

General Policy Issues

Dangers of purchasing medical products through the Internet

The value and uniqueness of the Internet as a worldwide communications system is evidenced by its popularity. Among its many attributes, the Internet provides a valuable tool for retrieving information on medicine and health and accessing important knowledge bases, such as those housed within universities. As an aid to scientific enquiry, it allows rapid and easy exchange of information among professional groups such as researchers, scientists and health care professionals. It also creates the potential for general public access to up-to-date medical information and news on developments in therapeutic strategies.

The Internet also allows users to post or exchange opinions, wares and information irrespective of origin, status or global location and one of its many features is an international commercial directory for the cross-border advertising, promotion and sale of products. Despite the visible advantages offered by the Internet, however, concern is growing at the possible misuse of the system. It is apparent that an increasing number of medical products are sold through the Internet. The consequence of cross-border commerce in medical products is that without regulatory control the safety, efficacy and quality of products cannot be assured. Inappropriate claims are being made for products which, in increasing instances, are promoted for indications which do not correspond to the approved use. Products with significant health risks — such as abortion and self-sterilization kits or home test kits for HIV or hepatitis — have been advertised for sale. The problem is furthermore compounded by the diversity of the products offered.

Even when medical products purchased over the Internet are not considered dangerous, patients could compromise their health by not seeking proper medical advice and individual treatment. When purchasing in this way, a consumer may also be wasting valuable resources on ineffective, improper or needless products and potent prescription-only medicines may have the potential for serious side-effects. Medical products which are

sold outside the official channels could also be improperly manufactured, packaged or stored. Most importantly, there is no guarantee that the purchaser is, in fact, receiving the brand product and not a fraudulent or adulterated copy and it is often difficult to identify the true source and integrity of the information used in its promotion.

This particular use of the Internet has drawn attention to the differences between Member States with regard to legislation and regulations. While historically these have addressed the promotion, advertising and sale of medical products nationally, it has now become an issue of concern to every country. Given the difficulty in locating the company that is responsible for posting information on the Internet, a further problem for enforcement agencies is to identify the responsible party. In many cases, a web site which has been closed down may rapidly be reopened in another area or even another country.

Given the urgency of the situation, WHO convened an ad hoc working group of experts to prepare a report and recommendations for discussion at the World Health Organization's Executive Board meeting held in January 1998. It is hoped that these recommendations will guide health authorities and other interested parties in handling the issue of cross-border advertising, promotion and sale of medical products through the Internet or similar electronic information systems.

A full report of the meeting of the ad hoc working group is available from WHO¹. The recommendations prepared for discussion by the WHO Executive Board are set out below.

1. Member States should:

- review existing legislation, regulation and guidelines to ensure that they are adequate and applicable to cover issues concerning cross-border advertising, promotion and sale of medical products using the Internet;

¹ World Health Organization. *Cross-border advertising, promotion and sale of medical products through the Internet*. Report of the ad hoc Working Group. Unpublished document DMP/Internet/97.1.

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- develop, evaluate and implement strategies for monitoring, surveillance and enforcement activities regarding cross-border advertising, promotion and sale of medical products using the Internet. When appropriate, measures for enforcement should be taken and, except in exceptional circumstances, widely published;
 - collaborate with other Member States on the issues raised by the Internet, and designate appropriate contact points, and disseminate this information also through WHO to all Member States;
 - disseminate information on problem cases and aspects of cross-border advertising, promotion and sale of medical products using the Internet to WHO, other Member States, and the public, when appropriate;
 - establish Web-sites, where feasible, for dissemination of information about medical products, and regulatory information;
 - maintain and/or establish mechanism(s) for responding to inquiries from the public;
 - inform the public that the Internet is a powerful new medium for the provision of health information, and educate health professionals and consumers on using the Internet; such education should include the ability to assess, to the extent possible, the benefits and risks of the products in order to prevent harm to people from false or misleading information about medical products;
 - in the case of information, promotion and advertising of medical products on the Internet, Member States should encourage the development and implementation of a voluntary code of conduct applicable to all organizations posting information on the Internet; this includes, for example, identification of the information source and its status (e.g. advertisement, data sheet, patient information leaflet) and operate within the context of a self-regulatory system, if necessary, backed up by legislation; adherence to the principles of the WHO Ethical Criteria for Medicinal Drug Promotion should be encouraged; and
 - collaborate with other Member States in order to establish appropriate measures to prevent cross-border advertising, promotion or sale of medical products using the Internet to countries in which it is illegal; where possible, an organized system of licensing of all entities engaged in the sale of medical products should be developed.
2. The pharmaceutical industry, health professionals and consumer organizations and other interested parties should:
- educate their members to use the Internet effectively;
 - encourage their members, where appropriate, to promote the formulation and use of good informational practices; where applicable, consistent with the principles embodied in WHO Ethical Criteria for Medicinal Drug Promotion; and
 - monitor and report problem cases and aspects relating to the cross-border advertising, promotion and sale of medical products using the Internet.
3. WHO should:
- encourage the international community to formulate self-regulatory guidelines for good informational practices, consistent with the principles of the WHO Ethical Criteria for Medicinal Drug Promotion;
 - develop a model guide for Member States to educate people using the Internet on how best to obtain information on medical products through the Internet;
 - collaborate with other relevant international organizations and institutions on Internet issues relating to medical products;
 - urge Member States to set up or strengthen mechanisms to monitor and survey, where appropriate, cross-border advertising, promotion and sale of medical products using the Internet, and provide technical assistance as required;
 - urge Member States to take regulatory action, where appropriate, for violations of their national laws regarding advertising, promotion and sale of medical products using the Internet;
 - encourage Member States and concerned non-governmental organizations to report to WHO problem cases and aspects of the cross-border advertising, promotion and sale of medical products using the Internet; and
 - report problem cases and concerns, as appropriate, to Member States.
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