The pharmaceutical industry tries to wrest control over health information in the EU

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Medicines in Europe Forum (MiEF). The Medicines in Europe Forum, launched in March 2002, covers 12 European member states. It includes more than 70 member organizations representing the four key players on the health field, i.e. patients groups, family and consumer bodies, social security systems, and health professionals. Such a grouping is unique in the history of the EU, and it certainly reflects the important stakes and expectations regarding European medicines policy. Admittedly, medicines are no simple consumer goods, and the Union represents an opportunity for European citizens when it comes to guarantees of efficacy, safety and pricing.

HEALTH INFORMATION

A clear division of roles is needed to protect public health

Pharmaceutical companies have initiated many campaigns to advertise medicines directly to patients and consumers. These are varied and recurrent and take many different forms, from lobbying at all levels of European and national policy development, to setting up convenient "patient groups", and inventing services and campaigns such as so-called "compliance support" programmes to promote patients' adherence to therapy.

Everyone has a role to play. The various actors involved in health care are easily identified: patients/citizens, either individually or collectively through patients' associations, health professionals, government agencies, and the healthcare industries. The citizens who become patients due to a temporary or permanent deterioration in their health are at the centre of this equation. Even when they are constrained by illness, their ability to make treatment decisions must be preserved. It is up to patients/citizens to choose what they consider to be the most suitable care and to question treatment decisions whenever necessary, depending on the disease's progression, their own response to their evolving condition, their priorities at a given point in time, etc.

Patients must safeguard the freedom to act on their health, to decide when to take a drug or not, or to pursue or stop treatment. In order to make these decisions, they need access to impartial information on what they can and cannot expect from treatment.

Associations of patients that are set up by patients themselves and are able to resist intrusion by the pharmaceutical industry can help to provide appropriate information.

The role of health professionals is to act as assistants and advisors, to encourage patients to exercise this freedom and to provide support in a respectful manner, while being closely attuned to patients' social and cultural circumstances and health condition. It is their professional responsibility to supply patients with the comparative information they need to make up their own minds.

It is up to government agencies to enable health professionals to fulfil this task as well as possible by facilitating, among other things, access to objective information on illnesses and their treatment. To do this, they must remain impervious to the pressures of specific interest groups demanding to be allowed to disseminate their own "communications", and thus maintain a focus on public health and the public interest. It is up to them as well to guarantee equal access to all to drugs that are effective and thoroughly evaluated.

It is up to the healthcare industries to produce drugs and medical devices, and make them available to health professionals and patients, which have a well-established balance of benefit versus harm and safe administration procedures.

A clear division of roles is needed to protect public health. Confusions of roles and conflicts of interest between these different actors are likely to damage the quality of care. At risk, ultimately, is patients' freedom to make the best possible treatment choices depending on their individual needs.

That is why the Medicines in Europe Forum together with the International Society of Drug Bulletins, Health Action International Europe and others are resolutely committed to this struggle to defend public health.

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The Medicines in Europe Forum (MiEF), launched in March 2002, covers 12 European Member States. It includes more than 70 member organizations representing the four key players on the health field, i.e. patients groups, family and consumer bodies, social security systems, and health professionals. Such a grouping is unique in the history of the EU, and it certainly reflects the important stakes and expectations regarding European medicines policy. Admittedly, medicines are no simple consumer goods, and the Union represents an opportunity for European citizens when it comes to guarantees of efficacy, safety and pricing.

The International Society of Drug Bulletins (ISDB), founded in 1986, is a world wide Network of bulletins and journals on drugs and therapeutics that are financially and intellectually independent of pharmaceutical industry. Currently, their members include 57 members in 35 countries around the world. More info: www.isdbweb.org

Health Action International (HAI) is an independent global network of health, consumer and development organisations working to increase access to essential medicines and improve rational use. More info: www.haiweb.org

BigPharma's health information: a growing danger in Europe

According to the European Commission, the way to maintain the competitiveness of the pharmaceutical industry is to lift the barriers that prevent pharmaceutical companies from communicating directly with the public. After a first failed attempt to introduce changes to EU legislation, the Commission and drug manufacturers, together with a few active members of the EU Parliament, are again determined to attain their goal in 2007. Five European or international associations have joined forces in order to combat this initiative.

Drug companies would very much like to advertise prescription-only drugs directly to the public, but current European legislation prevents them from doing so. Only vaccine campaigns are allowed. There are also a few national exceptions such as advertisements for drugs for smoking cessation.

This existing legislative framework is already interpreted in a flexible manner in various European Union Member States. In addition, the European definition of drug advertising does not cover "*statements relating to human health or diseases, provided there is no reference, even indirect, to medicinal products*" (1,2).

As expected, drug companies and their proxy organisations already exploit these loopholes to their fullest. During the past decade they have developed a plethora of tools and techniques, such as newspaper articles that focus on specific symptoms or health conditions, often encouraging self-diagnosis, and announce the arrival of a promising new drug; radio and TV programmes showing opinion leaders repeating the same messages over and over; campaigns in classrooms; and multimedia prevention campaigns in public spaces and even on the streets.

In a never-ending attempt to improve competitiveness, the most influential companies, together with the European Commission, decided in the late 1990s to rid themselves of the remaining obstacles to unbridled marketing in Europe, including regulatory barriers that prevent them from addressing the public directly. The main stages in this plan are described below.

2001: the failed attempt to modify the legislative framework, the "G10" masquerade

In March 2001 the European Commission (Directorate for Enterprise and Industry) convened the G10 'high-level group on innovation and the provision of medicines'. The group had 13 members, which included only one patient representative, sitting at the table with European Commissioners, Health Ministers of Member States, and the President of GlaxoSmithKline, for example…

The conclusions of this task force, published in May 2002 after only 3 meetings, reflected the industry's priorities. It served as a justification for the draft Directive on human medicines that was submitted to the EU Parliament in 2001 (3).

A pilot project targeting 3 chronic diseases. The memorandum on the proposal to change the current Directive (2001/83/EC) (including advertising), openly stated the objectives: *"(…) It is proposed that there should be public advertising of three classes of medicinal products. This type of information would be subject to the principles of good practice to be adopted by the Commission and to the drafting of a code of conduct by the industry"* (4). The three health conditions targeted were all chronic diseases: asthma, diabetes and HIV infection.

A strong reaction by the European Parliament. The Commission and drug companies attempted to disguise this advertising as 'information on diseases and treatments' through the use of euphemisms. These efforts were in vain.

The European Parliament clearly perceived this as an attempt to get a foot in the regulatory door and to ensure that Europe gradually allowed direct-to-consumer advertising of prescription-only drugs. The disastrous results of direct-to-consumer advertising in the United States and New Zealand led EU parliamentarians to solidly reject the Commission's proposal to change article 88: 494 votes against versus 42 votes in favour (5-7).

2005: the 'Pharmaceutical Forum': a new masquerade

In late 2005 the European Commission replaced the G10 by a new group called the 'Pharmaceutical Forum' ("*a high-level political platform*", no less…) in order to continue "*discussions*" on three themes of the ex-G10, including drug information for patients (**a**).

Secrecy. This 'forum', far larger than the ex-G10, includes two European commissioners (Enterprise and Industry, plus Health and Consumer Protection), as well as member state ministers, 3 representatives of the European Parliament, representatives of 5 European pharmaceutical industry federations, and representatives of healthcare professionals, patients, and health insurers.

However, the full list of participants in the 'Pharmaceutical Forum' has not been made public, nor have the selection criteria, the forum's working methods, nor the management of conflicts of interest. Reports made by several participants suggest that several dozen people travel to Brussels to participate in each of the three working groups, including the one on patient information. They also report that the working group's methods are poorly defined and its objectives unclear. Only two flimsy reports released by the committee responsible for leading the "forum", as well as a very vague interim report, are available on the European Commission's website (8,9).

Untruths. On 29 September 2006, at the first meeting of the 'Pharmaceutical Forum' (convened after preliminary work), a speech by the European Enterprise Commissioner nevertheless clearly stated its objectives (10). According to the Commissioner, the status of health information in Europe is "*unsatisfactory, and even unacceptable*". He described access to information as inadequate for those with no internet access and for non-English speakers. Access to 'information' should therefore be improved, and efforts should be made to "*create confidence of citizens and health professionals in the quality of any information provided by industry*".

The Commissioner described the pharmaceutical industry as the source of 'information', having the "*knowledge, skills and resources* (…)" necessary to provide it (**b**)(10). The Commissioner responsible for Health and Consumer Protection declared

a- The other two themes are drug prices and relative effectiveness (ref 19).

b- A French example puts these claims into perspective. A survey done in 2003 by the Centre de recherche pour l'étude et l'observation des conditions de vie (Credoc), at the health authorities' request, based on a representative sample of 2007 persons, showed that 76% of respondents "easily" found answers to their questions on health issues, and that only 4% found it "very difficult". The respondents said their main sources of information were doctors (94%) and pharmacists (30%); the internet appeared only in 7th place (4%) (ref 20).

that "*Industry can help to provide information that is trusted. It wants to be able to play a legitimate role in communication about its own products*" (11).

The Commission regretted that its "*last attempt to modernise the legislation failed*" [referring to the massive rejection of its 2001 proposal], and announced that in 2007 it would present a report to the Council and to the European Parliament aimed at modifying the framework of patient information (10).

'Patient representatives' in line with industry claims

According to the vague description of the 'Pharmaceutical Forum' posted on the European Commission's website, patients are represented by the 'European Patients' Forum'.

Big pharma spokespeople. This organisation, created in 2003, is referred to in the report of a survey published in July 2005 by Health Action International, as "*a model of secrecy and conflict of interest*" (12). The evidence is overwhelming: this organisation's activities are funded by drug companies; events are held jointly with organisations representing drug companies; and when the European Patients' Forum represented patients on the Board of the European Medicines Agency (EMEA), sources of funding were not disclosed (**c**). Yet the European Commission chooses to give this organisation a central role each time patients' interests are to be represented, including in discussions of patient health information.

Industry funding. 'Friends of Europe' also provided their opinion on patient information in Europe. Claiming to be a think-tank independent of European institutions, 'Friends of Europe' published a report on patient information in September 2006. This report was based on interviews with 15 representatives of the various sectors affected, and was entirely funded by Pfizer (**d**)(13).

The report mentions the European Patients' Forum (see above), and the conclusions of the Cambridge University 'Informed Patient Project' (funded by Johnson & Johnson), and concluded that there is insufficient health information in Europe. One "*promising approach*" was the distinction between unsolicited direct-to-consumer advertising which should be banned, and "*information, even with some promotional content, provided at the request of consumers (…)*" which should be allowed (13).

These few examples suffice to demonstrate the artificial nature of the dialogue on patient information organised by the European Commission.

2007: a crucial year

After this preparatory phase, the European Commission and the pharmaceutical industry are determined to make 2007 a decisive year in the deregulation of industry 'communication' with the public.

At the European Health Forum held in October 2006 in Gastein (Austria), drug companies clearly reiterated their desire to be able to advertise all their products directly to the public (14,15).

Some MEPs as industry advocates. In March 2006, a group of European parliamentarians, the 'Patient Information Network' (PIN), has also started appealing for the ban on direct-to-consumer advertising to be lifted (16).

Jorgo Chatzimarkakis, German liberal Member of European Parliament (MEPs), has specialised in consulting for companies in the EU. He was managing director of 'polit data concept' until 2004 (17). He participates in PIN and the Pharmaceutical Forum, and he initiated the European Life Science Circle, a think-tank created at the same time as the Pharmaceutical Forum. He takes many initiatives promoting drug companies' views, particularly on direct-to-consumer 'information' (18).

Sham consultation. In March 2007, the Pharmaceutical Forum submitted to public consultation 2 documents on information to patients: a list of quality criteria and a diabetes information package, without specifying the methods that led to the documents. Not only these 2 documents are irrelevant, also their preconceived and industry biased questions mean all this is just another sham consultation. The aim is actually to prepare the ground for new legislative projects that would result in approving direct-to-consumer 'information' by the pharmaceutical industry.

A reorientation to defend public interests. It is against this backdrop that the Medicines in Europe Forum decided, in collaboration with Health Action International, the International Society of Drug Bulletins), the European consumers' organisation and Association Internationale de la Mutualité, to publish a joint declaration entitled 'Relevant health information for empowered citizens' (see details on page 4).

This declaration stresses the simple principle that relevant, comparative and appropriate information on health issues, i.e. the information that patients need, cannot be provided by drug companies. In a competitive marketplace, pharmaceutical companies must present their own products in a more favourable light than other preventive or therapeutic options. The declaration also reminds readers that Europe is not the information desert decried by drug companies and the European Commission, describing many positive examples of available independent, reliable information.

This joint declaration is as a tool for those who will take action to ensure that patients continue to receive health information that is independent of the vested interests of those who have medicines for sale. ■

c- This infringement of article 63 of Regulation 726/2004, on the functioning of the European Medicines Agency, was reported to the President of the EU Parliament (who is consulted during the nomination procedure to the EMEA steering committee), with no significant repercussions (ref 12).

d- Among other activities, Friends of Europe's debate on the REACH Directive (concerning chemical products) was funded by Unilever (ref 21).

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Joint Declaration on Relevant Health Information

For more information, the joint declaration by Health Action International (HAI) Europe, the International Society of Drug Bulletins (ISDB), the Association Internationale de la Mutualité (AIM), the European consumers' organisation (BEUC) and the Medicines in Europe Forum (MiEF), published on 3 October 2006, is available in English at www.isdbweb.org or at www.haiweb.org (8 pages) and in French at www.prescrire.org (9 pages) and on request.

RELEVANT HEALTH INFORMATION FOR EMPOWERED CITIZENS

Joint Declaration of HAI Europe, ISDB, AIM, BEUC, Medicines in Europe Forum

3 October 2006

Executive summary

Health information is a fundamental and necessary part of healthcare. However, the development of direct to consumer advertising, of disease awareness (or "disease mongering") campaigns, "compliance programs", and direct and indirect pharmaceutical industry support of patient's organizations have blurred the boundaries between drug promotion and health information. If patients are to be able to make informed choices about their health, there needs to be a clear distinction between information and advertising that is disguised as "information".

Relevant health information should be:
– **reliable:** evidence based (listing data sources), unbiased, and up-to-date, with full transparency on authorship and financing (enabling rejection of information influenced by conflicts of interests);
– **comparative:** presenting benefits and harms of the full range of available treatment options (including, where appropriate, the option not to treat), together with an explanation of the natural history of the disease,or condition; and
– **adapted to users:** understandable, accessible, and culturally sensitive.

Currently, there are many sources of relevant health information for the public both in Europe and internationally. There is room for improvement but to state that a "*patient information deprivation syndrome*" exists in Europe is not true. Specific tools have been developed to assess and rate the quality of health information. The aim of these tools is to help both information providers and users to ensure accuracy, quality and relevance to health care choices. This declaration includes many examples of quality assessment tools and information sources provided by health authorities, medical product agencies, healthcare assessment agencies, health care providers, health professionals, consumers' organizations and independent patient groups.

The role of pharmaceutical companies is strictly limited because of their inherent conflicts of interest. Recommendations on treatment choice must be independent both of individual companies that have a product for sale, and the industry as a whole. The statement by industry lobbyists that "*Consumers and patients are effectively excluded from receiving information about their medicine and its comparative effects [because of the] ban [for] drug developers from informing patients [...] even on the developers own web sites*", makes no sense. Pharmaceutical companies, and all "partners" financed by pharmaceutical companies, cannot provide unbiased comparative information on available drug and non-drug treatment alternatives.

Pharmaceutical companies do have a specific role to play: by law, they must provide well labelled drugs, including patient information leaflets. Directive 2004/27/CE requires package leaflet evaluation by patients. This is an important and much-needed step. Informative packaging and patient information leaflets are likely to contribute to better medication use and prevention of errors.

Proposals for improvement of European citizens access to relevant information include:
– ensuring transparency of medical products agencies to guarantee full public access to pre-market studies of drug safety and effectiveness, and pharmacovigilance data;
– requiring pharmaceutical companies to fulfil their obligations concerning packaging;
– developing and reinforcing sources of comparative, unbiased information on treatment choices;
– optimising communication between patients and health professionals;
– directly including patients in reporting of side effects of drugs;
– putting an end to the confusion of roles between pharmaceutical companies and other actors;
– full implementation and enforcement of the European regulation on drug promotion. ■

HAI HEALTH ACTION INTERNATIONAL EUROPE · INTERNATIONAL SOCIETY OF DRUG BULLETINS ISDB · beuc · Medicines in Europe Forum

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Patient information driven by pharmaceutical companies: the aim is to boost sales

Pharmaceutical companies are seeking greater influence over the general public so as to create and expand demand for medicines. They are using a variety of strategies which are becoming more and more insidious.

Since the 1990s, healthcare has increasingly been treated as a commodity and the pharmaceutical market has become increasingly globalised. There are more and more 'blockbuster drugs', achieving sales worth several billion dollars, and this has made pharmaceutical companies more attractive than ever to investors. But the euphoria of the 1990s and the early twenty-first century has now given way to a tougher period, with patents on blockbuster drugs expiring and fewer promising new products in the pipeline, either in terms of fulfilment of real public health needs or achievement of blockbuster sales.

Faced with these difficulties, pharmaceutical companies have devised a range of commercial strategies, one of which is to advertise their products - including prescription drugs - directly to the public in various ways (1).

The public is key to the market

Direct-to-consumer advertising is advantageous to the pharmaceutical companies in several ways: patients are not as well educated as health professionals about health or drugs; people who are ill are more vulnerable and their desire for a cure may make them less critical; they are often ready to try anything and can easily be persuaded that newer drugs are better; they can convince doctors to prescribe a drug which they have heard about via the media; they are a particularly good target for pharmaceutical companies seeking to expand the pharmaceutical market by creating new 'needs' and medicalising various aspects of human existence. The experience in the USA demonstrates that direct-to-consumer advertising of prescription drugs plays on patients' anxieties, fosters exaggerated hopes and prompts them to ask their doctors for drugs which are not the most appropriate for them (2,3).

At present, pharmaceutical companies are diverting a growing share of their marketing budget away from health professionals and towards consumers; there is more than 4 billion dollars worth of consumer advertising a year in the USA (4). The pharmaceutical industry is lobbying intensively to obtain the right to communicate directly to consumers in all countries.

Many forms of direct-to-consumer advertising

Pharmaceutical companies have already developed many different means of reaching the public directly, in some cases in ways that are more insidious than clearly identifiable direct advertising.

Disease-awareness campaigns. "Information" on illnesses and health conditions distributed by pharmaceutical companies, with no mention of a drug name, is allowed in Europe and is not considered to be advertising. But when a pharmaceutical company provides information on a disease advising people to "*discuss it with their GP*", there is no need for the drug to be mentioned by name for the GP to realise which medicine is being discussed when the patient asks about treatments (5).

To claim that disease-awareness campaigns and advertising are separate is naive, even hypocritical. In practice, pharmaceutical companies provide information on illnesses and health conditions only if they have a drug available for those conditions. Drug companies are highly unlikely to tell patients that the problem might clear up on its own, or that non-drug approaches are effective for prevention or treatment, or that a competitor's drug is the first-line treatment.

Disease mongering. The boundary between disease-awareness campaigns and disease-mongering, in which companies create new illnesses for the drugs they market, is often blurred. Companies do not exactly invent illnesses out of nothing. Instead, they often lump together real and sometimes disparate symptoms, naming a new creation and declaring it to be a serious health problem for which drug treatment is offered. They may also artificially widen the boundaries of treatable illness to include a larger group of people as needing treatment. Another approach is to medicalise the ups and downs of daily life and redefine them as "pathological" (5).

"Information" from pharmaceutical companies often supports the idea that many people who are ill are unaware of their condition, and that a drug treatment exists for every problem, thus opening up pharmaceutical markets to fulfil patient "needs" and "demand" (6 to 10).

For example, in 1999, Lilly succeeded in obtaining approval from the US Food and Drug Administration for *fluoxetine* (Prozac°) for "premenstrual dysphoric disorder", a new indication corresponding to mood swings in premenstrual women. Thus far, the European Medicines Agency (EMEA) has refused this indication on the grounds that it is not an established diagnosis.

More recently Sanofi Aventis has promoted *rimonabant* (Acomplia°) as helping to combat "metabolic syndrome". "Metabolic syndrome" is an umbrella term encompassing several loosely related disorders, which often include obesity, high cholesterol levels (dyslipidaemia), impaired glucose metabolism (particularly type 2 diabetes) and high blood pressure. "Metabolic syndrome" is defined according to different lists of criteria in different countries. The large disparities between these lists emphasises the artificial nature of this syndrome. In practice, there is no value in diagnosing "metabolic syndrome" as there is no specific treatment with demonstrated clinical effectiveness.

Fabrication of medical news stories. Pharmaceutical companies start preparing for the launch of their new products earlier and earlier. New medicines are trumpeted years in advance by the consumer press, which is constantly on the lookout for headline-making medical news. This was the case with the Cox-2 inhibitors, the non-steroidal anti-inflammatory drugs *celecoxib* (Celebrex°) and *rofecoxib* (Vioxx°), and *rimonabant* (Acomplia°), which was promoted initially by the manufacturer as being effective against obesity and nicotine addiction, then against metabolic ►►

▶ syndrome, and finally indicated at best solely for some obese and diabetic patients. Another example is, *varenicline* (Champix°) a drug to help smokers to quit.

This initial medicinal product promotion often takes the form of a campaign to raise journalists' and consumers' awareness of health problems "*that are undertreated*", or "*mistakenly considered to be trivial or unimportant*", or are becoming "*increasingly common*". The drugs being developed are often presented uncritically by the consumer press as "*a major breakthrough*", "*a revolutionary innovation*" or even a "*miracle drug*". Several studies have revealed the deceptive nature of most of these drug news stories" (11,12).

"Key opinion leaders" – health professionals with undisclosed or even knowingly concealed connections to the pharmaceutical companies – often take part in these pre-launch drug campaigns (13).

"Support" for patient groups. Pharmaceutical companies now involve patient groups in their commercial strategies. This sometimes extends to setting up patient groups themselves. One such example is the "National Alliance for the mentally ill" founded up by Lilly in the USA, and another is the organisation "Action for access", created by Biogen in the UK (14). The pharmaceutical industry is also aware that many policies are defined at an international level and also supports transnational associations or federations such as the International Alliance of Patients' Organizations (IAPO) and the European Patients' Forum (15,16). It is regrettable that the European Commission often chooses to consult such organisations as patient representatives under the pretext that they are international or pan-European (15).

A study published in the *New Scientist* in October 2006 revealed that in 2005 the US Restless Legs Syndrome Foundation received US $ 450,000 from GSK, which sells *ropinirol* (Adartrel°), and US $ 178,000 dollars from Boehringer Ingelheim, marketing *pramipexol* (Sifrol°). Both drugs are treatments for restless legs syndrome. The hidden agenda behind these donations is highlighted even further by the fact that Pfizer, which was one of the Foundation's major donors in 2003 and 2004, stopped contributing in 2005 after abandoning the development of a drug to treat "restless leg syndrome" (17).

In providing these organisations with "information" and funding, pharmaceutical companies turn them into allies and advocates vis-à-vis patients and health authorities. Patient groups prove useful to the companies when governments balk at a drug's high cost or refuse reimbursement, for example (15,18).

"Compliance support programmes". The aim of direct-to-consumer advertising of prescription drugs is not only to convince a new patient to become a new "customer", but also to help build "customer" loyalty. The annual cost per patient of long-term treatment sometimes represents a large sum of money. If patients interrupt or discontinue treatments, manufacturers stand to lose money.

Marketing experts have estimated that the pharmaceutical industry could lose US $ 30 billion of sales a year through patient 'non-compliance'. They recommend that manufacturers set up "compliance support programmes" for their treatments (19,20). It is clear from the professional pharmaceutical marketing literature that these compliance support programmes are designed as customer loyalty advertising campaigns (21,22).

"Risk minimisation". As with compliance support programmes, unless we are vigilant, pharmaceutical companies could soon have the opportunity to provide patients with information directly in the guise of "risk management plans" currently being introduced in the Guidelines implementing Directive 2004/27/EC. These risk management plans attempt to mitigate the disadvantages of increasingly premature market approvals (23). Here too, as with the "compliance support programmes", it is hard to see how manufacturers, with their innate conflicts of interest, are going to be able to help patients to respond to potential adverse effects in a way that is either credible or that is in patients' best interests. The recent case of Zyprexa° (*olanzapine*), which is indicated to treat schizophrenia, highlights the problem. Lilly is accused of having concealed unfavourable evidence concerning adverse effects of *olanzapine*. This example illustrates how tempting it is for pharmaceutical companies to keep potentially damaging information on the adverse effects of their drugs to themselves (24).

Illusory self regulation

The possibility that information supplied to the public by drug manufacturers can be effectively regulated through codes of practice or monitored by governments is unrealistic.

The "Code of conduct" drawn up by the pharmaceutical industry in the USA to try to prevent the introduction of tighter controls and even a ban on direct-to-consumer advertising for prescription drugs has proved to be a smokescreen (25). And the experience of recent years shows that regulatory authorities often respond too slowly to advertising and promotional abuses. A study by the US Government accountability office (GAO) has shown that the Food and Drug Administration (FDA) is unable effectively to regulate direct-to-consumer advertising (4,26). Repeat violations were common and on average advertisements continued to run for 4 months after the FDA had found them to be in violation of US law.

The priority today should not for pharmaceutical companies be to advertise directly to patients, but to improve significantly the patient information leaflets that accompany their drugs. And the priority for drug regulatory authorities should not be to permit the pharmaceutical industry to provide 'information' to the public, but to improve transparency of regulatory decisions and to squarely put the patient and public health at the centre of decision-making. And if governments want to be truly useful in the area of patient information, they can support independent sources of information and patient groups which are independent of the pharmaceutical industry (4,14).

The Medicines in Europe Forum

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Further reading...

For more in-depth articles on direct-to-consumer advertising (DTCA), here are a few additional references.

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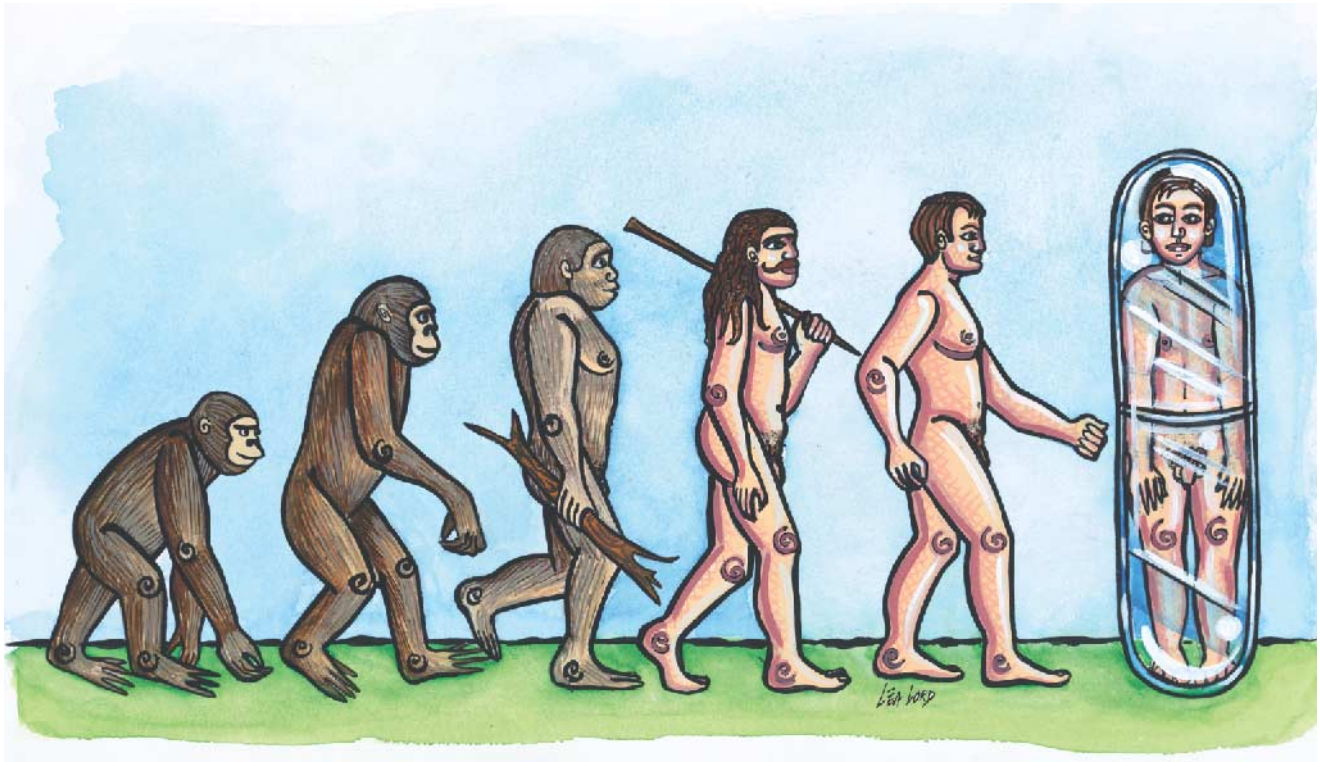

Open letter
to interested parties:
- European Pharmaceutical Forum's working group on information to patients;
- Members of European Parliament;
- the Media

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Paris, May 3. 2007

Dear Commissioner Verheugen,
Dear Commissioner Kyprianou,

In mid-March 2007, the European Pharmaceutical Forum's working group on information to patients released two documents for public consultation: a list of 'quality criteria' for patient information, and a sample patient information sheet on diabetes.

We are concerned that the questions that accompany this consultation frame it in such a way as to prevent any real democratic debate and to predetermine the type of responses that are likely to be received. This creates yet another sham consultation process, designed to justify a long-term plan for legislative change aiming to remove the ban on direct-to-consumer advertising of prescription drugs.
The Medicines in Europe Forum cannot in all conscience take part in this consultation. Nevertheless, as key stakeholders with responsibilities for medicines information policies, we would like to contribute towards an honest, balanced debate by means of this open letter. Health Action International* (HAI) Europe and the International Society of Drug Bulletins** (ISDB) support the content of this letter and shares the concerns expressed by the Medicines in Europe Forum.

Both the Pharmaceutical Forum's lack of transparency and lack of explicitly described methods remain unacceptable. The Medicines in Europe Forum, together with Health Action International (HAI) and the International Society of Drug Bulletins (ISDB), deplore the fact that since its inception the Pharmaceutical Forum has operated with an almost total lack of transparency. (1) This consultation provides additional evidence of this lack of transparency: two documents have been submitted for public consultation with no explanation on methods that were used to produce them, nor any disclosure of information on authors or their potential conflicts of interest. In fact, many of the participants of the Pharmaceutical Forum have suggested that no systematic methods were used to develop these documents, which is even more serious. Under these circumstances, the poor quality of the results is not surprising.

The proposed quality criteria are vague and far removed from patients' best interests. The proposed list of criteria is long and uses ambiguous terms that are susceptible to 'flexible' interpretation. Moreover, the title of this document is likely to create confusion between 'health information' and 'information on illnesses and drugs'.

It is important to remember that the sole purpose of patient information is to provide answers to patients' questions. The information provided should help patients to better understand their concerns and should provide them with realistic expectations of their future health status. It should help them to understand diagnoses and the likely results of different treatment options, as well as the various choices of treatments and services available. Finally, this information should help patients to cope with the suffering and to obtain help. (2)

To make an informed decision, patients need comparative information that presents the whole range of available options and, for each option, expected benefits and harm. Recent tragic examples such as Vioxx° and more recently Zyprexa° are potent reminders that pharmaceutical companies often minimize or even fail to disclose adverse effects.

Above all, health information should fulfil three very simple criteria. It should be:

- **Reliable:** evidence-based (with references cited to back each claim), totally transparent as regards to authors and their conflicts of interest, and up-to-date;
- **Comparative:** presenting benefits and risks for all treatment options, including, if appropriate, the option not to treat, as well as information on natural disease and symptom progression;
- **Adapted to users' needs:** understandable, adapted to patient's social, linguistic and cultural backgrounds, and easily accessible.

In a fiercely competitive marketplace, pharmaceutical manufacturers naturally have an obligation to their shareholders to realize profits from sales. They must therefore promote their own drugs rather than other preventative or treatment options. As a result, pharmaceutical companies are utterly incapable of providing the reliable comparative information needed by patients.

The diabetes 'example' is a counterexample of patient information. Those involved in health care provision, such as health professionals, consumer and patient groups that are independent of the pharmaceutical industry, health authorities and reimbursement agencies have not waited for pharmaceutical companies to take an interest in patient-'information' to produce relevant information for patients.

Many sources of high quality information are now available to the public in Europe and internationally. (2) Granted, improvements are still needed, especially when it comes to helping the public evaluate the ever-growing mass of information in order to better distinguish between useful and useless information. (**a**)

With the diabetes patient information 'example', the Pharmaceutical Forum asks citizens to express an opinion on a document when they do not even know how it was produced. Transparency concerning the methods used to produce patient information is an essential prerequisite if the people whose opinions are being sought are to be treated in a responsible and respectful manner.

We have however made the effort to read the document and are alarmed at the poor quality of its content. It does not answer patients' basic questions, nor does it prioritize information in terms of its importance. It does not compare existing treatment options and fails to provide any information on the amount of evidence available concerning effects of long-term use, nor does it cite references to back claims. It is pointless to give a detailed list of the changes required: the entire document needs to be rewritten if it is to provide the type of information needed to meet patients' needs. Currently, it patently fails to do.

This purported 'example' demonstrates -- as if proof were necessary -- that standardised 'information' produced at European level as part of a public-private partnership without rigorous literature search criteria or editorial methods, is of no benefit to patients.

We would like to believe that the European Commission is capable of challenging this process and will stop funding projects of this type, which are completely unsuited to the needs of European citizens.

We demand an end to the skilfully maintained confusion of roles. In recent months, a few Members of the European Parliament, claiming to defend patients' 'right to information', have been attempting to sway public opinion by creating the misleading impression that Europe is devoid of quality

health information, and that only the pharmaceutical industry is capable of remedying this situation. This has been done through a fanfare of publicity of all kinds including seminars, facilitation of workshops, conferences opportunely set-up by so-called think-tanks, etc.

The Medicines in Europe Forum, together with HAI and the ISDB, stresses once again that the 'information' provided by pharmaceutical companies is by definition promotional, and that the use of the word 'information' in this context is an abuse of the term: ultimately this is advertising. Patients' and citizens' ability to make decisions concerning their own care must be protected all the more from the influence of advertising masquerading as 'information', especially as illness increases people's vulnerability.

Information needs are complex and vary from person to person. Differences in physical and/or mental abilities, educational background and socio-economic status help to determine the type of information expected by patients and how they will use it. Providing information that meets patients' expectations as closely as possible implies a relationship of trust that is part of the day-to-day work of health professionals independent patient groups, families, and the mission of independent drug bulletins aimed at the public. (2)

Pharmaceutical manufacturers have a different and very specific role to play: the law requires them to supply properly labelled medicinal products accompanied by a patient information leaflet. Directive 2004/27/EC specifies additionally that these leaflets must be evaluated by patients. (3) This important measure was much needed. The development of safe, informative packaging and relevant patient leaflets by pharmaceutical manufacturers can contribute to improved medicine use and to prevention of medication errors. (4) There is still much room for improvement, and some companies have begun to make important progress.

Any confusion of roles between these different actors runs the risk of jeopardizing the quality of care and the freedom of each person to make choices that meet their own health needs.

May we remind you of your mission to protect public health. After an initial failure to introduce legislation removing the ban on direct-to-consumer advertising of prescription medicines in 2002, due to overwhelming rejection by the European Parliament, the European Commission and the pharmaceutical industry, actively supported by a few Members of the European Parliament (MEP's), appear to wish to reintroduce this initiative, taking advantage of the fact that more than 70% of MEP's are new. Will this little game, which consists of regularly challenging democratic choices for the benefit of a small interest group, be repeated with each new European Parliament? We sincerely hope not.

The Medicines in Europe Forum, together with HAI and the ISDB, condemns the fact that the European Commission has overstepped its remit from Parliament, which was merely to present a report in 2007 on the benefits and risks of current approaches to information provision, including information on the Internet (Directive 2004/27/EC - article 88a). (**b**) The Commission is biasing this debate by clearly supporting direct-to-consumer advertising under cover of 'public-private-partnerships' in patient information. This misrepresentation fools no one. (5,6,7) This position fails to take into account the evidence of harm from direct-to-consumer advertising, nor the ongoing efforts of health care providers to improve patient information for the benefit of public health.

The health products market is not a market like any other. Patients who are facing illness are vulnerable; they are not simply consumers. In allowing pharmaceutical firms to be competitive the Commission must not forget the key role it has to play in protecting European citizens' health (article 152 of the Treaty establishing the European Community).

We wish to draw your attention to a few simple proposals to improve citizens' access to relevant information. In practice, improved access for European citizens to relevant health information requires:

- Guaranteeing the transparency of drug regulatory agencies to ensure that the public has full access to effectiveness and safety data on drugs or health technologies both before and after market approval;
- Ensuring that pharmaceutical manufacturers fulfil their drug packaging obligations;
- Developing and strengthening sources of reliable, comparative information on treatment options in every member state;
- Allowing patients to be directly involved in reporting drugs' adverse effects and thus contribute to improved drug use;
- Ensuring that EU regulations on drug advertising are fully implemented;

- And above all, putting an end to the confusion of roles between pharmaceutical companies and other actors.

The Medicines in Europe Forum, Health Action International Europe and the International Society of Drug Bulletins call on the European Commission to fulfil its responsibilities by including these proposals in the report on patient information in Europe required by Directive 2004/27/EC, the preliminary version of which has just been made available for consultation. (**b**)

The Medicines in Europe Forum, HAI Europe and the ISDB thank you for acknowledging these concerns, which are shared by many European citizens who fear that healthcare is being treated as a mere commodity.

Medicines in Europe Forum with the exception of those who are involved in the work of the Pharmaceutical Forum*.**

HAI Europe*

International Society of Drug Bulletins**

* HAI Europe provides also an individual reply to the consultation.

** ISDB also produced a press release 'Patient-'information' by Big Pharma: A threat to public health' (www.isdbweb.org).

*** The members of the Medicines in Europe Forum who are involved in the work of the Pharmaceutical Forum wish, in accordance with their commitments, to present objections and proposals to the Commission during the Forum's working parties.

……..

a- *To do this, a number of specific tools for evaluating and measuring the quality of health information have been developed to identify quality information available (ref. 2).*

b- *We will be sending you a second open letter on the subject of the 'draft report on current practices with regard to the provision of information to patients on medicinal products' in the European Union, available for consultation until 30 June 2007.*

……..

1- Joint position of the Medicines in Europe Forum, the International Society of Drug Bulletins, Health Action International Europe "Health information: A clear division of roles is needed to protect public health" March 2007: 4 pages.

2- Joint declaration by HAI Europe, the ISDB, BEUC, the AIM and the Medicines in Europe Forum "Relevant information for empowered citizens" 3 October 2006: 9 pages. Website: http://www.isdbweb.org accessed 30 April 2007: 8 pages.

3- European Commission "Guidance concerning consultations with target patient groups for the package leaflet" May 2006: 5 pages.

4- European Commission Notice to applicants "Guideline on the packaging information of medicinal products for human use authorised by the Community" March 2007 : 34 pages.

5- Verheugen G "Pharmaceutical Forum: delivering better information, better access and better prices" Brussels 29 September 2006. Website http://europa.eu accessed 23 October 2006: 4 pages.

6- Kyprianou M "Pharmaceutical Forum: delivering better information, better access and better prices" Brussels 29 September 2006. Website http://europa.eu accessed 23 October 2006: 5 pages.

7- European Commission "Draft report on current practices with regard to provision of information to patients on medicinal products, in accordance with article 88a of Directive 2001/83/EC, as amended by Directive 2004/27/EC on the community code relating to medicinal products" 19 April 2007 : 27 pages.

Patient information in Europe: many concerns

In March 2007, the European Pharmaceutical Forum's working group on information to patients released two documents for public consultation: a list of 'quality criteria' for patient information, and a sample patient information sheet on diabetes.

Bellow are reprinted extracts from some contributions to the consultation and other reactions related to this consultation (origine specified when different from a contribution to the consultation).

Extracts from the press:

- *The Lancet*

"The direct-to-consumer advertising genie" 2007 ; 369 : 1.

- *The British Medical Journal*

Direct to consumer advertising should not come to Europe" by Ray Moynihan 2007; 19 May.

"Sweetening the pill – Can big pharma be trusted to provide independent health information to patients?" by Hannah Brown 2007; **334**: 664-666.

"Pfizer conducts survey of French patients on information provided by industry" by Barbara Mintzes 2007; **334**: 1027.

- *The Guardian*

"Coming soon: the shopping channel run by drug firms" by Sarah Boseley May 21, 2007

- *Test Achats*

Consumer organisation - Belgium)
"Non aux "programmes d'accompagnement" des firmes pharmaceutiques ! Oui à une information indépendante et objective sur les médicaments"
Press release – 30/05/2007 (www.test-achats.be)

- *Bulletin national de l'ordre de l'Ordre des Pharmaciens* (Pharmacists Representative Organisation - France)

"Information des patients : l'Ordre est inquiet" 2007, May 31

- *APTEKARZ Pharmaco-Economic Society Journal* (Poland)

"Look at EU drug policy" *APTEKARZ* 2007; 15 (3) : 73.

For more information:
Submissions to the consultation available at:
http://ec.europa.eu/health/ph_overview/other_policies/pharmaceutical/results_consultation_en.htm

Medicines in Europe Forum (MiEF). We are concerned that the questions that accompany this consultation frame it in such a way (...) as to predetermine the type of responses that are likely to be received. (…)

To make an informed decision, patients need comparative information that presents the whole range of available options and, for each option, expected benefits and harm. Recent tragic examples are potent reminders that pharmaceutical companies often minimize or even fail to disclose adverse effects. (…)

The Commission is biasing this debate by clearly supporting direct-to-consumer advertising under cover of 'public-private-partnerships' in patient information. This misrepresentation fools no one. (…)

We demand an end to the skilfully maintained confusion of roles. (…) Pharmaceutical manufacturers have a different and very specific role to play: the law requires them to supply properly labelled medicinal products accompanied by a patient information leaflet [which] can contribute to improved medicine use and to prevention of medication errors.

(Extracts from a joint MiEF, HAI and ISDB Open letter sent to Commissioners Verheugen and Kiprianou May 4, 2007. Complementary briefing papers on the subject available on Prescrire's website: www.prescrire.org).

International Society of Drug Bulletins (ISDB). Why should one sit together with industry to develop patient information? Health professionals, consumer and patient groups that are independent of the pharmaceutical companies, health authorities and funding bodies have not waited for the pharmaceutical companies to take an interest in patient information and to produce relevant information for patients. Many quality sources of information are now available to the public in Europe and worldwide. (…)

How to increase pharma companies competitiveness? By making medicines which offer real therapeutic advantage as defined in the ISDB Declaration on therapeutic advance. In contrast to pseudo-innovations such products do not need big marketing efforts.

(Extract from ISDB Press release May 3, 2007 : www.isdbweb.org)

Health Action International (HAI Europe). The Pharmaceutical Forum follows on the G-10; both advisory committees are heavily dominated by the pharmaceutical industry and appear to have an industry-driven agenda. (…) The Parliament did not ask the Commission to examine ways to assist the industry in promoting its products to the European Public. (…) Information needs can only be met by information providers without conflict of interests. (www.haiweb.org)

European Public Health Alliance (EPHA). EPHA consider that the High Level Pharmaceutical Forum or results from the consultation should not replace or interfere with the standard decision making procedures in the EU. (…) As stated in the EU Health Policy Forum recommendations on health information [May 2005], EPHA would like to stress that no relaxation of the current EU legislation which prohibits the advertising of prescription only medicines should be envisaged.
(www.epha.org)

Association Internationale de la Mutualité (AIM). AIM strongly demands that public health interests are not mixed or even replaced by commercial interests. (…) AIM insists that "unbiased" has to be included in the list of criteria. (www.aim-mutual.org)

Insulin Dependent Diabetes Trust. General Comments about the document as a whole: (…) there are inaccuracies and at times wrong information; (…) no information about suspected adverse effects of medications and insulin; no information to inform patients that they should have an informed choice of treatment based on independent, high quality evidence; a lack of comparative information about the various treatments to enable patients to make an informed choice based on independent evidence; a lack of information about comparative costs of treatment options.
(www.iddtinternational.org)

European Social Insurance Platform (ESIP). (…) The Pharmaceutical Forum Patient information working group are divergent on crucial aspects (…). ESIP fully supports the ban on DTCA which was clearly reaffirmed by the European Parliament and the Council of Ministers in 2004. Weakening the ban on DTCA would open the door to a wave of marketing that will be difficult to control following international experience. (…) ESIP has some important concerns regarding the drafting procedure as well as the factual content of the proposed diabetes fact-sheet: it is to be regretted that this document has been drafted without any agreed methodology and procedure, (…)

the draft does not comply with the quality criteria discussed above (…), omissions and mistakes. ESIP has serious concerns about the added value of such factsheets. (www.esip.org)

Diabetes UK. It is difficult to see how one source of information about a condition would be valid or applicable in every nation state. (www.diabetes.org.uk)

Which? (United Kingdom). (…) Is this about improving consumers' health and use of medicines, or is it about increasing the competitiveness and market for pharmaceutical products? (…) Research has shown a high level of consumer mistrust of information supplied by the pharmaceutical industry. (…) Pharmaceutical companies' remit is to sell their medicines, not inform choice. Any funding or sponsorship they enter into will be biased by virtue of what they choose to fund (such that information provision about less potentially profitable illnesses would be unlikely) and how they choose to present such information (in a manner designed to boost sales). (…) We do not believe that there is any value in further development of this type of information package (…). (www.which.co.uk)

European Respiratory Society (ERS) and European Lung Foundation (ELF). We are concerned by the transparency of the process to produce an information package for patients and how the results of this exercise will be used in the future. (…) Any information package should be developed and agreed at a national level (…) by one or a combination of the following organisations: national health services, national regulatory agencies, centers for reference, medical societies and patient groups or charities. (…) Health information (…) should not be confused with advertising for treatment drugs. (www.ersnet.org ; www.european-lung-foundation.org)

Consumer International (CI) and the Bureau Européen des Unions de Consommateurs (BEUC). (…) Providing health related information is a primary responsibility of the Member States who are in the best position to address the specific needs of the citizens. (…) The methods and the outcomes of the working group of the High level Pharmaceutical Forum (…) do not bring added value and are not the way to develop information for patients. Health and social policy on information to patients should be based on the rights of patients to independent information and not on the rights of pharmaceutical companies to market their products. (…) Pharmaceutical companies' role in the production of good quality information for patients and consumers should be limited to clear labelling and informative patients' leaflet. (www.beuc.org; www.consumersinternational.org)

European Federation of Neurological Associations (EFNA). There is little need for additional information to be produced at European level for most illnesses. Serious effort should be put into (…) finding ways effectively to disseminate existing high quality information.

European Cancer Patient Coalition (ECPC). ECPC considers that an important principle to be added is that the information provided considers and responds to patients' real needs (…). (www.cancerworld.org)

European Management Health Association (EMHA). We suggest that (…) the type of information destined to patients should be offered in an unbiased way. (…) EHMA stresses that EU legislation which relaxes rules on direct-to-consumer advertising should not be encouraged! (…)The relationship of a patient with a health professional is nonetheless one that will continue to remain of utmost importance. (www.ehma.org)

French Government. (…) It is necessary to address all concerns regarding the methodology used to produce the fact sheet. It is also necessary to address any conflicts of interest arising from the involvement of the healthcare industry in establishing patient information on treatment options.

France insists that the following principles be complied with: no direct-to-patient promotional activities by the pharmaceutical industry for prescription- only medicines (…) ; information on diseases for patients should be validated ex ante. (…) All elements relating to national context, for instance, diagnosis and treatment options should be provided at the national level to ensure that national specificities and financing constraints are taken into account.

European Aids Treatment Groups (EATG). Info is not info if it concerns one product (…). If we can't trust Pharma to tell everything to drug regulatory authorities, how can we trust them to tell everything to us ?
(European Parliament Intergroup on Patient Information 6/10/2006. www.guscairns.com)

Pharmaceutical Group of the European Union (PGEU). (…) Undertaking two consultations in this key area at the same time creates confusion. (…) We believe patients would expect objective AND unbiased information on medicines and health-related issues to be made available and not solely commercial/ brand information with no comparative data. (…) The existing EU legislation on medicinal products (…), in particular in the field of information to patients, helps ensure a high level of public health, and should, therefore, be maintained. We expect that the Commission's proposals resulting from this consultation will (…) prevent industry produced information from being directly communicated to the general public. (www.pgeu.org)

The Royal Pharmaceutical Society of Great Britain. (…) We would expect that the Commission's proposals resulting from this consultation will not only respect the decisions of the European Parliament (in 2002) to prevent industry produced information to be directly communicated to the general public but also reinforce what has already been achieved with this.

APTEKARZ Pharmaco-Economic Society Journal (Poland). There is actually a big pharma's pressure in Europe on the free promotion of prescription drugs. The European Commission would like but has no courage to do so, therefore, it has started to prepare the Pharmaceutical Forum to the turn of the worst. ("Extracted from Look at EU drug policy" *APTEKARZ* 2007; 15 (3) : 73.)

Medicines and Healthcare products Regulatory Agency (MHRA ; United Kingkdom). Much work is required to make this [diabetes information package] a truly patient-centred document (…). (www.mhra.gov.uk)

Medical Products Agency (Sweden). Patient information should be provided on a national level. (www.lakemedelsverket.se)

Institut for Rationel Farmakotherapi (IRF) (Danemark). There is a need to focus on the already existing national evidence-based comparative information, prepared by those involved in public health care and independent of the pharmaceutical industry. (www.irf.dk)

Danish Consumer Council. (…) Today (…) the industry is focusing at the consumers, to make them aware of diseases or life conditions, for which there is a possible treatment. (…) A demand and expectation from the consumer is placed on the doctor, who is already reached by the industry's marketing. This pincer movement makes the distance to the prescription pad very short. (…) (www.fbr.dk)

European Association of Hospital Pharmacists (EAHP). Information has to be adapted to the one receiving it and to his needs. EAHP considers that there is no better source of information on patients' conditions, treatments, procedures, examinations than the patients' healthcare professionals. (…) The High Level Pharmaceutical Forum set up by the European Commission (…) does not represent the breadth of organisation working on information to patient, and is composed of members that have been appointed arbitrarily. (…) The outcome of its work cannot be considered as a reliable source of information. (www.eahp.eu)

2nd Open letter
to interested parties:
- European Pharmaceutical Forum's working group on information to patients;
- Members of European Parliament;
- the Media

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Paris, June 14 2007

Dear Commissioner Verheugen,
Dear Commissioner Kyprianou,

When Directive 2004/27/EC on medicinal products for human use was adopted, the Parliament and Council asked the Commission to prepare a report in 2007 on the benefits and risks of information currently available to the public (article 88a). This was to include information that is available via the Internet, and was meant to put forward proposals for improvements in information provision, if needed. In late April 2007 the Commission (Enterprise and Industry Directorate-General) released a consultation paper entitled '*Draft report on current practices with regard to the provision of information to patients on medicinal products*', supposed to answer this request.

The report's review of sources of patient information on drugs and other treatments is so incomplete that it casts doubts on the Commission's willingness to address the issues raised by article 88a. Additionally, the report's conclusions are exclusively biased in favour of allowing drug companies to communicate directly with the public, further undermining the Commission's credibility. In short, the Commission failed to respond to the mandate set out in article 88a. The Medicines in Forum Europe (MiEF), Health Action International Europe (HAI Europe), Association Internationale de la Mutualité (AIM) and the International Society of Drug Bulletins (ISDB) are four organizations with strong concerns about the future of patient information in Europe. We are addressing this open letter to you in order to contribute to an honest, balanced and public debate on the issue, with a focus on public health as an overriding priority.

The report's methodology: multiplication of trickery

Despite a first legislative failure in 2002, when the European Parliament rejected by 494 votes to 42 the Commission's proposal to lift the ban on direct-to-consumer advertising for prescription-only drugs (even within the framework of a 'pilot project') the Commission still appears to be pursuing the same objective: removal of all obstacles, including regulatory barriers, to direct-to-consumer communication by pharmaceutical companies (**a**[i])(1).

The Commission has confused the issue by carrying out a number of initiatives simultaneously. With no respect for logical progression or timing, the Commission released a consultation paper on patient

[i] - Notes and references: page 5.

information containing proposals made by its Pharmaceutical Forum before releasing its report on the current state of patient information in the European Union. Both documents were produced in a near-total secrecy (**b**).

The methodology used to prepare the Commission report on patient information in Europe is described in vague terms and in just a few lines. The main body of the report is badly organised and unclear and the annexes are incomplete. No list is included of the individuals and organizations who were consulted when the report was produced and the table listing sources of information fails to indicate who supplied information within each Member State, apart from regulatory agencies. Additionally, the table entitled 'Information available on the Internet' only lists approved product information and accompanying administrative documents (**c**) and omits all other types of information. The text accompanying this table mentions a few other sources of information, provided by various sources in a few Member States only, without providing details on how these initiatives were financed, methods used to produce the information, nor what types of information are covered.

Despite the incomplete inventory of sources of information in Europe in this report, and the flawed methodology used to produce it, the authors come to the firm conclusion that only the pharmaceutical industry is capable of providing patients with the information they would otherwise miss.

► MiEF, together with HAI Europe, the ISDB and the AIM, consider that no proposal for legislative change should be based on a report that has been produced without any clearly defined methodology and with a near-total lack of transparency.

An incomplete and biased report

The Parliament and Council asked for a report on the benefits and risks of current patient information, including information that is available via the Internet, which is difficult to regulate. The report focuses on information on prescription-only drugs (and other therapies) available on the Internet, and proposes means of improving access to this type of information (**d,e**). Thus, the Commission's report fails to fulfill the mandate entrusted by Parliament.

A poor report on current sources of information. The report provides an incomplete list of current sources of information. For example, it omits many information providers in Europe that are independent of drug companies and regulatory bodies, including the 33 ISDB member bulletins (many of which are accessible to the public), health professional organizations, patients and consumer groups, agencies that carry out pharmaco-economic evaluations, health technology assessment groups, healthcare service providers, drug reimbursement agencies, and patient health education organizations settled up by Member States. However, these sources of information are clearly mentioned, including many examples, in the Joint Declaration 'Relevant health information for empowered citizens', signed by AIM, BEUC, HAI Europe, ISDB and the MiEF. This Declaration was published in October 2006 and has been widely circulated (2). Furthermore, not all the results of the survey conducted by the Commission concerning sources of patient information in EU Member States appear to have been taken into account in the report.

In the last few months, without carrying out a proper investigation of sources of information in Europe, the Commission has unremittingly repeated the same argument, which is also that of the pharmaceutical industry: namely that Europe is a health information 'desert' and that only drug companies are capable of remedying the situation (1,3).

► MiEF, together with HAI Europe, the ISDB and the AIM, regret that this report is used as a further source of public opinion disinformation.

A biased description of risks and benefits. The report provides no substantive evidence on the benefits to patients of the many existing sources of information to which they have access. The risk analysis is brief and combines issues as diverse as counterfeiting and the risks associated with uninformed choices due to a lack of comparative information on treatments (**f**).

Comparative information, which is indeed crucial for informed decisions, cannot be provided by pharmaceutical companies, because of inherent conflicts of interest (4). What company could possibly recommend a competitor's product over its own, or recommend discontinuing treatment with its own product?

At the end of the section on benefits and risks, the Commission highlights the paucity of the published literature on the subject. Indeed, few references accompany the report, suggesting that the authors failed to conduct an extensive literature search before editing this document.

► **MiEF, together with HAI Europe, the ISDB and the AIM, condemn the shaky and undocumented nature of the Commission's analysis, and the resultant bias in its conclusions.**

Patient exploitation. The report's description of patient information needs comes down to a simple claim that patients have a 'fundamental right' to information on medicines (**g**). However, information needs are defined by 'quality criteria' developed by the Pharmaceutical Forum, even though the results of the consultation on these criteria were not available when the discussion paper was released (**h**)!

The report does not even mention that patient information must answer patients' own questions, especially when it comes to making informed choices among available options and services (2). Considering the real needs of patients would have lead to propose very different solutions from those proposed by the Commission (see for example the proposals of MiEF, HAI Europe, AIM and ISDB on the next page).

► **MiEF, together with HAI Europe, the ISDB and the AIM, believe that if patients have a fundamental right to information, this right should be to the comparative information that forms the basis for informed treatment choices. The Commission's report disregards this key fact.**

Bypassing health professionals and regulatory bodies. Providing patients with the information they are seeking implies the need for trust, which is at the heart of the relationship between patients and health professionals, patients and their families, independent patient groups, and independent drug bulletins that produce information for the public (2). Yet the Commission's report marginalizes health professionals, mentioning them only in passing. As a result health professionals would be simple intermediaries for information provided by pharmaceutical companies (**i**).

One of the responsibilities of regulatory agencies is to ensure the availability and quality of patient information leaflets, assessment reports, and also information on drug safety, as required by EU transparency obligations. The Commission needs to strongly encourage regulatory agencies in all EU Member States to implement these transparency obligations. The responsibilities and mission of regulatory agencies must not be allowed to be hijacked by drug companies, as the report implies, under the pretext that companies "possess key information about their products".

To argue that companies should be allowed to communicate directly with patients because they possess key information is a sophism: what "key information" are companies going to provide to patients that they would not provide to regulatory agencies or health professionals? Companies are not known for publicly revealing "key information" they hold, such as evidence of health risks associated with their products. Recent examples such as the Vioxx° disaster (**j**) or the current Zyprexa° and Avandia° scandals (**k,l**) are potent reminders that adverse effects are often minimized and sometimes even concealed by drug companies as long as they can do.

► **MiEF, together with HAI Europe, the ISDB and the AIM, condemn the fact that this report skillfully maintains the confusion of roles between the pharmaceutical industry and other actors in the healthcare sector. This confusion of roles interferes with the ability of individuals to make rational choices based on reliable comparative evidence. In other words, it undermines healthcare quality.**

Further weakening of the legislative framework. The current European legislative framework prohibits companies from advertising prescription-only medicines directly to the public. There is no prohibition of "*information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products*" (Directive 2001/83/EC article 86).

This legislative framework is clear. However, pharmaceutical companies and industry associations already exploit and sometimes abuse the possibilities available under existing regulations (4). Public-private partnerships have already led to concerns about conflicts of interest in information provision. Curiously, among listed national sources of information, the Commission's report highlights three ventures that involve public-private partnerships (annex 2). The Commission is in essence admitting that the existing legal framework is already loosely interpreted in some EU Member States (1). The risk in making these approaches into the norm, rather than the exception, is a shift towards the lowest common denominator (**m**).

► **MiEF, together with HAI Europe, the ISDB and the AIM, stress the importance of article 88 of Directive 2001/83/EC, which is the only legislative safeguard against full introduction of direct-to-consumer advertising of prescription drugs. All four organisations condemn the Commission's attempt to undermine this prohibition.**

Concrete proposals

A report of such low quality cannot contribute to an improvement in the provision of reliable health information to EU citizens. The following changes are needed if the aim is to bring about real improvement:
- a rapid and permanent end to the confusion between the role of pharmaceutical companies and other actors in the healthcare sector;
- recognition of the many existing sources of information in European Union Member States (see reference 2) and the role of local caregivers;
- development and reinforcement, in each Member State, of the existing sources of reliable comparative information on available treatment options;
- actions to ensure that pharmaceutical companies consistently respect their obligations to provide high-quality drug packaging and patient leaflets;
- full enforcement of European regulations on pharmaceutical advertising, including measures to ensure that article 88 of Directive 2001/83/EC is not weakened or undermined;
- a guarantee of the full transparency of drug regulatory agencies, to ensure that the public has access to data on the efficacy and safety of medicines and other healthcare products, both before and after a product is marketed;
- provisions for the direct consumer reporting of adverse drug reactions, which will contribute to improvements in the use of medicines.

MiEF, HAI Europe, ISDB, and AIM reaffirm that the market for healthcare products has unique characteristics. Patients are not consumers. One of the Commission's central responsibilities is protection of the health of European citizens (article 152 of the European Treaty). Support for industrial competitiveness must not be allowed to supersede public health interests.

Increasingly frequent health scandals are ongoing reminders of the medical and legal dangers of excessive promotion of new medicines. One cannot ignore the consequences of the drug disasters not only for public health but also for healthcare costs. These include both direct costs and costs of management of adverse effects. The Commission cannot continue to ignore the economic implications of deregulation and direct-to-consumer communication by pharmaceutical companies on healthcare expenditures supported by healthcare services within Member States. Sooner or later the negative long-term consequences will become apparent to all, including the pharmaceutical industry.

MiEF, HAI Europe, ISDB and AIM thank you for your attention to these concerns, which are shared by many European citizens increasingly worried by the commercialization of healthcare.

Medicines in Europe Forum

HAI Europe*

International Society of Drug Bulletins

Association Internationale de la Mutualité

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* HAI Europe is also submitting a response to the report.

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Notes :

a- Already in 2002, an explanatory memorandum concerning the 2002 proposal to modify Directive 2001/83/EC clearly laid out the aim of this proposal in the following terms: "*It is proposed that there should be public advertising of three classes of medicinal products. This type of information would be subject to the principles of good practice to be adopted by the Commission and to the drafting of a code of conduct by the industry*." (ref 5).

b- In our first open letter we alerted you to the flawed methodology and deficiencies of documents issued by the Pharmaceutical Forum (only in English) (ref 6). In addition, on 10 May 2007, i.e. 2 working days only after the end of the consultation of the Pharmaceutical Forum, when the results of the Forum's and Commission's consultations were not yet available, MEP Jorgo Chatzimarkakis recommended during an oral presentation by the Pharmaceutical Forum the introduction of direct-to-public communication by pharmaceutical companies on prescription medicines, within a self-regulatory framework, despite evidence that self-regulation of pharmaceutical advertising is ineffective (ref 4).

c- The following documents are listed: summaries of product characteristics (SPC); patient information leaflets (PIL); and European public assessment reports (EPARs).

d- In addition to this report, the Pharmaceutical Forum conducted a 'literature search' on access to information by children and adolescents, the elderly, the deaf, the blind and the illiterate. The methodology of this 'search' is not clearly described. Online publication of the results on DG Enterprise's website, in early May 2007, seemed intended solely to provide companies with a pretext for distributing information via the Internet, and also by any other means that might increase their audience such as: interactive television; distribution of brochures in community and hospital pharmacies by healthcare professionals (who would in effect become company representatives); telephone contacts; cassettes; pictograms; school education; etc. (ref 7).

e- Furthermore, two pseudo-workshops were organized in November 2006, apparently to address the criticisms of some healthcare professionals. The reports generated by those workshops were of poor quality and were only published online in early May 2007 on DG Enterprise's website; they were not circulated for consultation (refs 8,9).

f- There is evidence of bias in the information provided by pharmaceutical companies on counterfeiting (ref 10).

g- Drug companies have used a variety of techniques to justify their attempts to legitimize the view that patients 'need' information on medicines that can only be provided by pharmaceutical companies. For example, Pfizer organized a national survey of patient groups that included biased questions and went so far as to ask "whether the law prohibiting companies from mentioning the name and the characteristics of drugs in advertising to the public 'should evolve'" (ref 11).

h- Responses to the consultation show there is no consensus on the proposed quality criteria.

i- The role of health professionals in providing information to patients on behalf of pharmaceutical companies already has a name: "infomediaries", and pharmacists are already being asked to become "brochure distributors". These brochures are for example being included in some community pharmacies' computer programmes that are used to manage sales.

j- After being intensely promoted to the public in the USA, Vioxx° (rofecoxib), a non-steroidal antiinflammatory drug whose cardiovascular adverse effects had been played down, caused many deaths (ref 12).

k- Zyprexa° (olanzapine) is a antipsychotic drug whose serious adverse effects (diabetes and cardiotoxicity) were concealed by the company. There are currently several legal actions against the manufacturer, Eli Lilly, in the United States (ref 13).

l- Avandia° (rosiglitazone) is an antidiabetic drug with cardiovascular adverse effects. Patients were not adequately informed of these adverse effects, even though they had been known for several years (refs 14,15).

m- The "information model" on diabetes released for consultation by the Pharmaceutical Forum, clearly illustrates the fact that "information" produced in a private-public partnership, without systematic literature search procedures and editorial methods, is of no use to patients (ref 6). It mentioned for exemple the glitazones as a therapeutic option despite concerns about their safety. Cardiovascular adverse effects of rosiglitazone (Avandia°) have since been disclosed (ref 14,15).

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RELEVANT HEALTH INFORMATION FOR EMPOWERED CITIZENS

Joint Declaration of HAI Europe, ISDB, AIM, BEUC, Medicines in Europe Forum

3 October 2006

Executive summary

Health information is a fundamental and necessary part of healthcare. However, the development of direct to consumer advertising, of disease awareness (or "disease mongering") campaigns, "compliance programs", and direct and indirect pharmaceutical industry support of patient's organizations have blurred the boundaries between drug promotion and health information. If patients are to be able to make informed choices about their health, there needs to be a clear distinction between information and advertising that is disguised as "information".

Relevant health information should be:
– **reliable:** evidence based (listing data sources), unbiased, and up-to-date, with full transparency on authorship and financing (enabling rejection of information influenced by conflicts of interests);
– **comparative:** presenting benefits and harms of the full range of available treatment options (including, where appropriate, the option not to treat), together with an explanation of the natural history of the disease,or condition; and
– **adapted to users:** understandable, accessible, and culturally sensitive.

Currently, there are many sources of relevant health information for the public both in Europe and internationally. There is room for improvement but to state that a "*patient information deprivation syndrome"* exists in Europe is not true. Specific tools have been developed to assess and rate the quality of health information. The aim of these tools is to help both information providers and users to ensure accuracy, quality and relevance to health care choices. This declaration includes many examples of quality assessment tools and information sources provided by health authorities, medical product agencies, healthcare assessment agencies, health care providers, health professionals, consumers' organizations and independent patient groups.

The role of pharmaceutical companies is strictly limited because of their inherent conflicts of interest. Recommendations on treatment choice must be independent both of individual companies that have a product for sale, and the industry as a whole. The statement by industry lobbyists that "*Consumers and patients are effectively excluded from receiving information about their medicine and its comparative effects [because of the] ban [for] drug developers from informing patients […] even on the developers own web sites*", makes no sense. Pharmaceutical companies, and all "partners" financed by pharmaceutical companies, cannot provide unbiased comparative information on available drug and non-drug treatment alternatives.

Pharmaceutical companies do have a specific role to play: by law, they must provide well labelled drugs, including patient information leaflets. Directive 2004/27/CE requires package leaflet evaluation by patients. This is an important and much-needed step. Informative packaging and patient information leaflets are likely to contribute to better medication use and prevention of errors.

Proposals for improvement of European citizens access to relevant information include:
– ensuring transparency of medical products agencies to guarantee full public access to pre-market studies of drug safety and effectiveness, and pharmacovigilance data;
– requiring pharmaceutical companies to fulfil their obligations concerning packaging;
– developing and reinforcing sources of comparative, unbiased information on treatment choices;
– optimising communication between patients and health professionals;
– directly including patients in reporting of side effects of drugs;
– putting an end to the confusion of roles between pharmaceutical companies and other actors;
– full implementation and enforcement of the European regulation on drug promotion. ■

Endorsers

Health Action International Europe

Health Action International (HAI) is an independent global network of health, consumer and development organizations working to increase access to essential medicines and improve rational use. HAI-Europe is one of the network's four regional coordinating offices (also in Africa, Asia and Latin America). HAI works for greater transparency in pharmaceutical regulation; to promote the rational use of medicines; for better controls on drug promotion and the provision of balanced, independent information for prescribers and consumers.
More info: www.haiweb.org

International Society of Drug Bulletins

The International Society of Drug Bulletins (ISDB) is a world wide Network of bulletins and journals on drugs and therapeutics that are financially and intellectually independent of pharmaceutical industry. Currently, their members include 57 members in 35 countries around the world. It was founded in 1986. The main requirements for membership are editorial and financial independence, and the quality of the information published. The bulletins audience target are mainly health professionals but also consumers. The overall aim of ISDB is to encourage and assist the development of independent drug bulletins in all countries and to facilitate co-operation amongst them, particularly exchanges of information on new drugs, adverse effects, drug promotion and regulation.
More info: www.isdbweb.org

Association Internationale de la Mutualité

The Association Internationale de la Mutualité (AIM) is a grouping of autonomous health insurance and social protection bodies operating according to the principles of solidarity and non-profit-making orientation. Currently, AIM's membership consists of 41 national federations representing 29 countries. In Europe, they provide social coverage against sickness and other risks to more than 150 million people, either by participating directly in the management of compulsory health insurance or by offering supplementary, alternative or substitute coverage. AIM constitutes a particularly appropriate forum for exchange and debate concerning social protection and health. AIM strives via its network to make an active contribution to the preservation and improvement of access to health care for everyone.
More info: www.aim-mutual.org

Bureau Européen des Unions de Consommateurs

BEUC is a European association, based in Brussels. It was created on 6 March 1962 by the consumer organizations of Belgium, Luxembourg, France, the Netherlands, Italy and Germany, right at the heart of Community policy. BEUC promotes the development of a Single Market that truly works in the interests of consumers. Currently, their members include 40 independent national consumer organisations from some thirty European countries (EU, EEA and applicant countries). BEUC is acknowledged as a trustworthy representative by both decision-makers and opponents alike, thanks in particular to the collective skills, knowledge and expertise of their member organizations.
More info: www.beuc.org.

Medicines in Europe Forum

The Medicines in Europe Forum, launched in March 2002, covers 12 European member states. It includes more than 70 member organizations representing the four key players on the health field, i.e. patients groups, family and consumer bodies, social security systems, and health professionals. Such a grouping is unique in the history of the EU, and it certainly reflects the important stakes and expectations regarding European medicines policy. Admittedly, medicines are no simple consumer goods, and the Union represents an opportunity for European citizens when it comes to guarantees of efficacy, safety and pricing.

Contents of the full text Declaration

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RELEVANT HEALTH INFORMATION FOR EMPOWERED CITIZENS

Joint Declaration of HAI Europe, ISDB, AIM, BEUC, Medicines in Europe Forum

3 October 2006

Full text

PURPOSE AND CONTEXT

Information is an integral part of healthcare: the need for patients to give informed consent is the basis of all care and treatment. Over time, health information has acquired a wider role and greater significance, with an expansion in the range and number of sources of that information. This has raised the question as to reliability of that information.

The recent interest of pharmaceutical companies in the provision of "patient information" in the 80s and 90s has blurred the boundaries between drug promotion and health information. The development by pharmaceutical companies of "direct-to-consumer advertising" (DTCA) in some countries (the USA, New Zealand), of disease awareness campaigns all over the world, and more recently perhaps of disease mongering (the manufacturing of diseases) and "compliance programs", together with direct and indirect industry support of patients organisations have increased the confusion and concerns.

The situation in Europe is now acute. After the rejection by the European Parliament, in 2002, and the European Council, in 2003, of a European Commission proposal to change European advertising regulations to allow pharmaceutical companies to promote "awareness of the availability" of products for asthma, diabetes and AIDS, companies have sought alternate ways of providing "information" to patients and consumers. Although the term 'information' is used, the activities in question include direct and disguised advertising. In essence, the industrial challenge remains the same: lifting the ban on direct-to-consumer advertising in Europe. If patients are to make truly informed choices about their health, clarification is needed to distinguish between information and advertising presented as "information".

1- IDENTIFYING THE FUNDAMENTAL NEED OF CITIZENS FOR HEALTH INFORMATION

Information plays an important role in preventing ill-health, both individually and in a wider society through public health promotion. Potentially, good information has both direct and indirect outcomes. Immediate outcomes include improvements in knowledge and understanding, whereas the longer-term outcomes can be improvements in health and well-being. There are many possible outcomes in between, such as greater confidence to engage in shared decision-making with healthcare professionals. Addressing information needs of patients and consumers is not only a matter of content, but also of communication.

1.1. Information as part of health education

Over-medicalisation of the European population tends to introduce confusion between "health information" and "information on illnesses and medicines". Basic health information includes knowledge on how the human body functions, at different life stages, and on what can help to remain healthy. A solid background on the basic concepts such as benefit/harm balance, symptoms/aetiology, etc. is needed to empower people to take more responsibility for their own health and engage more widely in self-care.

1.2. Information as part of health care

Citizens need various type of information to improve their access to health care: information on prevention (screening, vaccination, contraception, etc.), on illnesses and treatments, specific information when they participate to clinical trials (for a real informed consent). Written information is useful, but face to face exchanges, trustful relationship is essential for adapting the content to each situation.

1.3. Information in case of illness

In the case of health problems which require professional assistance, patients and their families need to be able to express their worries and their feelings, they need to be listened to, and to obtain answers to their questions, for example:

1- What is the cause of the problem?
2- Will the symptoms spontaneously disappear?
3- What would be the purpose of tests and investigations?
4- Is there anything I can do myself to improve my condition?
5- Are there effective interventions to relieve symptoms, cure the disease, or prevent recurrence?
6- What are the different treatment options?
7- What are the potential benefits and harms of the treatment? In the short- and particularly in the long-term?
8- How can I reduce the side effects if treatment is worth using?

The information needed has therefore to be developed for different purposes, for example to: understand what's wrong, gain a realistic idea of prognosis, understand the processes and likely outcomes of tests and treatments, identify the most relevant options and services, help to cope, learn about available services and sources of help, etc. Such information should enable people to shared decision-making with health professionals.

1.4. Comparative information for informed decisions

Decision-making requires comparative information including the pros and cons of all options. This kind of information is sometimes scarce or lacking due to inadequate or biased research or to the absence of research. However, all comparative data which exist must be accessible to patients as well as health professionals, and to families or other care givers. It includes information on the natural history of the disease (self limiting or with possible repercussions on an individual's life, either short- or long-term) and on the potential consequences of not treating the disease.

Comparative information also addresses different treatment options: different drug treatments, but also non-drug treatment, life-style changes, social support, surgery, physiotherapy, psychotherapy and all other therapeutic means which have been evaluated for a given condition. For each option patients should be able to clearly identify benefits (degree of clinical effectiveness on important outcomes, convenience, etc.) and harms (potential side effects, disturbances of personal and social life, etc).

2- TOOLS THAT AID ASSESSMENT AND USE OF RELEVANT HEALTH INFORMATION

Various initiatives have been undertaken to provide lists of quality criteria for patient and consumer health information. The following criteria are common to many of these lists:

Reliable: transparent as to the origin of the information (enabling rejection of information influenced by conflicts of interests), evidence based (stating reliable data sources), unbiased, up-to-date;

Comparative: explaining the natural history of the disease, presenting benefits and harms of interventions, the full range of treatment options (including non treatment), enabling informed choice;

Adapted to users: understandable, easy to use, and accessible, in accordance with the cultural context.

Specific tools for assessing and rating the quality of information materials on treatment choices have been developed, in Europe and the world, to train information users in critical appraisal, or to help them identify reliable sources. Such examples should be widely disseminated and employed.

Examples of tools

- DISCERN questionnaire: www.discern.org.uk
- The UK Centre for Health Information Quality (www.quick.org.uk)
- Which? Lists of useful sources (www.which.co.uk)
- Stiftung Warentestlist of information sources (www.stiftung-warentest.de)
- Patient decision aids: http://www.ohri.ca/DecisionAid/
- HealthInsite: http://www.healthinsite.gov.au
- Women's guide for understanding evidence about health and healthcare: www.cwhn.ca
- James Lind Alliance: www.lindalliance.org
- James Lind Library: http://www.jameslindlibrary.org

3- OBSTACLES TO ACCESSING RELEVANT HEALTH INFORMATION

The challenge of health information is two-fold: ensuring that the information provided to people is of good quality and patient-centred, i.e. presenting all the options in a balanced way, and ensuring that it is provided as an integral part of their healthcare. Several types of obstacles make this challenge particularly difficult.

3.1. Quantity outweighs quality

Sources of health information are increasing in number, especially with the growth of the internet, but "more" does not necessarily mean "better". The reliability of some of this information is uncertain. Even if not biased due to conflicts of interest, health information can be inaccurate, out of date, inconsistent, incomplete or irrelevant, giving patients unhelpful and conflicting messages. It may not be evidence-based. It may not be produced to meet the needs of patients and be difficult to understand and use. If patients and consumers are not equipped with critical appraisal skills, the reliable information is liable to be diluted by the mass of information.

3.2. Drug promotion presented as "information"

The growing amount of "information" disseminated by drug companies or related bodies, often presented as "disease awareness" together with pharmaceutical solutions, is a major obstacle to the provision of objective health information. Such "information" is presented in attractive format, using current marketing methods, and sometimes disseminated through sponsored patients associations, creating a climate of confidence for those who receive such messages.

Pharmaceutical companies have a dual responsibility: to the patients who take their medicines and to their shareholders. Because of this conflict of interest, pharmaceutical companies' information cannot be impartial and should be treated with caution. In an extremely competitive market, with every attempt being made to maximise sales, the pharmaceutical industry cannot be expected to provide reliable comparisons with other drug treatments, non-drug treatments and the not-to-treat option. Hence DTCA masquerades as "information", but is simply promotion to maximise sales. Regulation of these areas of activity is vague or non-pro-active, and the sanctions imposed are often meaningless.

3.3. Lack of time for communication and tradition of secrecy

Ensuring the quality of information is only part of the challenge. The purpose of conveying information is to ensure it meets a person's needs so they can benefit from it. Communication of information requires time and availability to listen to those who receive the information.

Patients, their carers and families are being encouraged to become more empowered and take more responsibility for their own health. However, health professionals often do not take or do not have the time or resources to meet the needs of 'expert patients'. Professionals often lack easy access to certain information (e.g. data on drug side effects) to inform their patients of the potential harms. Lack of transparency by companies and medical product agencies is, in some situations, an obstacle to the communication of balanced information. The challenge also lies in ensuring that whenever health professionals communicate with and inform patients, they do so in a patient-centred way that is free from bias, undue influence or paternalistic values and attitudes.

3.4. Diversity of individual needs

Information needs are complex and they differ from person to person. They can change throughout the course of life, illness and treatment. Differences in physical and/or mental abilities, language, literacy and resources are not always considered.

These factors influence what type of information patients are looking for and how patients use health information. Addressing children or the elderly, migrant populations, persons with visual or hearing impairment or with learning difficulties is a constant challenge. Local, regional, cultural differences should also be considered when adapting information to patients and consumers needs.

4- POSITIVE ACTION IN EUROPE AND ACROSS THE GLOBE

Despite the obstacles mentioned above, examples of good practice exist among the many stakeholders involved in providing health information in Europe. There is room for improvement, and a need to empower people who are confronted with a growing amount of "information". But stating that a "Patient Information Deprivation Syndrome" exists in the European Union is simply not true: readily accessible sources, adapted to the different national or regional contexts are available, offering patients relevant information to make informed choices.

Article 152 of the Treaty dictates that the European Commission has a role to play in assuring the public health of its citizens. But all actors involved in the healthcare system of each Member State also play a major role in contributing to patient education and information.

4.1. Health authorities (ministries of health and related institutions)

At the EU Member State level, the national health authorities conduct education and information campaigns, both directly through their central and regional services and websites, and also through other publicly funded institutions. Themes include the major public health questions: nutrition, vaccination, smoking cessation, correct use of drugs such as antibiotics, prevention of misuse of drugs such as hypnotics, epidemic situations, etc. In addition, other government bodies provide specific public information on drugs, for example those that may affect driver vigilance. Other examples from outside Europe confirm the important potential role of health authorities in providing education and information.

Examples of Health authority resources

- Belgian health ministry campaigns on good usage of antibiotics, benzodiazepines, etc. (http://portal.health.fgov.be) and (http://www.bcfi.be)
- French Institute for Health Prevention and Education campaigns on hepatitis, cancer prevention, vaccinations, etc. (www.inpes.sante.fr)
- United Kingdom information on drugs affecting driver's vigilance (www.dft.gov.uk)

  Outside Europe:
- Australian Consumer portal of the National Prescribing Service (www.nps.org.au)
- Health Canada Drug Safety Advisories: www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/

4.2. Medical products agencies (European and national)

These agencies, which are mainly funded by pharmaceutical companies by way of fees for the authorisation process of new medicines, generally focus on drug authorisation and post-marketing surveillance and rarely produce health information. They provide statutory technical information on drugs (summary of product characteristics and patient information leaflet) and some evaluation reports, which might be useful, when not too deeply influenced by their clients. They rarely provide comparative information which helps patients and health professionals to choose treatments. Some agencies nevertheless produce recommendations for the public.

When medicines agencies follow transparency rules concerning the reasons underlying their decisions (as required by the present European legislative framework, but not yet fully implemented), they also provide original information that, although non comparative, is relevant to the public, notably concerning pharmacovigilance measures.

Examples of Medical products agency resources

- Swedish medicines agency recommendations (http://www.lakemedelsverket.se).
- Finnish medicines agency review on drug information for consumers and patients (http://www.nam.fi)

  Outside Europe:
- American Food and Drug Administration drug-safety consumer information portal (www.fda.gov/cder/drug/drugsafety/DrugIndex.htm)

4.3. Healthcare assessment agencies

The Agencies for assessment in healthcare, which are usually publicly funded, are in charge of evaluating new and existing therapies and preventive treatments for the purpose of preparing evidence-based political and financial decisions on reimbursement. The information they generate may be useful for patients, and in some cases is presented in appropriate format for the public.

Examples of Healthcare assessment agency resources

- German Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG) offers evidence-based advice on treatments and healthcare in its section called Gesundheitsinformation (http://www.iqwig.de).
- National Institute for Health and Clinical Evidence (NICE) provides information for both the public and healthcare professionals (http://www.nice.org.uk/).
- Swedish organisation Statens beredning för medicinsk utvärdering (SBU) provide advice on available treatments and preventive measures, both online (http://www.sbu.se) and in pharmacies.

4.4. Healthcare providers (payers)

Some healthcare providers disseminate information on the rational use of drugs to their clients in the form of leaflets, training, web-based resources. Some also conduct information and disease management campaigns and collaborate with health authorities and health professionals associations to distribute patient-oriented information. Some payers organizations have long experience in providing information to patients and citizens at national, regional and local level.

Examples of Healthcare providers resources

- British National Health Service distributes information on diseases, their diagnosis and treatments through NHS Direct Online (http://www.nhsdirect.nhs.uk).
- French Caisse nationale d'assurance maladie des travailleurs salariés campaign on good use of antibiotic has contributed to start reducing antibiotic consumption in a country where it was extremely high (http://www.ameli.fr/174/DOC/2641/cp.html).
- Modellverbund "Unabhängige Patientenberatung Deutschland gGmbH, a recent network of independent patients organisations financed by German statutory sickness funds
- German Arzneimittelkommission der deutschen Arzteschaft produces brochures containing guidelines on the treatment and prevention of various diseases (http://www.akdae.de). They are published by Technikerkankenkasse and other healthcare authorities.

4.5. Healthcare professionals (doctors, pharmacists and others)

In addition to the information and advice they convey in their everyday practice, some healthcare professionals who are determined to avoid pharmaceutical companies influence produce a variety of independent patient-oriented information in the form of printed and/or electronic bulletins and journals. Others media include leaflets and brochures dealing with particular health issues. Healthcare professionals in some countries have also opened permanent information centres, and some centers even help train patients to select their information sources. Other professionals organize training sessions for schoolchildren on matters like generic drugs, communicable diseases such as influenza, etc. Information campaigns on rational use of drugs are also regularly organised by healthcare professionals.

Examples of Healthcare professionals resources

- German *Gute Pillen Schlechte Pillen* jointly founded by three member journals of the International Society of Drug Bulletins (arznei-telegramm, Pharma-Brief, Der Arzneimittelbrief) (www.gutepillen-schlechtepillen.de).
- British *Treatment Notes* edited by the *Drug and Therapeutics Bulletin* belonging to the International Society of Drug Bulletins (www.dtb.org.uk/idtb/portal/public/intro_tn.html).
- Italian Health and Drug Information Centre of the Mother-Child Health Research Laboratory of Mario Negri Institute (www.marionegri.it).
- German organisation Arzliches Zentrum für Qualität in der Medizin (www.patienten-information.de).
- Moldovan organisation Medex (ISDB full member) (website under construction).
- Andalusia campaign on international non proprietary names, supported by the regional authority and the public health school (www.easp.es).

4.6. Consumer organizations (European, national and regional organizations)

Most consumer organizations include sections on health issues in their publications. They produce special issues on health and medicines, or specific publications or websites on health matters offering advice and guidelines. Some organizations are specifically oriented towards rational use of drugs, side effects of drugs (identification and prevention), and patients' experiences, amongst others.

Examples of Consumer organizations resources

- Which? offers advice for patients seeking reliable information (www.which.co.uk).
- Dipex collects patients' personal experiences for improving the quality of care (www.dipex.org).
- Stiftung Warentest, publishes "Handbuch Medikamente", a handbook containing up-to-date comprehensive treatment information for patients (also "Handbuch Selbstmedikation", for self-treatment) (www.stiftung-warentest.de).
- Verbraucherzentralen Bundesverband produces information on diseases and their treatments intended for patients and the general public (www.vzbv.de).
- Kilen works particularly on drug adverse effects (patient reporting and prevention) (www.kilen.org).
- Joint actions are conducted by consumers and other independent partners such as the campaign promoting good drug usage based on the INN system, led by Que Choisir, La revue Prescrire, and Fédération nationale de la mutualité (www.prescrire.org/cahiers/dossierDciAccueil.php).

4.7. Patients' associations

By way of number and proximity to patients and citizens, patients associations generate large amounts of health and disease information. They play an important role in transferring knowledge and life skill experiences, particularly on chronic diseases (how to live with diseases and/or disabilities in the short or long-term, either as individual or in the family). Pharmaceutical companies consider these associations as an excellent means of getting commercial messages across to patients, and of strengthening their political pressure. Nevertheless, independent patients associations, having clear guidelines and mechanisms to avoid conflicts of interests, do produce high quality health information and conduct useful information campaigns.

Examples of Independent patient organizations resources

- DES Action is defending victims of diethylstilbestrol (DES) and has generated a wealth of information on this subject (www.desaction.org)
- German Buko Pharma-Kampagne provides critical information on drugs for patients and the public, and also represents patients on the advisory committee of the self-governing healthcare administration in Germany (www.bukopharma.de).
- Belgian Ligue des Usagers des Services de Santé debates about public health issues in day to day patients reality (i.e. generics or smoking ban in restaurants, etc.) and provides practical information (http://luss.daaboo.net/)
- Mind, the British National Association for Mental Health is an example of association with a strict policy of independence and producing information for the public (www.mind.org.uk).
- Insulin Dependent Diabetes Trust does not accept funding from the pharmaceutical industry and provides information for the public (http://www.iddtinternational.org)

4.8. Pharmaceutical companies obligations

Their role regarding patient information is strictly limited by way of their natural conflict of interest, which cannot give credibility to their recommendations on treatment choice. Stating that "*Consumers and patients are effectively excluded from receiving information about their medicine and its comparative effects [because of the] ban [for] drug developers from informing patients […] even on the developers own web sites*", as lobbyists of the pharmaceutical industry put it, does not make sense since pharmaceutical companies, and all "partners" financed by pharmaceutical companies, cannot provide the comparative information required.

However, pharmaceutical companies must by law provide well labelled drugs and a patient information leaflet included in the packaging. The leaflet content must be accurate, and readable by patients, and Directive 2004/27/CE requires leaflet evaluation by patients. When companies develop informative packaging and relevant patient information leaflets, this may contribute to the better use of drugs and to the prevention of medication errors. There is indeed room for improvement but some examples show the way.

5. PROPOSALS FOR IMPROVEMENT: PUTTING AN END TO CONFUSION OF ROLES

Improving the relevance of patient information, in Europe and across the globe, is a crucial challenge for public health reasons and also for economic reasons, considering the serious consequences of inappropriate drug consumption. There are a number of actions which could contribute to this improvement.

5.1. Ensuring transparency of medical products agencies

Access to drug evaluation data (existence, protocols and results of clinical trials; reasons for agencies decisions granting or modifying authorisations) and to pharmacovigilance data is not yet guaranteed in the European Union. The new regulatory framework (Directive 2004/27/EC and Regulation EC/726/2004) which requires transparency by medical products agencies has yet to be strictly implemented, giving health professionals, patients and citizens access to essential data.

5.2. Making pharmaceutical companies fulfil their obligations concerning packaging

The new European regulatory framework requires good quality labelling of drugs, including for partially sighted or blind citizens, and consultation on patients' leaflets with targeted groups of patients to ensure that leaflets are legible, clear and easy to use. Member States had to bring the Directive into force no later than October 2005, but many countries did not meet this deadline. Urgent consideration of these practical aspects is needed.

5.3. Developing and reinforcing the sources of relevant information

Readily accessible sources of good quality health information exist in different regional or national contexts, allowing patients and consumers to make informed choices. They should be supported, and other appropriate sources should be developed with local actors in Member States where they are lacking. When needed, public funding of such sources should be guaranteed mid- and long-term.

5.4. Optimising communication between patients and health professionals

Part of the challenge to engage patient in shared decision-making is to provide sufficient time and resources to meet the growing expectations of patients for information. Communication between patients and healthcare professionals needs to be a two-way dialogue. Simple initiatives such as encouragement to prepare consultations with health professionals by writing down all the questions the patient wishes to raise, can help optimise the use of time and the outcome. The use of international non-proprietary names (INN) instead of multiple trade names can facilitate understanding of drug treatments and improve dialogue.

5.5. Including patients as actors in the pharmacovigilance system

Patient reporting of adverse drug reactions is precious and needed. It contributes to a better knowledge of drugs, but also to adequate feedback information. Various Member States already collect reports directly from patients including Denmark, Italy, the Netherlands (LAREB), and the United Kingdom (MHRA yellow card system). Independent organisations also collect this information, e.g. the DGV in the Netherlands, or Kilen in Sweden. Moreover, education on adverse reactions can contribute to the rational use of drugs.

5.6. Considering individual patient needs

European or even national databases, websites, TV campaigns, etc will not replace face-to-face dialogue between patients and health professionals or independent patients organisations. Proximity and common culture are among the ingredients of effective information. European financial support should be given to initiatives which consider these social and cultural aspects instead of focusing on global initiatives which are not a panacea.

5.7. Putting an end to confusion of roles

The production of good quality information for patients and consumers requires a clear separation of the roles of the different actors: clear labelling and informative patient leaflets by drug companies; comparative information on health, diseases and treatments by health authorities, health professionals, payers, consumers and independent patients' associations. Confusion of roles is detrimental to the quality of health information and eventually to the health of citizens.

5.8. Maintaining and enforcing the European regulations on drug promotion

Lifting the ban on "direct to consumer advertising" in Europe would increase drug consumption but would not improve access to relevant patient information. The present European legislative framework should remain and be rigorously applied to all kinds of drug promotion, even when they masquerade as "information".

CONCLUSION

The authors of this paper call on European institutions and Member States to support the relevant existing sources of health information for patients. They call on the different stakeholders in European healthcare systems to identify and share best information practices, and develop new ones. They call for campaigning to help patients and citizens avoid confusion between health information and drug promotion by the pharmaceutical industry purporting to be "patient information". ■

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