



Providing prescription medicine
information to consumers:
Is there a role for direct-to-consumer
promotion?

Symposium Report

Credits

The symposium was held on 10 January 2002, in Brussels.

This report was written by Lisa Hayes and edited by Barbara Mintzes.
It was designed by Sadara.

ISBN no.: 90-74006-14-0.

Funding for this event was provided by the Dag Hammarskjöld Foundation and The Netherlands Ministry of Health, Welfare and Sport.

HAI Europe wishes to acknowledge the contribution made by members of the HAI international working group on DTCA. It would also like to thank the staff of the European Public Health Alliance (EPHA) for its co-operation in organising this symposium.

HAI Europe is responsible for any editing errors that appear in the text, however, the views presented are those of the speakers and do not necessarily reflect the opinion of HAI Europe.

About the seminar's organisers:

The European Public Health Alliance (EPHA) is a European public interest NGO network of health organisations striving to promote public health across Europe. Its members include about 90 health advocacy groups, patient groups, professionals, academic institutions and local authorities — all representing the voluntary sector. The network aims to monitor and share information on EU policy developments that have an impact on public health. EPHA also campaigns to ensure that policies adopted in the EU promote and protect health.

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 around the world. HAI actively promotes a more rational use of drugs through advocacy, research, education and campaigns.

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Glossary of terms

DTCA	Direct-to-consumer advertising
FDA	United States Food and Drug Administration
R&D	Research and development
WHO	World Health Organization

Foreword

In the European Union, as in most countries worldwide, advertising of prescription drugs to the public is prohibited by law. This restriction is part of the protection offered to the public by prescription-only status. However, in July 2001 the European Commission announced a proposal that—if passed—may open up the countries of the European Union to prescription drug advertising.

The Commission has presented this proposal for legislative change as “information”, not direct-to-consumer advertising. However, it involves a change to advertising legislation. The proposal is limited to three types of drugs, for AIDS, asthma and diabetes, but there are concerns that once the industry has a “foot in the door”, it will be very difficult to limit prescription drug advertising.

During January 2002, Health Action International (HAI) Europe and the European Public Health Alliance (EPHA) co-organised a symposium to discuss the actual intent of the Commission’s proposal relating to Article 88 (the article covering prescription drug advertising) and to debate the industry’s role in providing promotional information about medicines to consumers. At the symposium, researchers and representatives from consumer organisations, patient groups, WHO, health insurers, pharmacists and the research-based pharmaceutical industry shared their perspectives on the proposal and its possible impact on public health in Europe.

Consumer advocates and public health experts stated strongly that the proposal’s likely outcome would be US-style spiraling health costs and irrational drug use. They also emphasised that the Commission’s proposal to allow industry to supply advertising about medicines available for treatment of diabetes, asthma and HIV/AIDS failed to follow the EU’s own precautionary principle of “first, do no harm.” The symposium’s presentations and discussion revealed an obvious need for better independent information about medicines for consumers.

“Drug treatment has two vital components - the medicine itself and information about the medicine. In the past, the focus has been on the product. At this meeting the focus is on information. The public needs quality information in order to make informed choices and manage their own therapy.”

--**Margaret Ewen**, Co-ordinator, Health Action International (HAI) Europe, The Netherlands during her welcoming remarks

“In response to the Commission’s proposals for better information to patients...EPHA developed a survey to assess what patient groups and other EPHA members thought about the Commission’s proposal, and how to assess information needs. The preliminary results illustrate that patient groups are very interested in improving information on prescription medicines but they do not think it will be achieved by the current Commission’s proposals.

More importantly, these results include responses from some of the major AIDS, diabetes and asthma groups, those that will be directly affected by the Commission’s draft proposals.”

--**Genon Jansen**, Secretary General, European Public Health Alliance (EPHA), Belgium in her opening remarks

While many groups prepare and distribute information about medicines for consumers, its quality varies tremendously. In addition, access to this information is far from optimal. However, speakers pointed out that this results from policy decisions choosing not to prioritise patient information rather than any kind of a legal barrier. Neither individual pharmaceutical companies nor the industry as a whole can provide independent information on medicines, as they have a vested interest in promoting the sales of their products.

At the time of this report's publication the proposal on Article 88 is being discussed by members of the European Parliament and Council of Ministers. The main aim of this report is to contribute to informed discussion about what the Commission's proposals may mean for European consumers and national health care services. An additional aim is to consider how patients' and the public's need for information on medicines might best be met.

The Commission's proposal to weaken the ban on advertising could have profound effects on public health, suggested Danielle Bardelay, co-editor, New drug section of *La revue Prescrire* and representative of the International Society of Drug Bulletins, France in her introduction to the symposium. If consumers receive the same kind of information as health professionals currently get from the pharmaceutical industry, she predicted that irrational prescribing and medicine use is the likely result.

"Today, scientific events are often marketing events" she said. "Opinion leaders are seen as acting as puppets. The same thing could happen to the public if the Commission decides to relax its ban on prescription medicine promotion to consumers."

La revue Prescrire is an independent drug bulletin aimed at French doctors and pharmacists, with extensive experience monitoring promotion aimed at health professionals.

Presentation 1: The politics of direct-to-consumer promotion of prescription medicines by Charles Medawar, Director, Social Audit Ltd., United Kingdom

Why has the international pharmaceutical industry been pushing so hard to get EU law changed to allow direct-to-consumer promotion of prescription-only medicines? In his presentation, Charles Medawar suggested that the recent push for direct-to-consumer advertising (DTCA) is directly linked to the fact that the pharmaceutical industry is in crisis and has become unsustainable. He pointed out that companies are no longer able to innovate enough to grow, a problem so far largely obscured by a flurry of mergers and acquisitions. In his analysis, Medawar stated that the industry will only be able to survive in its present form by expanding markets and selling 'blockbuster drugs' – which demand direct-to-consumer advertising and promotion.

All advertising, by its nature tends to be partial, superficial, and predicated on denial - and the same may be said about the quality of the debate on DTCA, so far. "This is not about direct-to-consumer advertising" the European authorities keep saying, while making proposals that seem an obstacle to honest science and an affront to basic medical principles. The people proposing

"One-quarter of US direct-to-consumer advertisements and one-third in New Zealand have been found to be in violation of national laws."

this change in Europe have yet to address some very fundamental questions – for example, has advertising really helped doctors to prescribe better? And how much can one trust self-regulation of DTC promotion in Europe, when one-quarter of

US direct-to-consumer advertisements and one-third in New Zealand have been found to be in violation of national laws?

What happens when commercially inspired messages about diagnosis and treatment dominate the information diet? Will it encourage rational drug use and understanding of the balance of benefit and risk? Will it promote drug treatments over possibly better alternatives, including non-

"I dread the process of medicalisation which turns every runny nose into allergic rhinitis, hormonal mood swings into premenstrual dysphoria disorder and forgetfulness into Alzheimer's."

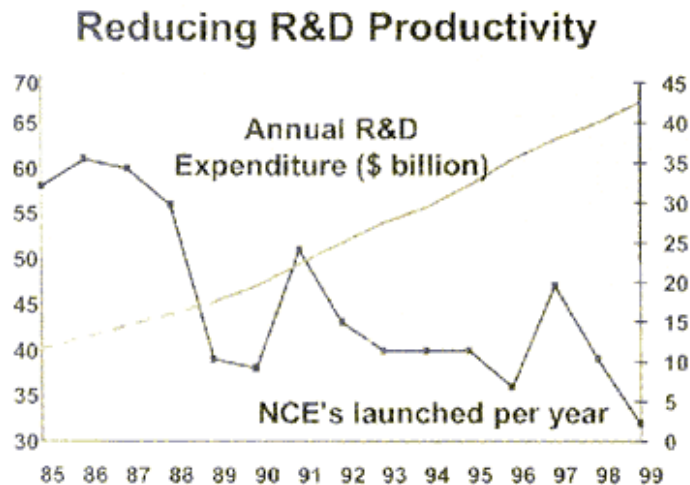
intervention and/or less effective and cost-effective medical treatments? Will it overwhelm the supply of drug information from independent sources, and compromise the editorial independence of the press and media and their coverage of health issues? Will it make people feel healthier or reduce their confidence in their own abilities (and responsibility) to get better and stay well? Will it tend to promote the

medicalisation of everyday life? I dread the process of medicalisation which turns a runny nose into allergic rhinitis, hormonal mood swings into premenstrual dysphoria disorder and forgetfulness into Alzheimer's.

Why DTCA now?

The underlying reason for the introduction of this debate is not a patient-led campaign. The pressure has mainly been coming from the US and the multinational pharmaceutical industry. If

you are a major player you behave like a US company. The US market has clear advantages, as a relatively free market environment with the potential for continuing double-digit growth. Because the US represents 40% of the world market, companies naturally lobby for the introduction of similar market conditions elsewhere.



Source: Arlington S, Pharma 2005: The challenges, presentation to the American Society for Clinical Pharmacology and Therapeutics, Price Waterhouse Coopers, 2001.

The underlying reason for all this pressure for DTCA is the crisis in drug innovation. The number of new chemical entities is going down while the number of dollars needed to develop them is going up. None of the companies is developing the number of drugs they need to survive. So far this problem has been largely masked by an endless rounds of mergers and acquisitions. So the companies will go on merging and the problem will get worse. Companies need drugs that will sell huge volumes in order to generate the revenues shareholders have grown to expect. It is hard to make a blockbuster drug. But the major companies need them to survive. That's why they need DTCA – to expand markets and generate blockbuster sales – but it is not a sustainable solution. The US is already in crisis due to its drug prices. How can small and medium-sized companies compete when you need huge marketing budgets to be in the game? Half of the increasing retail drug costs is attributable to sales of the 50 most advertised drugs. This reveals a complete lack of proportion.

It's not helpful to think of big pharma as greedy - profitability is for the industry now very much a matter of survival. If DTCA stimulates sales, companies will push hard for it. A published report of a meeting with the Association of the British Pharmaceutical Industry (ABPI) reflects how far the industry is willing to go to push for this new marketing possibility:

Now the ABPI has announced that it is launching the final stages of a campaign before it tackles the Government and the EU head on...It is the spearhead of a carefully thought-out campaign. The ABPI battle plan is to employ ground troops

in the form of patient support groups, sympathetic medical opinion and healthcare professionals--known as 'stakeholders'--which will lead the debate on the informed patient issue. This will have the effect of weakening political, ideological and professional defences...Then the ABPI will follow through with high-level precision strikes on specific regulatory enclaves in both Whitehall and Brussels.¹

The EU Commission's proposal raises some serious concerns about how public health matters are dealt with in Brussels. In national systems, pharmaceutical regulations fall under the jurisdiction of the Ministry of Health. However, in Brussels, pharmaceutical policy is under the control of DG Enterprise and frankly the proposals reflect it. While DG Enterprise and assorted industry task forces have called for market liberalisation as a means of increasing innovation, they forget a key point. Just because a drug is new, doesn't mean that it's innovative. It is alarming to see that the European Commission and some national governments value innovation as a means of generating sales, rather than as a way of achieving therapeutic advantage over existing treatment.

"To date, the Commission has not come up with a single document explaining how it came to the proposal on Article 88. There is no evidence that it needs to be improved."

To date, the Commission has not come up with a single document explaining how it came to the proposal on Article 88. There is no evidence that it needs to be improved. Commission spokespeople say they want a "toe in the water" and want it regulated, but look at the US experience. They say they want a five-year trial for AIDS, asthma and diabetes drugs, but no one believes it will be confined to these three diseases. Once you allow industry to provide advertising to consumers the floodgates will open.

In public statements so far, the Commission has suggested that there is a need to allow industry to provide promotional information because patients want to receive it from them. However, I have serious doubts about that claim: too many patient groups that are promoting this have been "sweetened" or even set up by the industry itself. The idea that DTCA is driven by patients is untrue. The measure seems to be driven overwhelmingly by commercial interests and on their behalf.

Conclusions

What the US decides to do about direct-to-consumer advertising is that country's own business and own choice. But there cannot be many countries whose people would gain by embracing the American way of life. It is unaffordable to any national community. European health systems tend to prioritise general health needs. The American model makes a sharp distinction between "health winners" and "health losers" and is hard driven by market imperatives and needs. Let's not forget that three-quarters of a million people declare bankruptcy each year in the US because of catastrophic

"... the obvious first step is disclosure of the vast amount of information that is now kept secret about the testing and regulation of drugs and the realities of drug benefits and risks."

¹ Jeffries, M., *The Mark of Zorro, Pharmaceutical Marketing*, May 2000, 4-5.

illness – and that more than 40 million have no health insurance at all. The EU's health care systems need protection from the ravages of uncontrollable demand that direct-to-consumer advertising would bring. It is also worth keeping in mind that no other country in the world has the regulatory capacity of the US Food and Drug Administration. Indeed, two-thirds of the world's countries "still do not have laws to regulate pharmaceutical promotion or do not enforce the ones they have."² What the EU decides about direct-to-consumer marketing will greatly influence what happens in candidate countries and in other areas of the world.

If the international pharmaceutical industry and European governments are serious about people getting better quality information about medicines, the obvious first step is disclosure of the vast amount of information that is now kept secret about the testing and regulation of drugs and the realities of drug benefits and risks.

² Mintzes, B: *Blurring the Boundaries: New Trends in Drug Promotion*, Amsterdam: Health Action International Europe, 1998.

Presentation 2: Direct-to-consumer prescription drug advertising: Is there evidence of health benefits?

by Barbara Mintzes, Centre for Health Services and Policy Research, University of British Columbia, Canada

In her contribution, Barbara Mintzes outlined the proposed changes to Article 88 and suggested how they might affect public health. She relayed the history of direct-to-consumer advertising in the US and used US and New Zealand examples of it to raise questions about the quality of the information included in such promotion and, the growing costs.

The EU Commission is now proposing to change its law governing the advertising of prescription-only medicines. In order to judge the merits of that proposal, we have to first ask: Is there any evidence of health benefits from direct-to-consumer advertising? If the Commission wants to change such an important public health safeguard, there should be some evidence that there will be benefits to patients and to health services.

The proposed changes

Currently there are two advertising restrictions in the Community Code on Medicinal Products for Human Use. The first one is found in Article 88-2 which bans advertising drugs with prescription status. This ban is meant to offer consumers protection against drugs having greater toxicity. The second related restriction appears in Article 88-3. This prohibits advertising of treatments for a specified list of serious diseases. The key reason for this restriction is the extra vulnerability of those who are ill.

The Commission's new proposal would introduce changes to both of these sections. First, it would allow advertising of prescription drugs for three illnesses: diabetes, AIDS and asthma, and, in addition--it would remove the serious disease restriction.

Arguments favouring DTCA

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

Arguments against DTCA

- Prescription drugs are not like other consumer goods. Even when used properly, they can cause serious harm.
- People are vulnerable when they are ill.
- Ads aim to stimulate sales. They cannot provide impartial, objective information.
- Advertising drives up prescription drug costs and total health care costs.

As we consider the Commission's proposal it is important to remember that it is not only the EU that is feeling pressure to allow prescription drug advertising to consumers. The pharmaceutical

industry and related lobby groups are pushing for advertising changes in Canada and Australia too. The proponents of direct-to-consumer advertising argue it would be a way to empower patients. But is that actually true?

The US experience

The US has never had a law prohibiting direct-to-consumer advertising. The first print direct-to-consumer ads appeared in the early 1980's. However, in 1982 disaster struck when Eli Lilly's new anti-arthritic drug benoxaprofen (Oraflex)³ was recalled by the FDA after only 5 months on the market because of severe adverse effects, including deaths. The FDA's action came after the company had mounted an aggressive public relations campaign aimed at the public and health professionals. In its wake, prescriptions for the drug skyrocketed from 2,000 to 55,000 a week earning the manufacturer more than US\$1 million a week in sales. The Oraflex case was a catalyst for the FDA to adopt a moratorium on direct-to-consumer advertising of prescription drugs between 1983-85 so that a widespread consultation could be held with all stakeholders. In 1985 the moratorium was lifted.

"Direct-to-consumer advertising has got nothing to do with the public's education and it has got absolutely everything to do with advertising and boosting product sales."

- Dr. Drummond Rennie, senior editor,
Journal of the American Medical
Association, 1999

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 ads were bound by the same regulations as the information sent to health professionals, which included the full approved product labelling information on risks and contraindications (what the FDA calls the "brief summary").

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

Effects on costs

How has direct-to-consumer advertising affected health spending in the US? To begin, 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 direct-to-consumer advertising has led to more prescriptions per person and that it has increased demand for newer, more expensive drugs.

"Direct-to-consumer advertising has led to more prescriptions per person and that it has increased demand for newer, more expensive drugs."

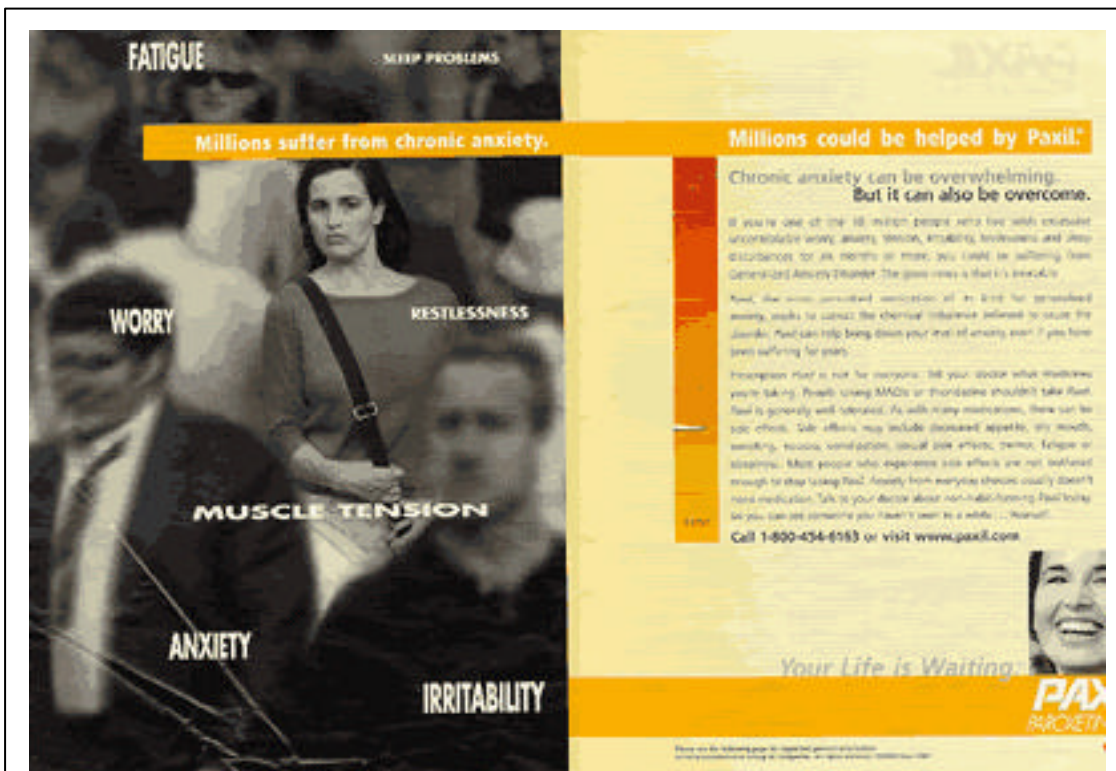
³ The brand name in the UK was Opren.

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 to inform 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.

“Around 40% of the money spent by companies to advertise directly to consumers each year is spent on only 10 drugs.”


Consumers’ reactions to DTCA

US consumer surveys have been carried out to find out more about the public's views on direct-to-consumer advertising. In national surveys, one-fourth of respondents spoke to a doctor about a drug or condition in response to direct-to-consumer advertisements—and 6-9%



Above is an advertisement for the drug (paroxetine) Paxil indicated for generalised anxiety. This ad ran in *The New York Times Magazine* only two months after the attack on the World Trade Center. Is it any wonder that New Yorkers feel anxious? Do they really need drug treatment as a result? Where do you draw the line between a natural human reaction to stress and a condition requiring medication? A company aiming to maximise sales will always be tempted to push the limits.

reported having directly requested a drug from their healthcare provider, most of whom (80-84%) received a prescription.



Now predict your chances of getting breast cancer.

And act on it.

Nolvadex TABLETS
TAMOXIFEN CITRATE
There is something you can do

Take the Risk Assessment Test. It's 6 simple questions.
Many of us sense we might be at high risk for getting breast cancer—especially if we've watched a mother or sister battle the disease. Well, now there's a way to stop wondering and actually do something about it. Because now your doctor has a way to

The proof? In a landmark study of women 35 and older at high risk for breast cancer, women who took Nolvadex had 44% fewer breast cancers than women taking sugar pills. Nolvadex decreases but doesn't eliminate the risk of breast cancer and didn't show an increase in survival.

Nolvadex isn't for every woman at high risk. In the study,

This ad for tamoxifen (Nolvadex) plays upon healthy women's emotions--in this case, fear of disease and offering a sure solution--without making it clear that the drug's potential risks can outweigh its benefits in many potential users.

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 ads? 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 ads lead to an informed, educated consumer?

320 prescription drug ads from 1989-1998, in 18 major US magazines	
<i>Does the ad mention:</i>	
The likelihood of treatment success?	No, in 91%
On average, how long a person needs to take this drug?	No, in 89%
Other helpful activities like exercise or diet?	No, in 76%
Any other possible treatments?	No, in 71%
How the drug works?	No, in 64%

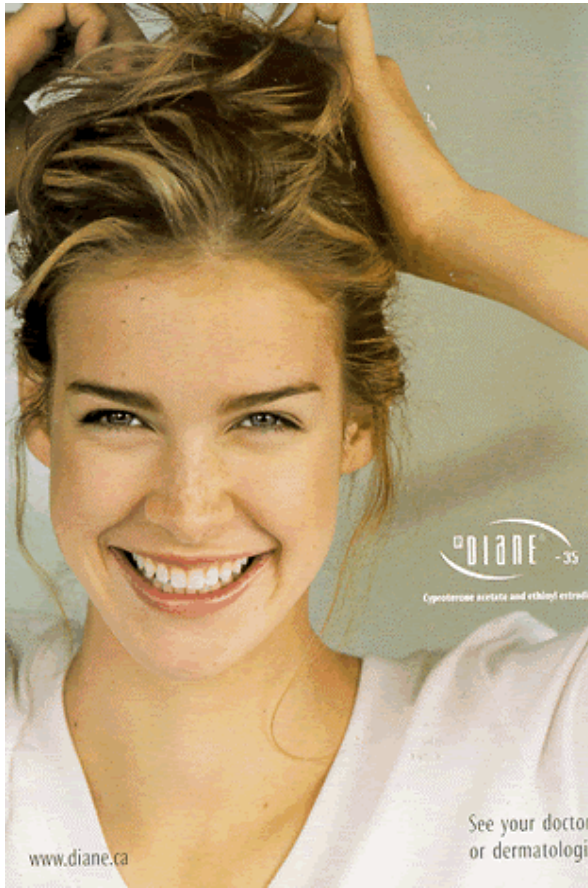
Robert Bell and colleagues, 2000

The quality of US DTC advertisements

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

DTCA in New Zealand

Like the US, New Zealand has direct-to-consumer advertising by default, as there has never been a law against it. It just wasn't done until recently. While the FDA regulates direct-to-consumer advertising in the US, New Zealand relies on industry self-regulation like many European countries. This often means that advertisements include less risk information than



This is a New Zealand ad that was eventually found to violate the Act because of inadequate risk information. In Europe the use of Diane-35 has been restricted to treating severe acne which is unresponsive to other treatment due to concerns about liver toxicity. However, this ad looks like a cosmetic ad.

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 5 of 6 voluntarily submitted television ads and one-quarter of print ads violated the Medicines Act. The main reasons were inadequate or absent risk information.

Pharmac, New Zealand's drug management agency, commissioned a survey in November 2000 on consumer responses to this Diane-35 ad (shown at left). They showed the ad to 200 women aged 16-30 and asked them a few questions. Nearly half thought the ad provided enough information to decide whether to take Diane-35. One-quarter thought the ad clearly stated risks and side effects. The only risk information given is a line in tiny print saying that the risks are similar to other birth control pills. This is untrue and does not explain what those risks are. This example suggests that misleading advertisements work and shows how difficult it can be for the public to judge the information in pharmaceutical ads.

Direct-to-consumer advertising 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 Commission's proposal 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 Rezulin⁴ (troglitazone) advertised to the public has now been withdrawn for safety reasons. Troglitazone was withdrawn from the UK in 1997 because of liver toxicity. It remained available in the US until March 2000 and was advertised to the public, as well as to doctors. By the time it was withdrawn it had generated US\$2.1 billion in sales within 3 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 same class; Avandia (rosiglitazone) and Actos (pioglitazone), are currently being advertised to the US public despite warnings of serious cardiac risks. This example highlights a key public health concern with direct-to-consumer advertising: the rapid, widespread use of new drugs before risks or benefits are fully known.

irritability
Think it's PMS? Think again.

it could be PMDD.
Premenstrual Dysphoric Disorder (PMDD) is a severe form of PMS that causes intense mood and physical symptoms right before a period. If extreme irritability, mood swings, and fatigue interfere with day-to-day activities and relationships, now there's a solution. Introducing Sarafem—the first and only FDA-approved prescription medication for PMDD. To learn more about PMDD, visit Sarafem.com or call 1-877-599-PMDD.

Sarafem
fluoxetine hydrochloride
More like the woman you are.

Why live this way another month? Talk to your doctor.

Important Safety Information: If you develop a rash or hives while taking Sarafem, call your doctor right away. This may be a sign of a serious medical condition. You should not take Sarafem if you are pregnant or while breastfeeding. Do not take an MAOI (for example, phenelzamine) for at least 14 days before starting Sarafem. Do not take Sarafem at the same time as or within 5 weeks of stopping Sarafem. Some women may experience side effects such as drowsiness, dizziness, and difficulty concentrating. Side effects may gradually go away over a few weeks. Sarafem contains fluoxetine hydrochloride, the same active ingredient found in Prozac. Tell your doctor if you are pregnant or planning to become pregnant. Please see the following page for additional product information.

⁴ The UK brand name is Rozolin.

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 how 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 ads. The agency stated that ads like the one printed here, showing images of men climbing mountains, bore little resemblance to the reality of life on anti-retroviral therapy.

A common argument made for allowing direct-to-consumer advertising 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 very different than one made by a company trying to sell a product.

Conclusions

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

"In nearly 20 years of use, there is no evidence that direct-to-consumer advertisements have reduced hospitalisations, serious disease or deaths. There is no reliable evidence of improved medicines use either. In fact, most advertised drugs are no more effective and no safer than older, cheaper alternatives."

In addition, do direct-to-consumer advertisements lead to better health? In nearly 20 years of use, there is no evidence that direct-to-consumer advertisements have reduced hospitalisations, serious disease or deaths. There is no reliable evidence of improved medicines use either. In fact, 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. A change in advertising regulations will not fill this gap. By definition, advertising aims to sell a product. Consumers need more information about prescription medicines, but advertising is not the way to get it.

Dire qu'un simple test de cholestérol aurait pu lui éviter ça.

Si vous présentez un de ces facteurs de risque, consultez votre médecin pour faire mesurer votre taux de cholestérol :

- Hypertension (haute pression)
- Diabète
- Maladie cardiaque
- Cas de maladie cardiaque dans la famille
- Homme de plus de 40 ans
- Femme de plus de 50 ans
- Usage du tabac

Pour bien des gens, la crise cardiaque est le premier signe de la maladie. Malheureusement, 50 % des personnes ne survivent pas à une première crise cardiaque. La réalité pourrait toutefois être fort différente.

On sait qu'un taux trop élevé de cholestérol dans le sang est un facteur de risque important de maladie cardiaque, et, il est relativement facile de le faire baisser.

SERVICE DE PATHOLOGIE

Embonpoint: *Normal*

Age: *52*

Sexe: *F*

Nom: *J. B.*

N° de dossier: *5341-96*

Cause du décès: *Crise cardiaque*

Appelez le 1 877 438-9115 pour recevoir cette brochure gratuite qui vous renseignera sur le lien entre le cholestérol et les maladies cardiaques.

Niveau canadien de personnel infirmier spécialisé en lipidologie

Pfizer

Presentation 3: Information for shared decision-making in medicine -taking
By Prof. Angela Coulter, Chief Executive, Picker Institute Europe, United Kingdom
and member of the G10 Medicines Group

The Picker Institute conducts research on patient needs to feed back to health care providers. It is an educational charity that carries out research, education and policy advice work. It is not a membership organisation, rather it represents patient views as they emerge from research. Angela Coulter is the consumer representative in the EU's G10 Group. The aim of the G10 is to examine ways to make Europe's pharmaceutical industry more competitive while at the same time optimising public health. In her presentation, Coulter described the irreplaceable role that high quality, independent information about medicines and treatment options plays in enabling patients to make well-informed decisions about their own health care.

Years ago patients did what the doctor told them to do. This scene has certainly changed as more and more consumers choose to play an active role in their own health care. Studies today suggest that young people want more information about health than those who are older. Is it just the age group or does it signal a real change in the culture? Many experts expect the latter and think that as today's youths grow older they will continue to seek out more information. Such a change in the patient's role means that facilitation of quality information is critical.

To begin, one must ask: Why should patients be informed and involved? The answers are multiple. To begin, it helps meet their expectations about their care. It also works to ensure appropriate treatment. There is evidence that involving patients can improve care. Some studies suggest it can also improve health outcomes and heighten safety while reducing errors. Active patients are less likely to make formal complaints, to feel dependent and disempowered. As taxpayers or payers of insurance fees, it seems reasonable that consumers should be able to demand accountability that their money is spent wisely.

Research reveals that information and participation are highly valued by many consumers. Studies suggest most patients want more information about their care and options. Many, but not all, patients want to participate in decisions about their care. Interestingly, evidence shows that clinicians tend to underestimate patients' desire for information and are often unaware of patients' preferences, preferring instead to follow their own. However, gaining access to good information remains a real problem. It is often difficult to find balanced information about treatment options.

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Because patients are decision-makers about their own health, they need reliable independent information on a variety of topics, including:

- decisions about self treatment

- the decision to consult
- decisions needed along the care pathway
- decisions about prevention.

In order to make the necessary decisions, patients need solid information on important topics affecting their care, such as their illness and its symptoms; available tests and treatment options; advice on self-help and prevention; possible services and sources of help and the quality of health care providers.

There is a lot of evidence showing that patients are not getting this kind of information. A Picker study examining patients' experience of hospital found that many patients wanted more information about their medication when they were being discharged from hospital. Particularly, they wanted more information about side effects. This desire for information isn't surprising considering the study results showed that a large proportion of the study's patient group received no information about their medicines upon discharge.

The quality of existing patient information

While patients want solid information about their illness, the fact remains that many of the patient information materials available today are of poor quality. Often topics of relevance to the patient are omitted. Many times there is incomplete coverage of the available treatment options. Unfortunately, a lot of inaccurate or out-of-date material finds its way into patients' hands. And some material is plainly biased, discussing benefits much more than any risks and ignoring or glossing over uncertainties.

The Picker Institute carried out a study examining the information available to patients on 10 common conditions for which there is a good evidence base on treatment. We asked providers what kind of information they give patients having one of those 10 conditions. An abundance of material was received from commercial publishers, patient groups, health authorities and the pharmaceutical industry, among others. We gave the information to 10 focus groups comprised of patients with the concerned health condition as well as a group of health professionals involved in research on that area of treatment efficacy.

Crucial questions for patients to ask about their treatment

- what are the options ?
- what are the benefits and harms?
- will treatment relieve the symptoms?
- is treatment essential?
- what is the recovery time?
- what impact will this have on my quality of life?

Most patients in the focus group initially welcomed the large amount of material saying that they often had problems finding information about their illness. However, when they began looking

more closely at the material they realised most of it didn't address patients' real information needs. The professionals were also critical. Patients said many of their questions remained unanswered. A lot of the material promoted one treatment. Some of it was inaccurate; other items were out-of-date. In general, the material tended to be very biased, highly optimistic, and provided little information on risks or side effects. Most of it never mentioned uncertainties or controversies.

There are a number of quality standards necessary for patient information regardless of the topic covered. For example, it should use patients' questions as a starting point and clearly address patients' concerns. It must include information about all treatment options plus the consequences of having no treatment. The material should be honest about benefits and harms and quantify them where possible. It should also suggest related questions for patients to ask their doctor as many people do not know what to ask. Some people find numerical information difficult to absorb. The information needs to respect this fact and make statistical information comprehensible. Information for patients should also list its sources and indicate the strength of the evidence while also providing ideas on further information sources. Importantly, it should be non-alarmist and non-patronising in tone. The material should be well-designed and concise and always be explicit about authorship, sponsorship and its publication date.

The need to share expertise

Both the patient and the health care provider can contribute to the conversation about the patient's condition. The patient is an expert on his/her own health. This is related to each person's particular experience of illness, the social circumstances surrounding their life, personal attitudes about risk, as well as individual values and preferences.

The clinician can inform the patient about the actual diagnosis, the illness's cause (disease aetiology), the patient's prognosis, all available treatment options and the related outcome probabilities. Although the goal is shared information and decision-making, this can only happen if the two players actually do share information. Many obstacles stop this process from happening including practical problems such as short consultation times; the fact that some patients find it hard to ask questions; the equal problem that clinicians don't know all the answers and that quality information is hard to find.

Inadequate time spent sharing information about a condition can lead to significant misunderstandings in prescribing. For example, some important patient information may be unknown to the doctor. In the same way, a great deal of the information influencing the doctor's prescribing can remain unknown to the patient. There can be conflict in the information given by both actors and disagreement about the attribution of side effects. And the relationship between the doctor and the patient can have a strong bearing on any prescription.

"Patients need evidence-based information to assist in making informed choices. Advertising will not help. In addition, information about specific drugs found on individual pharmaceutical company websites will not help either. People need more and better quality information about medicines. The kind of full, balanced information that consumers need cannot, by definition, be provided by advertising."

It is not enough for patients to rely on doctors to make informed choices. They have a responsibility to become involved themselves in order to ensure their own health receives the maximum benefit possible. Poor communication and a lack of patient involvement in decisions leads to inappropriate prescribing, unwanted prescriptions, non-adherence, errors and safety risks, and bad health outcomes.

Information about medicines

Patients need evidence-based information to assist in making informed choices. Advertising will not help. In addition, information about specific drugs found on individual pharmaceutical company websites will not help either. People need to know about the full range of treatment options if they are to make informed choices. The kind of full, balanced information that consumers need cannot, by definition, be provided by advertising.

And advertising is not the only problem. The Internet is playing a growing role in promoting medicines. But there are many ways to get around current advertising restrictions. Often other promotional means are more effective than actual ads. Just telling the EU Commission to “keep the ban” on advertising of prescription-only medicines is not enough. It won’t address the kinds of information needs that have been identified in this presentation.

The way forward

If informed patients are the real goal, there are a number of actions needed. The EU Commission’s proposal on providing information on medicines needs to be revised. The idea of allowing companies to disseminate information on asthma, diabetes and HIV/AIDS through company websites or other means should be turned into something more positive. This is an opportunity to organise a positive initiative to develop the type of information patients really need. It could be done as a public-private partnership involving all of the stakeholders including consumer groups.

“The idea of allowing companies to disseminate information on asthma, diabetes and HIV/AIDS through company websites or other means should be turned into something more positive.”

Governments must help but they alone are not the answer. There is a need for something much more inclusive. It calls for more resources and we need to agree on quality standards for patient information and mechanisms to monitor them. It is important to have a debate on those standards and determine if they are acceptable. Finally, it is crucial to evaluate pilot schemes rigorously to assess the extent to which they meet patients’ needs.

Presentation 4: Direct-to-consumer advertising or direct-to-consumer information on pharmaceuticals?

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

The government of The Netherlands has already had to combat direct-to-consumer advertising campaigns launched by companies despite the fact that the practice remains illegal. Companies are attempting to expand the limits of what can be advertised and how this may be done. Given this background, Leon Wever takes the suggestion that companies will disseminate neutral information with a grain of salt. He believes that the Commission's proposal is actually a way to introduce direct-to-consumer advertising into Europe. This is the only rationale for a change in European regulations governing prescription drug advertising. The advent of such advertising is a huge concern for Dutch policy-makers, due to the country's modest level of prescribing and medicines use at present. They fear its implications on public health, health budgets and the government's ability to enforce the law.

At present, there are large differences in the amount of medicines consumed within the EU member states. These differences are sometimes enormous. The prices of medicines also vary greatly from country to country within the EU. The same is true for prescribing practices in each EU country. For example, The Netherlands has a moderate prescribing practice compared to some of its neighbouring countries such as France and Belgium. From the pharmaceutical industry's point of view, these current differences provide an enormous opportunity to harmonise consumption figures upwards. That fact makes the EU Commission's proposal on Article 88 very worrying. One has to ask: What is the actual purpose of this proposal?

To start, it is helpful to review the main goals of the EU pharmaceutical legislation:

- to guarantee a high level of public health
- to increase transparency
- to complete the single market
- to favour competitiveness of the industry
- to prepare for EU enlargement

All of these goals are reasonable and are things that we cannot oppose. The proposed legislation contains changes related to a number of areas including patient access to information about medicines; the role of the European Medicines Evaluation Agency; drug evaluation procedures and time frames; industry competitiveness and competition; and reducing red tape. Again, no one is against better access to patient information and the other proposals for change.

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

“...We are concerned that DTCA could be the inevitable outcome of this pilot phase.”

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 concerned that DTCA could be 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 (VWS) has had to take action against a number of “disease-awareness” campaigns that crossed the line into advertising. Below are two cases of interest.

Zyban

The anti-smoking product bupropion (Zyban) made by GlaxoWellcome was introduced in The Netherland on 1 December 1999. Between 25 December and 30 December (right before New Year’s Day when many smokers try to break their smoking habit) the company ran TV and cinema advertisements on smoking cessation. The ads referred viewers to the company’s website. The country’s health inspectorate intervened quickly to demand that the broadcasts be discontinued. While the broadcasts did end, the Ministry learned that the company had already set up a telephone line providing information about use of Zyban. It had also placed articles about the drug in media publications telling readers who smoked to consult their family doctor. At the same time, Zyban promotion had also been sent to doctors and promotional brochures about the drug could be found in their waiting rooms.

The Zyban case was brought to court. The court ruled that the Internet site and brochures contained inadmissible promotional text that was, in fact, advertising. It also ruled that the advertisements had a “funneling” effect as there was no other product available (with the same active compound) for this indication and that no alternative treatment options were given. It said that patients in a doctor’s waiting room must be considered members of the “general public” so that promotional texts were illegal. However, it said the company could carry out “supportive” programmes for smokers wishing to stop.

“The court ruled that the Internet site and brochures contained inadmissible promotional text that was, in fact, advertising.”

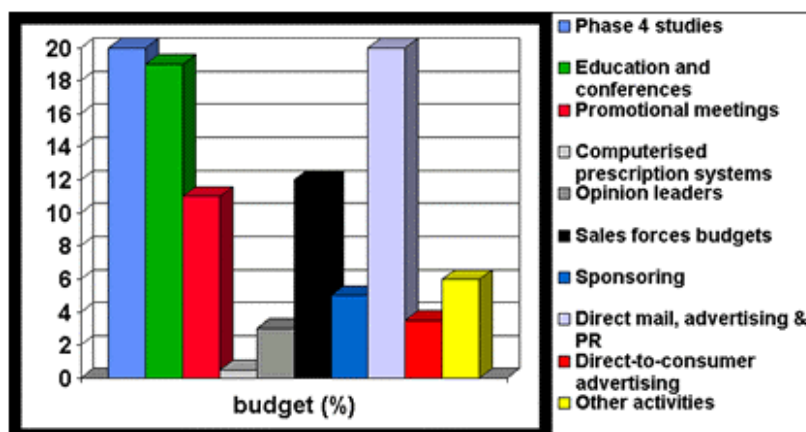
Xenical

The Ministry's health inspectorate obtained a copy of the marketing plan for orlistat (Xenical) made by Roche to treat obesity. In it, plans were described for advertorials and advertisements referring to Xenical and a telephone information line for consumers as well as reference to the website www.xenical.nl. Again, this case went to court and the judges said it was important to look at the context in which the information is used to determine if it is indeed information or advertising.

The court said, in this case it was advertising. It pointed out that the advertisements and advertorials did not contain "factual information" and were directed at the public. The court also emphasised that direct-to-consumer advertorials and ads were an essential part of the company's marketing plan obviously aimed at increasing sales. Consequently, the material provided by the company could not be considered information.

"The court also emphasised that direct-to-consumer advertorials and ads were an essential part of the company's marketing plan obviously aimed at increasing sales."

Conclusions drawn from both cases are important as we consider the EU's proposal on Article 88. 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 "gray 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?



It is interesting to examine how companies spend their marketing budgets. Since the Health Inspectorate demanded copies of companies' marketing plans we have learned some surprising things. For example, 4% of the budgets are spent on direct-to-consumer advertising. At first glance, this does not seem like much, but considering the fact that this type of advertising is prohibited, one has to wonder why they are spending any money on it at all. Most of the

marketing department's money is spent on phase IV studies. One may wonder what scientific studies have to do with marketing.

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?

Direct-to-consumer information is vital for patients and good health care. It addresses the fact that consumers have a right to be fully informed about their health conditions and their medicines; it enhances rational drug use; it stimulates compliance; it decreases unjustified and irrational self medication; and it improves transparency about drug availability.

"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."

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 organisations

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 websites. 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.

"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."

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.

Afternoon panel session introduction

by Dr. Philip Brown, Publisher, SCRIP, United Kingdom

SCRIP is a trade journal monitoring the European pharmaceutical industry. Its pages have given a great deal of attention to the direct-to-consumer advertising issue during the past few years. Philip Brown, its publisher, has worked within the pharmaceutical industry as well as in publishing. During the afternoon discussion, Philip Brown summed up the morning's conclusions and called on panelists to suggest ways to improve information about prescription medicines if advertising did not seem to be the answer.

The presentations and discussions thus far reveal a strong feeling that patients need information. There seems to be some consensus that we don't need direct-to-consumer advertising or new legislation to bring in patient information. But if we don't need these elements, what do we need? Pharmacists have training on medicines, do they give information effectively? Are drug bulletins doing it? Would the introduction of direct-to-consumer advertising motivate groups to produce better information? One has to ask why efforts at providing patient information haven't worked very well. And if in fact patient information is available, then it can offset any promotion given by the industry. It seems to me that people are afraid to allow direct-to-consumer advertising in Europe because there is nothing to oppose it.

Presentation 5: The pharmaceutical industry's perspective on providing prescription drug information directly to EU consumers

by Mr. Brian Ager, Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA), Brussels

Given the increasing reach of the Internet, it is unreasonable to attempt to exclude the research-based pharmaceutical industry from providing consumers with information about health conditions, argued Brian Ager in his presentation. He emphasised that manufacturers of medicines should be allowed to disseminate reputable information to consumers who otherwise might search for information about treatments from less trustworthy sources.

Members of the EFPIA consist of 18 national, European industry associations and 45 pharmaceutical companies involved in the research, development and manufacturing of medicinal products in Europe for human use. EFPIA's activities converge towards a common goal: the promotion of pharmaceutical research and development in Europe.

Addressing information needs

For EFPIA, the issue of information to patients is addressed in the context of the work carried out by the High Level Group on Innovation & Provision of Medicines (G10) under the chairmanship of Commissioners Liikanen and Byrne. EFPIA supports this initiative and is represented in G10 by its President, Mr Jean-Francois Dehecq from Sanofi-Synthelabo and Chris Viehbacher from GlaxoSmithKline.

At the Lisbon Summit in March 2000, Europe set itself a new strategic goal to become the most competitive and dynamic knowledge-based economy in the world, capable of sustainable economic growth with more and better jobs and great social cohesion. The G10 pursues objectives that are in line with this global strategy, identifying the pharmaceutical industry as a strategic sector for Europe.

The major health challenges now facing Europe require new technologies. Competitive research is the key. The research-based industry (and indeed the EU) needs the G10 process to lead to concrete actions aimed at improving the competitiveness of the European industry and stimulating the climate for R&D investment in Europe. Public health and health care systems have nothing to gain from a weakening of the European pharmaceutical industry. On the contrary, Europe and European patients would lose if the most innovative research activities would be pursued outside of its territory in the future.

The title of this symposium is "Providing prescription medicines information to consumers." Indeed it is important that the patient remains the primary focus for all of us. In that context, Europe's drive for a dynamic, knowledge-based information society and its goal of ensuring a high level of health protection will bring new opportunities to

"At present there is a ban on advertising, but the research-based industry has never called for direct-to-consumer advertising in Europe. We want patients to be able to access information about their own disease."

European citizens and patients to become health literate. Patients empowered with information can play a larger role in their health care. At present there is a ban on advertising, but the research-based industry has never called for direct-to-consumer advertising in Europe. We want patients to be able to access information about their own disease. Since access to the Internet and its information cannot be restricted, we call for responsible behaviour and self-regulation. We must remember that the Internet is here to stay. This new medium gives people the ability to find out what information is out there, including treatment information. If we don't start providing more information in this medium, we are denying the reality of the Internet.

The implications of the Internet on the health-care sectors are considerable. It will be a major influence on the way medicine is practiced and the way in which patients assume increasing responsibility for their own care. A testimony to its impact: a recent poll has shown that more than 98 million US adults have sought healthcare information online and 75% of those who have access to the Internet use it to find health-related information. Also in Europe, the Internet is increasingly used to access health data and information. Of course, this explosive growth brings threats as well as opportunities.

An often-expressed threat is the uncertain origin and quality of the information offered. This is well understood. The pharmaceutical industry strongly supports the right to use the Internet as a means for providing authentic information on medicines, in a responsible manner, for the benefit of both patients and healthcare professionals. Pharmaceutical manufacturers should be able to inform patients adequately about the benefits and risks of their products. Pharmaceutical companies that have conducted the research, development and clinical trials of their medicinal products are the best scientific source of information about them. Moreover, pharmaceutical companies are legally responsible to competent authorities for the accuracy of the information supplied.

The European Commission has recognised the importance of providing health information to consumers and patients via the Internet. Current EU legislation prohibits direct communication between pharmaceutical companies and the general public when the information provided is intended to promote use of medicinal products (i.e. advertising). But, in April 1999, the Pharmaceutical Committee advised that inclusion in company-sponsored Internet sites of summaries of product characteristics, patient leaflets and public assessment reports by competent authorities does not violate the ban on advertising to the public. It also left open the possibilities of guidelines identifying other permitted information.

At a symposium in Geneva (September 2000) involving representatives of WHO, academia, regulators, industry, physicians, and patient organisations, it was concluded that "good information practices" and "good Internet practices" are the way forward to safeguard the role of the Internet as a valuable source of information on medicines. And Commissioner Erkki Liikanen in a speech given at a symposium in Lyon (November 2000) indicated that it is the right time to reconsider the regulatory approach and to give increasing responsibility in the area

of self-regulation to companies in specifically defined sectors. He also called on companies to set themselves quality criteria that are in line with the interests of consumers.

The pharmaceutical industry has a long tradition and experience in self-regulation, and with the implementation of guidelines. Industry is legally responsible for the information it provides on its products. EFPIA is convinced that self-regulation is

"EFPIA is convinced that self-regulation is the method of choice for controlling the type and quality of information provided via the Internet on pharmaceutical products."

the method of choice for controlling the type and quality of information provided via the Internet on pharmaceutical products. Therefore and in line with policy orientation given by the Commission, EFPIA has recently adopted *Guidelines for Internet Web Sites Available to Health Professionals, Patients and the Public in the EU*. These guidelines are now available through its website.

The Internet is often considered as a library in which the general public is free to search for information about any product/services. The pharmaceutical industry considers that all providers of information through the Internet should adopt guiding principles to protect consumers and patients from misuse by the unscrupulous. The latter could use the Internet to bypass normal controls and to sell prescription medicines directly to patients, without appropriate professional consultation.

"The current situation cries out for us to provide information to patients."

The idea is that EFPIA's guidelines would be implemented at the national level through voluntary self-regulatory systems. Its main objective is to ensure that European citizens receive balanced and accurate information in their own language based on the summaries of product characteristics in Europe. At present, European consumers already have access to product-specific information from US websites. Hence, for obvious public health and safety reasons, information about medicinal products should be directly relevant to European conditions, be posted in national languages and be based on labels approved in Europe.

This idea to provide information to consumers will not bypass other information routes such as doctors and pharmacists. However, we believe we must do something to fill in the vacuum or people will scan the Internet for information and there will be much less control over it. The current situation cries out for us to provide information to patients. Of course, this by no means suggests that this is the only thing that should happen regarding information provision.

Presentation 6: Patients' medicine information needs

by Mr. Rob Camp, European AIDS Treatment Group (EATG), Germany

The EATG is a pan-European NGO advocating at the European level for the treatment-related interests of people living with HIV and AIDS. As an NGO playing an active role in the well-being of more than 500,000 Europeans with HIV, the EATG seeks to work together with the European institutions to build an AIDS policy which is truly effective in addressing the needs of those living with HIV. The network now has 100 members based in 27 countries. In his presentation, Rob Camp explained EATG's stand on the proposed changes to Article 88 and raised concerns about the consultation process.

This initiative is not a patient-led initiative. Although HIV/AIDS is one of three illnesses covered by the proposed changes, the EATG has never been asked about its position on the proposed text. One has to ask: Why is DG Enterprise (trade) interested in improving drug information instead of DG Sanco (health)? This seems like a "done deal", and for this reason we have limited our comments to reviewing and revising the EC proposal.

Patients' right to information

The EATG views access to information as every adult's legitimate right. Patients should be granted freedom of access to information that is available to the experts. However, one has to determine if the Commission's proposal is actually about drug information. The network has concerns that it may be about advertising medicines. Making information available to patients directly from manufacturers necessarily begs the question of the difference between information and advertising.

The EATG is vehemently opposed to the creation of a situation in Europe similar to that in the US where consumers are exposed to frequently unclear/misleading advertising. The Commission proposes that "better, clear and reliable information on authorised pharmaceuticals" should be made available. Information made available to patients in Europe must be exclusively factual.

"This proposal should not be made simply to counter the fact that the Internet is a growing source of health information. Its wording should be based upon positive reasons why people should have information about their medicines."

In addition, the EATG believes that restricting the advertising directive's liberalisation to three indications is inequitable. Specifically, those living with HIV/AIDS often suffer from opportunistic infections. Why should patients be able to inform themselves about products for HIV infection, and not about those available to treat side effects such as high cholesterol, for example?

Means to ensure that patients benefit from the proposal

This proposal should not be made simply to counter the fact that the Internet is a growing source of health information. Its wording should be based upon positive reasons why people should have information about their medicines. That is what should be driving the legislation.

It seems that there is very little means to have input into this process. EATG believes the legislative process itself needs to become more transparent and inviting, so that stakeholders can play a real role.

What information do patients want?

For patients to benefit, product information disseminated by companies must include:

- Advice on adverse events
- Information about risks and dangers
- The summary of product characteristics
- Information contained on product insert leaflets (in terms that are easy for the public to understand)
- A highly visible reminder that it is essential to discuss all treatment regimes with a doctor
- Any EMEA-led pharmacovigilance alerts
- Access to full study and trial results for reference
- Access to ongoing study protocols

It should **not** include:

- Photos of anything other than the product
- Studies other than those that have been published in a scientific journal or regulatory studies (part of the legal product dossier). In both cases, these should specify whether the study has been funded by a pharmaceutical company and/or the author of the study or the author's institution has received funding from the owner of the product
- Comparisons with other products other than those comparisons conducted within studies
- Statements which suggest that the effects of taking the medicine are guaranteed, or are unaccompanied by side effects

Presentation 7: Consumers' medicine information needs

By Ms. Clara MacKay, Principal Policy Advisor, Consumers' Association (CA), United Kingdom

Consumers Association has studied the issue of direct-to-consumer advertising in great detail and has published a number of reports and articles on the subject. In her presentation, Clara MacKay emphasised what CA has learned about the kind of information consumers and patients really want about medicines.

To begin, I think it is important to make a distinction between consumers and patients when we talk about information and medicines. There is no question that someone with a long-term disease or condition will have a different perspective and different interests than someone who is prescribed medicines on a short-term basis. Certainly people with long-term conditions will almost always develop a level of expertise about their illness and treatments that is well beyond that of the day-to-day consumer.

"There is no question that someone with a long-term disease or condition will have a different perspective and different interests than someone who is prescribed medicines on a short-term basis."

On the other hand, I would caution against the idea that the "consumer's" information needs are insignificant. For example, when Consumers' Association did some research on patient information leaflets that come with prescription drugs we found that mothers with young children in particular have a significant interest in information about the medicines that their children are taking. This is true even if these medicines were for minor episodes of illness, like colds and coughs. They want to know about side effects and whether this is the right drug and so on.

What consumers want to know

In general terms, I would say media coverage and public awareness of issues around things like immunisation, antibiotic resistance, and even allergies and allergic reactions, have made consumers much more interested in accessing information about medicines.

Our research has told us a lot about consumers needs relating to information. Firstly, and this is where there is common ground between patients and consumers, consumers want information that allows them to put prescription drugs into context. They do not want information that relates only to the very specific drug in question. By context, I mean that consumers want to know, for example, how does this drug compare to other drugs? Or in practical terms, why is my neighbour taking a different kind of antibiotic for exactly the same problem that I have? How comes she has a patch and I take tablets? People, naturally want to know that they are getting the best treatment possible and not just any treatment. But, also, consumers are increasingly interested in doing more than just

"Consumers want information that allows them to put prescription drugs into context. They do not want information that relates only to the very specific drug in question."

comparing one prescription drug with another. They want to compare prescription drugs with other approaches to treatment.

This is especially true in relation to prescription drugs and herbal remedies - or other alternative treatments. Even in the last couple of years we see more and more herbal remedies on the market that are considered treatments for stress, mild depression, circulation problems and so on. Although not always substantiated by the evidence, there is a growing view that “natural” is better than manufactured.

Taking one step further back, I'd also like to suggest that consumers will increasingly want information about the company that produces the medication and not just the medicine. We have already seen a growth in the number of people wanting to exert consumer power in relation to ethical investments and financial services. I predict that in the future more and more people will become interested in the ethical aspects of the drug industry.

Once people pick up their prescription from the pharmacy their information needs become more focused. They want to know how to take this medicine safely and effectively. Just recently I received a letter from a man complaining about the information provided with his medication. His complaint reinforces everything most participants in this room already know. The label and patient information leaflet on his medication were written in print too small for him to read properly and gave too much information about the manufacturer upfront. He also found it confusing and difficult to understand. It is crucial to remember that consumers need information that is accessible in every sense of the word.

At the same time, it also needs to be practical. For example, one person taking part in a focus group on this topic wanted to know whether or not he could have a couple of beers with his mates while taking a particular medicine. The patient information leaflet he had received only said something very general about interaction with alcohol. Other people want to know, for example, when your prescription says take a tablet every four hours, does that mean during the night as well? So practical information about how to take medication and about side effects is really important to consumers.

So in summation, I would say that consumers want information about medicines that puts that medicine in context, that is accessible and is practical and relevant.

Presentation 8: Providing prescription medicine information to consumers: is there a role for direct-to-consumer promotion: A WHO perspective

by Mr. Kees de Joncheere, Regional Adviser for Pharmaceuticals and Technology, World Health Organization, Regional Office for Europe, Denmark

The World Health Organization (WHO) has been involved in promoting the rational use of drugs for years. Some of its specific activities in this field include the creation of the WHO Ethical Criteria for Medicinal Drug Promotion. In addition, there have been many World Health Assembly resolutions on rational drug use, drug promotion and the role of the Internet. It also published a guide for finding reliable medicines information on the Internet. Most recently, WHO-Copenhagen organised a meeting in December 2001 bringing together the European health authorities responsible for controlling drug promotion. In his presentation for the seminar, Kees de Joncheere indicated that direct-to-consumer advertising of prescription medicines is not in accordance with the principles of the WHO Ethical Criteria and cautioned against changing legislation without strong evidence that it will benefit public health.

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.

"... 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."

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.

The Ethical Criteria as a guide

The WHO *Ethical Criteria* were adopted by the Member States at the World Health Assembly held in 1988. In the document, promotion is defined 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."

It goes 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."

"We cannot expect companies to provide information on all of the treatment options."

Based on the *Ethical Criteria*, WHO believes the EU and any country must be cautious in changing legislation where there is considerable potential for harm and little if any documented evidence of benefit.

How to optimise drug information

For improving drug information there are a number of actions to be taken, including:

- operationalising definitions on promotion, advertising and information. There must be more clarity on what constitutes what.
- examining the role of the Internet as a medium for information. While some see the Internet as a problem or threat, it can also provide an opportunity.
- determining what information consumers need: about a disease, about a product, and about comparative information on treatment options. Different people have different needs. It is important for people to know about all of their available options, but we cannot expect companies to provide information on all of the treatment options.
- taking on a more pro-active role for health services in providing information to patients
- finding ways to use the media as sources of health information

National health authorities need to get the right information out to the public. This is often not happening. Problems are often related to the fact that they are not generating enough quality information about medicines or that they are prioritising other things.

At the meeting on drug promotion held late last year - participants from health authorities reviewed the EU legislation, but found that definitions of drug promotion and information varied by country. Implementation at the national level can be quite difficult to implement or enforce. This has led to substantially different enforcement regimes. Most countries have different ways of regulating and controlling promotion than their neighbouring states. They often also have different perceptions on priorities. Many are hindered by a lack of resources to carry out vigorous implementation and regulation of existing laws governing promotion and advertising. Considerable difficulties were reported in dealing with the often “hidden” advertising (disease symptom-oriented material, TV news programmes, etc) and the targeting areas of “undertreatment” of certain diseases.

The meeting concluded that there is a need for increased networking, communication and information exchange among the health authorities. They said Ministries of Health and health insurers must have an active policy on rational drug use and consumer information. Governments must also address existing gaps in legislation (setting boundaries, monitoring phase IV studies, and the levels of inducements). They must also collaborate with the mass media in a way that benefits public health and should raise awareness on the issue among the general public and health professionals. They should also monitor the relationship between health professionals and the industry and its consequences on rational drug use.

Presentation 9: Direct-to-consumer advertising and patient information

By Mr. Willy Palm, Director, Association Internationale de la Mutualite (AIM), Belgium

Social health insurers in the European Union have great concerns about the impact of direct-to-consumer advertising in Europe. In this contribution, Willy Palm, director of a large international network of insurers, explains how the introduction of this type of advertising could damage public health while increasing costs for both consumers and national health budgets.

AIM comprises 45 national federations of statutory and voluntary health insurance funds. It focuses on three elements of pharmaceuticals. The first one is quality, of the product (safety, efficacy) but also of its use and prescription. AIM also considers financial access to medicines, that is, are they available at socially affordable prices for patients and social protection services? Finally, it examines drugs' clinical and economic effectiveness.

Drug promotion and direct-to-consumer advertising don't seem to bring any benefit in these three respects. On the contrary, they seem to hamper these objectives. For example, direct-to-consumer advertising is likely to:

- lead to inappropriate prescribing and use
- provide misleading information (overstating the efficacy of the product and minimising or not disclosing risks and side effects)
- promote the use of newer, more expensive drugs that often provide no added therapeutic value
- increase the pharmaceutical bill for patients and social protection systems (insurers).

DTCA as part of a larger strategy

AIM believes that direct-to-consumer advertising is part of a larger marketing strategy aimed at influencing prescribers' behaviour. For prescription drugs, the prescriber is the target. Although this type of advertising is forbidden in Europe, direct influencing of prescribing behaviour is already operating through different channels, such as the visits that manufacturers' representatives make to doctors and hospitals, their dispensing of free product samples, companies' advertising in the medical press, and the industry's organisation of "educational" events.

"AIM believes that direct-to-consumer advertising is part of a larger marketing strategy aimed at influencing prescribers' behaviour."

It is difficult to know how much money is spent on these kinds of activities. According to the pharmaceutical trade journal *Scrip*, French pharmaceutical companies spent US\$ 2.1 billion in 1997 or 14% of sales on this type of activity. In the US, research suggests that spending on promotional activities represented approximately 13.2% of total sales in 2000. And an

international survey found that typical brand-based drug companies themselves estimate that they spend an average of 35% of sales on promotion around the world.

Spending such large amounts on promotion indicates that drug promotion is effective in influencing prescribing behaviour. Since public policies, aimed at rationalising health care delivery, are trying to produce incentives for prescribers to better monitor what they prescribe, direct-to-consumer advertising is the missing link to put further pressure on prescribers.

Many doctors in the US claim that their ability to practice evidence-based medicine is being undermined by direct-to-consumer advertising. A study carried out in 1999 among primary doctors in the states of Ohio and Pennsylvania found that most felt under pressure by patients to prescribe promoted drugs. Between 30-36% admitted that they gave in to this pressure. Significant in this respect is that prescriptions for the top 50 of the most heavily promoted drugs in the US rose by 24.6% from 1999 to 2000, compared with the 4.3% increase for all other prescription drugs (six times the rate of the rest of the market). Another study by the National Centre for Health Statistics and Centre for Disease Control and Prevention found that between 1997 and 1999 80% of new and heavily promoted medicines appeared among the top 20 most prescribed drugs.

The effect on costs

This means that direct-to-consumer advertising pays its way. Indeed, when looking at sales figures, these 50 most promoted drugs represented 31.3% of sales in 2000 and were responsible for almost half of the sales increase compared to 1999 (meaning that their sales increased 2.3 times the rate of all other drugs). Consequently, 22 of the 50 most heavily promoted drugs were also found in the top 50 of the best-sold prescription drugs in 2000. It is important to note when assessing the Commission's proposals on Article 88 that products for treating asthma and diabetes were found among the best represented products in these lists.

The US studies cited here give a clear indication that direct-to-consumer advertising in Europe would lead to a further increase in pharmaceutical expenditure. Even without direct-to-consumer advertising, pharmaceuticals are among the fastest rising item in the health care budget of all European countries.

Protecting health or pushing prescribing?

To conclude, AIM's members believe that direct-to-consumer advertising is not in the public interest and does not help inform the patient. The idea of health literate citizens, making informed choices, is ideal but not realistic, at least not for the vast majority of the population. It seems quite obvious that most patients will continue to rely upon secondary sources to help them make choices about the best treatment, in which medicines are only a part of the possible solution. Cutting out the advice of the "middlemen" (the doctor and pharmacist) raises the prospect of inappropriate use.

"The EC Treaty states in Article 152 that all Community policies should ensure a high level of health protection. We do not think the current Commission's proposal on Article 88 meets this standard."

Information to patients (and prescribers) should be independent, objective and comparative. We would prefer that the Commission take on initiatives to promote and fund such information sources.

The EC Treaty states in Article 152 that all Community policies should ensure a high level of health protection. We do not think the current Commission's proposal on Article 88 meets this standard.

**Presentation 10: The role of health professionals in providing information on medicines
By Flora Giorgio, Secretary-General, Pharmaceutical Group of the European Union
(PGEU), Belgium**

As health information becomes more available from a variety of sources, Flora Giorgio emphasised the continuing need for local health professionals to provide solid advice and counseling about medicines and health directly to patients. Unlike advertising or Internet information, health professionals can use their training and patient knowledge to offer a broader spectrum of possible treatments and explain their consequences.

What is information on medicines from a health professional's point of view? Informing includes advising patients about the availability of new medical treatments. It also means advising not to take any medicine but rather to follow another course of action, such as a lifestyle change, if necessary. Informing also means explaining why

"Informing includes advising patients about the availability of new medical treatments. It also means advising not to take any medicine but rather to follow another course of action, such as a lifestyle change, if necessary. Informing also means explaining why one

one medicine would be more appropriate than another. But much more often, informing means ensuring that the patient understands how and when to take a particular medicine and why, with certain treatments, precautions are very important. In every case, however, the final objective is always to ensure that patients have confidence in their treatment and have all the necessary information to comply with it.

Information on medicines covers several aspects of the duties of a health professional. As a pharmacist myself, and representing community pharmacists, I have to underline the specific role my profession plays in informing citizens about medicines. This special role is made possible through the combination of the training we receive and the well distributed network of community pharmacies. Community pharmacists are readily accessible, can be consulted without an appointment, and they have easy access to reliable and regularly updated information.

As a supplier of medicines the pharmacist is the final link between the patient and the drug. This is a privileged and important position. The day-to-day interaction with the patient is at the core of all health professionals' activities. And I am convinced that this direct interaction is the most appropriate way to guarantee a successful treatment - and to best respond to the needs of citizens. Through our day-to-day contact, in a relatively informal environment, pharmacists can build a direct relationship with patients that enables them to respond well to their needs and particularly to provide the information they seek

However, during the past few years, these needs have changed. Patients and all citizens seek more information about their health. How should we respond to these changes? One of the most

often suggested “solutions” is the Internet. The challenge health professionals now face is how to combine direct, personal interaction with the new “global media.” More and more pharmacists, health care providers and professional bodies are addressing this new challenge and, in my view, handling it rather successfully.

There are a number of information projects taking place with the PGEU that illustrate this. The first project is called *sundhead.dk* (health.denmark). It is a health portal developed by the Danish Pharmacists Association in collaboration with other professional bodies and patient organisations. The portal is set up to provide only authorised information, be independent from advertising, guarantee high quality and security of services.

A second example is a health portal developed by the Spanish Pharmacists Association. Called “Portalfarma”, it shares similar principles with the Danish model. In this case, the project is totally owned by pharmacists who guarantee the quality of the information provided. Some of its services include health news, information on medicines, and pharmaceutical publications. These are only two examples of the trend of developing additional means to provide information about health and medicines to consumers.

“When we are sick, and have a cold, headache or any other health problem, our computer is not likely to be our first choice contact when seeking advice or counseling.”

When we are sick, and have a cold, headache or any other health problem, our computer is not likely to be our first choice contact when seeking advice or counseling. The vital network of health professionals on the ground, around the corner, is there to respond to the needs of sick people, by proposing solutions to their problem and seeking to ensure a high quality treatment outcome.

Health professionals are continuously developing their role as providers of information on medicines and on health using all appropriate media. However, I believe it is important that the possibility of having a “traditional” face-to-face consultation with a healthcare professional should not be placed at risk in the name of trendy e-fashion.

Closing Remarks

By Dr. Anita Hardon, Department of Medical Anthropology, University of Amsterdam, The Netherlands

In her summation about the meeting's themes and conclusions, Anita Hardon emphasised that support for the Commission's proposal was thin, if not non-existent among most of the stakeholders attending the symposium. She pointed out the positive and negative aspects of direct-to-consumer advertising mentioned during the day. Her summary also highlighted concerns associated with the proposal and suggested future steps for action to advocate for better drug information for the public.

One of the reasons HAI-Europe and EPHA decided to organise this meeting was because of many people's growing concern about the US experience with prescription medicine advertising. Many public health advocates fear that Europe will inherit a similar situation if the EU's advertising regulation is relaxed to allow drug companies to provide consumers with information about medicines for three specific health conditions.

Reasons to favour the Commission's proposal

Proponents of the Commission's proposal say that this kind of advertising could benefit consumers. They point out that in fact, US-originated, direct-to-consumer advertising is already available on US-based websites. They say that European consumers should have information about medicines in their own languages and directly from manufacturers so that they do not have to rely on foreign sites or unscrupulous sources. Some say that direct-to-consumer advertising can raise awareness about diseases and can increase treatment compliance. Proponents believe that this kind of advertising can complement other information methods, and because the doctor must still prescribe medicines, the risk of possible harm is limited.

Objections to DTCA

Many opponents of the current proposal believe it is just the first step, a "foot in the door" to change the advertising ban and eventually bring in US-style, direct-to-consumer advertising in Europe. Speakers at this symposium have suggested that this kind of advertising will lead to increased drug costs and threaten equitable access to medicines. They also pointed out that consumers are ill equipped to judge the value of the information given in drug promotion and say that such promotion can mislead the public about the potential harm of such potent medicines.

We have heard that there is little if any documented evidence of benefit from this kind of advertising and growing evidence of possible harm. Speakers have also highlighted the fact that advertising always plays up benefit and minimises risk, which is not the balanced type of information that patients need. Presenters stated that companies cannot be expected to provide a full range of treatment options in their information to consumers. In addition, the EFPIA representative and others suggested that companies may fight the Commission's proposal to limit this type of "information provision" to only three health conditions due to unfair competition

if, in fact, the proposal is adopted. Finally, the representative from the WHO clearly stated that direct-to-consumer advertising is in violation of the WHO's *Ethical Criteria for Medicinal Drug Promotion*, a document endorsed in 1988 by all Member States.

Direct-to-consumer advertising was described as part of comprehensive marketing plans now being advanced by the industry. Participants at the symposium related how direct-to-consumer advertising is already common practice in a number of EU Member States and Canada as part of larger promotion campaigns despite the fact that it is prohibited. Currently, there seems to be a lack of mechanisms and political will to ensure adherence to existing legislation. And companies that do break the law hardly receive any sanctions for their infractions.

Who wants DTCA?

Today, no one, except the representative from DG-Enterprise actually defended the Commission's proposed changes to the advertising regulation. Although the representative insisted that the proposals had been made in response to "expectations expressed by patient groups", patient groups represented at the symposium

"Today, no one, except the representative from DG-Enterprise actually defended the Commission's proposed changes to the advertising regulation."

said they had not been consulted about the proposal. The representative from the European research-based pharmaceutical industry stated during the discussion that his association has no position on the issue. In addition, national health policy-makers said they want to strengthen EU legislation rather than weaken it and the Dutch government representative stated that his government plans to vote against the proposal in its present form. Even the representative from the G10 speaking today said that that group was not involved at all in the drafting of the proposal. All of the different organisations and sectors represented at the meeting appeared to oppose the proposal. Because there was no real conflict among expressed opinions, the meeting moved on to the next step: what to do next?

The next steps

Consumers and patients want and need information about medicines and health. The public needs access to balanced, relevant, up-to-date, accurate and unbiased information about drug and non-drug treatments. As we heard from patient advocates at this symposium, they want information on all treatment options, including non-medical interventions. This information must be presented in a realistic way that is relevant to their daily lives. The evidence suggests that an insufficient amount of this type of information is now available to the public.

There is an obvious need to address gaps in legislation on advertising to cover new "gray areas" such as prescription-medicine advertising to the public, post-marketing phase IV studies, and the levels of inducements offered to prescribers.

The Commission's proposal on Article 88 is a serious one and should be considered as such despite the fact that public support for its provisions is not easy to find.

"...There is a clear need to develop European consumer information initiatives and to strengthen legislation controlling drug promotion and empowering its implementation at the national level."

On the short term, public health groups should encourage national level debates on the proposal and its possible repercussions. Groups should also contribute to an informed European Parliament and European Health Council debate. On the longer term, there is a clear need to develop European consumer information initiatives and to strengthen legislation controlling drug promotion and empowering its implementation at the national level. In addition, this proposal has also raised serious questions about the Commission's lack of transparency in decision-making.

Annexes:

Programme

9.30 - 9.40

Ms. Margaret Ewen, Co-ordinator Health Action International (HAI) Europe, **and Ms. Genon Jensen**, General Secretary European Public Health Alliance (EPHA)

Welcome on behalf of the organisers

9.40 - 9.45

Ms. Danielle Bardelay, Co-editor New Drug Section, *La revue Prescrire*, France, and representative of the International Society of Drug Bulletins (ISDB)

Introduction

Keynote speakers

9.45 - 10.10

Mr. Charles Medawar, Director Social Audit Ltd., United Kingdom

The politics of direct-to-consumer promotion of prescription medicines

10.10 - 10.35

Ms. Barbara Mintzes, Centre for Health Services and Policy Research, University of British Columbia, Canada

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

10.35 - 11.00

Coffee and tea

11.00 - 11.25

Prof. Angela Coulter, Chief Executive Picker Institute, United Kingdom, and member of G10 Medicines group

Information for shared decision-making in medicine-taking

11.25- 11.50

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

Direct-to-consumer advertising or direct-to-consumer information on pharmaceuticals?

12.00 - 12.30

Discussion

12.30 - 13.30

Lunch

13.30- 16.40

PANEL DISCUSSION

Facilitator: **Dr Philip Brown**, Publisher, SCRIP, United Kingdom

13.30- 15.15

5 minute presentations by panel members:

Mr. Brian Ager, Director General European Federation of Pharmaceutical Industries and Associations (EFPIA), Brussels

The pharmaceutical industry's perspective on providing prescription drug information directly to EU consumers

Mr. Rob Camp, European AIDS Treatment Group, Germany

Patients' medicine information needs

Ms. Clara MacKay, Principal Policy Advisor Consumers' Association, United Kingdom

Consumers' medicine information needs

Mr Kees de Joncheere, Regional Adviser for Pharmaceuticals and Technology, World Health Organisation, Regional Office for Europe, Denmark

Providing prescription medicine information to consumers: Is there a role for direct-to-consumer promotion: A WHO perspective

Mr. Willy Palm, Director Association Internationale de la Mutualité (AIM), Belgium

Direct-to-consumer advertising and patient information

Ms. Flora Giorgio, Secretary-General Pharmaceutical Group of the European Union (PGEU), Belgium

The role of health professionals in providing information on medicines

15.15 - 15.40

Coffee and tea

15.40- 16.40

PANEL DISCUSSION continued

16.40- 16.55

Prof. dr. Anita Hardon, Department of Medical Anthropology, University of Amsterdam, The Netherlands

Closing remarks

16.55- 17.00

Ms. Danielle Bardelay

Closing of the day

List of participants

Brian Ager	Director General EFPIA (European Federation of Pharmaceutical Industries and Associations) Belgium
Peter Aka	Co-ordinator NARUD (National Association for the Rational Use of Drugs) Cameroon
Jan Albinson	KILEN (Consumer Institute for Medicines and Health) Sweden
Danielle Bardelay	Prescrire International France
Edward Baumgartner	World Markets Research Centre United Kingdom
Nils Behrndt	European Commission, DG Enterprise/F/2 Belgium
Annet Beukema	De Consumentenbond (Dutch Consumers' Association) The Netherlands
Thomas Bols	GPC International Belgium
Marie-Louise Bouffioux	Inspection Générale de la Pharmacie Ministerie de la Santé Publique (Ministry of Public Health) Belgium
Philip Brown	Executive Chairman, PJB Publications Ltd. Editor, <i>SCRIP</i> United Kingdom
Catriona Burness	Assistant to MEP Catherine Stihler European Parliament Belgium
Thomas Burkant	Assistant to MEP Rosemarie Müller European Parliament Belgium
Brigitte Calles	La Mutualité Française France
Rob Camp	European AIDS Treatment Group Germany
Alan Cassels	Health Action International Canada
Fabrice Clouzeau	SIDA Info Service/ European Network of Aids Helplines France

Dorette Corbey	Member of the European Parliament Belgium
Angela Coulter	Chief Executive The Picker Institute Europe United Kingdom
Annette Dumas	Merck Sharp & Dohme Belgium
Rose de Groot	Health Action International (HAI Europe) The Netherlands
Kees de Joncheere	Regional Advisor for Pharmaceuticals and Technology WHO Regional Office for Europe Denmark
Charlotte de Roo	BEUC (The European Consumers' Organisation) Belgium
Carole Défossé	EPHA (European Public Health Alliance) Belgium
Ben Duncan	British Medical Association Belgium
Constanze Eidam	Europa Journal Belgium
Rodney Elgie	Gamian – Europe United Kingdom
G. Essers	Stichting DGV (Doelmatige Geneesmiddelen Voorziening (rational provision of medicines)) The Netherlands
Margaret Ewen	Co-ordinator Health Action International (HAI Europe) The Netherlands
Carlos Pracht Ferrer	Confederación Estatal de Pacientes en España Spain
Sarah Fogg	PHARM Committee Australia
Els Geeraerts	Pharmaceutical Inspectorate Belgium
Flora Giorgio	PGEU (Pharmaceutical Group of the EU) Belgium
Jackie Glatter	Senior Public Affairs Officer The Consumers' Association United Kingdom
Fiona Godfrey	European Respiratory Society Germany
Jannemieke Hanhart	Health Action International (HAI Europe) The Netherlands

Anita Hardon	Professor, Medical Anthropology Unit Faculty of Social and Behavioural Sciences University of Amsterdam The Netherlands
Hubert K. Hartl	State Secretary for Health Austria
Lisa Hayes	Health Action International The Netherlands
Arne Heimdal	EFA (European Federation of Asthma and Allergy Associations) Norway
Andrew Herxheimer	ISDB (International Society of Drug Bulletins) United Kingdom
Ann Heylens	Belga Belgium
Hilda Hoepman	Inspectorate of Healthcare IGZ Sector Reclamatoezicht (Advertising oversight) The Netherlands
Luc Hutsebaut	Lands Bond Christelijke Mutualiteiten Brussels
Génon Jensen	EPHA (European Public Health Alliance) Belgium
Beryl Keeley	Head of Advertising and Product Information Medicines Control Agency United Kingdom
Miriam Kroeze	CBO (Institute for Quality in Healthcare) The Netherlands
José Lalloum	LOGOS Belgium
Wanyu Louis Lambiv	NARUD (National Association for the Rational Use of Drugs) Cameroon
Carole Lochman	Novartis Pharma Switzerland
Clara MacKay	Principal Policy Advisor The Consumers' Association United Kingdom
Luis Matias	ANF (National Association of Pharmacies) Portugal
Maya Matthews	ENHPA (European Network of Health Promotion Agencies) Belgium
Charles Medawar	Social Audit Ltd. United Kingdom
Colin Meek	Consultant to the Royal Pharmaceutical Society of Great Britain

Astrid Meij	Scotland Inspectorate of Healthcare IGZ Sector Reclamatoezicht (Advertising oversight) The Netherlands
Barbara Mintzes	University of British Columbia Centre for Health Services and Policy Research Canada
Claudia Montenegro	International Relations Office ANF (National Association of Pharmacies) Portugal
Hubert Morsink	The Netherlands
Marybeth Morsink	Health Action International (HAI Europe) The Netherlands
Lyndsay Mountford	Public Health Directorate Health and Consumer Protection European Commission Luxembourg
Ulla Närhi	National Agency for Medicines Finland
Eileen Neilsen	Royal Pharmaceutical Society of Great Britain United Kingdom
Gil-Sang Nho	Korean Mission to the EU Belgium
Olle Nordberg	Dag Hammarskjöld Foundation Sweden
Peter O'Donnell	European Report Belgium
Willy Palm	Director AIM (Association Internationale de la Mutualité) Belgium
Matteo Pellegrini	Assistant to the Environment, Safety and Health Policy Advisor BEUC (The European Consumers' Organisation) Belgium
Erica Poot	European Federation of Pharmaceutical Industries Belgium
Jörn-Jakob Röber	LOGOS Belgium
Tamsin Rose	EPHA (European Public Health Alliance) Belgium
P. Rosier	CBO (Institute for Quality in Healthcare) The Netherlands
Sergio Pracht Ruiz	Confederación Estatal de Pacientes en España Spain

Regina Sauto Arce	Information and Policy Officer EPHA (European Public Health Alliance) Belgium
Armin Schafberger	Deutsche AIDS -Hilfe e.V. Germany
Margot Schmitz	GroenLinks in the EU The Netherlands
Kris Schutysor	HOPE (Hospitals for Europe) Belgium
Diana Smith	EPHA (European Public Health Alliance) Belgium
Kris Soenen	Projekt Farmaka Belgium
Otto Spranger	Osterreichische Lungen Union Austria
Jiri Stránský	Advisor of First Vice Minister Ministry of Health Czech Republic
Martijn ten Ham	Senior Advisor, International Affairs Ministry of Health, Welfare and Sports The Netherlands
Sue Thomas	Royal College of Nursing United Kingdom
Emmanuel Trenado	AIDES (Association de Lutte contre la SIDA) France
Erkka Valovirta	President EFA (European Federation of Asthma and Allergy Associations) Finland
Theo van Dam	LSD (Dutch National Interest Group of Drug Users) The Netherlands
Ann van den Broucke	General Pharmaceutical Inspectorate Belgium
Pascale van den Heede	Mental Health Europe Belgium
Gudrun van de Walle	University of Ghent, Faculty of Law Vakgroep Strafrecht en Criminologie Belgium
J.W.F. van Mil	Van Mil Consultancy The Netherlands
Hein Verkerk	GroenLinks in the EU European Parliament Belgium
Robert Vierhout	UEMO (European Organisation of General Practitioners)

M. Visscher	Belgium Assistant to MEP Dorette Corbey European Parliament
Lauri Vuorenkoski	Belgium STAKES (National Research and Development Centre for Welfare and Health) Finland
Christian Wagner	BUKO Pharma – Kampagne Germany
Arnaud Wasson-Simon	AIDES (Association de Lutte contre la SIDA) France
Lena Westin	KILEN (Consumer Institute for Medicines and Health) Sweden
Léon Wever	Director of Pharmaceutical Affairs and Medical Technology Ministry of Health, Welfare and Sports The Netherlands
Mia Willems	De Consumentenbond (Dutch Consumers' Association) The Netherlands
Jette Willer	Ministry of Health and the Interior Denmark
Marsha Williams	National Asthma Campaign United Kingdom
Paul Woods	AstraZeneca United Kingdom
Ghazan Zok	Novartis Belgium

Commission's proposed change to Article 88

Article 88 is replaced by the following:

"Article 88

1. Member States shall prohibit the advertising to the general public of medicinal products which:

(a) are available on medical prescription only, in accordance with Title VI;

(b) contain substances defined as psychotropic or narcotic by international convention, such as the United Nations Conventions of 1961 and 1971.

2. The communication of information on certain medicinal products is authorised under strict conditions in the interest of patients in order to respond to their legitimate needs. This provision applies to product information appended to the marketing authorisation as well as to additional related information.

By way of derogation from the prohibition in paragraph 1(a), Member States shall authorise the dissemination of information relating to certain medicinal products authorised in the framework of the affections set out below, in order to respond to the expectations expressed by the patients' groups:

This dissemination of information shall be carried out on the following conditions:

- a) the medicinal product shall be authorised and prescribed for the treatment of any of the following conditions:
 - acquired immune deficiency syndrome;
 - asthma and chronic bronchopulmonary disorders;
 - diabetes;
- b) the information disseminated complies with the principles set out in this Title;
- c) implementation of this paragraph shall be conditioned by the setting-up of self-regulatory procedures by the pharmaceutical industry at Member State level;
- d) the information and its dissemination shall be in conformity with the principles of good practice which are adopted, after consultation with interested parties, in conformity with the procedure set out in Article 121(2).
- e) in order to monitor the implementation of the principles of good practice referred to above:
 - the additional information related to the medicinal products shall be notified to the Agency. If the Agency does not object within thirty days following this notification, the information shall be deemed to be accepted;

- the Agency shall coordinate of the monitoring of the information on the medicinal products authorised in conformity with this Directive, in particular through the setting-up of a data base;
- on a yearly basis, the Agency shall prepare a report on the application of these principles of good practice;
- f) implementation of this paragraph shall be the subject of an evaluation and a detailed report no later than [date]. The Commission shall propose any changes required to improve its implementation.

3. Medicinal products may be advertised to the general public which, by virtue of their composition and purpose, are intended and designed for use without the intervention of a medical practitioner for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist, if necessary

4. Member States shall be able to ban, on their territory, advertising to the general public of medicinal products the cost of which may be reimbursed.

5. The prohibition contained in paragraph 1 shall not apply to vaccination campaigns carried out by the industry and approved by the competent authorities of the Member States.

6. The prohibition referred to in paragraph 1 shall apply without prejudice to Article 14 of Directive 89/552/EEC.

7. Member States shall prohibit the direct distribution of medicinal products to the public by the industry for promotional purposes."

HEALTH ACTION INTERNATIONAL (HAI) EUROPE
and the
EUROPEAN PUBLIC HEALTH ALLIANCE (EPHA)

JOINT STATEMENT ON THE

**PROPOSED RELAXATION OF THE EU BAN ON
DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION MEDICINES**

February 4, 2002

Background: On January 10, 2002, researchers, consumer, patient, WHO and pharmaceutical industry representatives, drug regulators, health professionals, insurers and others met to discuss the question: **Providing Prescription Medicine Information to Consumers: Is there a role for Direct-to-Consumer Advertising (DTCA)?** This meeting was held to discuss the European Commission's proposed amendment to Article 88 of the Directive on the Community Code relating to Medicinal Products for Human Use. This proposal will, for a five-year trial period, permit pharmaceutical companies to provide consumers with promotional information on prescription only medicines authorised to treat HIV/AIDS, asthma and diabetes. The concern is that this proposal will likely invite full-scale DTCA in the EU. DTCA of prescription medicines is currently banned in every industrialised country in the world, with the exception of the United States and New Zealand.

This meeting clarified a number of points:

1. **PEOPLE WANT OBJECTIVE INFORMATION ON PRESCRIPTION MEDICINES.** Everyone emphatically agreed that the public needs access to balanced, comparative, relevant, up-to-date, accurate and unbiased information on pharmaceuticals and non-pharmaceutical treatments but only DG Enterprise defended their proposal.
2. **NO ONE CLAIMS RESPONSIBILITY FOR THE COMMISSION'S PROPOSAL.** No one could say who exactly is driving this proposal. Specifically at this symposium:
 - DG Enterprise said that this proposal was based on expectations expressed by patient groups but it could not name a single patient group supporting this proposal. Patient groups attending said that they had not been consulted, did not support this proposal and promotional information provided by the drug industry would not meet their information needs.

- The director of the European Federation of Pharmaceutical Industries and Associations (EFPIA) claimed that they have no position on DTCA and representatives from AstraZeneca, Novartis and Merck Sharp & Dohme who attended offered no comment.
- It became clear that some national health policy makers (such as the Dutch Ministry of Health) reject DTCA but want to improve the quality and accessibility of information about medicines (which does not require any change in legislation).

1. **THERE IS NO EVIDENCE THAT THE COMMISSION'S PROPOSAL ON ARTICLE 88 WILL BENEFIT PUBLIC HEALTH.** Consumer advocates and public health officials all spoke strongly that they believe that the proposal to allow promotional information will not result in the provision of quality information to consumers. It was emphasised that the likely outcome of this proposal will encourage unsafe or unnecessary use of medicines and lead to a US-style spiral of unsustainable health care spending. This proposal does not adhere to the EU's precautionary principle of first "doing no harm".
2. **THERE IS EVIDENCE THAT DIRECT TO CONSUMER ADVERTISING OF PRESCRIPTION MEDICINES THREATENS PUBLIC HEALTH.** Based on the experience of DTCA in the US and New Zealand, advertising of prescription medicines is a grave threat to public health and puts the profits of the pharmaceutical industry ahead of public health. Considering nearly 20 years experience of DTCA in the US, it clearly places undue stress on public health budgets, increases the amount of misleading and unhelpful health information and increases the inappropriate and unnecessary use of medicines. Experience in the US has shown that enforcement of regulations controlling DTCA of pharmaceuticals is difficult and costly, and that violations are common mostly due to advertisers minimising risk information and exaggerating benefits.

RECOMMENDATIONS TO THE EU PARLIAMENT/COUNCIL/COMMISSION:

1. **Reject this proposal in its current form,** as it does not uphold the Community's Treaty obligation to ensure a high level of public health in all of its activities as set out in article 152 of the EU Treaty. Neither does it conform to the WHO's Ethical Criteria for Medicinal Drug Promotion as agreed on by all WHO member states in 1988. It is not necessary to change Article 88 to ensure that people get quality information on medicines. The changes proposed to this article will likely invite full-scale DTCA for prescription medicines in Europe with potentially devastating public health consequences. This will have a global impact that threatens to strain health systems and budgets in Eastern and Central Europe, and developing countries.
2. **Vigorously enforce the present legislation** with review, sanctions, and thorough monitoring of promotion to health professionals and the general public. Better enforcement mechanisms including strong inter-jurisdictional co-operation on the

monitoring of all means of promotion of medicines will prevent abuses and improve the overall quality of medicine information for consumers and prescribers.

3. Develop a robust consumer information and education strategy to ensure that people receive and can use quality, objective information on medicines.

Specifically,

- **Improve the quality of patient information leaflets to make them more reader-friendly, comprehensive, and understandable.**
- **Encourage the provision of independent and comparative information about medicines for health professionals and the public. Furthermore, promote regular independent testing of the effectiveness of medicine information in educating and informing professionals and the public.**
- **In the long term develop ways of teaching people the basic principles underlying rational therapies, and critical appraisal skills**

EUROPE

- Health Action International - Europe
- European Public Health Alliance [this statement is made on behalf of EPHA but doesn't necessarily reflect the position of all members]
- Act Up Paris
- Act Up Toulouse, France
- AIDES, association de lutte contre le SIDA, Pantin, France
- AGIHAS (PLWHA Support Group), Latvia
- Association Mieux Prescrire, France
- Boletín Terapéutico Andaluz, Spain
- BUKO Pharma-Kampagne, Germany
- Consumers' Association, United Kingdom
- Der Arzneimittelbrief, Germany
- Drug Information Centre, State Medicines Control Agency, Ministry of Health, Lithuania
- European Federation of Asthma and Allergy (Patient) Associations
- Farmacologiche "Mario Negri", Milan, Italy
- Farmakoterapeutice informace bulletin, Czech Republic
- Fundacis Institut Catala de Farmacologia, Spain
- Groupe de Recherche et d'Action pour la Santé, Roux, Belgium
- The Insulin Dependent Diabetes Trust (IDDT) United Kingdom
- International Society of Drug Bulletins
- KILEN - Consumer Institute for Medicines and Health, Sweden

- Projekt Farmaka, Belgium
- La revue Prescrire, France
- Sida Info Service, France
- Social Audit Ltd, United Kingdom
- Standing Committee of European Doctors
- TRT-5 (collective of 8 AIDS organizations), France
- Professor Björn Beermann, MDPHDMPA, Sweden
- Professor Albano Del Favero, Italy
- Dr Markus Fritz, Head, Swiss Drug Information Centre, SDIC/SMI, Switzerland
- Professor Dr. Anita Hardon, University of Amsterdam, The Netherlands
- Dr Andrew Herxheimer, DIPEX (Database of Individual Patients' Experiences of Illness), United Kingdom
- Dr Gianni Tognoni, Dept. of Cardiovascular Research, Istituto di Ricerche, Italy
- Professor Giampaolo Velo, Istituto Di Farmacologia, Italy
- Corinne Zara, Spain

OTHER REGIONS

- Breast Cancer Action, USA
- National Women's Health Network, USA
- Prevention First Coalition, USA
- Public Citizen's Health Research Group, Washington, USA
- The Center for Medical Consumers, New York, USA
- Warren Bell, BA MD CM CCFP, British Columbia, Canada
- Breast Cancer Action Montreal, Canada
- Alan Cassels, co-Chair, PharmaWatch, Canada
- Centre of Excellence in Women's Health, Dalhousie University, Halifax, Canada
- Consumers Association, Canada
- Assoc. Professor Joel Lexchin MD, School of Health Policy and Management, York University, Toronto, Canada
- Barbara Mintzes, Centre for Health Services and Policy Research, University of British Columbia, Canada
- Working Group on Women and Health Protection, Montreal, Canada
- Sharon Batt, Elizabeth May Chair in Women's Health and the Environment, Maritime, Canada
- Accion Internacional para la Salud, America Latina y el Caribe
- Health Action International - Asia/Pacific
- Healthy Skepticism, Australia
- Linda Curling, QA Manager (Pharmacist), Triomed (Pty) Ltd, Pinelands, South Africa
- Andy Gray, Senior Lecturer, Dept. of Experimental & Clinical Pharmacology. Nelson Mandela School of Medicine, Natal, South Africa
- P. Randles, Link Hills Pharmacy, Waterfall, South Africa