriate for representatives who promote medicines

			primarily on the basis of price, quality and availability to non-prescribers. Persons who have passed the ABPI Advanced Programme for Industry Personnel ~~Medical Representatives Examination~~ or similar whose duties change to those specified for generic sales representatives do not need to take another examination. However, persons who have passed the ABPI Intermediate Programme for Industry Personnel ~~Generic Sales Representatives Examination~~ or similar whose duties change to those specified for medical representatives must take an appropriate examination within one year of their change of duties and pass it within two years.
Clause 9.4 SI	**Clause 9.4 ~~(New)~~ Extensions to the Time Allowed to Pass an Examination as a Result of the COVID-19 Pandemic** *[Deletion of all the supplementary information under this heading and addition of the following text below]* Arrangements were put in place in the 2021 Code as the ABPI examination was not available between 13 March 2020 and 30 September 2020 due to the impact of the COVID-19 pandemic, Arrangements for Extensions to the Time Allowed to Pass an Examination as a Result of the COVID-19 Pandemic is set out in the Supplementary Information to Clause 9.4 of the 2021 Code.	Text removed due to the passage of time, however, some reference kept to the arrangements in the 2021 Code in the event that it may be relevant to an individual who has been on long term absence. Slightly amended from consultation to improve readability, including switching paragraphs around and removing capitals.	**Clause 9.4 ~~(New)~~ Extensions to the Time Allowed to Pass an Examination as a Result of the COVID-19 Pandemic** *[Deletion of all the supplementary information under this heading and addition of the following text]* Arrangements for extensions to the time allowed to pass an examination as a result of the COVID-19 pandemic are set out in the supplementary information to Clause 9.4 of the 2021 Code. Arrangements were put in place in the 2021 Code as the ABPI examination was not available between 13 March 2020 and 30 September 2020 due to the impact of the COVID-19 pandemic.

New Clause 10.4	Where companies provide support for individual health professionals and other relevant decision makers to attend events/meetings there must be a written agreement in place setting out what has been agreed including, where possible, a breakdown of costs.	Strengthened Code requirement to increase governance in relation to this high-risk area. Was previously referred to in the guidelines on company procedures as best practice but has now been made a Code requirement. Wording amended following consultation to improve clarity on what was required in the written agreement.	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.
New Clause 10.3 & Clause 10.4 SI	**Clause 10.3 & 10.4 Where Support for Individuals to Attend Events/Meetings is Provided** An educational needs assessment should be completed for the event/meeting and for the supported individual, which provides the rationale for the decision to support the individual in question.	Strengthened Code requirement as a result of findings from company audits. Amended wording following consultation. Removed reference to Clause 10.3 as requirements for patient organisation funding are covered in detail in Clause 27.	**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.
Clause 11.1 SI	**Clause 11.1 ~~(3)~~ Promotion at International Events/Meetings** Promotion at international events/meetings held in the UK may, on occasion, pose certain problems with regard to medicines or indications for medicines which do not have a marketing authorisation in the UK although they are so authorised in another major ~~industrialised country~~ developed country.	Minor word change to bring consistency to the term throughout the SI and to align with wording in MHRA Blue Guide. Amendment accepted as per consultation.	**Clause 11.1 ~~(3)~~ Promotion at International Events/Meetings** Promotion at international events/meetings held in the UK may, on occasion, pose certain problems with regard to medicines or indications for medicines which do not have a marketing authorisation in the UK although they are so authorised in another major ~~industrialised country~~ developed country.

Clause 16.5 SI	**Clause 16.5 Provision of Reprints** The proactive provision of a reprint of an article about a medicine constitutes promotion of that medicine and all relevant requirements of the Code must therefore be observed. Particular attention must be paid to the requirements of Clauses 12.1 and 12.2. When providing a reprint of an article about a medicine, it ~~should~~ must be accompanied by prescribing information and adverse event reporting information.	To clarify and strengthen the requirements regarding provision of prescribing information and adverse event reporting information in relation to reprints, and to align with the requirements of Clause 12. Amendment accepted as per consultation.	**Clause 16.5 Provision of Reprints** The proactive provision of a reprint of an article about a medicine constitutes promotion of that medicine and all relevant requirements of the Code must therefore be observed. Particular attention must be paid to the requirements of Clauses 12.1 and 12.2. When providing a reprint of an article about a medicine, it ~~should~~ must be accompanied by prescribing information and adverse event reporting information.
Clause 17.2	**Change was not in public consultation**	Deleted following feedback that it is now covered by the requirements of the new Clause 5.2 (see above) that 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, not just representatives.	~~Representatives must maintain a high standard of ethical conduct in the discharge of their duties and comply with all relevant requirements of the Code.~~
Clause 17.10	**Change was not in public consultation**	Deleted following feedback that it is now covered by the requirements of the new Clause 5.2 SI (see above) that 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, and that company personnel include members of staff, those retained by way of contract and third parties. The amendment ensures that the wording on the matter stays consistent throughout the Code.	~~Companies are responsible for the activities of their representatives if these are within the scope of their employment even if they are acting contrary to the instructions which they have been given.~~

Clause 19.1 SI	**Package Deals** Clause 19.1 does not prevent the offer of package deals which are commercial arrangements whereby the purchase of a particular medicine is linked to the provision of certain associated benefits as part of the purchase price, ~~such as~~ examples include, apparatus for administration of the medicine, the provision of training on its use or the services of a ~~nurse~~ health professional to administer it.	Minor wording amendment for clarity. Slight amendment from consultation to aid readability.	**Clause 19.1 Package Deals** Clause 19.1 does not prevent the offer of package deals which are commercial arrangements whereby the purchase of a particular medicine is linked to the provision of certain associated benefits as part of the purchase price, such as apparatus for administration of the medicine, the provision of training on its use or the services of a ~~nurse~~ health professional to administer it.
Clause 19.2	Health professionals may be provided with materials and items for patient support ~~which are~~ to be passed on to patients, the details of which must be appropriately documented and certified in advance as required by Clause 8.3. ~~The~~ Any item~~s~~ ~~p~~rovided must be inexpensive and directly benefit patient care. ~~They~~ It may bear the name of the company providing ~~them~~ it, but must not be product branded, unless the name of the medicine is essential for the correct use of the item by the patient. Items must not be given out from exhibition stands. They must not be given to administrative staff unless they are to be passed on to a health professional.	Minor wording update for readability Amendment accepted as per consultation, save correction of grammatical error.	Health professionals may be provided with materials and items for patient support ~~which are~~ to be passed on to patients, the details of which must be appropriately documented and certified in advance as required by Clause 8.3. ~~The~~ Any item~~s~~ provided must be inexpensive and directly benefit patient care. ~~They~~ It may bear the name of the company providing ~~them~~ it but must not be product branded, unless the name of the medicine is essential for the correct use of the item by the patient. Items must not be given out from exhibition stands. They must not be given to administrative staff unless they are to be passed on to a health professional.

Clause 19.2 SI	**Items for Patient Support** An 'inexpensive' item for patient support means one that has cost the donor company no more than ~~£10~~ £15, excluding VAT. The perceived value to the health professional and the patient must be similar.	Update to cost to reflect general price increases Amendment accepted as per consultation.	**Clause 19.2 Items for Patient Support** An 'inexpensive' item for patient support means one that has cost the donor company no more than ~~£10~~ £15, excluding VAT. The perceived value to the health professional and the patient must be similar.
Clause 20 SI	~~**Clause 20 Medical and Educational Goods and Services which Comply with Clause 19 of the 2019 ABPI Code, Including their Transition under the 2021 ABPI Code**~~ ~~Medical and educational goods and services (MEGS) provided under Clause 19 of the 2019 Code are likely to fall under donations in Clause 23 or collaborative working in Clause 20 of the 2021 Code. Companies wishing to continue with ongoing MEGS from 1 July 2021 can do so until 31 December 2021 under the 2021 Code without the need for them to be reclassified as either a donation or collaborative working and comply with any new requirements as a result of this change. Thus there is a six month transition period for MEGS.~~ ~~If the collaborative working involves services, then the supplementary information to Clause 23 Donations and Grants should be considered~~ The transition of Medical and Educational Goods and Services which Complied with Clause 19 of the 2019 Code under the 2021 Code are set out in the supplementary information to Clause 23 of the 2021 Code	The transition period is over and all MEGS should have now been re-classified so the text can be deleted. Following consultation, it was considered that the new proposed text was not required due to the passage of time. However, the following text should not have been deleted: "If the collaborative working involves services, then the supplementary information to Clause 23 Donations and Grants should be considered" and has been put under a new heading "Collaborative working which involves services".	**Clause 20 Collaborative Working Which Involves Services** If the collaborative working involves services, then the supplementary information to Clause 23 Donations and Grants should be considered.

Clause 20 SI (new)	**Change was not in public consultation**	Wording added to reflect that the ABPI joint working guidance has been replaced by broader collaborative working guidance, and to future proof the wording. Text has therefore also been deleted from the SI to Clause 20.4 which referred to guidance which has since been retired.	When considering collaborative working, companies should take account of relevant guidance documents.
Clause 20.3	Material relating to collaborative working must be certified, including the project initiation document (PID) and the summary of the collaborative working agreement. The collaborative working agreement does not need to be certified.	Broadened requirement to include certification of all collaborative working project initiation documents, not just joint working project initiation documents. Amend to be made as per consultation. without acronym "PID" as only referred to once in Code.	Material relating to collaborative working must be certified, including the project initiation document and the summary of the collaborative working agreement. The collaborative working agreement does not need to be certified.
Clause 20.4 SI	~~**(Third paragraph of) Joint Working as a form of Collaborative Working**~~ ~~In addition to the certification requirements set out in Clause 20.3, the joint working project initiation document must also be certified.~~	Deleted as the requirement for certification of the project initiation document for all collaborative working, which includes joint working, has now been included in Clause 20.3 (see above). Amend to be made as per consultation.	~~**(Third paragraph of) Joint Working as a form of Collaborative Working**~~ ~~In addition to the certification requirements set out in Clause 20.3, the joint working project initiation document must also be certified.~~

Clause 23 General SI	~~**Clause 23 Medical and Educational Goods and Services which comply with Clause 19 of the 2019 ABPI Code, Including their Transition under the 2021 Code**~~ ~~Medical Education Goods and Services (MEGS) provided under Clause 19 of the 2019 code are likely to full under donations in Clause 23 or collaborative working in Clause 20 of the 2021 Code. Companies wishing to continue with ongoing MEGS from 1 July 2021 can do so until 31 December 2021 under the 2021 Code without the need for them to be reclassified as either a donation or as collaborative working and comply with any new requirements as a result of this change. Thus there is a six month transition period for MEGS.~~	Section to be removed as transition period is now complete. Amendment accepted as per consultation.	~~**Clause 23 Medical and Educational Goods and Services which comply with Clause 19 of the 2019 ABPI Code, Including their Transition under the 2021 Code**~~ ~~Medical Education Goods and Services (MEGS) provided under Clause 19 of the 2019 code are likely to full under donations in Clause 23 or collaborative working in Clause 20 of the 2021 Code. Companies wishing to continue with ongoing MEGS from 1 July 2021 can do so until 31 December 2021 under the 2021 Code without the need for them to be reclassified as either a donation or as collaborative working and comply with any new requirements as a result of this change. Thus there is a six month transition period for MEGS.~~
Clause 26.3 SI	**Clause 26.3 Items for Patient Support** An 'inexpensive' item for patient support means one that has cost the donor company no more than ~~£10~~ £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.	To align with changes to Clause 19.2 SI Amendment accepted as per consultation.	**Clause 26.3 Items for Patient Support** An 'inexpensive' item for patient support means one that has cost the donor company no more than ~~£10~~ £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.

New Clause 27 SI	**Clause 27 Relationships with Patient Organisations** Most relationships between pharmaceutical companies and patient organisations are covered by the pharmaceutical company providing a donation, grant or sponsorship to the patient organisation or the patient organisation providing a fee for service to the company. In the event that the arrangements for an activity with a 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 Clauses 27 and 29.	This new supplementary information is to clarify that the Code does not necessarily prohibit activities with patient organisations that are not strictly defined in the Code, as long as the company is satisfied that the activity complies with the Code. Slight amendment from consultation for readability.	**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.

Clause 28.1 SI	**Clause 28.1 Mode of Disclosure for Health Professionals, Other Relevant Decision Makers and Healthcare Organisations** There is a central platform for disclosure in the UK which companies must use. HCP/ORDM/HCO disclosures made via the ABPI's central platform must be managed in line with the operational timelines of the platform. This includes submission of full and final HCP/ORDM/HCO disclosure information before the end of March, annually. The template to be used for submission is available from the PMCPA website www.pmcpa.org.uk.	The proposed update was to clarify the wording around timelines in relation to use of the platform itself. Following consultation, it was decided to move reference to platform operational timelines to Clause 31.1 SI (see below). Text in the SI to Clause 28.1 has been updated to refer to the website address for Disclosure UK and to clarify that the template is mandatory.	**Clause 28.1 Mode of Disclosure for Health Professionals, Other Relevant Decision Makers and Healthcare Organisations** ~~There is a central platform for disclosure in the UK which companies must use.~~ Disclosure UK is the central platform for disclosure in the UK which companies must use. Information is available at www.disclosureuk.org.uk The mandatory template to be used for submission is available from the PMCPA website www.pmcpa.org.uk.
Clause 28.5 SI	**Clause 28.5 Legal basis for individual disclosure** Disclosing companies should seek a legal basis pursuant of individual disclosure, and only disclose in aggregate where a legal basis cannot be obtained.	Additional wording to strengthen the requirement to seek a lawful basis for individual disclosure. Amended following consultation to align language with UK GDPR requiring a 'lawful basis' for collecting and using personal data, to correct a grammatical error and for readability/clarity.	**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.

NEW Clause 29.1 SI	**Clause 29.1 Patient Organisation Disclosure Timelines** Links provided to the central platform in relation to Patient Organisation disclosure information must be submitted in the first six months after the end of the calendar year in which the transfers of value/payments were made. **Clause 29.1 Patient Organisation Disclosure Method** Disclosure information for Patient Organisations must be disclosed on the company website either on a national or European level. Companies must also submit their link(s) via the relevant disclosure gateway available from the central platform. Submitted links must take visitors from the central disclosure platform to Patient Organisation disclosure information published on the company's website.	Strengthened Code requirement for companies to submit a link via the relevant disclosure gateway to take visitors from Disclosure UK to patient organisation disclosure information published on the company's website. Following consultation, it was decided to move reference to platform operational timelines to Clause 31.1 SI (see below). Disclosure method text was amended to remove information that was already stated in the clause itself, and to make clear when the requirement regarding the gateway link comes into force.	**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 30.1	Amendment did not go out to consultation. The gap was identified after consultation.	Updated to state where transfers of value to the public, including patients and journalists, information must be disclosed. This was a gap in the 2021 Code.	30.1 ~~(New Clause)~~ Companies must make publicly available annually details of the fees for certain contracted services paid to members of the UK public, including patients and journalists. These services include speaking at meetings, assistance with training, writing articles and/or publications, participating in advisory boards, advising on the design, etc. of clinical trials and participating in market research where such participation involves remuneration and/or travel. The information must be disclosed on the company website.

New Clause 30.1 SI	**Clause 30.1 The Public, Including Patients and Journalists, Disclosure Timelines** Links provided to the central platform in relation to The Public, including Patients and Journalists, disclosure information must be submitted in the first six months after the end of the calendar year in which the transfers of value/payments were made. **Clause 30.1 The Public, including Patients and Journalists, Disclosure Method** Disclosure information for The Public, including Patients and Journalists, must be disclosed on the company website either on a national or European level. Companies must also submit their link(s) via the relevant disclosure gateway available from the central platform. Submitted links must take visitors from the central disclosure platform to the Public, including Patients and Journalists, disclosure information published on the company's website.	Strengthened Code requirement for companies to submit a link via the relevant disclosure gateway to take visitors from Disclosure UK to public, including patients and journalists, disclosure information published on the company's website. Following consultation, it was decided to move reference to platform operational timelines to Clause 31.1 SI (see below). Disclosure method text was further amended to move information into the clause itself (see above), and to make clear when the requirement regarding the gateway link comes into force.	**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.
New Clause 31.1 SI	**Timings for Submissions to Disclosure UK** HCP/ORDM/HCO disclosures made via the ABPI's central platform must be managed in line with the operational timelines of the platform. This includes submission of full and final HCP/ORDM/HCO disclosure information before the end of March, annually.	The proposed update was to clarify the wording around timelines in relation to use of the platform itself. Amended following consultation as the exact date in March varies year on year. Instructions are published on the website. Therefore, the website address has been given.	**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.

Clause 31.1 SI	~~**Date of Implementation for Disclosure of Contracted Services Provided by the Public, Including Patients and Journalists**~~ ~~The information required by Clause 30 must be publicly disclosed annually in respect of transfers of value made in 2022 and each calendar year thereafter.~~	Removed due to the time period having elapsed Amendment accepted as per consultation.	~~**Date of Implementation for Disclosure of Contracted Services Provided by the Public, Including Patients and Journalists**~~ ~~The information required by Clause 30 must be publicly disclosed annually in respect of transfers of value made in 2022 and each calendar year thereafter.~~

General/house-keeping updates to the 2024 Code include:

- removal of cross-references to the 2019 Code clauses
- update to clause cross-references throughout document, where required due to addition/deletion of another clause
- updates to PMCPA address and job titles (all references to Director replaced with Chief Executive of the PMCPA)
- changes to reflect updates to other codes, laws, regulations and guidelines
- changes to reflect the introduction of VPAG (Clause 19.1 Patient Access Schemes supplementary information)

Proposed changes that were consulted upon that were not taken forward for the 2024 Code

- Clause 8 – due to extensive and differing feedback received from the public consultation on the proposed changes and other aspects of the signatory role and governance, the PMCPA decided that a broader review of the signatory role, training and governance was required to instruct any potential future update. Therefore, the proposed changes to Clause 8 were not proceeded with. This approach was agreed with the ABPI Board.
- Clause 10.1 supplementary information regarding materials/activities which directly or indirectly refer to the company's medicine – following feedback that the proposed wording was confusing, the PMCPA decided not to proceed with this wording and will instead look to produce a guidance document on medical education, which will be produced following consultation with the MHRA.
- Clause 17.9 (briefing material). Following consultation, the PMCPA considered that the additional proposed text would be better covered in an FAQ. N.B briefing material is now covered in Clause 17.8 of 2024 Code due to the deletion of Clause 17.2 (see table above).
- Clause 19.1 Promotional Aids supplementary information – No change following feedback that the text providing examples of items which are prohibited should be kept as it may help those that are new to the Code.
- Clause 19.2 Items for Patient Support supplementary information – Proposed changes to the wording of the supplementary information (including adding 'for a documented purpose') were not taken forward as it was considered that no change was required; the clause itself states '…details of which must be appropriately documented …'. N.B the proposed change to increase the cost of an item for patient support from £10 to £15, excluding VAT, was taken forward (see table above).

Changes to Clause 12 in the 2024 ABPI Code

Major changes to Clause 12 were publicly consulted upon, including the option for companies to provide prescribing information via a QR code in certain scenarios. The proposed changes were developed in consultation with the MHRA. The rationale was to provide an option whereby scanning a QR code would directly access the up-to-date version of the prescribing information which could be updated remotely by the pharmaceutical company, and therefore printed promotional material in the possession of health professionals would always directly link to the up-to-date prescribing information.

A large number of comments were received during public consultation, including feedback that the different requirements for different types of scenarios were difficult to understand and may be confusing for companies to follow.

Therefore, following consultation, the clause was re-written, which required further consultation with the MHRA.

The main changes made following public consultation include:

- Reducing the 'scenarios' in Clause 12.1 from five to three (see below)
- Broadening the requirement that all promotional material, where not immediately apparent, must include a clear prominent statement as to where the prescribing information can be found
- Reverting to the 2021 Code requirement in relation to the non-proprietary name on digital material being immediately adjacent to the brand name at its first appearance.
- Reverting to the 2021 Code requirement in relation to the black triangle symbol on digital material being located adjacent to the first mention of the product as this is likely to be considered the most prominent display of the name of the product.
- Removal of the digital material transition period; there is a general transition period stipulated at the front of the 2024 Code
- Addition of brief reference to the Windsor Framework
- A number of changes to the supplementary information to aid clarity regarding QR Codes

The Clause 12 that was re-written following public consultation feedback was re-reviewed and agreed by the MHRA. Requests for additional implementation guidance for the changes to Clause 12 will be provided via accompanying Q&As.

Below is a summary of the main changes **between the 2021 and 2024 Code** in relation to the newly written Clause 12. **This list only highlights the main changes and does not replace a detailed study of the new 2024 Code.**

1) **Main changes between the 2021 and 2024 Code in relation to Clause 12**

- Restructuring of Clause 12 so that Clause 12.1 details the ways in which prescribing information can be provided in:
    i. printed material
    ii. digital material accessed by a recipient on their own device
    iii. digital material shown to a recipient in person

- The option for prescribing information to be provided via a QR code in printed material and digital material shown to a recipient in person. Clause 12 and its supplementary

information include specific requirements if prescribing information is to be provided by way of 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

- New Clause 12.3 of the 2024 Code states that, where not immediately apparent, promotional material must include a clear prominent statement as to where the prescribing information can be found. This applies to ***all*** promotional material, in contrast to the 2021 Code which previously stated that promotional material provided on the internet must include a clear prominent statement as to where the prescribing information can be found (Clause 12.6 of 2021 Code).

- Clause 12.7 of the 2021 Code has been moved to the supplementary information of Clause 12.3 of the 2024 Code in relation to printed journal advertisements.

- Clause 12.6 of the 2024 Code now allows for the adverse event reporting statement to be provided in the same manner as prescribing information as set out in Clause 12.1. A new requirement has been added which states that, where not immediately apparent, promotional material must include a clear prominent statement as to where the adverse event reporting statement can be found. Therefore, while Clause 12.6 now allows for the adverse event reporting statement to be provided in ways which were not possible under the 2021 Code, there is a strengthened requirement that, where not immediately apparent, the material must include a clear prominent statement as to where the adverse event reporting statement can be found.

- Clause 12 supplementary information in 2024 Code now includes a general statement that arrangements for changes to the marketing authorisation number and the marketing authorisation holder name and address following changes resulting from the UK leaving the EU are set out in the supplementary information to Clause 12 of the 2021 Code. The 2024 Code makes brief reference to the Windsor Framework taking effect from 1 January 2025.

- Other changes to supplementary information in Clause 12 of the 2024 Code include reference to provision of prescribing information and adverse event reporting statement with reprints.

The above list is not exhaustive and companies should conduct a detailed study of the new Clause 12 in the 2024 Code and assess its impact on their current promotional materials. From 1 January 2025, all promotional material in use must comply with all the requirements of the 2024 Code.