DRUG PROMOTION

Health benefits?... cont'd from pg. 19

the information in pharmaceutical advertisements.

DTCA is aimed at bringing new, patented medicines to the attention of potential users. Unfortunately, when drugs first enter the market their risks and benefits are not fully known. This is a problem with all new drugs. The European Commission's proposal (see p. 14) includes introduction of advertising for diabetes, AIDS and asthma drugs. The US experience with drugs for each of these diseases stands as a warning.

In the US, a diabetes drug advertised to the public has now been withdrawn for safety reasons. It was withdrawn from the UK in 1997 because of liver toxicity but remained available in the US until March 2000 and was advertised to the public, as well as to doctors. By the time the drug was withdrawn it had generated US$2.1 billion in sales within three years. However, it had also been named as the suspected cause of 391 deaths. There is no evidence of lives saved by using this drug; like many new drugs, it simply had not been studied for long enough or in large enough groups of patients. Two new drugs in the same class are currently being advertised to the US public, despite warnings of serious cardiac risks. This example highlights a key public health concern with DTCA: the rapid, widespread use of new drugs before risks or benefits are fully known.

With AIDS, the main concern has been advertisements' unrealistic images of treatment success. In 2001, the San Francisco Public Health Department carried out a survey in city clinics for sexually transmitted diseases to find out about factors influencing gay men's decisions to practice safe sex. The study found that young gay men with greater advertising exposure were more likely to practice unsafe sex and to believe that HIV/AIDS was a less serious disease than it had been. As a result, the US FDA told companies to stop showing unrealistic images in AIDS drug advertisements. The Agency stated that publicity, showing men climbing mountains, for example, bore little resemblance to the reality of life on antiretroviral therapy.

A common argument made for allowing DTCA is that sophisticated marketing techniques can be used to get patients to seek needed treatment. Public health campaigns sometimes do use such advertising methods. However, if the focus is set by health authorities, the message is likely to be very different from that made by a company trying to sell a product. For example, in Canada, an advertisement showing the image of the tagged toe of a corpse aimed to convince healthy women to have their cholesterol tested and – hopefully – be prescribed a lipid-lowering drug. What this advertisement did not say – and a public health message might – is that there is no reliable evidence that lipid-lowering drugs prevent deaths in patients without pre-existing heart disease or in women. Men with previous heart disease are known to be undertreated and to benefit from cholesterol-lowering drugs. However, this is a much smaller market.

Direct-to-consumer advertising not the answer

Is there evidence of benefits to patients from DTCA? Do these advertisements educate, inform or empower patients? The answer is no. In fact, advertisements commonly contain misleading and inaccurate information, and the public rarely receives corrections. In general, the educational value is poor, and surveys indicate that doctors prescribe most requested drugs.

In addition, do direct-to-consumer advertisements lead to better health? In the nearly 20 years since the first US advertisements, there is no evidence that these advertisements have reduced hospitalisations, disease or deaths.

There is no reliable evidence of improved medicines use, and, most advertised drugs are no more effective and no safer than older, cheaper alternatives.

The public needs access to balanced, relevant, up-to-date, accurate and unbiased information about drugs and non-drug treatments. This information is difficult to obtain, mainly because of policy decisions giving low priority to patient information within health services. If informed health care choices are to become a reality, comparative health and treatment information must be integrated into national health care services.

A change in advertising regulations will not fill this gap. By definition, advertising aims to sell a product. ❑

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The Australian Pharmaceutical Manufacturers Association Code of Conduct: guiding the promotion of prescription medicines

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Promotional messages are designed to be persuasive. Pharmaceutical promotion can influence not only the use of a product, but also our beliefs about medicines. For this reason, it is essential that the information provided within promotional media is accurate, balanced and not misleading. In Australia, the promotion of prescription medicines is regulated by legislation and guided by the Australian Pharmaceutical Manufacturers Association Code of Conduct. The Code sets standards for promotional activities, including the information content. The system is dependent upon a complaints mechanism for ensuring promotion complies with the Code, as most promotional material is not monitored prior to publication by an independent body. Health professionals are encouraged to lodge complaints against misleading or inappropriate promotion to enhance the effectiveness of the system.

Advertising and promotion are part of everyday life. In the USA, people may be exposed to as many as 5,000 advertisements each day. Health professionals are particularly exposed to the promotion of medicines. This appears in our journals, on the pens and notepads on our desks, on displays at the conferences and symposia we attend and it is brought to our attention during the visits of pharmaceutical representatives. It is so pervasive that it is easy to think that it plays no part in our lives nor has any influence on the way we use medicines. Unfortunately, studies tell us otherwise. Promotional practices are influential on our beliefs about medicines and also on prescribing[1].

The need for regulation of promotion

Pharmaceutical promotion is a persuasive communication. It involves the conscious attempt to move health professionals from being unaware of a drug product's existence to a stage of repeated prescription. As promotion has the potential to change behaviour and because it is a major source of drug information for health professionals, the messages promoting prescribing should be factual, evidence-based, unambiguous and balanced.

Unfortunately, in many countries promotion is not factual nor evidence-based. Inaccurate and inappropriate promotional claims abound and this has the potential to contribute to irrational drug use. For example, aspirin is commonly promoted in developing countries as suitable for use in children, while antihistamines are promoted as appetite stimulants and other medicines as brain tonics. Consequently, many countries around the world have regulated the promotion of medicines. WHO advocates the regulation of promotion, urging all its Member States to develop guidelines for promotional practice, which are consistent with national health policy and which support rational drug use. WHO has published *Ethical Criteria for Medicinal Drug Promotion* as a model for such guidelines[2].

How is promotion regulated?

In Australia, promotion of medicinal drugs is regulated by Government legislation including the Therapeutic Goods Act. The Australian Pharmaceutical Manufacturers Association (APMA) Code of Conduct is a guide for industry on how to advertise and promote prescription medicines. Acceptance and observance of the Code is a condition of membership of the APMA. The current membership covers 95% of the prescription medicines industry.

What activities are regulated?

The APMA Code contains standards for all types of promotional material including all printed and audiovisual promotional material. The Code also articulates standards for pharmaceutical representatives, sample supply, hospitality, industry-sponsored market research and post-marketing surveillance studies, trade displays and communications targeting the general public.

All promotional claims should be current, accurate, balanced and not misleading either directly, by implication or by omission. The Code also states that promotional material should be in good taste and that comparative information, if provided, should be factual, fair and capable of substantiation. Claims must conform to approved product information or to the scientific literature, but only if