

The Internet, pharmaceuticals and the law

*Richard Binns and Bryan Driscoll, Pharmaceutical & Medical Group, Simmons & Simmons, 1 Ropemaker Street, London, UK EC2Y 9SS.

*tel +44 20 7628 2020; fax: +44 20 7628 2070, e-mail: richard.binns@simmons-simmons.com

It is now possible for consumers to find information about, and buy, almost any type of product over the Internet. Health-related information and pharmaceutical products are no exception to this trend. However, although there are many legitimate sites where one can find health-related information and buy pharmaceutical products online, in some cases, the information is misleading or false, and in others unapproved, or prescription drugs might be being supplied in violation of the law.

Internet sites can be viewed worldwide and are therefore potentially subject to every country's laws. However, this is not necessarily the case and, in any event, national authorities are generally powerless to take action outside their own borders. Even within their own jurisdiction, the regulatory authorities find enforcement difficult against Internet operators¹. The situation is unlikely to change in the near future and, whatever the legal position, there is still a continuing need for consumers to be educated about the potential pitfalls of using the Internet for their healthcare needs.

Information and advertising

The individual's freedom of expression, subject to limited exceptions, is an important constitutional right in most countries. Although there are laws in many countries against making defamatory statements, in most cases it is difficult to take action in respect of false or misleading information on a non-commercial site. By contrast, however, promotion and advertising of pharmaceutical products in

both Europe and the US is closely regulated. Other rules might also affect the provision of information about health and medicines by manufacturers, doctors and pharmacists.

Under European law, prescription drugs and certain other drugs cannot be advertised to the public at all and any other advertising is strictly controlled². In Europe, the placing of virtually any information, at least about a prescription medicine, by a manufacturer or pharmacist on an open-access site could be seen as a form of illegal advertising. By contrast, in the US, there are fewer restrictions and direct-to-consumer advertising of prescription products is permitted within certain limits³.

Partly as a result of this, manufacturers and pharmacists in the US have led the way in communication through the Internet. Consequently, European consumers can gain easy access to US product-related information but not to European product-related information. Some recognition that European legislation might be falling behind the 'real world' has led to a recent consultation by the European Commission on both advertising and e-commerce. Many in the European industry hope that this will at least result in a clarification of what information can acceptably be communicated to patients without breaking the law.

Online consultations

Many doctors are prepared to give consultations over the telephone and, in principle, an online consultation by e-mail would be very similar. Both the

American Medical Association⁴ and the UK General Medical Council⁵ have affirmed that a doctor can, under certain circumstances, provide a consultation by e-mail provided that this does not fall below the acceptable minimum standard of care. However, the doctor has to be very careful where the patient is not previously known to the doctor and no follow-up care is available or where proper diagnosis might require review of the patient's medical history, a physical examination or tests.

Several sites in the US and elsewhere enable users to buy prescription drugs solely by filling in a short questionnaire. Typically, it is claimed that the questionnaire is reviewed by a doctor and the drug is only prescribed if the doctor approves the questionnaire. The American Medical Association and US authorities disapprove of this practice, and doctors in several states have been prosecuted for offering this type of service⁶.

Online pharmacies

In the US, there are hundreds of online pharmacies, but in Europe there are only a handful. Restrictions on the sale of drugs (including over-the-counter medicines) other than in a licensed pharmacy, rules about patient/pharmacist contact and controls over advertising by pharmacists have all inhibited or prevented the growth of online pharmacies in Europe.

The UK is among the most progressive European countries in this area. The Royal Pharmaceutical Society of Great Britain has now issued guidance on the subject⁷ and the UK government has

recently stated its support for online pharmacies⁸. European countries might well embrace online pharmacies at different speeds, possibly with the UK, The Netherlands, Scandinavia and Switzerland in the forefront, Italy and France in the middle and Germany lagging behind.

One problem encountered by online pharmacies in countries like the UK is that an original, signed prescription is normally needed before a prescription drug can be dispensed. This makes online sale of prescription medicines more difficult. However, there is increasing recognition that electronic transmission of prescriptions can be made just as secure, whilst facilitating the collection and analysis of prescription data. Many states in the US now allow electronic prescriptions, and in the UK the government has promised that by 2004, electronic prescriptions will be used routinely⁹. Similar initiatives have been made or proposed in other countries.

Individual privacy

A further concern is the issue of maintaining the privacy of information about individuals. European law now contains strict legal safeguards in this respect, but outside Europe, the use of such information is generally less restricted. The

best strategy for individuals who want to maintain their privacy is to disclose their personal information and data only where necessary and only to entities that they know and trust, a process that might be facilitated by an effective site certification scheme.

Various organizations have prepared voluntary codes of conduct for health-related Internet services, each aimed at different categories of sites¹⁰. These not only cover privacy issues, but also areas such as quality of information, disclosure of ownership and sponsorship, identification of advertising content and so on. Eventually, it is hoped that this will lead to an effective system of self-regulation within the industry that will earn the trust of the consumer by certifying sites that adhere to the relevant code. However, whilst self-regulation by national groups of manufacturers, physicians and pharmacists has worked relatively well for traditional methods of communication, it remains to be seen whether self-regulation will work worldwide at a much more general level over the Internet.

References

- 1 Woodcock, J. (1999) Prepared statement of Janet Woodcock. In *Drugstores on the Net: The Benefits and Risks of On-line Pharmacies*. Hearing before the Subcommittee on Oversight and Investigations Committee 106th Congress, First Session, 30 July 1999

- (Committee on Commerce US House of Representatives), pp. 94–102, US Government Printing Office
- 2 Council of the European Communities (1992) Directive 92/28/EEC of 31 March 1992 on the advertising of medicinal products for human use. *Official J. Eur. Communities* L113, 13–18
- 3 Food and Drug Administration, Department of Health and Human Services (2000) Prescription drug advertising. In *Title 21 Code of Federal Regulations*, Chapt. 1 Part 202 (4-1-00 edn), pp. 72–81, US Government Printing Office
- 4 General Medical Council (1998) Providing advice and medical services on-line or by telephone. *GMC News* Winter Edn, 6
- 5 Abromowitz, H.I. (1999) Prepared statement of Hermin I Abromowitz. In *Drugstores on the Net: The Benefits and Risks of On-line Pharmacies*. Hearing before the Subcommittee on Oversight and Investigations Committee 106th Congress First Session 30 July 1999 (Committee on Commerce US House of Representatives), pp. 252–260, US Government Printing Office
- 6 Henney J.E. *et al.* (1999) Internet purchase of prescription drugs. *Ann. Intern. Med.* 131, 861–862
- 7 Council of the Royal Pharmaceutical Society (2000) Standards for the provision of online pharmacy services. *Pharm. J.* 264, 9
- 8 Department of Health (2000) E-pharmacy – a new choice. In *Pharmacy for the Future – Implementing the NHS Plan*, pp. 12–13, United Kingdom Department of Health
- 9 Department of Health (2000) Electronic prescribing – using technology to make access more convenient. In *Pharmacy for the Future – Implementing the NHS Plan*, pp. 11–12, United Kingdom Department of Health
- 10 Fried, B.M. *et al.* (2000) E-health: technologic revolution meets regulatory constraint. *Health Affairs* 19, 124–131

How do YOU think the use of the Internet in providing pharmaceutical-related information should be regulated?

Should we move towards the law in the US that allows advertising of prescription drugs?

...or should we stop the advertising of prescription products on the Internet worldwide to avoid the problems of differences in legislation between countries?

How do you think we should maintain privacy of information?

Please send your comments to Dr Rebecca Lawrence, News & Features Editor, *Drug Discovery Today*,
e-mail: Rebecca.Lawrence@current-trends.com

Editorial reserve the right to edit or to reject your comments when necessary.