

Direct-to-Consumer Prescription Drug Advertising The European Commission's Proposals for Legislative Change

Health Action International (HAI-Europe), December 2001

The European Union currently forbids advertising of prescription drugs to the public, as do all other countries except the United States and New Zealand. This restriction on advertising is part of the protection offered to the public by prescription-only status.

Last July, the Commission announced a proposal to change the law to allow advertising of prescription drugs to treat AIDS, diabetes and asthma. The key change involves the advertising regulations contained in Articles 86 to 88 of Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use.

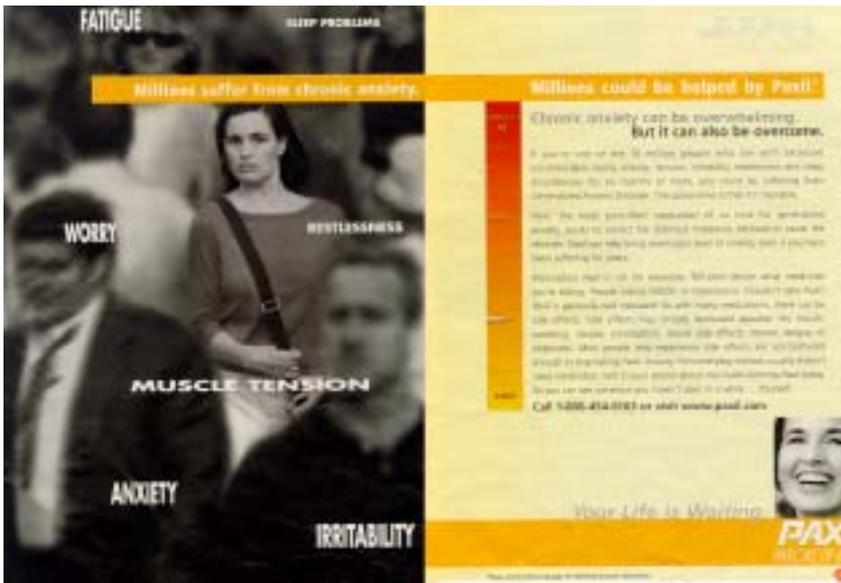
The proposed changes affect only a subset of prescription drugs. However, these are drugs for serious diseases. They would also represent an important 'foot in the door' for direct-to-consumer (DTC) advertising and drug promotion in Europe.

What will these changes mean for public health, for sustainability of national health care services, and for consumer and patient information rights?

This paper discusses the proposed changes, reviews the main evidence on effects of DTC advertising in the US and New Zealand, and concludes with recommendations.

Why maintain the current ban on direct-to-consumer (DTC) advertising of prescription drugs?

- **DTC advertising drives up prescription drugs costs**, threatening the sustainability of national health care services and universal access to health care as a fundamental human right.
- **DTC advertising fails to inform**. It does not provide the impartial, objective information consumers and patients need for informed health care decisions.
- **DTC advertising compromises public safety**. It can lead to rapid widespread exposure to dangerous drugs before risks are fully recognized, as occurred with troglitazone (Rezulin) for diabetes and cisapride (Propulsid) for nighttime heartburn in the US. Additionally, most new drugs are costlier than existing treatments, but few provide any therapeutic advantage.
- **DTC advertising promotes the medicalisation of normal life**. The most heavily advertised drugs are for long-term use by large target audiences, often for mild conditions and 'lifestyle' problems that may not need drug therapy.



Unnecessary Medicalisation

Why shouldn't normal New Yorkers feel anxious two months after the attack on the World Trade Centre, when this ad for paroxetine (Paxil) ran in the *New York Times Magazine*?

"Talk to your doctor about non-habit forming Paxil today," says the ad. The fine print on the back tells another story: discontinuation reactions include depression, somnolence, agitation, tremor, nausea, diarrhea, etc. Withdrawal reactions such as these signal a potential risk of drug dependence.

Why is prescription drug advertising currently forbidden?

Compared with medicines that can be bought over-the-counter (OTC), prescription-only products are generally used to treat more serious diseases, have greater toxicity, and a less well-understood profile of risks and benefits. Prescription-only medicines cannot be bought and sold freely. The aim of laws restricting companies' marketing and advertising rights is health protection.

As prescription drugs often treat serious diseases, restrictions on advertising also take account of the extra vulnerability of people who are seriously ill. Someone in pain, who has been diagnosed with a debilitating illness, or who is caring for an ill family member is vulnerable in a way that is different from someone who is going shopping for a new car or a loaf of bread.

The current legislation reflects both rationales. Article 88 (1) prohibits advertising of prescription-only medicines to the public. Article 88 (2) prohibits all advertisements mentioning a specified list of serious diseases.

What changes is the Commission proposing?

The Commission's proposal would allow manufacturers to advertise treatments for AIDS, diabetes and asthma and other chronic respiratory diseases.

Manufacturers must set up national self-regulatory procedures and submit ads to the European Medicines Evaluation Agency for pre-screening. The Agency, in turn, must examine materials and register any objections within 30 days or the ad can run as submitted. The Agency is also required to maintain a database of ads and write yearly reports, with a detailed review after five years.

Additionally, the Commission is proposing deletion of the section of Article 88 (2) that

prohibits advertisements to the public mentioning specified serious diseases: tuberculosis, sexually transmitted diseases, other serious infectious diseases, cancer and other chronic diseases, chronic insomnia, diabetes and other metabolic illnesses. The clause on serious diseases refers to all advertisements, not just prescription-only products. This deletion appears to pave the way for across-the-board advertising of treatments for serious illness.

Are there restrictions on how companies can advertise these products?

The proposal includes no explicit restrictions on media or content, other than conformity to general principles of pharmaceutical advertising listed in Article 87. Article 88 (2), clauses (a) to (f), sets out conditions for how this information would be disseminated. These conditions do not explicitly exclude any media –such as television –nor do they limit target audiences.

The proposal for Article 88 (2) broadly authorizes full product advertisements: “...This provision applies to product information appended to the marketing authorization as well as to additional related information.”

A separate clause, already in place, allows Member States to ban the advertising of publicly funded drugs should they choose to do so.

What rationale is presented for these changes?

The Commission states that these changes are being introduced “in order to respond to the expectations expressed by the patients’ groups”.

The current law does not limit the public’s access to drug information; it prohibits *advertising*. Many organizations currently provide drug information to the public. Access to information is often inadequate, but this results from policy decisions not to prioritize patient information, rather than legal barriers.

The Commission has not said which patient groups have requested changes to advertising regulations nor which groups may request advertising campaigns should the change be implemented. The Commission makes no reference to any measures taken to eliminate conflicts of interest. Increasing numbers of patient groups are substantially funded by drug companies, which have a vested interest in DTC advertising.

“... In July, DG Enterprise proposed to lift the ban for asthma, diabetes and HIV [and] companies will be allowed to impart information promoting “awareness of the availability” of products. Nobody believes it will end there.”

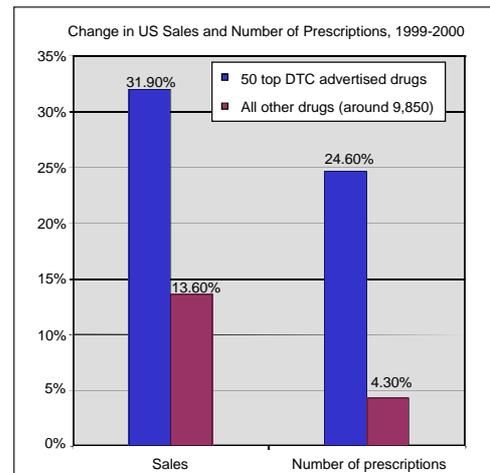
- Sarah Boseley, Just Say No to Drug Ads. The Guardian. UK. Dec 10, 2001

The US experience – drug costs out of control

Spending on DTC advertising has grown exponentially in the US within the last decade, from \$55 million in 1991 to \$2.5 billion in 2000. If DTCA did not stimulate sales, companies would not be spending more and more each year on this marketing strategy.

Top 50 DTC advertised drugs responsible for large cost increases

- In 2000 over 95% of DTC advertising spending was on 50 drugs;
- These 50 drugs had combined retail sales of \$41.3 billion;
- This was nearly one third of total US retail prescription drug spending in 2000;
- These 50 drugs were responsible for **\$9.94 billion** of the **\$20.8 billion** increase in US retail prescription drug spending from 1999 to 2000, or 47.8% of this increase. (Findlay, 2001)



Source: Figure 1, Findlay, NIHCM, 2001

The bottom line: why does the industry want legislative change?

A US market research firm, PERQ/CHI analyzed the returns on investments for print and television DTC ads in 1999, based on spending and sales data supplied by 25 major manufacturers. On each dollar invested in DTC advertising, the average return was \$1.69 for TV ads alone; \$2.51 for magazine advertising, and \$2.11 for campaigns involving a mix of print and TV ads. (PERQ/CHI, 1999) These are impressive returns – but they also mean impossible costs for public and private drug plans.

“Aggressive direct-to-patient marketing by pharmaceutical companies, high prices for new drugs are making prescription drugs one of the major costs of health care. This issue is not being given the attention it deserves. It’s time to put science ahead of marketing.”

- Premier Ujjal Dosanjh, May 24, 2000. British Columbia Government News Release. Victoria, B.C., Canada. [Canadians are heavily exposed to cross-border DTCA from the US.]

Can the public find out what drugs are available from DTC advertising?

DTC advertising does not provide an overview of available treatments. Very few drugs are advertised to the public. In the US, over 40% of spending each year goes towards just 10 products. These are mainly new, expensive drugs for chronic or intermittent long-term use by large numbers of people. They

exclude off-patent drugs even if these are superior first-line treatments, such as diuretics for uncomplicated high blood pressure. The decision to advertise a drug is a marketing decision, not a public health decision. Sales revenues for the top 10 drugs exceeded US \$16 billion last year.

Products with Top DTC Advertising Budgets in 2000			
Drug	Condition	DTC Spending Millions US\$	Sales Millions US\$
Vioxx (rofecoxib)	Arthritis	\$160.8	\$1,518.0
Prilosec (omeprazole)	Ulcer/Reflux	\$107.5	\$4,102.2
Claritin (loratadine)	Allergy	\$99.7	\$2,035.4
Paxil (paroxetine)	Anxiety/Depression	\$91.8	\$1,808.0
Zocor (simvastatin)	High cholesterol	\$91.2	\$2,207.0
Viagra (sildenafil)	Impotence	\$89.5	\$ 809.4
Celebrex (celecoxib)	Arthritis	\$78.3	\$2,015.5
Flonase (fluticasone)	Allergy	\$73.5	\$ 618.7
Allegra (fexofenadine)	Allergy	\$67.0	\$1,120.4
Meridia (sibutramine)	Obesity	\$65.0	\$ 113.2
Total		\$924.3	\$16,347.8

Source: Findlay, 2001

“I recently sat in on a focus group sponsored by a drug advertiser... The group remarks were mostly - how can you make statements like this since they wanted to show amazing benefits while downplaying any possible side effects. In the end it was a pure advertising show and all we disliked was overlooked. The ads run now and probably increased sales at the expense of doctors being pressured by regular patients for a drug they really do not need. Needless to say I support more stringent rules in this area.”

- John Madura, letter to British Medical Journal, Oct 19, 2001 [www.bmj.com/cgi/eletters/323/7318/889#EL1]

DTC advertising: an accurate information source?

DTC ads are commonly found to violate US law because they contain inaccurate and misleading information. The US Food and Drug Administration (FDA) directly regulates drug promotion. From 1997 to mid 2001, the FDA sent out 94 notices to companies about DTC advertisements that violated federal regulations, 48 on broadcast and 46 on print advertising. (Ostrove, 2001) In 1998, more than half of products advertised on TV violated regulatory standards. (Koerner, 1999) The most common reasons were exaggeration of benefits and minimization of risks.

New Zealand depends on industry self-regulation, but in a recent spot check (Pratt, 2000), the Ministry of Health found that five of six voluntarily submitted TV ads and a fourth of print ads violated the Medicines Act. This was in spite of voluntary pre-screening by the Therapeutic Advertising Advisory Service. In nearly all cases risk information was absent, incomplete or illegible.

Steven Woloshin and colleagues (2001) examined the content of DTC ads in 10 consumer magazines published in 1998 and 1999. Nearly 9 out of 10 ads “described the benefit of a medication in vague, qualitative terms” and did not provide any evidence to support claims; one-quarter used terms such as ‘proven relief, proven effective or clinically proven’; nearly one-fifth cited widespread use as a claim of benefit; and one eighth used personal testimonials.

Researchers in California looked at the educational content of US magazine ads published over a 10 year period, 1989-1998, based on whether the ad mentioned key pieces of information consumers need to know. (Bell et al, 2000) They found the educational value to be minimal:

- 91% did not say the likelihood of treatment success;
- 76% made no mention of other helpful activities, like exercise or diet;
- 73% did not mention any causes or risk factors for the treated condition;
- 71% made no mention of any other possible treatments;
- 64% failed to explain how the drug works.

“The 60-second ‘full-product’ TV advertisement is misleading because the totality of the images, the music and the audio statements that you present overstate the efficacy of Celebrex...[they] collectively suggest that Celebrex is more effective than has been demonstrated by substantial evidence.”

- US FDA letter to Searle, Nov 2000

“The graphics of the advertisement show a frustrated woman trying to pull her shopping cart out of its interlocked lineup in front of a store. The concurrent audio states “Think it’s PMS? It could be PMDD.” The imagery and audio presentation of the advertisement never completely define or accurately illustrate premenstrual dysphoric disorder (PMDD) and there is no clear distinction between premenstrual syndrome (PMS) and PMDD communicated. Consequently, the overall message broadens the indication and trivializes the seriousness of PMDD...”

- US FDA letter to Lilly, Nov 2000

US ads for diabetes, asthma and AIDS, a model for Europe?

Diabetes: blurring the distinction between life-threatening and life-saving

Rezulin (troglitazone) is a diabetes drug, banned in the UK in 1997 because of severe liver toxicity. Rezulin was advertised to the US public for over two years after the UK ban. It was eventually removed from the market in 2000. By that time it had been named as the suspected cause of nearly 400 deaths, 63 from liver failure. (Willman, 2000) US DTC ads for Rezulin stressed its widespread use: “more than 1,000,000 people have begun using Rezulin to help manage diabetes.” (Woloshin, 2001) These ads made no mention of the UK market withdrawal.

Two new drugs in the same class, Avandia (rosiglitazone) and Actos (pioglitazone) are currently on the US market, and are being advertised to the US public. Health authorities have issued warnings that both drugs can cause fluid retention leading to heart failure.

Any prescription drug may be advertised to the public in the US, even if it is similar to a drug withdrawn for safety reasons or has been associated with serious risks.

These new diabetes drugs have not been shown to save lives. They simply have not been tested for long enough in large enough groups of patients. They were approved for marketing on the basis of their ability to control blood glucose. This effect may or may not translate into long-term health benefits as compared to other drug and non-drug approaches. To quote an independent assessment: “*In patients with*

type 2 diabetes rosiglitazone improves some surrogate markers and worsens others. Long-term trials are required to know whether this class of drugs reduces morbidity and mortality outcomes.” (Therapeutics Initiative, 2000)

AIDS: Unrealistic Expectations of Treatment Success Linked to Risk-taking Behaviours

“Direct-to-consumer advertising may be influencing trends of increasing sexual risk behavior and subsequent STDs including new HIV infections among MSM in San Francisco. Strategies to reduce the possible harmful effects of HIV drug advertising are needed.”

-Jim Klausner, San Francisco Department of Public Health

The San Francisco Department of Health warned in early 2001 that it was considering banning DTCA for AIDS drugs within the city limits. A survey of 262 male patients in San Francisco’s STD clinics had shown that young men were less likely to practice safe sex because the unrealistic images in DTC ads for AIDS drugs made it seem like AIDS could be effectively controlled. Some adverts showed vigorous men climbing mountains. This is nothing like the reality of life on triple therapy. (Klausner and Kim, 2001)

Gay men with higher DTC advertising exposure were more likely to have engaged in unprotected sex with an HIV positive or unknown partner within the last month (27% vs. 16%) and were more likely to believe that triple therapy (HAART) had made HIV infection a less serious disease (25% vs. 17%).

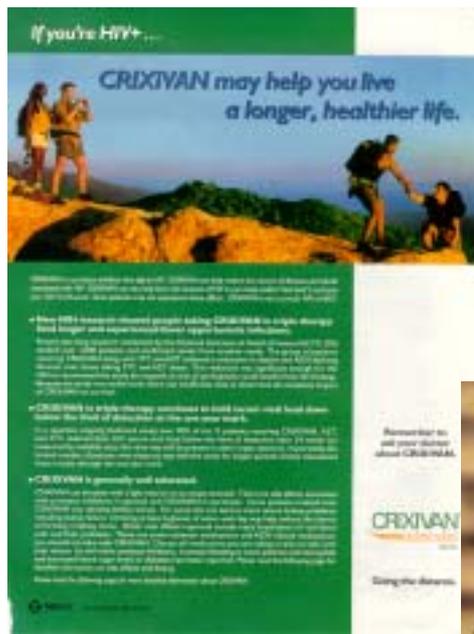
“... You present the statement “Avandia is not indicated for use with insulin” in the audio portion of your ‘Real Stories’ broadcast advertisement simultaneously with the super “Avandia- Help use the natural insulin in you.” This presentation minimizes the communication of the risk of the Bolded Warning by presenting consumers with conflicting messages about the use of Avandia and insulin...In addition your broadcast advertisement is misleading because you fail to present the precaution ...concerning weight gain caused by Avandia...Moreover, your print advertisement is misleading because the risk information is presented under the header “Strengthen your body’s own ability to help control blood sugar.” This presentation...minimizes the risks associated with Avandia treatment.”

US FDA letter to GSK, June 2001

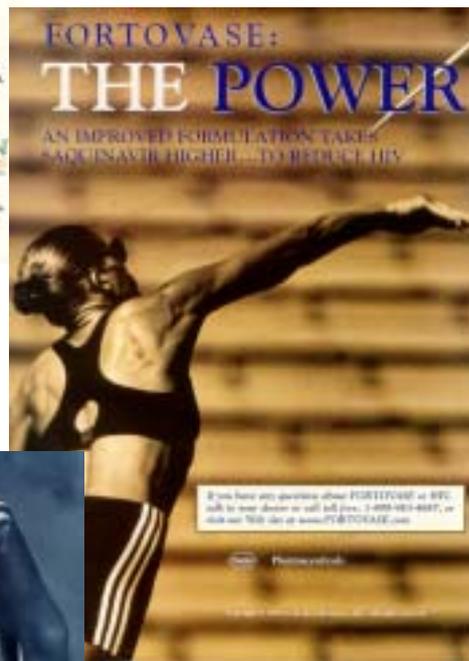
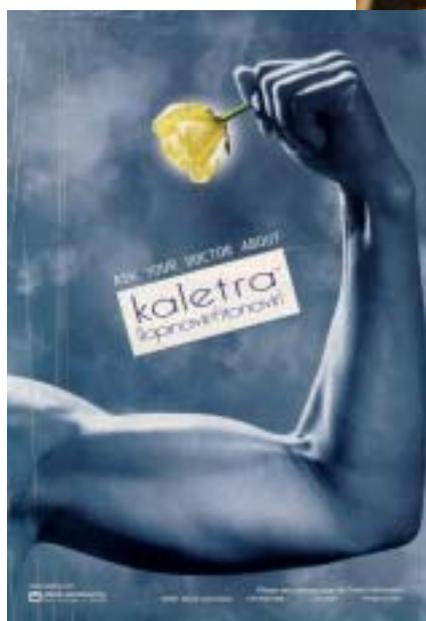
The most important public health message for AIDS is prevention. Unrealistic advertising campaigns for AIDS drugs have interfered with that message in the US. Are there any guarantees that the same companies will behave more responsibly in Europe?

Mistaken Impressions: ad for an asthma drug, Singulair (montelukast)

The US Kaiser Family Foundation published a study on consumer responses to three television DTC ads in November 2001. One of the ads was for an asthma drug, Singulair (montelukast).



Climbing mountains, flexing muscles and throwing a javelin: unrealistic images of the reality of antiretroviral therapy.



Singulair is one of two new oral asthma drugs in a class called leukotriene antagonists. Both are among the top 50 drugs advertised to the US public in 2000. Independent assessments have judged their place in the treatment of asthma to be limited. A 1999 drug bulletin states: "Average clinical effects are small and would unlikely be detectable by individual patients... [These drugs] cause average clinical benefits that are less than low-dose inhaled glucocorticoids." (Therapeutics Initiative, 1999)

The Kaiser Foundation study randomly assigned participants to view different ads, then compared knowledge between viewers and non-viewers. They found that more viewers of the Singulair ad knew that there were pills people could take to prevent or limit asthma attacks (71% vs. 36%). However, more Singulair ad viewers came away misinformed about what these pills do: 25% thought they could take a pill rather than use an inhaler during an asthma attack versus 13% of non-viewers. This is dangerous misinformation, as it could delay effective treatment during a potentially life-threatening situation.

The ad says that Singulair doesn't work during an acute attack. However, this voice-over is accompanied by different text on screen and viewers may be distracted. The main emotive message is one of effective relief. Nowhere does the ad even hint that effectiveness is mild or inferior to inhaled steroids, which are also used for prevention. The US FDA allowed Merck to run this ad. The EMEA might similarly allow it. The information it contains is not false. However, the lack of information on relative efficacy is misleading.

In New Zealand, Merck's ad campaign for Singulair included a promotional offer of one month's free medication.(MacKinven, 1999) Nearly 20% of New Zealand's GPs prescribed the drug during its first two weeks on the market. The free promotional offer was criticized as creating an unnecessary strain on patients, since Singulair is expensive and is intended for long-term use.

Advertising only non-subsidized drugs: is this the answer?

Under existing legislation, Member States can choose to impose a ban on advertising of publicly subsidized drugs. If the Commission's proposal is accepted, this clause could be used to avoid paying for the prescriptions stimulated by DTC advertising.

Unsubsidized drugs are products that drug benefit plans have decided not to fund, usually following an evaluation of cost-effectiveness. These drugs tend to be more expensive than equivalent alternatives, relatively ineffective, have a poor risk/benefit profile, or are for 'lifestyle problems' for which drug treatment may not be appropriate.

To allow advertising only of these products creates a perverse incentive for manufacturers. It also adds to the misleading impact of advertising because the public only sees emotive messages lauding the benefits of products that by definition are either overpriced, inferior or unnecessary.

Although the government is not paying for these drugs directly it faces associated costs:

- extra doctor visits
- extra diagnostic tests
- extra health care and hospitalizations from adverse events, especially in the case of additional discretionary drug use.

Do DTC ads lead to better health or health care services?

Pharmaceutical industry representatives claim that advertising improves communication between doctors and patients, that it will help untreated patients receive needed care at an earlier date, and that it improves compliance. (Holmer, 1999)

There is no evidence that DTC advertising improves doctor/patient relationships, and surveys of US doctors indicate that opinions are largely negative. (Lipsky, 1997; Time Magazine, 1998)

There is no evidence that exposure to DTC advertising can lead to better health, fewer

hospitalizations or lower mortality. The industry claims that patients will see the ads, recognize their symptoms and get earlier treatment and therefore avoid more serious disease. However, there is no research evidence to back this claim. Some market research studies show that ad campaigns increase the number of doctor visits for advertised conditions, but they don't distinguish between people who needed medical care and people who did not have a medical problem and were therefore unlikely to benefit. Ad campaigns cast a wide net in order to maximize sales, often suggesting that common symptoms are signs of serious problems, as in the case of this ad for an Alzheimer's drug. This approach is unlikely to attract only those in need of care.

The effect of DTC advertising on compliance has not been adequately tested. In two surveys by *Prevention Magazine*, between 5% and 8% of respondents said that seeing ads made them more likely to take their medicines. (Prevention, 1998, 1999) Most users of advertised medicines said the

Is it just forgetfulness...
or
Alzheimer's
disease?

• Memory loss • Asking repeated questions • Trouble using words

When signs like these begin to affect everyday life, they may not be a part of normal aging. They may be signs of Alzheimer's disease, an incurable, progressive illness that robs patients and their families of a lifetime of memories.

Today, however, the outlook for many is becoming more hopeful. ARICEPT® is a clinically proven, once-a-day prescription medicine available to treat symptoms in patients with mild to moderate Alzheimer's disease. Already, over 400,000 patients in the United States have begun ARICEPT® therapy.

ARICEPT® is well tolerated, but some people do experience side effects like nausea, diarrhea, vomiting, muscle cramps, fatigue, and loss of appetite. In clinical studies, these effects were generally mild, temporary, and went away with continued ARICEPT® use. 2% of people taking ARICEPT® experienced lightheadedness.

Only a doctor can evaluate symptoms such as forgetfulness and diagnose Alzheimer's disease. Speak to a doctor today about the benefits of ARICEPT® in treating Alzheimer's disease.

ARICEPT®
(donepezil HCl)
Today's Treatment For Alzheimer's Disease

To learn more, call toll-free today.
1-888-999-9616 ext. 33

Please see additional important information on accompanying page.

ads did not remind them to take the drug. This survey is frequently cited as evidence of improved compliance although it did not measure behaviour change and failed to mention what types of drugs the respondents were using. If they were symptomatic treatments such as allergy drugs or painkillers, improved compliance is of no health benefit and in some cases can cause serious harm. (Herxheimer, 1998)

Patients with chronic diseases such as AIDS or diabetes are often well informed about their illnesses. For such patients, the key role of ads is to stimulate a switch to newer, more expensive drugs. The US experience shows that this can cause harm: troglitazone was an unnecessarily harmful new drug for diabetes; the leukotriene antagonists for asthma have a limited role in asthma therapy because of unimpressive efficacy; and ads for new AIDS drugs appear to have convinced some younger gay men not to worry about disease prevention.

Recommendations

1. Above all, do no harm

Given the lack of evidence of benefit and considerable evidence of harm from the US experience, prescription drug advertising should not be introduced in Europe for drugs for diabetes, asthma and AIDS. These are serious illnesses for which glossy advertising campaigns are inappropriate and potentially dangerous.

Unless there is clear evidence of lack of harm and of health benefits, the prohibition against direct-to-consumer advertising of prescription drugs should be maintained. The European Union is committed to the precautionary principle. This principle is as relevant to advertising policies with health consequences as to direct chemical exposures.

2. Maintain universal coverage of essential medicines

“Access to health care is a right enshrined in the European Union’s Charter of Fundamental Rights and an essential element of human dignity. It must therefore be guaranteed for all.”

-European Commission, December 2001

Prescription drug advertising threatens universal health care coverage by pushing drug spending out of control. Annual increases in pharmaceutical costs similar to the US \$10 billion (15%) increase last year from sales of DTC advertised drugs would make public and non-profit drug plans unsustainable. Most of these drugs provide little to no advantage compared to existing alternatives. Most are more expensive.

The proposal to advertise only non-subsidized drugs would stimulate widespread use and sales of the least cost-effective products. European consumers would then suffer twice: first by paying out-of-pocket for drugs they mistakenly believe are better; secondly, because they will pay through their taxes for increased doctor visits, diagnostic tests and medical care for those suffering unnecessary adverse effects.

3. Make shared informed health care choices a reality

Patients and the public need independent, comparative information on the pros and cons of all drug and non-drug treatments and the option not to treat. This type of information does not require a change to advertising legislation. It cannot be produced by pharmaceutical companies, which have a vested interest in selling a specific product. However, if informed choice in health care decisions is to become a reality, independent information needs to become an integrated part of national health care systems.

The key issue from a public health perspective is not how to reduce the protection offered by prescription-only status, but how to ensure that the public, throughout Europe, has access to comprehensive, unbiased and reliable medicines information.◆

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Health Action International (HAI) is an informal network of some 150 consumer, health, development action and other public interest groups involved in health and pharmaceutical issues in more than 70 countries. HAI believes that all drugs marketed should meet real medical needs, have therapeutic advantages, be acceptably safe and offer value for money.

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