DRUG PROMOTION

Europe: call to leave current advertising regulations intact

THERE has been a strong reaction against a proposed relaxation of the European Union ban on direct-to-consumer advertising of prescription medicines. The proposal from the European Commission will permit pharmaceutical companies to provide consumers, at their request, with promotional information on prescription-only medicines authorised to treat HIV/AIDS, asthma and diabetes. There is concern that this change, for a five-year trial period, could open the way for full-scale direct to consumer advertising in the European Union. This type of advertising is banned in every industrialised country in the world, except the USA and New Zealand.

Negative effects

At a meeting in Brussels in January 2002, researchers, consumers, patients, WHO and pharmaceutical industry representatives, drug regulators, health professionals, insurers and others met to discuss the issue. Everyone agreed that the public needs access to balanced comparative, relevant up-to-date, accurate and unbiased information on pharmaceuticals and non-pharmaceutical treatments. But consumer advocates and public health officials asserted that the Commission's proposal would not result in this. Instead they argued that the likely outcome would lead to unnecessary and possibly unsafe use of medicines with spiralling health care spending, and increases in the amount of misleading and unhelpful health information. Those opposing a policy change commented that US experience showed that enforcing regulations to control direct-to-consumer pharmaceutical advertising is difficult and costly. Violations are common, due mostly to advertisers minimising risk information and exaggerating benefits. In a presentation entitled "Direct-to-consumer advertising or direct-to-consumer information on pharmaceuticals?", Mr. Léon Wever, Director, Pharmaceutical Affairs and Medical Technology, Ministry of Health, Welfare and Sport, The Netherlands, voiced the fears of many at the meeting (see box).

A WHO view

A WHO perspective was given by Mr Kees de Joncheere, Regional Adviser for Pharmaceuticals and Technology at the WHO Regional Office for Europe. The Office recently organized a meeting in Bonn for European health authorities responsible for regulating drug promotion (see page 5). Mr de Joncheere told delegates in Brussels that "Direct-to-consumer promotion raises concerns for WHO. At present, there are only two countries that officially allow this kind of advertising. Two other countries, South Africa and Australia, have considered it, but ultimately both decided against it. When we talk about advertising and drug information we have to remember their impact on people's health. It is good to emphasise that a medication is actually the product plus the information plus the culture in which it is being used. If we want to reap the full benefits that drugs offer, we have to make sure they are being prescribed and used appropriately."

Mr de Joncheere informed the meeting that at the 1988 World Health Assembly, WHO Member States had adopted the *Ethical Criteria for Medicinal Drug Promotion*[1]. These define promotion as "all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs." They go on to say: "advertisements to the general public...should not generally be permitted for prescription drugs or to promote drugs for certain serious conditions, that can be treated only by qualified health practitioners...scheduled narcotic and psychotropic drugs should not be advertised to the general public."

Mr de Joncheere told participants that, based on the *Ethical Criteria*, "WHO

The Netherlands' view

…"If we examine the idea of increasing patients' access to information about some prescription-only products, it seems clear that this information should be patient-oriented and controlled (approved) information. It should not be direct-to-consumer advertising. In addition, the EU should draw up a set of 'good information practices'".

"…In the proposed changes for Article 88, the Commission is trying to make it possible for industry to give information about certain illnesses directly to patients. But can the industry give objective information, or will it, in fact, be drug promotion? The Commission talks about allowing the changes in advertising as a "pilot phase." That is, for the next few years specific groups of long-term and chronic diseases related to AIDS, asthma and chronic bronchitis, and diabetes would be affected. The Commission says the change has been proposed on the basis of strong and specific patient demand for it. And that the effects will be monitored and assessed. Finally, in five years time the experiment will be reviewed. But we are not sure that DTCA is not the inevitable outcome of this pilot phase."

The Dutch experience

"Although direct-to-consumer advertising is banned in The Netherlands (as in all of the Member States) the Dutch Ministry of Health has had to take action against a number of "disease-awareness" campaigns that crossed the line into advertising"…

"Information about a product can only be assessed in its context. Information that is used as a sales tool is advertising. There will always be a "grey area" between information and promotion. This makes it hard to address in legislation. Instead, it has to be considered on a case-by-case basis. Does this say something about the EU Commission and the enormous workload the proposal will bring for national and EU level enforcement agencies?"…

"New European legislation should reflect a number of key points. First, it must be in the interest of patients and health care services. That means it must ensure quality and safety, accessibility, and aid efficiency (cost containment). In addition, providing more information for patients implies more transparency on the part of the pharmaceutical industry; it must also improve the quality of legislation and law enforcement. We must remember that good health care is the goal. There is a need for more industry transparency. To protect health, we want information on all aspects of drugs, not just positive information."

"Direct-to-consumer advertising implies that the consumer decides what drug to buy. In fact, it is the doctor who prescribes it and the bill is paid for by "society". Here in Europe patients do not pay the pharmaceutical bill themselves. The basic question remains: is direct-to-consumer advertising really necessary to improve drug information for patients? Is it direct-to-consumer advertising or rather direct-to-consumer information that is actually the way forward?"

"The EU's proposal raises some serious questions about the quality of the legislation being proposed and how it will be enforced. If access to information is the purpose, then new EU legislation is not necessary. If, on the other hand, permitting direct-to-consumer advertising is the purpose, then EU legislation is needed. Enforcement of the new legislation at both the EU and national level remains unclear. It seems difficult to start with three health conditions and stop there. Other groups affected by different health conditions could begin calling for it too."

Providing quality information

"Consumers and patient organizations

These groups have an important role to play in informing consumers about promotional activities by the pharmaceutical industry. These groups should also be involved in the formulation of codes of practice. They can provide information on practical experiences as well."

"Industry's role

What role should industry play? Pharmaceutical companies can provide factual information about drugs on their web sites. However, there is a great need for more transparency about their data. We need better access to information about existing research data."

"National governments

Governments are responsible for legislation and enforcement. They should support a system of drug development, quality control and supply of information (in connection with market authorisations). They may consider occasional information campaigns on specific health-related issues."

Should DTCA be permitted?: some conclusions

"Promotion of rational drug use by the pharmaceutical industry remains unlikely. It is not their primary goal. Experience in the US has shown us that increasing direct-to-consumer advertising leads to increasing drug use and higher health care costs. The US has also shown us that patients are easy to influence through direct-to-consumer advertising while they are not the ones who make buying decisions or ultimately pay most of the bill. They also may not know the risks involved in the prescription of medically unjustified therapy."

"If the industry really wants to inform consumers, it should bring about greater transparency of its data. For all of these reasons and more, we need to say no to direct-to-consumer advertising."

Mr. Léon Wever, Director, Pharmaceutical Affairs and Medical Technology, Ministry of Health, Welfare and Sport, The Netherlands.