Using the Internet to Provide Information

Jackie Vincenti and *Christine Bendall* discuss European and UK laws and guidance on providing information via the internet and advise companies on how they can ensure compliance.

Pharmaceutical companies use the internet in a number of ways: most, if not all, companies have a website. This article addresses the current legislation and guidance in place at a European level and in the UK in relation to the provision of non-promotional information about prescription-only medicines on the internet by pharmaceutical companies. It also provides some practical advice for companies trying to negotiate their way through the regulatory requirements and limited guidance.

Legislation (both European and national) contains extensive provisions relating to the advertising and promotion of medicinal products. However, there is little detail about the provision of non-promotional material (which is simply excluded from the definition of "advertising") and there is no specific regulation on the provision of information through websites, although the legislation applies to a wide range of communications. Furthermore, the International Federation of Pharmaceutical Manufacturers and Associations Code[1] states that the same rules apply to electronic promotions as to printed materials. Pharmaceutical companies must, therefore, apply the general rules when using new technology.

There is little detail about the provision of non-promotional material in EU legislation

In the modern doctor-patient relationship, both parties have access to a broad library of information about medicinal products from various sources, and patients have become more proactive at researching the medicinal products available, particularly via the internet[2]. The need for guidance on how to apply the regulations to website design and management has, therefore, increased.

European legislation and guidance

Under Directive 2001/83/EC (the Community code on human medicines)[3], "advertising" includes a wide range of activities that are designed to promote the prescription, supply, sale or consumption of medicinal products. The directive also contains a direct prohibition on advertising prescription-only medicinal products to the general public. However, the definition of "advertising" does not include factual, informative announcements and reference material, or information relating to human health or diseases, provided there is no reference, even indirect, to specific medicinal products. Companies are, therefore, able to provide such "information" to the public (and healthcare professionals) without being subject to the stringent requirements of the directive. For example, a company provides information to healthcare professionals in the summary of product characteristics (SmPC), and to patients in the patient information leaflet (PIL).

The definition of advertising does not include factual, informative announcements and reference material

However, the distinction between "advertising" and "information" in relation to other, seemingly factual documents can be difficult to draw and there is little detail within the directive as to how this exception operates in practice. Equally, national legislation contains few details about how the exemption should be interpreted, and as such, the requirements are interpreted inconsistently throughout the European Union. When considering a piece of so-called information, it is important to consider what may be inferred about the intention behind its provision, taking into account the context and form in which it is provided. These matters may incline regulators to treat the provision of "information" as "advertising".

In practice, companies rely on several codes of practice (and cases determined by regulators and industry bodies) to determine what can be done within the scope of providing "information". These codes are available at international level (IFPMA code), European level (European Federation of Pharmaceutical Industries and Associations code[4]) and national level (in the UK, the Association of the British Pharmaceutical Industry code of practice[5] and the Medicines and Healthcare products Regulatory Agency Blue Guide[6]). These codes all provide some fairly consistent detail on the provision of non-promotional information.

The EFPIA code includes some specific guidelines for websites at Annex B. This discusses what information may be included on a website and guidance on the acceptable content of a company website when aimed at different audiences, ie healthcare professionals or lay persons. However, the EFPIA code refers to compliance with local rules and it is recognised that more stringent guidelines could be applied by member states.

The EFPIA code includes some specific guidelines for websites

Guidance in national industry guidelines should be consistent with the principles of the EFPIA code. However, national guidelines vary in the amount of detail they contain and in their interpretation of the rules. The French Health Products Safety Agency (AFSSAPS), for example, has published a specific code on communications by pharmaceutical companies on the internet[7].

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It provides guidance similar to that in the EFPIA code, but affords French companies greater clarity as to how these requirements operate in France. For example, the code contains a specific time period by which information must be updated.

On the whole, national guidance tends to lack practical detail

Other countries, such as the UK, Germany and Spain, do not have discrete website guidance, but include guidance within general codes of practice. On the whole, the guidance tends to lack practical detail, and pharmaceutical companies are left to apply general guidance that is not specific to the medium.

UK approach

The legislation, the ABPI code and MHRA guidance

In the UK, the Medicines Act 1968 sets out a brief definition of advertising[8], which, in rather circular fashion, includes "every form of advertising". This definition is clearly extremely wide, although it does not include product labelling, or the PIL.

The Advertising Regulations 1994[9] set out the national requirements in relation to the advertising of medicinal products. Part III of these regulations deals with advertising medicinal products to the public and contains the same prohibition against advertising prescription-only products to the public as Directive 2001/83/EC. It is an offence to contravene this provision. In this context, therefore, it is important to ensure the provision only of non-promotional information to the general public.

The ABPI code of practice is designed to be fully consistent with the regulations. However, it also extends beyond them, providing a framework for what is acceptable good practice for its members and those who agree to apply it and be bound by the decisions of the Prescription Medicines Code of Practice Authority, the organisation that enforces and monitors the ABPI code in the UK. Its rules apply, as appropriate, whatever medium is used for information communication.

The code states, at clause 22.2, that information on prescription-only medicines that is made available to the public must be factual, presented in a balanced way and must not be made for the purpose of encouraging members of the public to ask their health professionals to prescribe a specific product. The supplementary information to this provision expressly confirms that this includes information made available on websites.

The supplementary information divides information provided to the public into three categories: (i) information, such as booklets and disease awareness campaigns; (ii) reference information intended to be a resource for patients; and (iii) information supplied in response to a request. Websites are listed as a category of reference material under (ii).

Under the ABPI code, companies are not obliged to provide reference information

Under the ABPI code, pharmaceutical companies are not obliged to provide reference information, but it is considered good practice, as a minimum, to make available "on their websites or by way of a link from their website or by some other means", the SmPC, the PIL and other reference material that may be appropriate, such as public assessment reports[10] and studies relating to the product (note that the EFPIA code states that the website must contain full, unedited copies of the current SmPC and PIL). These documents should be provided without editing and as approved by the relevant regulatory authority. The rules also apply to any statements that accompany such documents (such as press releases), and companies should ensure that any accompanying documents could not be classed as advertising. For example, having the SmPC attached to a press statement that makes unsupported claims about the product's ability to treat a particular disease may not be appropriate.

Clause 24 of the ABPI code specifically concerns the internet. It is quite limited and states that materials provided on the internet must comply with the general requirements of the code including that information on medicines intended for the public must comply with clause 22 (on the provision of information, discussed above).

The MHRA Blue Guide also contains some guidance on providing information to the public on the internet that is generally consistent with the provisions of the ABPI code, for example, that the SmPC and PIL should be included. It also states that it is good practice that each page of a website should clearly identify the intended audience and that "adequate" information should be provided in public areas so that lay individuals do not need to access sections directed at healthcare professionals.

Website content

Taking account of the law and guidance mentioned above, companies in the EU should consider the following when providing information via their websites.

General information on the company

The EFPIA code says that the identity of the website owner should be clearly set out

Annex B of the EFPIA code states that the identity of the owner of the website (for example, the marketing authorisation holder) should be clearly set out, together with details of sources of information on the website and the date of its publication.

The ABPI code clarifies that "financial information" may be included on a website in order to inform shareholders and the Stock Exchange, eg in the form of annual reports and announcements. Such information would include financial data, descriptions of research and development programmes, and information for prospective employees.

Information for patients

Information can be provided to the general public on the internet about diseases or health concerns, and the general guidance in place in relation to such campaigns must be followed. Websites can, therefore, provide information on the characteristics of a disease, methods of disease/illness prevention, screening, treatments and other information intended to promote health[11].

Websites can provide information to promote health such as methods of prevention

Despite the provisions of Directive 2001/83/EC, which states that there should be no reference, "even indirect", to medicinal products, the EFPIA code states that websites can refer to specific medicinal products, but that the information has to be accurate and balanced. Information about alternative, non-medicinal forms of treatment should also be included where this is appropriate. Careful thought should always be given to naming specific products because of the risk that the piece will become promotional.

A published case before the PMCPA in October 2008 set out advice about the scope of information that could be included in such educational websites. Lilly had set up a website to provide information about erectile dysfunction, which contained information about the medicines and devices available to patients[12]. This did not name any specific medicinal product, but the products were identifiable by the information provided about side effects and duration of effect. The PMCPA panel considered that this could result in patients asking doctors for a specific prescription-only medicine, and this was a breach of clause 22 of the ABPI code.

The panel noted that such programmes may improve the market awareness of a company's products and that this was not necessarily a breach of the ABPI code. However, the use of brand or non-proprietary names might be likely to lead to the request for or use of a specific medicine, and particular care must be taken where the company's product is the only medicine relevant to the disease or symptoms in question. This is particularly important where the internet is concerned, as consumers are able to assemble information on a product very quickly from a variety of sources and to "de-code" the carefully worded language used by a pharmaceutical company.

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Information to healthcare professionals

In relation to "information" that is not promotional, the principles are the same as those that apply when providing information to the public. However, companies can also include promotional text, provided that it complies with the law and relevant code provisions on advertising to healthcare professionals. In particular, promotional material should include a clear statement of where the prescribing information can be found. Any information directed at healthcare professionals must be clearly identified so members of the public are able to identify and avoid it.

It is worth considering how the same factual information should be presented in different ways so that it is properly tailored to the intended audience. For example, information on the side effects of a product may be worded differently in sections intended for healthcare professionals compared with those intended for patients.

Access to information and security protection

The ABPI code states that the general public should not need to access information intended for healthcare professionals in order to obtain information about a product. However, in practice, looking at a number of pharmaceutical companies' websites where there is no separate site for patients, product information is either on the part of the website intended for healthcare professionals, or on sites intended for other jurisdictions. Therefore, patients may inadvertently access information (and advertising) that is not intended for them in order to view the non-promotional product information. It is recommended that basic, factual product information should be included (either in both the sections for healthcare professionals and the public, or in a separate, generally accessible section containing non-promotional and reference material) in line with the provisions set out above and in an appropriate manner for the specific audience.

Similarly, the public should not need to access non-UK websites to obtain information about a product on the UK market. Problems arise with regard to products that are not authorised in the UK. Both European and UK legislation make it clear that advertising medicines that do not have a marketing authorisation is prohibited. However, "information" on such products may be published, in accordance with the principles set out above. The fact that the product is not authorised in the UK should be clearly indicated (either on a UK website, or on websites from other jurisdictions if they can be accessed from the UK) to both healthcare professionals and the public

The public should not need to access non-UK websites to get information about a product on the UK market

so that there is no confusion as to the availability of the product. A company should also consider how much information, if any, a patient or healthcare professional should be given or be able to access on non-UK websites if the product is not authorised in the UK. It is also worth considering the jurisdictional concerns set out below, as a patient may be accessing information intended for patients in another jurisdiction. For example, the website should clearly identify to users from the UK if the content is not appropriate for a UK audience.

The ABPI code no longer contains specific provisions on the need for consumer access restrictions…

Previous versions of the ABPI code specifically stated that "promotional material should ideally be access restricted" so the public cannot access the information intended for healthcare professionals. However, this provision has been relaxed in the 2008 code and the need for access restriction is not specifically advised. Instead, the code states that unless access is limited to healthcare professionals, the website must provide information for the public as well as to healthcare professionals, with the sections for the specific target audience clearly separated and identified. The EFPIA code also states that the information need not be encrypted or otherwise restricted.

However, a PMCPA case in 2006[13] suggests that the PMCPA takes a restrictive view of safeguarding measures, and that a site requires more than a simple warning unless there is a valid reason why this is not possible. In this case, there was a warning that the website contained additional information addressed to those patients who had been prescribed the medicinal product, or, on an alternative page, for healthcare professionals. However, there was no control over the access to any specific page. The panel found that, as the whole of the website was accessible to the public, including the healthcare professionals' part, this part was in breach of the ABPI code:

> *…whatever system was used, companies must ensure that if promotional material was made available on the internet, this was accessible to health professionals only via a secure closed system.*

…while the French AFSSAPS code is much more stringent on advertising aimed at health professionals

While the change in emphasis in the 2008 ABPI code may show a realisation by the PMCPA of the practical issues involved with applying password protection (such as, for example, the need for additional software, problems with verifying the information provided, and the processing of personal data), the cautious approach for a company would be to apply/retain the access restriction. It is interesting to note that the French AFSSAPS code is rather more restrictive than the ABPI code, and requires that advertising aimed at healthcare professionals should have "real" restrictions on access by consumers, and that access codes should only be given after qualifications have been verified. In addition, the practices in many EU countries, including Spain and Germany, for example, are such that more stringent security provisions apply – this is usually done by requesting the medical licence number of the healthcare professional, or use of an independent verification service.

Jurisdictional issues

It is obvious that websites can be accessed from countries other than the country where the information is placed on the internet, and by people who are not its intended audience. Conversely, companies can add information to the internet in countries that have less stringent controls over promotion of medicinal products, and this information can be accessed by patients within the UK. There is, therefore, a problem as to which regulatory body can enforce which advertising rules in order to regulate the website, and secondly as to the extent to which a regulator can actually enforce the rules in its country.

In general, a regulator is only able to enforce the local rules against entities with a presence in that jurisdiction. The ABPI code states that information that is placed on the internet outside the UK will be regarded as coming within the scope of the code "if it was placed there by a UK company or an affiliate of a UK company or at the instigation or with the authority of such a company and it makes specific reference to the availability or use of the medicine in the UK". Therefore, if a UK subsidiary is named on a website, or UK prescribing information is published on the website, the website will be subject to the UK regulations. Companies should, therefore, ensure good intra-company communication so the local company can ensure no breaches of the relevant code as a result of the act of an affiliate.

Concerns over updates and website links

The speed with which websites are updated is particularly relevant

One issue that is particularly relevant to websites is the speed in which they should be updated in order to ensure that the information on the website is consistent with the product information. The EFPIA code states that information on websites should be regularly updated and should clearly display the date when the information was last updated. In an MHRA case in June 2008[14], the MHRA was concerned that out-of-date information about the product was available on the website – the change to the product information was approved in March 2008. This ruling potentially puts

companies under a great deal of pressure to update websites quickly, and arguably more quickly than for hard copy product information. However, this case appears to relate to a specific safety issue, rather than a more routine/administrative change to the product information.

Although the 2008 ABPI code states that websites linked via a company's website are not necessarily covered by the code, a company will be responsible for ensuring that material on a website linked from its website complies with the code and other relevant laws and guidance. Websites may contain links to other websites containing reliable information on medicinal products, such as websites maintained by national competent authorities, medical research bodies and patient organisations. In an MHRA case in 2008, the MHRA found that although the website included a link to the corporate website, it made it clear to users that they had left the original site by opening a new window – in accordance with MHRA guidance[15].

A company must ensure that material on a website linked from its own website complies with the ABPI code

If a third party provides a link to a company website, the company will only be responsible for any breaches of the ABPI code that may arise if the link has been established with its knowledge and consent.

Clarity in the future?

In December 2008, the European Commission published two proposals on the provision of information to patients[16,17]. These acknowledged the difficulties caused by the lack of harmonisation across the EU and proposed amendments to Directive 2001/83/EC so that information to patients could be controlled by regulatory authorities and only provided through specific channels, including the internet. The provisions did not particularly change the existing concepts of "information" and "advertising" but aimed to provide a clear framework for the provision of information by marketing authorisation holders.

It was proposed that websites containing information for the general public would have to be registered by the national competent authority of the relevant member state. There are also provisions to manage the cross-border nature of websites, whereby companies would need to select and register a website in a particular country. The competent authority in that member state would then be responsible for monitoring the website.

The MHRA published a consultation on these proposals in May 2009[18]. This consultation closed on 14 August, and a summary of responses was published in November. Overall, the majority of respondents agreed with the commission's and UK government's proposals for a self-regulatory approach underpinned by national enforcement provisions. There was no support in the UK for establishing a new European body to approve information prior to dissemination. There was also overwhelming support for maintaining the current ban on direct-to-consumer advertising of prescription-only medicines. The UK government acknowledged that clarification was needed in relation to the use of "webclips" on pharmaceutical companies' websites, and the responses to the consultation indicated that pharmaceutical companies were concerned about being held liable for the content of third-party websites, and that patients should be able to identify regulated or unregulated websites. However, there was little in-depth discussion about websites or the internet per se.

There was no support in the UK for a new European body to pre-approve information

There has been considerable opposition in Europe to the proposals relating to information to patients, as many people consider that this is the first step on the road to DTC advertising. As a result, progress has been limited and it is unclear when and how, if ever, this issue will be clarified. Currently, the commission has said that it would change the text of the proposal to take into account concerns from member states, but it has not explained what changes may be made. The Council of Ministers has, therefore, decided to put off consideration of the proposal until it is considered by the European Parliament in the spring[19]. However, European commissioner for enterprise and industry Günter Verheugen said that some form of legislation would need to be implemented because of the current legal uncertainty and the large amount of information available to the public, particularly on the internet.

It is also worth noting that the Pharmaceutical Marketing Society in the UK has set up a Digital Marketing Working Group (ie promotion and provision of information over the internet) made up of representatives of pharmaceutical companies. The group hopes to publish clearer guidelines on the use of the internet, which will then be submitted to the PMCPA to consider possible changes to the ABPI code. The group planned to complete its review at the end of November 2009[20], but we understand that it will submit its proposals to the PMCPA for comment before they are published.

The current "mish-mash" of guidance on information and websites, developed piecemeal by various different sources in different countries, is not helpful for pharmaceutical companies. Hopefully, clearer guidance will be developed in the future. In the meantime, companies would be advised to adopt a cautious approach to the provision of information in general and to the information they post on their websites (see Table 1 for some practical tips).

Companies should adopt a cautious approach until clearer guidance is developed

Users should know when they are leaving the company's website

The public should not be encouraged to view information aimed at health professionals

Table 1. Providing information on the internet: Dos and Don'ts

Do clearly identify your company. **Do** clearly identify, on each page, the intended audience. **Do** ensure the content and presentation is appropriate for the intended audience. **Do** ensure that country-specific information complies with local laws and regulations. **Do** ensure that the purpose and objectives of (each part of) your website is apparent. **Do** ensure that brand names are accompanied by non-proprietary names. **Do** consider options to restrict access to certain parts of the website that contain promotional materials.	**Do** make it clear when a user is leaving your website or is being directed to a website that is not sponsored by you. **Do** make sure that any information is consistent with the authorised product information, and include copies of these documents. **Do** monitor links to ensure that patients are not being encouraged to move from websites intended for the general public to websites intended for healthcare professionals. Any such move must be accompanied by a clear warning. **Do** include a clear warning when a user is accessing information intended for patients in another jurisdiction. **Do** be aware of the information provided on third-party websites that link to your website.
Don't encourage members of the public to access information intended for healthcare professionals.	**Don't** leave out-of-date information on your website (review and if necessary update information regularly).

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