



E-Commerce

Moderator: Dr Björn Beermann, Sweden

Drug promotion and sales through the Internet Dr Justina A. Molzon, United States of America

In the United States, more than 22 million people used the Internet last year for medical information. According to Investors Business Daily, 43% of Web surfers access health care data online each year and as many as 50% of the patients in the USA have checked the Internet to find medical information. For the consumers, prescription drug sales on the Internet can provide tremendous benefits, including access to drugs for the disabled or homebound, the convenience of shopping 24 hours a day, privacy and anonymity for those who do not want to discuss their medical condition in a public place, and in some cases, lower prices.

As beneficial as this new technology can be, the Internet also creates a marketplace for activity that is illegal under existing law, such as the sale of unapproved new drugs, sale of prescription drugs without a valid prescription, or marketing of products with fraudulent health claims, as well as bypassing the health professional/patient interaction.

The Food and Drug Administration (FDA) in the USA has the legal authority and responsibility to prevent the importation, sale, and distribution of unapproved new drugs; the importation, sale, or distribution of adulterated, misbranded or counterfeit drugs; the sale or dispensing of prescription drugs without a valid prescription; and the illegal promotion of drugs.

The unique qualities of the Internet, including its broad reach, relative anonymity, and the ease of creating Websites or removing old ones,

pose new challenges for the enforcement of existing laws. To address these new challenges, FDA has developed an action plan that defines its mission regarding the regulation of pharmaceutical products sold over the Internet. The goals of the action plan are to ensure that consumers receive FDA-approved products and that online customers are afforded the same protection as traditional consumers, and to encourage consumers to involve their health care professionals in their treatment decisions. In order to implement the action plan, FDA will have to customize and expand enforcement efforts, to identify law enforcement and regulatory partners, to interact with professional organizations, and to engage in public outreach.

The FDA has established enforcement priorities, focusing on unapproved new drugs, health fraud and prescription drugs sold without a valid prescription. By improving our capability to monitor the Internet and to identify potentially violative sites through the use of various search tools, and by upgrading our data handling capabilities, we have improved data acquisition. In addition, a team of representatives from throughout the agency has been set up to prioritize potential cases based on the potential harm to the public posed by the products. This resulted in the evaluation of over 400 Websites for possible regulatory or criminal actions and an increased number of civil and criminal actions. With improved collaboration with International Regulatory Officials, “cyber” letters were also issued. This was the first time the FDA used the Internet to reach those who are potentially violating the Federal Food, Drug, and Cosmetic Act. Cyber letters represent a new stage in the agency’s efforts to protect the public against illegal and potentially dangerous products sold through Websites. The cyber letters explain the statutory provisions that govern interstate commerce of drugs in the United States. The Website operators identified will be warned that future shipments of their products to this country may be automatically detained and subject to refusal of entry.

Hard copies of each cyber letter are sent to the Website operator, the US Customs Service and regulatory officials in the country in which the operator is based. FDA would appreciate it if countries would use their own authority to take action against the operators located in their countries.

In addition to FDA, several Federal and State agencies have a role in regulating online drug sales, so FDA works with the Federal Trade Commission, the United States Department of Justice, the Drug Enforcement Agency, the Federal Bureau of Investigation, the United States Postal Inspection Service, the United States Customs Service, and the state law enforcement agencies.

FDA has also worked with various professional and other organizations to address how best to regulate online drug sales, including the World Health Organization, the American Medical Association, the Federation of State Medical Boards, the National Association of Attorneys General, the American Association of Retired Persons, the National Association of Boards of Pharmacy, the American Pharmaceutical Association, the National Association of Chain Drug Stores, the National Community Pharmacists Association, and the Pharmaceutical Research and Manufacturers of America.

FDA has engaged in an ongoing media campaign and has established a Website that explains the dangers of purchasing drugs online, www.fda.gov/oc/buyonline/default.htm. We have also issued “talk papers” on FDA’s enforcement efforts. We have focused on educating consumers about sites that violate the regulations and we have educated consumers about the dangers of certain products sold via the Internet. We encourage consumers to interact with a health care professional before purchasing products over the Internet. We have also initiated a media campaign about safe ways to purchase pharmaceutical products over the Internet and have established a site where consumers can submit complaints about violative Web sites.

Medicines and the Internet — regulatory approaches in Singapore

Dr John Lim, Singapore

The Internet challenges traditional controls on medicinal products and may pose risks to consumers, for example, allowing inappropriate access to unapproved medicines. Furthermore, advertising information over the Internet could be unreliable. The challenge for regulators is to safeguard public health and promote the safety, efficacy and quality of medicines, without losing the advantages of the new technology.

The Internet is a new means of delivery of goods and services. Its use to supply pharmaceuticals in Singapore is governed by the Medicines Act, which controls supply of medicinal and related products including western medicines, Chinese proprietary medicines, cosmetic products, contact lens substances, etc., provides for the licensing of all medicinal products, manufacturers, wholesalers and importers, and enables the regulation of the safety, efficacy and quality of medicinal products in the country. A new Health Products Act is being drawn up with wider scope and greater flexibility.

Two key concerns are emerging in Singapore: the sale of medicines through the Internet, and the advertising of health information. A survey conducted in July 2001 revealed that around 1% of consumers purchased drugs from other countries through the mail or Internet. It is likely that the percentage will increase, bringing increased risks of inappropriate access, misinformation and lack of patient counselling.

In Singapore, the Internet sale of medicines is regulated using the same basic principles as apply to conventional pharmacies. All online pharmacies must be extensions of services provided by licensed bricks-and-mortar pharmacies, supervised by registered pharmacists. Dispensing of prescription medicines still requires a physician's prescription. The use of electronic prescribing is being currently under review. As a matter of fact, the Health Sciences Authority (HAS) has approved the first hospital online pharmacy, under the conditions that it shall be for the online sale of prescription refills only, that patients will be counselled on their medication by pharmacists over the phone, and that medicines shall be delivered to patients in a secure and reliable manner.

For the regulation of Internet advertisements and dissemination of health information originating from Singapore, only "pharmacy" and "general sales list" medicines are allowed to be advertised. Permits from the Centre for Pharmaceutical Administration are required for all advertisements and sales promotions. Advertisements must not contain false or misleading claims. Singapore health Websites are screened regularly, and site owners with noncompliant materials are required to remove them. Better coregulation with the pharmaceutical industry is also being explored to achieve greater cooperation through a more efficient and less complicated process. For sites outside Singapore, the approach is to empower consumers to make informed

choices by stepping up public education efforts and provision of objective and unbiased information.

As recommended by the Drug Cost Review Task Force in December 2001, HSA advises consumers on the dangers of buying drugs over the Internet, and on transparency of prescription charges and drug prices, and empowers consumers to make informed choices on medicines and their appropriate use. One approach is by providing information through the HSA Website, with links to other reliable sites. The formation of a National Committee on Quality Use of Medicines is under consideration.

In conclusion, in the Internet era, all regulatory agencies need to take measures to protect public health within their respective jurisdictions by enhancing active cooperation and collaboration among national agencies. Public education is the key to empowering consumers to assess medicinal and health information on the Internet.

Pharmaceuticals and e-commerce: the Netherlands **Dr Hans Heuvelmans, the Netherlands**

In the Netherlands, two units under the Inspectorate of Health Care, namely the Unit for Application and Use of Medicines, and the Unit for Advertisements on Medicines, are responsible for the regulation of pharmaceuticals. The European Union market currently comprises 15 member states, with 377 million inhabitants. There is free movement of commodities such as pharmaceuticals among member states, but differences and distinctions do exist, such as in registration criteria, requirements for outlets for over-the-counter drugs, property and qualification standards, and acceptability of mail-order pharmacies. The prices of medicines sold in different member states also show significant variation. There is nothing specific on Internet matters in the laws or regulations for pharmaceuticals and e-commerce in the Netherlands.

Day-to-day practice relies on collaborative efforts with the authorities of other countries in the world. The development of a quality seal of approval, such as the HON Code of Conduct (HONCode) for medical and health Websites, and Web Trader, may be useful in some instances. On a daily basis, all notices from various sources, e.g. police units, customs, citizens, foreign inspectorates are channelled to the Chief Inspectorate. After evaluation of information,

appropriate actions are taken in collaboration with foreign services, police, customs, financial departments, etc. The measures mainly concentrate on information gathering, preparation of counteraction and international cooperation.

On a national basis, measures based on repression, such as increased penalties, regular customs checks, and contact with foreign agencies, have been deployed. By using existing tools and by informing the public, the health authority can fulfil its role of safeguarding public health. But how far can or should consumers be protected?

Recommendations

1. Patient/consumer protection should be the first priority of regulatory authorities in their approach to e-commerce. National authorities should endeavour to ensure that patients have the same level of protection whether they purchase pharmaceuticals through legitimate Internet sites or through the traditional channels.
2. Regulatory authorities should improve the information contents of their websites and establish appropriate programmes, including mass media campaigns, aimed at providing unbiased information and warn the public on the possible risks of unregulated pharmaceutical e-commerce. These programmes must be designed in a way that ensures that they effectively reach health professionals and consumers.
3. National authorities should establish and encourage the use of simple mechanisms for consumers and health professionals to report illegal sites and negative experience they have had with e-commerce.
4. WHO should establish and maintain a list of national focal points and circulate it to all regulatory authorities in order to foster international collaboration in combating illegal pharmaceutical e-commerce.
5. WHO should continue to create opportunities, through international meetings of national regulatory officials, for discussing and foster awareness on the public-health issues related to pharmaceutical e-commerce.
6. Progress should be reported back to the ICDRA.