Translated from *Rev Prescrire* December 2006; **26** (278): 863-865

POSITION BigPharma's health information: a growing danger

Stop industry interference. It is time to put an end to this dangerous trend. One major conclusion of a recent French Senate report on medicines is that conflicts of interest are widespread and that the roles of the different players in the medico-pharmaceutical field are becoming increasingly confused (6). These "medicine compliance programmes" could only worsen this confusion: how could anyone imagine that a pharmaceutical company, in the position of both judge and jury, would willingly explain to a patient that he or she had better stop taking one of its drugs, or switch to a competitor's product?

- **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 are again determined to attain their goal in 2007.**
- **Five European or international associations have joined forces in order to combat this initiative. They have published a declaration outlining the fundamental principles for the provision of reliable information on disease and health for the benefit of all patients.**

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 products 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 principle stages in this plan are described below.

2001: the "G10" masquerade and the failed attempt to modify the Directive on human medicines

In March 2001 the European Commission (Directorate for Enterprise and Industry, plus Health and Consumer Protection Directorate) 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 by the Commission's pilot project 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). ►►

a- A similar article was published by the French daily newspaper Le Monde on 28 September 2006, under the title "Big pharma nous surveille" ("BigPharma is watching us").

Selected references from Prescrire's literature watch.

1- "Patient compliance is a 30 billion complaint". Website http://www.bioportfolio.com accessed 25 September 2006: 4 pages.

2- Prescrire Rédaction "Alerte citoyenne" *Rev Prescrire* 2006; **26** (271): 241.

3- Prescrire Editorial Staff "Transposition of Directive 2004/27/EC on human medicines: beware" *Prescrire Int* 2006; **15** (83): 115.

4- Prescrire Rédaction "Programme des firmes pharmaceutiques d'"aide à l'observance": l'imposture" *Rev Prescrire* 2006; **26** (271): 300.

5- "Ordonnance: rapport au Président de la République". Website http://www.prescrire.org accessed 25 September 2006: 9 pages.

6- Hermange MT and Payet AM "Rapport d'information fait au nom de la commission des affaires sociales sur les conditions de mise sur le marché et de suivi des médicaments" Sénat 2006: 105 pages.

Three years later, 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 never 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. 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, but they contain little concrete information (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 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).

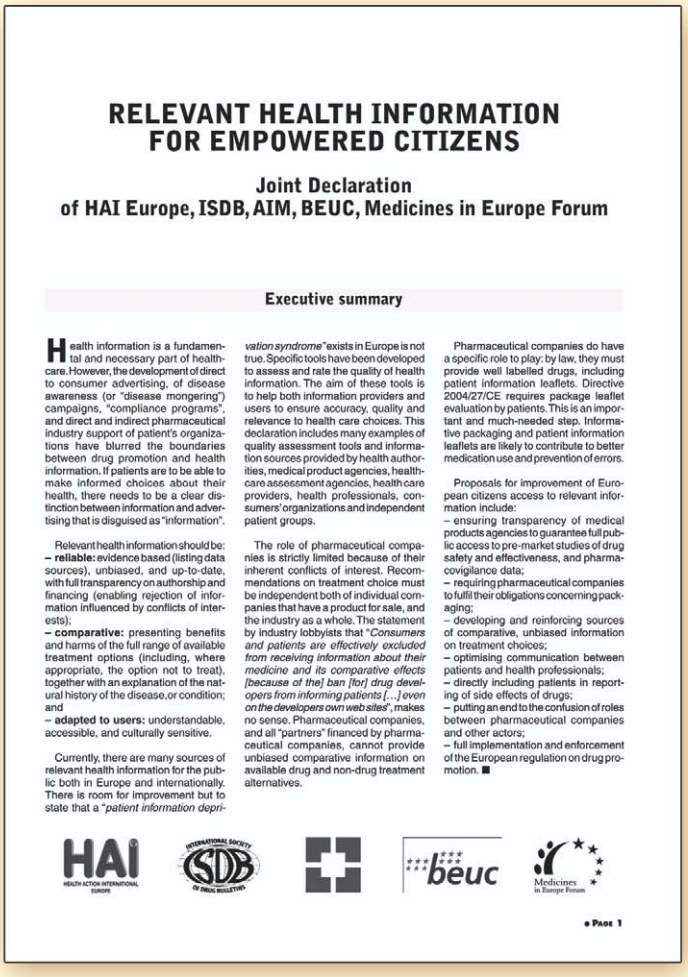
'Patient representatives' curiously in line with industry claims

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' inter-

Read and pass along the joint declaration

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, published on 3 October 2006, is available in French at www.prescrire.org (9 pages) and in English at www.isdbweb.org (8 pages). It was also included with the December 2006 issue of *Prescrire International*.



RELEVANT HEALTH INFORMATION FOR EMPOWERED CITIZENS

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

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 EUROPE · ISDB · beuc · Medicines in Europe Forum

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ests 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. In France, 'treatment compliance programmes' run by pharmaceutical companies (see page 32), are part of the same offensive (14), as is the 'dialogue' organised by the French Health Ministry on patient information (15).

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, even if the European Federation of Pharmaceutical Industries and Associations (EFPIA) continues to use the term "*information sources*" that patients should receive and that would not constitute advertising (16,17).

A group of European parliamentarians, the 'Patient Information Network' (PIN), has also appealed for the ban on direct-to-consumer advertising to be lifted (18). It is likely that the conclusions of the 'Pharmaceutical Forum' will form the basis for draft legislation.

A reorientation to defend public interests

It is against this backdrop that *Prescrire* (a member of the International Society of Drug Bulletins) and the Medicines in Europe Forum decided, in collaboration with Health Action International, the European consumers' organisation and *Association Internationale de la Mutualité*, to publish a joint declaration entitled 'Relevant health information for empowered citizens' (attached to Prescrire International December 2006 issue). This declaration is also posted in French on the *Prescrire* website at www.prescrire.org, and in English on the ISDB website (isdbweb.org).

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 will serve as a tool for those who, in the coming battle, 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. Watch this space.

a- The other two themes are drug prices and relative efficacy (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).

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).

Selected references from Prescrire's literature watch.

1- "Article 86 of Directive 2001/83/EC", non amended by Directive 2004/27/EC. Website http://eur-lex.europa.eu accessed 23 October 2006: 2 pages.

2- "Article L. 5122-1 du Code français de la santé publique". Website http://www.legifrance.org accessed 23 October 2006: 1 page.

3- Prescrire Editorial Staff "Reorienting European medicines policy - An industry-serving pharmaceutical policy" *Prescrire Int* 2002 available from http://www.prescrire.org/aLaUne/dossierEurope3En.php

4- Prescrire Rédaction "Redresser le cap de la politique du médicament (suite). Publicité directe au public: la désastreuse expérience américaine" *Rev Prescrire* 2002; **22** (232): 703-706.

5- Prescrire Rédaction "Europe et médicament. Résultats du vote en première lecture sur les projets de Directive et de Règlement relatifs aux médicaments à usage humain" *Rev Prescrire* 2002; **22** (234): 852-854.

6- Prescrire Editorial Staff "Medicines in Europe: the most important changes in the new legislation" *Prescrire Int* 2004 available from http://www.prescrire.org/aLaUne/dossierEuropeSynthese2En.php

7- Prescrire Rédaction "Publicité grand public pour les médicaments de prescription: abus et confusion" *Rev Prescrire* 2006; **26** (277): 777-778.

8- Pharmaceutical Forum "1st meeting of the Steering Committee" 6 December 2005 , and "2nd meeting of the Steering Committee" 30 March 2006 . Website http://ec.europa.eu/health accessed 23 October 2006: 11 pages.

9- Pharmaceutical Forum "First progress report" 29th September 2006. Website http://ec.europa.eu/health accessed 23 October 2006: 8 pages.

10- 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.

11- 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.

12- HAI "Does the European Patients' Forum represent patient or industry interests? A case study in the need for mandatory financial disclosure" 14 July 2005. Website http://www.haiweb.org accessed 23 October 2006: 7 pages.

13- Friends of Europe "Background report - Information for patients - The EU's policy options" September 2006. Website http://www.friendsofeurope.org accessed 23 October 2006: 21 pages.

14- Prescrire Editorial Staff ""Programmes d'aide à l'observance" des firmes pharmaceutiques: non merci !" *Rev Prescrire* 2006; 26 (277): 779.

15- "Annonce consultation mise en place par M. Xavier Bertrand", meeting of 2 October 2006: 1 page.

16- Hofmann J "Patient information still causing controversy" *Scrip* 2006; (3199): 6.

17- Mazière M "Compétitivité - Le casse-tête de l'Europe" *Pharmaceutiques* October 2006: 37-41.

18- "Call for action - Patient Information Network (PIN) - European Parliament" 21 March 2006: 1 page.

19- Pharmaceutical Forum "Introduction" Website http://ec.europa.eu accessed 23 October 2006: 4 pages.

20- Crédoc "Enquête "Conditions de vie et aspirations des français" - Chapitre 2. L'information et l'implication du grand public en matière de santé" (extract) Website http://www.sante.gouv.fr/htm/dossiers/credoc/ accessed 23 October 2006: 7 pages.

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.