

Guidelines for Internet Web Sites  
Available to Health Professionals, Patients and the Public in the EU

**This paper was produced for a meeting organized by Health & Consumer Protection DG and represents the views of its author on the subject. These views have not been adopted or in any way approved by the Commission and should not be relied upon as a statement of the Commission's or Health & Consumer Protection DG's views. The European Commission does not guarantee the accuracy of the data included in this paper, nor does it accept responsibility for any use made thereof.**

*Introduction*

The following are guidelines for company-sponsored Web sites containing information on prescription-only medicinal products intended for health professionals, patients and the general public in the EU. It may be necessary to adapt the guidelines to meet requirements or needs of specific member states. Where appropriate, the guidelines would be enforced at the national level through voluntary self-regulatory systems.

*Principles*

1. *Sponsor's identity* - The sponsor of the Web site(s) should be clearly identified.
2. *Content of sites* - Examples of the information that may be included in a single site or in multiple sites are: (i) general information on the company; (ii) health education information; (iii) information intended for health professionals, including advertisements and promotional information; and (iv) information intended for patients and the general public about specific medicinal products marketed by the company.
  - 2.1 *General information on the company* - Sites may contain information that would be of interest to investors, the news media and the general public, including financial data, descriptions of research and development programmes, discussion of regulatory developments affecting the company and its products, information for prospective employees, etc. The content of this information is not regulated by these guidelines or provisions of medicines advertising law.
  - 2.2 *Health education information* - Sites may contain information about the characteristics of diseases, methods of prevention and screening and treatments, as well as other information intended to promote public health. They may refer to medicinal products, provided that the discussion is balanced and accurate. Relevant information may be given about alternative treatments, including, where appropriate, surgery, diet, behavioural change and other interventions that do not require use of medicinal products. Sites containing health education information must always advise persons to consult a health professional for further information.

- 2.3 *Information for health professionals* - Any information in sites directed to health professionals that constitutes advertising must comply with applicable requirements of national regulations and industry codes of practice governing the content and format of advertisements for medicinal products. It must be clearly identified as information for health professionals, but need not be encrypted or otherwise restricted.
- 2.4 *Information for patients and the general public* - Sites may include information for patients and the general public on products distributed by the company (including information on their indications, side-effects, interactions with other medicines, proper use, reports of clinical research, etc.), provided that such information is balanced, accurate and consistent with the approved summary of product characteristics. For each product that is discussed, the site must contain full, unedited copies of the current summary of product characteristics and patient leaflet. These documents should be posted in conjunction with other information about the products or be connected with that discussion by a prominent link advising the reader to consult them. In addition, the site may provide a link to the full, unedited copy of any public assessment report issued by the Committee for Proprietary Medicinal Products or a relevant national competent authority. Brand names should be accompanied by nonproprietary names. The site may include links to other Web sites containing reliable information on medicinal products, including sites maintained by government authorities, medical research bodies, patient organisations, etc. The site must always advise persons to consult a health professional for further information.
3. *E-mail enquiries* - A site may invite electronic mail communications from health professionals and patients or the general public seeking further information regarding the company's products or other matters. The company may reply to such communications in the same manner as it would reply to enquiries received by post, telephone or other media. In communications with patients or members of the general public, discussion of personal medical matters should be avoided. If personal medical information is revealed, it must be held in confidence. Where appropriate, replies shall recommend that a health professional be consulted for further information.
4. *Links from other sites* - Links may be established to a company-sponsored Web site from Web sites sponsored by other persons, but companies should not establish links from sites designed for the general public to company-sponsored sites that are designed for health professionals. In the same manner, links may be established to separate Web sites, including sites sponsored by the company or by other persons. Links should ordinarily be made to the home page of a site or otherwise managed so that the reader is aware of the identity of the site.
5. *Web site addresses in packaging* - Uniform resource locators (URLs) of company-sponsored sites that comply with these guidelines may be included in packaging of medicinal products.
6. *Scientific review* - Companies should ensure that scientific and medical information prepared by them for inclusion in their sites is reviewed for accuracy. The scientific service established within the company pursuant to legislation implementing Council Directive 92/28/EEC of 31 March 1992 on the advertising of medicinal products for

human use (or other Community measures codifying or amending that directive) may perform this function, or it may be entrusted to other appropriately qualified persons.

7. *Privacy* - The site must conform to legislation and applicable codes of conduct governing privacy of personal information.