2024 ABPI Code of Practice

Proposed Changes to 2021 Code Clauses and Supplementary Information

Note this document only contains extracts of those Clauses/Supplementary Information (SI) where a change has been made e.g., deletion/addition of wording or a new section has been included. Where a Clause or SI has not been included, it does not mean the excluded wording in that Clause/SI has been removed. For ease of use, new wording/sections are highlighted in red and underlined, removed wording/sections are highlighted in blue with a strikethrough.

Note: All cross-referencing of Clauses will be completed following consultation

Clause	2021 Code Wording	Proposed Wording	Rationale for Change
Clause 5.1	High standards must be maintained at all times.	Companies must maintain high standards ~~must be maintained~~ at all times.	Update 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 vs the requirements of company employees
General Clause 5 Supplementary Information (SI)	**Clauses 5.1 and 5.2 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. It follows, therefore, that certain types, styles and methods of communication, even where they might be acceptable for products other than medicines, are unacceptable.	**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**	High standards and suitability are applicable to the whole of Clause 5 Supports the update to Clause 5.1 to include the requirements companies should have in place to deliver their compliance programme – aligned with Guidelines on company procedures relating to the ABPI Code of Practice for the Pharmaceutical Industry (referred to on page 64 of 2021 Code with details on the PMCPA website)

	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.	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.~~	The first paragraph of the SI to 5.1 and 5.2 applies to Clauses 5.1 and 5.2 but the subsequent paragraphs are in relation to the new Clause 5.3 only - SI amended to reflect this.
New Clause 5.2	N/A	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
New Clause 5.2 SI	N/A	**Clause 5.2 High Standards of Ethical Conduct**	Strengthens the expectations upon companies regarding contracted personnel and third parties

		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.	
Note:	**Clauses 5.2 to 5.7 (and their SI) of the 2021 Code will be renumbered following Consultation**		
Clause 5.3 SI	N/A	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 • '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.	**Note: Clause 5.3 SI has been moved from previous Clause 5.1/5.2 SI to support/align with Clause 5.3 (which was previously Clause 5.2). Removal of 'even where they might be acceptable for products other than medicines' to reflect changing times in relation to all advertising.**

		Care should be taken with language, use of abbreviations etc and the use of emojis and the like.	
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 by a pharmaceutical company.	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 5.5 moved to Clause 5.6, and wording changed to recognise market research is not sponsored by a company under the definition of Sponsorship in Clause 1.22. The research is commissioned by the company.
Clause 8.1	Promotional material must not be issued unless its final form, to which no subsequent amendments will be made, has been certified by one person on behalf of the company in the manner provided for by this clause, subject to the provisions of the supplementary information to this clause where relevant. This person must be a registered medical practitioner or a pharmacist registered in the UK or alternatively, in the case of a product for dental use only, a UK registered dentist. The person certifying on behalf of the company must not be the person responsible for developing or drawing up the material.	Promotional material must not be issued unless its final form, to which no subsequent amendments will be made, has been certified by ~~one person~~ a medical signatory on behalf of the company in the manner provided for by this clause, subject to the provisions of the supplementary information to this clause where relevant. ~~This person~~ A medical signatory must be a registered medical practitioner or a pharmacist registered in the UK or alternatively, in the case of a product for dental use only, a UK registered dentist.	To amend the terms used to describe signatories. To introduce the term 'medical signatory' to cover certain health professionals (a registered medical practitioner, or a pharmacist registered in the UK or alternatively, in the case of a product for dental use only, a UK registered dentist). To replace appropriately qualified person (AQP) signatory with the term 'non-medical signatory' (see Clause 8.2). To delete any mention of AQP signatory. To continue to use AQP for examination as set out in the current supplementary information to Clause 8.

		The person certifying on behalf of the company must not be the person responsible for developing or drawing up the material.	To make a clear distinction between a medical signatory, a non-medical signatory and an AQP.
Clause 8.1 SI	**Certification** All promotional material must be certified in this way, including audio and audiovisual material, promotional material on databases, interactive data systems and the internet and relevant representatives briefing material. Promotional aids must also be certified – although not strictly promotional material, they are used for a promotional purpose. … Alternatively, companies may certify material on interactive systems by means of producing an electronic copy, for example, on a CD ROM or data stick; if the electronic copy is write protected and unable to be changed.	**Certification** All promotional material must be certified in this way, including audio and audiovisual material, promotional material on databases, interactive data systems and the internet ~~and relevant representatives' briefing materials~~. Promotional aids must also be certified – although not strictly promotional material, they are used for a promotional purpose. In addition, relevant representatives' briefing materials must also be certified - although not in itself promotional material, they are associated with promotion. See Clause 17.9 and its supplementary information. … Alternatively, companies may certify material on interactive systems by means of producing a write-protected electronic copy, ~~for example, on a CD-ROM or data stick, if the electronic copy is write protected and~~ that is unable to be changed.	To make clear that the representative briefing material referred to in Clause 17.9 and its supplementary information is not considered in itself promotional material – i.e. it does not require prescribing information, however, it must still be certified in a similar manner to promotional material as it is associated with how the representative should promote. Removal of reference to examples CD ROM and data stick as there are many more ways to create write protected electronic copies.
Clause 8.2	All events/meetings involving travel outside the UK, unless the company's only involvement is to support a speaker to present at the meeting, must be certified in advance as set out in Clause 8.1 or by an appropriately qualified person signatory (AQP signatory). That person	~~All events/meetings involving travel outside the UK, unless the company's only involvement is to support a speaker to present at the meeting~~ The following must be certified in advance as set out in Clause	To introduce more categories which can be certified by the non-medical signatory.

	does not need to be either a registered medical practitioner or a pharmacist registered in the UK.	8.1 or by ~~an appropriately qualified person signatory (AQP signatory).~~ ~~That person~~ a non-medical signatory who does not need to be either a registered medical practitioner or a pharmacist registered in the UK: • the arrangements for all events/meetings involving travel outside the UK, unless the company's only involvement is to support a speaker to present at the meeting • written agreements relating to working with patient organisations as described in Clause 27 and its supplementary information (excluding fee for service written agreements which do not require certification) • summary of the collaborative working agreement as described in Clause 20 and its supplementary information • written agreements relating to donations and grants as described in Clause 23 and Clause 27	
New Clause 8.2 SI	N/A	**Clause 8.2 Non-Medical Signatory** If the materials used at events/meetings involving travel outside the UK for which the company is responsible is promotional, it must be certified by a medical signatory under Clause 8.1. Whilst a non-medical signatory (e.g., a compliance officer or a lawyer) may be able to certify the written agreements referred to in Clause 8.2, the decision to approve the	

		activity must remain with the appropriate function e.g., scientific services/medical.	
Clause 8.2 SI	**Clause 8.2 Qualifications for those who Certify Events/Meetings Involving Travel Outside the UK** In deciding whether someone other than a registered medical practitioner or a pharmacist registered in the UK is appropriately qualified to certify events/meetings involving travel outside the UK (AQP signatory), account should be taken of relevant experience both within and outside the industry, length of service and seniority. In addition, such a person must have an up-to-date and detailed knowledge of the Code.	**Clause 8.2 Qualifications for Non-Medical Signatories ~~those who Certify Events/Meetings Involving Travel Outside the UK~~** In deciding whether someone other than a registered medical practitioner or a pharmacist registered in the UK, or a UK registered dentist (in the case of a product for dental use only) is appropriately qualified to certify ~~events/meetings involving travel outside the UK (AQP signatory)~~ the materials as listed in Clause 8.2, account should be taken of relevant experience both within and outside the industry, length of service and seniority. In addition, such a person must have an up-to-date and detailed knowledge of the Code. A non-medical signatory can work within any part of the business, however, they must be appropriately trained. Non-medical signatories should have the same understanding of the Code as medical signatories and should be subject to the same Code training and signatory validation/re-validation by the company.	Update in line with changes to Clauses 8.1 and 8.2.
Clause 8.3	The following must be certified in advance in a manner similar to that provided for by Clause 8.1: • educational material for the public or patients issued by companies which relates to diseases or medicines but is not intended as promotion for those medicines	The following must be certified in advance by a medical signatory in a manner similar to that provided for by Clause 8.1: • educational material for the public or patients issued by companies which relates to diseases or medicines but is not intended as promotion for those medicines	To standardise the requirement for a collaborative working project initiation document (PID) and for it to be certified in line with the joint working PID. Although the summary of the written agreement for collaborative working can be certified by a non-medical signatory,

	• material relating to working with patient organisations as described in Clause 27 and its supplementary information • material relating to collaborative working as described in Clause 20 and its supplementary information • material and items for patient support whether provided directly to patients or to health professionals to be passed on to patients as described in Clauses 19.2, 26.3 and associated supplementary information • the written agreement for donations and grants, including where relevant internal company and service provider instructions as described in Clause 23 and its supplementary information • protocols relating to non-interventional studies.	• material, other than that listed in Clause 8.2, relating to working with patient organisations as described in Clause 27 and its supplementary information • material, other than that listed in Clause 8.2, relating to collaborative working as described in Clause 20 and its supplementary information, including the project initiation document • material and items for patient support whether provided directly to patients or to health professionals to be passed on to patients as described in Clauses 19.2, 26.3 and associated supplementary information • ~~The written agreement for donations and grants, including where relevant~~ internal company and service provider instructions for donations and grants as described in Clause 23 and its supplementary information. • protocols relating to non-interventional studies.	PIDs must be certified by a medical signatory.
Clause 8.3 SI	**Examination of Other Material** Material issued by companies which is not required to be certified under the Code should be examined by a signatory or an AQP, who needs not be a signatory, to ensure that it does not contravene the Code or the relevant statutory requirements. Such material might include corporate advertising, press releases, market research material, financial information to inform shareholders, the Stock Exchange and the like, and	**Examination of Other Material** Material issued by companies which is not required to be certified under the Code should be examined by a signatory (medical or non-medical) or an appropriately qualified person (AQP), who need~~s~~ not be a signatory, to ensure that it does not contravene the Code or the relevant statutory requirements. Such material might include corporate	Updating the terminology to align with Clause 8

	written responses from medical information departments or similar to unsolicited enquiries from the public etc.	advertising, press releases, market research material, financial information to inform shareholders, the Stock Exchange and the like, and written responses from medical information departments or similar to unsolicited enquiries from the public etc.	
Clause 8.4 SI	**Clause 8.4 (14.4) Notification of Signatories** The names and qualifications of signatories and changes to them should be notified to the MHRA by email to signatories.advertising@mhra.gov.uk. The PMCPA can be notified by completing the nominated signatory form which can be found at www.pmcpa.org.uk. The names and qualifications to be sent to the MHRA and PMCPA are those of the registered medical practitioner or the pharmacist registered in the UK or, if the product is for dental use only, a UK registered dentist as set out in Clause 8.1 and the AQP signatory as set out in Clause 8.2.	**Clause 8.4 ~~(14.4)~~ Notification of Signatories** The names and qualifications of signatories and changes to them should be notified to the MHRA by email to signatories.advertising@mhra.gov.uk. The PMCPA can be notified by completing the nominated signatory form which can be found at www.pmcpa.org.uk. The names and qualifications to be sent to the MHRA and PMCPA are those of the registered medical practitioner or the pharmacist registered in the UK or, if the product is for dental use only, a UK registered dentist as set out in Clause 8.1 (the medical signatory) and the ~~AQP~~ non-medical signatory as set out in Clause 8.2.	Updating the terminology to align with Clause 8
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** In addition to the information for extensions set out above, further arrangements were put in place as the ABPI examination was not available between 13 March 2020 and 30 September 2020 due to the impact of the COVID-19 pandemic, and as a consequence, certain representatives could not meet the time periods for taking and/or passing the examination as required by	**Clause 9.4 ~~(New)~~ Extensions to the Time Allowed to Pass an Examination as a Result of the COVID-19 Pandemic** ~~In addition to the information for extensions set out above, further arrangements were put in place as the ABPI examination was not available between 13 March 2020 and 30 September 2020 due to the impact of the COVID-19 pandemic, and as a consequence, certain representatives could not meet the~~	Note this time period has now elapsed – referenced to 2021 Code

	the Code. Extensions have been granted during 2020 when requested. Everyone's circumstances are different and will need to be taken into account. Companies should make every effort to comply with the spirit of the Code and ensure that representatives take and pass the appropriate examination as soon as possible. An examination is now available online. In order to assist, the following arrangements for all affected representatives were put in place in late 2020 and are set out below. **Representatives who started work as a representative for the first time from 1 July 2020** For representatives who were employed as a representative for the first time from 1 July 2020, the time periods as set out in the Code will apply. **Representatives who worked as representatives during 2019 and have continued to work as representatives in 2020** For those representatives working as such in 2019 and whose one year or two year time periods include any time between 13 March 2020 and 31 October 2020, these eight months will not count towards their time period for taking and passing the examination. Representatives making use of these additional eight months do not need to contact the PMCPA for an extension but must ensure that their employers are informed and a record is kept. **Representatives who started their first role as a representative between 1 January 2020 and 30 June 2020** For representatives who were employed as a representative in their first role anytime from 1 January 2020 to 30 June 2020, the relevant months they worked when the examination was not available will not count towards their time period. For example, a	~~time periods for taking and/or passing the examination as required by the Code. Extensions have been granted during 2020 when requested. Everyone's circumstances are different and will need to be taken into account. Companies should make every effort to comply with the spirit of the Code and ensure that representatives take and pass the appropriate examination as soon as possible.~~ ~~An examination is now available online. In order to assist, the following arrangements for all affected representatives were put in place in late 2020 and are set out below.~~ ~~**Representatives who started work as a representative for the first time from 1 July 2020**~~ ~~For representatives who were employed as a representative for the first time from 1 July 2020, the time periods as set out in the Code will apply.~~ ~~**Representatives who worked as representatives during 2019 and have continued to work as representatives in 2020**~~ ~~For those representatives working as such in 2019 and whose one year or two year time periods include any time between 13 March 2020 and 31 October 2020, these eight months will not count towards their time period for taking and passing the examination. Representatives making use of these additional eight months do not need to contact the PMCPA for an extension but must ensure that their employers are~~	

	representative starting in January 2020 will have eight months to add to the time period to take the examination for the first time, ie they must take the examination by September 2021 and pass it by September 2022. A representative starting in February or March 2020 will also have eight months to add to the time period to take the examination for the first time. A representative starting in April 2020 will have seven months to add to their time period, and a representative starting in June 2020 will have five months to add to their time period. A representative starting in such a role for the first time in July 2020 will not have an extension in relation to the cancellation of the examination. Representatives making use of these additional months do not need to contact the PMCPA for an extension but must ensure that their employers are informed and a record is kept. **Representatives who were previously employed as a representative and who returned to such a role in anytime between 1 January and 31 October 2020 following a gap in service (for example, due to a change of role, career break, parental leave)** For representatives who have been employed as a representative and returned to work as a representative in 2020 (perhaps after a career break, maternity leave, etc), including during the time the examination was not available (between 13 March 2020 and 30 September 2020), then the relevant months they worked when the examination was not available will not count towards their time period for taking and passing the examination. For example, a representative restarting such work in January 2020 will have eight months to add to their time period, a representative restarting in April 2020 will have seven months to add to their time period and a representative restarting in September 2020 will have two months to add to their time period.	~~informed and a record is kept.~~ ~~**Representatives who started their first role as a representative between 1 January 2020 and 30 June 2020**~~ ~~For representatives who were employed as a representative in their first role anytime from 1 January 2020 to 30 June 2020, the relevant months they worked when the examination was not available will not count towards their time period. For example, a representative starting in January 2020 will have eight months to add to the time period to take the examination for the first time, ie they must take the examination by September 2021 and pass it by September 2022. A representative starting in February or March 2020 will also have eight months to add to the time period to take the examination for the first time. A representative starting in April 2020 will have seven months to add to their time period, and a representative starting in June 2020 will have five months to add to their time period. A representative starting in such a role for the first time in July 2020 will not have an extension in relation to the cancellation of the examination. Representatives making use of these additional months do not need to contact the PMCPA for an extension but must ensure that their employers are informed and a record is kept.~~ ~~**Representatives who were previously employed as a representative and who returned to such a role in anytime between 1 January and 31 October 2020 following a**~~	

	Representatives who returned to work in 2020 anytime after 31 October will not have an extension in relation to the cancellation of the examination. Representatives making use of these additional months do not need to contact the PMCPA for an extension but must ensure that their employers are informed and a record is kept. **Extensions in addition to those set out above** There may be some representatives who might need longer extensions than those referred to above. This is most likely to apply to those whose time periods completed around February/March 2020. Applications should be made to the PMCPA in the usual way.	~~**gap in service (for example, due to a change of role, career break, parental leave)**~~ ~~For representatives who have been employed as a representative and returned to work as a representative in 2020 (perhaps after a career break, maternity leave, etc), including during the time the examination was not available (between 13 March 2020 and 30 September 2020), then the relevant months they worked when the examination was not available will not count towards their time period for taking and passing the examination. For example, a representative restarting such work in January 2020 will have eight months to add to their time period, a representative restarting in April 2020 will have seven months to add to their time period and a representative restarting in September 2020 will have two months to add to their time period. Representatives who returned to work in 2020 anytime after 31 October will not have an extension in relation to the cancellation of the examination. Representatives making use of these additional months do not need to contact the PMCPA for an extension but must ensure that their employers are informed and a record is kept.~~ ~~**Extensions in addition to those set out above**~~ ~~There may be some representatives who might need longer extensions than those referred to above. This is most likely to apply to those whose time periods completed around February/March 2020. Applications~~	

		~~should be made to the PMCPA in the usual way.~~ 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.	

Clause 10.1 SI	**Clause 10.1 (22.1) Types of Events/Meetings** Events/meetings range from small lunchtime audiovisual presentations in a group practice; hospital meetings and events/meetings at postgraduate education centres; advisory board meetings; visits to research and manufacturing facilities; planning, training and investigator meetings for clinical trials and non-interventional studies; launch events/meetings for new products; management training courses; patient support group meetings; and satellite symposia through to large international events/meetings organised by independent bodies with sponsorship from pharmaceutical companies	**Clause 10.1 Types of Events/Meetings** Events/meetings range from small lunchtime audiovisual presentations in a group practice; hospital meetings and events/meetings at postgraduate education centres; advisory board meetings; visits to research and manufacturing facilities; planning, training and investigator meetings for clinical trials and non-interventional studies; launch events/meetings for new products; management training courses; patient support group meetings; and satellite symposia through to large international events/meetings organised by independent bodies with sponsorship from pharmaceutical companies The purpose of every meeting, including promotional meetings, must be educational. The definition of promotion in Clause 1.17 is broad and therefore if company materials/activities directly or indirectly refer to the company's medicine(s), the company should consider and be able to demonstrate how this would not be defined as promotion under the Code.	NOTE – Guidance document to be developed on non-promotional medical education.

New Clause 10.4	N/A	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.	To increase governance in relation to this high-risk area. **Note: Clauses 10.4 to 10.11 in 2021 Code will be renumbered for the 2024 Code after the consultation process**
New Clause 10.3 & Clause 10.4 SI	N/A	**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.	Raised as a result of findings from company audits – thus providing clarity
Clause 11.1 SI	**Clause 11.1 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 authorization in the UK although they are so authorized in another major industrialised country	**Clause 11.1 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 in line with the supplementary information to Clause 11.3 and the MHRA BLUE GUIDE
Clause 12		See full proposal below	
Clause 12 General SI	Arrangements for changes to the MA number and the MA holder name and address following changes resulting from the UK leaving the EU …	~~Arrangements for changes to the MA number and the MA holder name and address following changes resulting from the UK leaving the EU…~~ Arrangements for Changes to the Marketing Authorisation	Cross referenced to 2021 Code

		Number and the Marketing Authorisation Holder Name and Address Following Changes Resulting from the UK leaving the EU is set out in the Supplementary Information to Clause 12 of the 2021 Code.	
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 be accompanied by prescribing information.	**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 further clarify the requirements regarding provision of prescribing information and adverse event reporting information in relation to reprints.
Clause 17.9 SI	**Briefing Material** The briefing material referred to in this clause includes the training material used to instruct representatives about a medicine and the instructions given to them as to how the product should be promoted.	**Briefing Material** The briefing material referred to in this clause includes the training material used to instruct representatives about a medicine and the instructions given to them as to how the product should be promoted. Such material, whilst associated with promotion, is not promotional material in itself, and therefore does not necessarily require prescribing information and other obligatory information as referred to in Clause 12. It is, however, good practice to include the black triangle and the non-proprietary name as referred to in Clause 12.	To further clarify the guidance on the requirements for representative briefing materials in accordance with Clause 8.1

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 apparatus for administration, the provision of training on its use or the services of a nurse to administer it.	**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 amendments – Package Deal guidance to be developed to support this Clause
Clause 19.1 SI	**Promotional Aids** Items for the personal benefit of health professionals or other relevant decision makers must not be offered or provided. Coffee mugs, stationery, computer accessories, diaries, calendars and the like and items for use in the home or car are not acceptable. Items for use with patients in the clinic, surgery or treatment room etc, such as surgical gloves, nail brushes, tongue depressors, tissues and the like, are also not acceptable. Toys and puzzles intended for children to play with while waiting must not be provided.	**Promotional Aids** Items for the personal benefit of health professionals or other relevant decision makers must not be offered or provided. ~~Coffee mugs, stationery, computer accessories, diaries, calendars and the like and items for use in the home or car are not acceptable~~. Items for use with patients in the clinic, surgery or treatment room etc, ~~such as surgical gloves, nail brushes, tongue depressors, tissues and the like~~, are also not acceptable. Toys and puzzles intended for children to play with while waiting must not be provided.	Examples removed and to be added to FAQ
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.	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.	Minor wording update

	The items provided must be inexpensive and directly benefit patient care. They may bear the name of the company providing them 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.	~~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(1)	**Items for Patient Support** Items for patient support may be provided to health professionals by representatives during the course of a promotional call and representatives may deliver such items when they are requested by health professionals. Examples of items which might be acceptable include a peak flow meter as part of a scheme for patients to regularly record readings or a pedometer as part of a scheme to encourage exercise.	**Items for Patient Support** Items for patient support, for a documented purpose, may be provided to health professionals by representatives during the course of a promotional call and representatives may deliver such items when they are requested by health professionals. Examples of items which might be acceptable include a peak flow meter ~~as part of a scheme~~ for patients to regularly record readings or a pedometer ~~as part of a scheme~~ to encourage exercise.	Minor wording update
Clause 19.2 SI(2)	**Items for Patient Support** An 'inexpensive' item for patient support means one that has cost the donor company no more than £10, excluding VAT. The perceived value to the health professional and the patient must be similar.	**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
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	~~**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**~~	Removed as no longer required due to the time period having elapsed

	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	~~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	
Clause 20.3	Material relating to collaborative working must be certified, including the summary of the collaborative working agreement. The collaborative working agreement does not need to be certified.	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.	Updated to include certification of Collaborative Working PID to align with joint working requirements – previously a Collaborative Working PID was not explicitly referred to in the Code – this now aligns with Joint Working requirements.
Clause 20.4 SI	**(Third paragraph of) Joint Working as a form of Collaborative Working**	~~**(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~~	Deleted as the requirement for the project initiation document for all collaborative working which includes joint working has now been in

	In addition to the certification requirements set out in Clause 20.3, the joint working project initiation document must also be certified.	~~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.	~~**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.~~	Whole section to be removed as transition period is now complete
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, 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 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
New Clause 27 SI	N/A	**Clause 27 Relationships with Patient Organisations**	Working with patient organisations is important for the shaping of future healthcare. The Code does not prohibit such working relationships between

		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.	pharmaceutical companies and patient organisations and this new supplementary information helps to clarify such arrangements.
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. The template to use is available from the PMCPA website www.pmcpa.org.uk.	**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.	To strengthen the wording around disclosure requirements and timelines for HCPs/ORDMs and HCOs.
Clause 28.5 SI	Additional wording	**Clause 28.5 Legal basis for individual disclosure** Disclosing companies should seek a legal basis pursuant of individual disclosure, and	Additional wording to strengthen the requirement to seek a legal basis for individual disclosure of Transfers of Value (ToVs)

		only disclose in aggregate where a legal basis cannot be obtained.	
NEW Clause 29.1 SI	N/A	**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.	To provide clarity regarding disclosure timelines for patient organisation Transfers of Value (ToVs)
New Clause 30.1 SI	N/A	**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.	To provide clarity regarding disclosure timelines for the Public, including Patients and Journalists, Transfers of Value (ToVs)

		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.	
New Clause 31.1 SI	**N/A**	**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.	To clarify the timelines for HCP/ORDM and HCO disclosures on the Disclosure UK platform
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.	~~**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

Proposed New Clause 12 and Supplementary Information

Please note this wording was developed in consultation with the MHRA.

Clause 12

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.

i) In **printed materials** (including digital materials intended for downloading and printing), prescribing information must be included within the promotional material itself, either as text or through a Quick Response (QR) Code with clear instructions to scan it for the prescribing information clearly displayed.

ii) For **exhibition stands,** the prescribing information for medicines promoted on posters and exhibition panels at events/meetings may be provided either:
- by inclusion on the posters or panels themselves as set out in point i) above, or
- by way of a document containing the prescribing information which is made available at the company stand and this must be referred to on the posters or panels

iii) In **digital materials other than audiovisual material, interactive data systems and electronic detail aids which are covered at points iv and v below** (such as advertisements in electronic journals, emails, websites, etc which are not intended for printing) the prescribing information may be provided either:
- by inclusion in the digital material itself as text, or
- by way of a clear, and prominent direct single click link

iv) In **audiovisual material and interactive data systems** to be presented (such as presentations, videos etc) prescribing information may be provided either:
- by inclusion within the promotional material itself, either as text or through a QR Code with clear instructions to scan it for the prescribing information clearly displayed, or
- by way of a document containing the prescribing information which is made available to the audience and this must be referred to within the audiovisual material

When prescribing information is included in an interactive data system, instructions for accessing it must be clearly displayed.

v) In **electronic detail aids to be** presented prescribing information may be provided:

- by inclusion within the promotional material itself, either as text or through a QR Code with clear instructions to scan it for the prescribing information clearly displayed, or
- by way of a clear, and prominent direct single click link, or
- by way of a document containing prescribing information which is made available to the audience and this must be referred to within the material

12.2 The prescribing information consists of the following:

- the legal classification of the product (such as POM (prescription only medicine))
- the cost (excluding VAT) of either a specified package of the medicine to which the advertisement relates, or a specified quantity or recommended daily dose, calculated by reference to any specified package of the product, except in the case of advertisements in journals printed in the UK which have more than 15 per cent of their circulation outside the UK and audiovisual advertisements and prescribing information provided in association with them
- and

i. the name of the medicine (which may be either a brand name or a non-proprietary name)
ii. a quantitative list of the active ingredients, using approved names where such exist, or other non-proprietary names; alternatively, the non-proprietary name of the product if it is the subject of an accepted monograph
iii. at least one authorised indication for use consistent with the summary of product characteristics
iv. a succinct statement of the information in the summary of product characteristics relating to the dosage and method of use relevant to the indications quoted in the advertisement and, where not otherwise obvious, the route of administration
v. a succinct statement of common adverse reactions likely to be encountered in clinical practice, serious adverse reactions and precautions and contra-indications relevant to the indications in the advertisement, giving, in an abbreviated form, the substance of the relevant information in the summary of product characteristics, together with a statement that prescribers should consult the summary of product characteristics in relation to other adverse reactions
vi. any warning issued by the Medicines Commission, the Commission on Human Medicines, the Committee on Safety of Medicines or the licensing authority, which is required to be included in advertisements
vii. the number of the relevant marketing authorisation and the name and address of the holder of the authorisation or the name and address of the part of the business responsible for its sale or supply
viii. the date the prescribing information was drawn up or last revised.

The summary of product characteristics may be provided instead of i-viii above.

If the summary of product characteristics is not used, then the information specified above in relation to iv, v and vi which is required to be included in advertisements, must be placed in such a position in the advertisement that its relationship to the claims and indications for the product can be appreciated by the reader.

12.3 Where not immediately apparent, promotional material as referred to at points iii, iv, and v in Clause 12.1 above must include a clear prominent statement as to where the prescribing information can be found.

12.4 In a printed journal advertisement, the prescribing information must be provided as described in Clause 12.1, on at least one of the pages. The pages where the prescribing information is not visible must include a reference on the outer edge of the page as to where the prescribing information can be found in a type size such that a lower case 'x' is no less than 2mm in height.

12.5 The non-proprietary name of the medicine or a list of the active ingredients using approved names where such exist must appear immediately adjacent to the most prominent display of the brand name in bold type of a size such that a lower case 'x' is no less than 2mm in height or in type of such a size that the non-proprietary name or list of active ingredients occupies a total area no less than that taken up by the brand name.

For electronic advertisements, the non-proprietary name of the medicine or the list of active ingredients, as required by Clause 12.5, must appear immediately adjacent to the brand name at its most prominent appearance. The size and location must be such that it is easily noticed and readable.

12.6 Promotional material other than advertisements in professional publications must include the date on which the promotional material was created or last revised.

12.7 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 may be provided in promotional materials in the same way 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.

12.8 When required by the licensing authority, all promotional material must clearly show an inverted black equilateral triangle to denote that additional monitoring is required in relation to adverse reactions. The symbol should always be black, and its size should normally be not less than 5mm per side but with a smaller size of 3mm per side for A5 size advertisements and a larger size of 7.5mm per side for A3 size advertisements.

The symbol should appear once and be located adjacent to the most prominent display of the name of the product.

No written explanation of the symbol is necessary.

Digital communications are also covered by this requirement, and the black triangle symbol should be located adjacent to the most prominent mention of the product name. The size and location must be such that it is easily noticed.

Clause 12 Supplementary Information

Clause 12 Digital Material Transition Period

Digital material which complies with Clause 12 of the 2021 Code (where relevant) does not need to be altered to comply with Clause 12 of the 2024 Code. Material certified after [date the Code comes into operation] will need to comply with the 2024 Code (where relevant) requirements.

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.

Clause 12.1 Use of a QR Code for Prescribing Information

It is not acceptable to use a QR Code to fulfil the requirement to provide prescribing information when it is expected that the material is likely to be viewed offline. This is to ensure that current prescribing information is available at the time of reading promotional material.

A health professional is not expected to have two devices to view promotional material and to be able to scan a QR Code on that material.

As the content of QR Codes cannot be viewed when offline, when material is more likely to be viewed offline, then the requisite information must be provided as text within printed material or as a prominent, direct single click link in materials referred to in points iv and v that does not require the reader to be online.

***Clause 12.1 Electronic detail aids,* audiovisual material and interactive data systems**

Although electronic detail aids, audiovisual material and interactive data systems *are digital materials, when presented to health professionals, the prescribing information may be provided through a QR Code. This is because the health professional will be able to use their own device to scan the QR Code on the electronic detail aid.*

Clause 12.1 Use of Links for Prescribing Information

When digital material and electronic detail aids include a link to prescribing information on another website then such a link should only be included for use when the material is generally expected to be viewed online, for example, advertisements in electronic journals, emails or electronic detail aids when used remotely and the like. This is to ensure that at the time of reading, the link is active and will provide readers with the necessary information.

When material is more likely to be viewed offline, such as electronic detail aids to be used by representatives when visiting health professionals, then the requisite information must be provided as part of the item itself as text or as a link that does not require the reader to be online.

Clause 12.1 Prescribing Information on Audiovisual Material

Where prescribing information is shown on audiovisual material as part of the recording itself, either as text or through a QR Code, it:

- *Must be of sufficient clarity and duration so that it is easily readable and/or scannable*
- *Must be an integral part of the promotional content and must appear with it*
- *Is not acceptable for the promotional content and the prescribing information to be separated by any other material.*

Clause 12.1 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 separate 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. (See

Clause 16.5 for further Information).

Clause 12.1 Multiple Prescribing Information

Where more than one medicine is being advertised, then the prescribing information for each must be provided.

Where multiple prescribing information is provided by provision of more than one QR code, each should be clear which product it relates to and each should be sized and positioned so as to be easy to scan independently from each other.

Clause 12.1 Prescribing Information and Summaries of Product Characteristics

Each promotional item for a medicine must be able to stand alone. For example, when a promotional letter on a medicine is sent in the same envelope as a brochure about the same medicine, each item has to include the prescribing information. It does not suffice to have the prescribing information on only one of the items. The inclusion of a separate summary of product characteristics is not sufficient to conform with the provisions of this clause.

Clause 12.1 Legibility of Prescribing Information

The prescribing information is the essential information which must be provided in promotional material. It follows therefore, that the information must be given in a clear and legible manner which assists readability. The prescribing information must be positioned for ease of reference and must not be presented in a manner such that the reader has to turn the material round in order to read it, for example, by providing it diagonally or around the page borders.

Clause 12.1 Prescribing Information on Printed Material and Reference to Online Current Regulatory Documents

In addition to including prescribing information, companies are encouraged to include references on printed materials to an online resource where the current regulatory documents for each medicine promoted can be found.

Clauses 12.1 and 12.6 Date of Prescribing Information and Promotional Material

If the summary of product characteristics is not used, then the date that the prescribing information was last drawn up or last revised must be included (Clause 12.2 viii). In addition, promotional material (other than journal advertising) must include the date that the material as a whole, ie the copy plus the prescribing information, was created or last revised

Clause 12.1 Advertisements in Electronic Journals and on independent websites

The first part of an advertisement in an electronic journal, such as the banner, is often the only part of the advertisement that is seen by readers. It must therefore include a clear, prominent statement as to where the prescribing information can be found. This should be in the form of a prominent, direct, single click link. The first part of the advertisement is often linked to other parts and in such circumstances, the linked parts will be considered as one advertisement. The requirement of Clause 15.6 that promotional material and activities must not be disguised and Clauses 12.5 in relation to the non-proprietary name and 12.8 in relation to the black triangle symbol should also be borne in mind.

Clause 12.1 Advertisements for Devices

Where an advertisement relates to the merits of a device used for administering medicines, such as an inhaler, which is supplied containing a variety of medicines, the prescribing information for one only need be given if the advertisement makes no reference to any particular medicine. However, if particular medicines are referred to, then the prescribing information for each must be provided.

Clause 12.2 Use of the Summary of Product Characteristics

The Code defines prescribing information to consist of three parts: the legal classification, the cost and other elements (listed as i-viii) in Clause 12.2.

In printed material, elements i-viii can be provided by reproducing the summary of product characteristics within the material itself as text or through a QR Code with clear instructions to scan it for such information. It would not be acceptable to provide only a website address for the summary of product characteristics on printed material as a means of meeting the requirements to provide elements i-viii.

In digital materials, elements i-viii could be provided by a prominent, direct single click link to the summary of product characteristics.

Clause 12.5 Non-Proprietary Name

'Immediately adjacent to…' means immediately before, after, above or below.

In a promotional letter, the most prominent display of the brand name will usually be that in the letter itself, rather than that in prescribing information provided on the reverse of the letter.

The first part of an advertisement in an electronic journal, such as the banner, is often the only part of the advertisement that is seen by readers. The first part is often linked to other parts and in such circumstances, the linked parts will be considered as one advertisement.
If the first part mentions the product name, then this is the most prominent display of the brand name, and so the non-proprietary name of the medicine or a list of the active ingredients using approved names where such exist must appear immediately adjacent to it in a size such that the information is easily readable.

Clause 12.6 Date Created or Last Revised

This is in addition to the requirement in Clause 12.2 that the date of the prescribing information be included.

Clause 12.6 Dates on Loose Inserts

A loose insert is not regarded for this purpose as appearing in the professional publication with which it is sent and must therefore bear the date on which it was created or last revised.

Clause 12.7 Adverse Event Reporting

A telephone number or email address for the relevant department of the company may be included. Text is more likely to be deemed to be prominent if it is presented in a larger type size than that used for the prescribing information. In the event that the website address required in Clause 12.7 is changed by the Medicines and Healthcare products Regulatory Agency (MHRA), companies must use the new address within one year of the change.

Clause 12.8 Black Triangle Symbol

The black triangle symbol is also required on summaries of product characteristics and on package leaflets. The size of the black triangle on these documents has to be proportionate to the font size of the subsequent text with a minimum length of 5mm per side. Obligatory explanatory wording is also required on these documents.

The first part of an advertisement in an electronic journal, such as the banner, is often the only part of the advertisement that is seen by readers. The first part is often linked to other parts and in such circumstances, the linked parts will be considered as one advertisement. If the first part mentions the product name, then this is the most prominent display of the brand name.

If the product is one that is required to show an inverted black equilateral triangle on its promotional material then that symbol must appear adjacent to most prominent mention of the product name. The size must be such that it would not be easily overlooked.

Rational for change

Clause 12 has been re-written and re-structured and therefore does not appear in tracked changes. The updates include the option to include prescribing information within promotional material itself through a Quick Response (QR) Code in certain circumstances. The requirements for the adverse event reporting statement have also been updated to be provided in promotional materials in a similar way as prescribing information as set out in Clause 12.1.

These changes were developed in consultation with the MHRA. The rationale is to give health professionals and other relevant decision makers an additional option to view prescribing information as part of promotional material itself, with consideration to updates of prescribing information and sustainability.

Minor changes have also been made in relation to the position of the non-proprietary name and black triangle in electronic advertisements and digital communications.