DRUG PROMOTION

and consumers about drug promotion.

Drug promotion will undoubtedly continue as a major industry tool to increase the sales of its products. Our task is to understand and educate both health professionals and consumers about the limitations of ethical drug promotion as a source of treatment information; its considerable potential for harm when inaccurate, inappropriate or biased; and its powerful influence on prescribers and users. Promotion is a reality of the commercial market place but we need to ensure that drug promotion:

- is adequately regulated;
- problem areas are rapidly identified and tackled;
- potential influence on treatment decisions, outcomes and costs is better understood;
- is adequately balanced by complete and scientifically validated sources of treatment information. ❑

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Direct-to-consumer prescription drug advertising: is there evidence of health benefits?

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PRESSURE from the pharmaceutical industry and related lobby groups to allow prescription drug advertising to consumers is growing in Australia, Canada and the European Union. Proponents of direct-to-consumer advertising (DTCA) argue it would be a way to empower patients. But is that actually true?

Arguments favouring direct-to-consumer advertising

- people want and need information on medicines;
- advertisements will help people to get needed medical care at an earlier stage;
- advertisements will lead to better compliance;
- a doctor's prescription is needed, so the patient will still be protected.

Arguments against direct-to-consumer advertising

- prescription drugs are not like other consumer goods. Even when used properly, they can cause serious harm;
- people are vulnerable when they are ill;
- advertisements aim to stimulate sales – they cannot provide impartial, objective information;
- advertising drives up prescription drug costs and total health care costs.

The US experience

The US has never had a law prohibiting DTCA. The first print direct-to-consumer advertisements appeared in the early 1980's. However, in 1982 disaster struck when a new anti-arthritic drug was recalled by the Food and Drug Administration (FDA) after only five months on the market because of severe adverse effects, including deaths. The FDA's action came after the company had mounted an intensive public relations campaign aimed at health professionals and the public. In its wake, prescriptions for the drug rocketed from 2,000 to 55,000 a week, earning the manufacturer more than US$1 million a week in sales. Following this case, the FDA called for a moratorium on DTCA of prescription drugs so that there could be wide consultation with all stakeholders. In 1985, two years later, the moratorium was lifted.

In 1997 the FDA issued new guidelines that relaxed the regulations governing TV and radio advertising. In effect it greatly reduced the amount of risk information broadcast advertisements had to include. Before that, broadcast advertisements were bound by the same regulations as the information sent to health professionals, including the full approved product labelling information on risks and contraindications (what the FDA calls the "brief summary").

Since the early 1990's spending on DTCA has grown exponentially from approximately US$55 million in 1991 to US$2.5 billion in 2000.

Effects on spending

How has DTCA affected health spending in the US? In 1999, US consumers spent US$111.1 billion on retail prescription drugs – up from US$93 million just one year earlier. Interestingly, the top 25 prescription drugs advertised to the public accounted for US$7.2 billion of the US$17.7 billion increase (40%). In 2000, the top 50 advertised prescription drugs accounted for US$9.94 billion of the US$20.8 billion increase over 1999 (48%). This rapid increase in drug costs reveals two trends: that DTCA has led to more prescriptions per person, and that it has increased demand for newer, more expensive drugs.

What products are being advertised for which health conditions? Around 40% of the money spent by companies to advertise directly to consumers each year is spent on only 10 drugs. Most drugs are never advertised to the public. Because so few drugs are advertised to consumers, DTCA is a poor means of informing patients about the treatment options available. The top 10 drugs are typically costly, new drugs meant for long-term use by a large target audience. They include treatments for common, mild problems such as allergy and "lifestyle" conditions including baldness, impotence and shyness.

Consumers' reactions

US consumer surveys have been carried out to find out more about the public's views on DTCA. In national surveys, 25% of respondents spoke to a doctor about a drug or condition in response to direct-to-consumer advertisements – and 6–9% reported having directly requested a drug from their health care provider, most of whom (80–84%) received a prescription.

The idea that the doctor will still be able to protect the patient from toxic medicines falls short if the doctor simply prescribes what the patient asks for. One has to ask: how well do consumers actually understand direct-to-consumer advertisements? In a California survey, 43% – nearly half of the respondents – thought that only completely safe medicines could be advertised to the public. Another national survey carried out by the FDA found that over half of respondents could not explain what prescription-only status meant.

Do advertisements lead to an informed, educated consumer?

The quality of US direct-to-consumer advertisements

In the US, many TV advertisements have been found to be in violation of regulations and there are frequent infractions. To be more specific, 17 of 33 (52%) of US TV advertisements violated FDA regulations in 1998. The agency sent out 94 notices of violations between 1997 and mid-2001 (48 broadcast, 46 print). The key reasons included inadequate risk information, exaggerated benefits and unapproved uses.

Direct-to-consumer advertising in New Zealand

Like the US, New Zealand has DTCA by default, as there has never been a law against it. It just wasn't done until recently. While the FDA regulates DTCA in the US, New Zealand relies on industry self-regulation, like many European countries. This often means that advertisements include less risk information than those appearing in the US. In February 2000, MedSafe (the country's drug regulatory agency) checked compliance on direct-to-consumer advertising and found that five out of six voluntarily submitted television advertisements and one-quarter of print advertisements violated the Medicines Act. The main reasons were inadequate or absent risk information. Pharmac, New Zealand's drug management agency, commissioned a survey in 2000 on consumer responses to an advertisement that had been found to violate the Act because of inadequate risk information. Pharmac showed the advertisement to 200 women aged 16–30 and asked them a few questions. Nearly half of them thought the advertisement provided enough information to decide whether to take the drug. One-quarter thought that it clearly stated risks and side-effects. In fact, the only risk information was a line in tiny print saying that the risks were similar to other drugs used for the same indication. This was untrue and did not explain what those risks were. The example suggests that misleading advertisements work, and shows how difficult it can be for the public to judge

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