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 MEDICOPHARMACEUTICAL 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?

EDITORIAL

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POSITION

BigPharma’s health information: a growing danger

● 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.

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 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 product; radio and TV programmes showing opinion leaders repeating the same message 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).
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.

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.

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 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 patient information is a component of discussion.
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 (isdweb.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.

Selected references from Prescrire’s literature watch.
5- Prescrire “This infringement of article 63 of Regulation 726/2004, as well as others, is an infringement of article 24 of the REACH Directive (concerning chemical products) was reported to the President of the EU Parliament (who is conjunctioned with the European Council) and to the European Council during the nomination procedure to the EMEA steering committee, with no significant repercussions (ref 12).”
6- Prescrire Editorial Staff “Medicines in Europe: 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).”
7- 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 direct 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).
8- 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.

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