



Digital Media Working Group

This document contains a set of questions and suggested answers in relation to the ABPI Code of Practice and the application of the Code to Digital Media.

Having first gained the agreement of the PMCPA, the PM Society embarked on a consultation process to identify the most common and most challenging queries in relation to the digital environment. This document is the result and was developed during a consultation process lasting over 6 months and involving a wide range of companies and agencies within the UK pharmaceutical industry. It reflects their combined queries and challenges and proposes a set of pragmatic solutions.

We hope that these will help form a framework of formal answers that the PMCPA might be able to issue to the industry in due course.

The PM Society would like to offer its support and help in disseminating the formal answers should the PMCPA deem it appropriate.

The original plan to develop a proposed set of actual new clauses will not now be pursued, at the PMCPA's request.

All feedback is warmly welcomed.

Steve Gray
PM Society
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Scope

1. When does on-line activity fall specifically within the scope of the (UK) ABPI Code of Practice?

Answer: When any of the following apply:

- When it was created by or on behalf of a UK pharmaceutical company
 - When it contains content intended specifically (but not necessarily exclusively) for UK HCPs or the UK public
 - When it is placed on a company-controlled web-address usually associated with the UK (e.g.: .co.uk, .org.uk., .me.uk, etc)
 - When it is referenced in material issued by the UK pharmaceutical company
 - When UK company employees direct people to the site
2. What aspects of digital media is the pharmaceutical company responsible for?
 - The company is responsible for all information pertaining to digital media that is under the control or influence of that company (e.g. website attachments)
 3. If a UK HCP (or consumer) registers independently for an information service or website provided by a non-UK part of a pharmaceutical company, what is the UK company accountable for? Is there a need for the global organisation to actively block registrations from UK customers?
 - The UK company is not normally responsible for material issued outside the UK and intended primarily for a non-UK audience, such as a global website designed for access by all countries. Under such circumstances the prevailing applicable Code is the IFPMA Code. There is no requirement for the Global team to block applications received from the UK, however the website should not be promoted in the UK unless it meets the requirements of the UK Code.
 - It is not acceptable for the UK company to *encourage* or promote registration with a site that does not comply with the UK Code.
 4. How does scientific exchange differ between the digital and non-digital environments? When is it acceptable to place off-licence content on a website?
 - Digital content must comply with the Code in exactly the same way as for hard-copy material.

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- Digital content that is pro-actively promoted to HCPs by a pharmaceutical company or its agents will usually be regarded as promotional if it contains references to products
 - It is acceptable to provide a secure website (etc) that contains information for consultants and advisors to the company (such as results of recently published trials). Because the information is for advisors, it will not be regarded as 'promotion', unless it is promotional in nature.
5. Since pharmaceutical companies cannot control the size of screen that an HCP uses to view promotional content, how can Pharma meet the requirements of clauses that require minimum font size (e.g. for PI)?
- The company is responsible for distributing material in accordance with its intended use. Therefore material intended for a hand-held computer must be formatted so the requirements of the minimum font size are met.
 - The company is not responsible if material intended for a laptop computer (e.g. a 13" screen), is viewed by the recipient on a hand-held device (e.g. with a 3" screen).
 - Other requirements related to the visibility of mandatory information also apply to digital media (e.g. sufficient contrast between font colour and background).
6. Is a pharmaceutical company responsible for monitoring chat rooms and social media sites, etc, in order to identify all adverse events pertaining to its products?
- This is not an area that falls within the scope of the ABPI Code of Practice and the question should more properly be addressed to the MHRA.
 - The MHRA has previously indicated that Marketing Authorisation Holders (MAHs) are responsible for screening websites and areas of user-generated text on all their websites. UK Government solicitors have confirmed that there is a proactive duty for MAHs to monitor such sites. It is recommended that the sites notify visitors that the information is monitored for this purpose. The usual pharmacovigilance reporting and monitoring timelines and standards apply. However Pharma is not responsible for scanning the internet in order to find adverse event reports.
 - We believe that automated monitoring is acceptable to highlight initial reports that then require human review.

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7. When is it acceptable to utilise digital media for non-promotional purposes?
 - Promotional and non-promotional digital content must comply with the Code in exactly the same way as for hard-copy material.

8. Is an email between a representative and HCPs subject to the Code? For example, if the representative is sending an invitation to attend or speak at a meeting?
 - All communications from representatives are subject to the Code.
 - Emailed invitations to speak at a meeting would usually be regarded as non-promotional (depending on the content)
 - Companies can issue representatives templates or approved content that can be emailed to HCPs to invite them to attend a meeting. If the meeting is in relation to a product, then the email is regarded as promotional and subject to prior certification and the requirements of clause 9.9, etc.
 - Emails that only concern the logistical details of a future contact that do not mention any product or claims would usually be considered non-promotional.
 - It is acceptable to email the answer to a question raised in a face-face meeting, so long as the answer is limited to the scope of the original question.

Access controls

9. Clause 24 of the Code says that a password is not required to access a promotional HCP site if information is also provided that is suitable for the general public. Does that information have to be part of the same website or can it be a link to a different website?
 - It should be part of the same website.

10. To what extent is Pharma responsible for controlling the security of a password once issued? Is it OK to use cookies to make it easier for the HCP to access the site in the future?
 - Once issued, it is the responsibility of the HCP to control access to the password.
 - It is acceptable for Pharma sites to utilise cookies and similar password retrieval methods for identification purposes.

11. Where the Code requires documents, etc, to be *signed*, are digital signatures acceptable? (e.g. Medical Samples and Speaker agreements)

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- Yes. Acceptable formats would be if the HCP registers for a site using a password, or a digitally encrypted signature. Scanned signatures are acceptable.

Material & activities for healthcare professionals (inc business managers)

12. Does promotional digital material need to include a link to the www.yellowcard.gov.uk website?
- No. The usual AE statement must be included on the website; a hypertext link to the reporting site itself helpful, but not mandatory.
13. How many pages of advertising can be included in an on-line journal?
- On-line journals are regarded in the same manner as hard-copy journals. Only 2 web-pages may bear advertisements for any individual product.
14. How should banner ads be regarded under the Code? Do they count towards the 2-page rule?
- For websites, the count should more properly be the number of placements, rather than ‘pages’ since some banner ads, etc, are rotated so that each user might have a different experience. The principle remains that a user should not be subjected to numerous adverts for the same product in a particular medical ‘document’ – regardless of the medium.
 - Banner ads do count towards the allowed 2-‘placements’ of advertising. (However, websites containing more than 100 pages may bear 2 banner ads in *addition* to a full journal advert).
 - Banner ads must meet the requirements of the Code. They are either full adverts, abbreviated adverts, or point directly to a full advert. Therefore a banner ad that bears a promotional claim must either display all obligatory information within the banner ad, or link directly to a full advert (not an abbreviated advert). As an absolute minimum, the banner ad must always display generic name, black triangle (if relevant), job bag number, date of prep and a direct link to the AE statement & PI.
15. How does a company meet the requirements of clause 9.10 in relation to digital media?

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- All digital material must prominently declare the company's involvement. This means on the home page or entry page as a minimum, or at the beginning of disease awareness videos, etc.
- A clear written declaration should be given on the home page. A prominent company logo must be displayed on all subsequent pages; the logo should contain a hypertext link to the statement on the home page or an area with more substantive information about the involvement of the pharmaceutical company in the creation or funding of the website
- The target audience must be declared on the home page. Note: the MHRA Blue Guide states that it is good practice to declare the target audience on every page

Promotion of websites

16. Is it acceptable to use search engine optimisation techniques?

- Yes.
- It is acceptable to use search engine optimisation techniques to secure a high-ranking search engine placement for company sites that are directly related to the relevant search terms.
- It is acceptable to use legitimate paid-for techniques to secure a high-ranking search engine return for company sites that are directly related to the relevant search terms. (e.g. payment can be made to rank a diabetes product site highly in response to a search for that product or 'diabetes drugs', but not for a general term such as 'diabetes'.
- It is acceptable to use search terms to direct to product related pages or disease pages of corporate websites
- A disease awareness site could use the general disease term. E.g. a diabetes disease awareness site could use search term 'diabetes'
- All text visible to the public should reflect content of the site and not be promotional.

Sponsorship of third party content /sites

17. Can a pharmaceutical company sponsor a third-party site without being held accountable for the content?

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- A company can provide an educational grant to a reputable professional society or Patient Group or reputable health information sites to support a non-product specific website without being accountable for the content. As with all arms-length support, the company must not influence the content in any meaningful way. However the company has a responsibility to check that the *nature* of the site generally meets the principles of the Code prior to agreeing sponsorship.
- If a company commissions or influences the content of an area (e.g. a page) of a larger website, that *area* will be regarded as subject to the Code.
- This does not preclude the company from reviewing content in the context of technical accuracy or Code compliance.
- As with all material, websites, etc should declare the fact of the sponsorship on the home page.

On-line meetings

18. Is it acceptable to convene on-line advisory boards?

- On-line advisory boards are acceptable, and are subject to the same Code considerations as all other advisory boards, with the following additional considerations:
 - Some on-line advisory boards might be in the form of several conversation threads (rather than an on-line meeting per se). The conversation thread might extend over several days or weeks. Since it is expected that the company requires a timely answer to each question, a time-limit should be included for each discussion thread, after which no additional responses are allowed.
 - Each discussion thread should be removed from visibility within 5 working days following the conclusion of the discussion. (The delay allows time for all advisors to see the conclusions of the discussion).
- Honoraria payments should reflect the lower levels of time commitment that may be required for on-line contributions (including the fact that travel is not involved).
- Access to on-line advisory boards must be restricted so that only invited advisors can participate.

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19. How should webcasts be considered under the Code?

- On-line promotional & educational meetings (such as webcasts) must be managed in accordance with clause 19, with the following additional considerations:
 - Live monitoring is required for the live Q&A sessions during a webcast or online meeting.
 - Following the conclusion of the live Q&A session, the presentation and Q&A must be removed from visibility. The presentation and Q&A can be uploaded for permanent display following certification in accordance with clause 14 so that it can remain visible to the original audience or be made available to a wider audience.
 - Webcasts, etc, are regarded as meetings **and** as on-line activities (i.e. clauses 19 and 24 apply in particular).
 - A pharmaceutical company can issue a live webcast containing off-licence information (e.g. from a company symposium at a third party scientific congress) via a company website. A recording of the webcast can subsequently be made available on request through medical information or provided for inclusion on the official congress site. Alternatively, a recording of the webcast can be included on company websites in the context of the wider scientific discussion (i.e. if the recording comprises a reasonable précis of the entire congress and the coverage of the company symposium is proportionally representative. Representatives can advertise forthcoming webcasts that are limited to on-licence content, but not those that relate to forthcoming indications (i.e. off-licence indications).
 - It would not be appropriate to present a webcast on an off-licence subject on a promotional website.

Services to medicine

20. Can company websites contain newsfeeds? What if the news includes references to company or competitor products?

- Medical newsfeeds are acceptable content. Companies will not be responsible for the content so long as it comes from a reputable independent source and the company has not influenced the filtering of content in a manner favourable to its own products. The content of newsfeeds is not subject to the requirements of clause 14 (certification).

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- i. On a non-promotional site, it is acceptable to filter such that newsfeeds are limited to relevant disease areas; but not to discriminate towards releases concerning company products or to discriminate against competitor products
 - ii. On a promotional site, newsfeeds can be filtered to product-specific content, but cannot contain off-licence information
21. Can a company produce or sponsor an on-line quiz for HCPs?
- Medical quizzes are acceptable so long as no prize is offered, they are a genuine test of skill and they are non-promotional in nature.
22. Can a company produce digital offerings such as mobile device applications?
- Companies might produce a range of such applications in accordance with clauses 18 and 22 of the Code. The involvement of the company must always be prominently displayed and the application must meet all the conditions of the Code.

Free text areas

23. Can a company provide or sponsor websites that include user-generated text and content?
- Yes. However companies are responsible for monitoring and controlling the content of free text areas in online areas they commission, initiate or control (including social media sites).
 - It is acceptable to include discussion areas / forums, etc, so long as all content is monitored. The minimum requirement is that the content of discussion areas must be examined at least once during each working day. Comments that do not comply with the Code must be removed within three working days. This includes all conversation threads that concern off-licence topics. The company may respond to the User to explain why the post was removed.
 - It is *recommended* that text is moderated and approved (certified) prior to being made public. The site should include a statement so users are aware that moderation is occurring.
 - We understand that Adverse Events discussed within free text areas are subject to reporting and follow-up in the usual way and in line with standard AE timelines (as per previous MHRA communications).
 - Where appropriate, the company should provide a formal statement in regard to any conversation threads related to its own products. (For

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example, the company might need to clarify the extent of the product licence or refer users to relevant safety data)

- All entries made by the pharmaceutical company must be by a member of the medical team acting in an official capacity. Readers must be aware that the entry is made by a company employee.
- All discussion areas must contain clear statements indicating the audience (HCP or public).
- All company-initiated discussion topics must be within licence if product-related.
- All public-facing free text areas must contain clear statements advising patients to:
 - Contact their HCP or NHS Direct for personal medical advice
 - Report adverse events to the company or via the patient yellow card reporting scheme
- Companies can provide educational grants to fund websites sites that include free-text areas under certain strict conditions:
 - The website owner must commit in writing to monitor the content and remove all disparaging references to individual products and companies
 - Pharma funding must be clearly declared on the home page of the website
 - The area surrounding the free text area must advise users that the content is monitored and include appropriate reminders regarding adverse event reporting (e.g. www.yellowcard.gov.uk for HCPs)
 - It is not acceptable to sponsor only the specific *page* on which the free text area appears; funding must be provided to support the website as a whole

Responding to on-line comments

24. Can a company respond to comments made about its products on third-party sites and discussion forums

- Companies may respond to comments made in discussion forums, wikis (including sidewikis), etc, as long as the responses are compatible with the Code.
- Comments should be non-promotional and seek to correct inaccuracies or misleading information
- Comments that are visible to the general public should always encourage consultations with a healthcare professional if appropriate
- It should be noted that where companies are responding to comments in text areas outside their control (including Sidewikis) that

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consideration should be given to any adverse events posted on the website during the period that the company is monitoring the site.

Links to other websites

25. If a company adds links to other sites, when is it responsible for the content?

- Companies can add links from their websites to reputable third-party sites or the areas of social media sites operated by reputable medical societies, etc. The link should be to a balanced landing page such as the home page or to the beginning of the relevant section.
- If the link is to the home-page of a professional society or Government site, etc then the company will not be regarded as accountable for the content of the linked site
- If the link is to a *specific* page of a professional society, reputable patient group or Government site, then the company may be regarded as accountable for the content of the landing page (but not the whole site). This is because the company will be seen to have deliberately directed the audience to specific content. The company would not normally be accountable for any third-party advertisements on the site.
- If the link is directly to a company-owned site, the company is responsible for the entire content (including overseas sites). For the sake of clarity, it is acceptable to provide a list of national corporate sites e.g .de, .it, fr; it is not appropriate to provide a list of product-related .com sites (especially because the US allows direct-to-consumer advertising).
- It must always be clear when a user is leaving a company site
- The content of the original site will always be a consideration in judging the suitability of a link (e.g. links between non-promotional sites are likely to be judged more favourably than links that join non-promotional (off-licence content) with promotional sites.
- Companies can include links to the home page of social media sites. Pharma will not be responsible for the content of the social media sites so long as:
 - The Pharma site bears a suitable declaration indicating that it has not reviewed the content of the social media entry
 - The link is 'interrupted' by a Pharma message reminding the user that they are leaving the Pharma site and that the destination area has not been checked for content

Medical Information

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26. Is it acceptable to provide on-line Medical Information resources?

- It is acceptable to provide on-line Medical Information resources.
- The list of displayed Q&As should only relate to on-licence subjects (because reference information provided for consumers can only relate to on-licence subjects).
- The company can additionally provide an option for the user to enter a free-text question, whereby the returned list of potential answers can include off-licence topics. (This is in accordance with the current rules regarding unsolicited Medical Information enquiries).
- The arrangements for free-text answers must be certified rather than examined.
- It is permissible for the company to retain a list of HCPs who wish to be included on the circulation lists for medical press releases related to developments with particular products. It would not be appropriate to send these individuals additional information that was created specifically for them, for example as a means of bypassing rules relating to off-licence promotion
- It is acceptable to provide direct interaction with MI professionals via on-line chat, etc. This must be a closed environment and the discussion must not be visible to other users.
- It is not acceptable to answer personal medical questions raised by a user in a free text area, regardless of whether that area is controlled or sponsored by pharma (e.g. third-party posts). However an answer can be supplied directly and privately to the person who asked the question as long as it is not visible to all users (for example by opening a temporary side-room). This does not preclude the company from also posting a general answer that is suitable for all readers, however great care must be taken when interacting with the general public as per the current conditions defined in clause 21 of the Code.

Material & activities for public (including journalists)

27. Is there a difference in the content allowed for non-medical journalists and the content allowed for members of the public?

- No. There is no discernible difference between information that can be provided to non-medical journalists, and information that can be provided to the general public

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- Websites for journalists must meet the requirements of clause 22 in general, however it is permissible to provide a resource area including pack-shots, explanation of statistical terms, etc.
- The content and style might be directed more specifically for a journalist audience and should be clearly labelled as being intended for journalists.
- Prominent bloggers can be communicated with in the same manner as journalists.

28. Are there any additional considerations that should be made in relation to digital media content aimed at members of the public?

- Public-facing product reference websites created by the company should include a link to the patient-reporting yellowcard scheme; and a downloadable copy of the relevant PIL or a link to the relevant section of the EMC.
- It is acceptable to register product reference sites under the product brand name (e.g. www.Diabease.co.uk)
- It is acceptable to add limited relevant non-medical content to a consumer site so long as the theme is related to the topic of the overall site and is certified. Additional content enhances the likelihood of users revisiting the site, thereby enhancing the effectiveness of the medical messages.
 - i. Examples might include a health-related game or cartoon.
 - ii. Patient diaries, etc are acceptable as long as the content is moderated and certified prior to public display
 - iii. Newsfeeds are acceptable so long as the content is relevant to the medical condition and the company has not influenced the filtering of content in a manner favourable to its own products.
- It is worth noting that current European Commission advice does not support including the address of any pharmaceutical company websites within Patient Information Leaflets.

29. Can companies provide on-line resource areas for patients taking their medicines? What rules apply?

- Yes.
- There is no discernible difference between information that can be provided to patients taking the company's medicine, and information that can be provided to the general public
- There is no need for this content to be password protected

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- It is acceptable to advise patients that the site exists via their HCP or via in-pack leaflets. The site should not otherwise be advertised
- On-line public facing material placed requires certification
- Companies can provide disease awareness information to consumers under the terms of clause 22. There must be no connection to the promotion of specific medicines and all information must be within the product licence. This includes adding links to areas within social networking sites, and contacting prominent bloggers, etc, to direct traffic to appropriate information sources. It is helpful if all disease awareness sites signpost the patient yellowcard reporting scheme.

Review and Certification of digital media

30. Is it acceptable to certify digital media in a Read-Only electronic format (e.g. CD ROM / DVD) without the need for an accompanying printed transcript?

- Yes. However a printed transcript is required for all spoken content (e.g. video / audio content).

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