

# HEALTH INFORMATION

## A clear division of roles is needed to protect public health

**P**harmaceutical 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](http://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](http://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.**

**D**rug 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 7<sup>th</sup> 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 (EMA), 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 EMA 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).

### **Selected references from literature watch.**

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- 2- "Article L. 5122-1 du Code français de la santé publique". Website <http://www.legifrance.org> accessed 23 October 2006: 1 page.
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- 21- Friends of Europe "Policy makers lunch debate - How safe is Reach making Europe's consumers?" Website <http://www.friendsofeurope.org> consulted on 23 October 2006: 1 page.

# 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](http://www.isdbweb.org) or at [www.haiweb.org](http://www.haiweb.org) (8 pages) and in French at [www.prescrire.org](http://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

**H**ealth information is a fundamental and necessary part of health-care. 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, health-care 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. ■

## Contents of the full text Declaration

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- 1.1. Information as part of health education
- 1.2. Information as part of health care
- 1.3. Information in case of illness
- 1.4. Comparative information for informed decisions

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

### 3- OBSTACLES TO ACCESSING RELEVANT HEALTH INFORMATION

- 3.1. Quantity outweighs quality
- 3.2. Drug promotion presented as "information"
- 3.3. Lack of time for communication and tradition of secrecy
- 3.4. Diversity of individual needs

### 4- POSITIVE ACTION IN EUROPE AND ACROSS THE GLOBE

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

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## CONCLUSION



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