Press release
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Pharmaceutical companies' direct-to-consumer communication: No thanks!

Despite the European Parliament's overwhelming rejection of attempts to legalize direct-to-consumer advertising of prescription drugs in 2003, the pharmaceutical industry has continuously sought direct access to patients. Indeed, the public is seen as the strategic key to broadening the market for pharmaceutical products.
The European Commission is supportive of the industry's moves: its "consultations" are little more than an attempt to sway public opinion. The underlying risks to health are conveniently overlooked, and the likely impact on the financial sustainability of member state's public health systems is consistently ignored.

Inevitable conflicts of interest, duly acknowledged by the industry. During the consultation organized by the Commission in June 2007, drug companies themselves acknowledged that the frontier between advertising and "patient information" is not clear-cut (1). This clearly undermines the credibility of the Commission's plans, which are to allow companies to communicate directly with patients about prescription drugs: the claim to uphold the ban on advertising for these same drugs would then be no more than a smokescreen (2).
In a highly competitive environment, drug companies must promote their products above the use of other preventive or curative options, thus any "information" they provide is, by definition, of promotional nature. This inevitable conflict of interest means that a drug company could never be expected to provide reliable comparative information.

Make-believe regulations do not protect against infringements. Measures intended to control direct-to-consumer advertising in the United States and direct-to-prescriber advertising in Europe have clearly failed. The relevant 'regulatory bodies' tend to detect infringements too late, often when the damage has already been done, and have difficulties imposing penalties (3,4). And who would possibly trust that the not-legally binding measures being proposed by companies (such as "self-regulation" based on a "code of good conduct", etc.) would properly safeguard direct-to-consumer communication?

Concrete proposals. Tailored patient information should help users to assess their medical status, to understand when further investigations are necessary, to know what treatments exist, along with their respective benefits and drawbacks, and to choose (or participate in the choice) among the different available options (5).
The following measures would go a long way towards improving the situation:
- enforcing (with proper sanctions) the existing European regulation on drug advertising, thus bringing a rapid and permanent end to the confusion between the role of the pharmaceutical companies and other stakeholders;
- **upholding articles 86 and 88 of Directive 2001/83/EC**, which are the only safeguards against total deregulation of direct-to-consumer communication by drug companies (**a**) (6);
- recognizing that companies already have a defined role to play in improving drug use, which is simply to provide clear and practical product labeling and information leaflets, as required by existing European legislation (**b**);
- acknowledging the many existing sources of independent and comparative information in European Union member states, and reinforcing their role (5);
- further strengthening and promoting the role of healthcare professionals and local care providers in giving patients the information they need;
- guaranteeing the full transparency of medicines agencies, in order to ensure public access to data on efficacy and adverse effects, both before and after marketing authorisation is granted;
- establishing provisions for direct consumer reporting of adverse drug reactions, which will contribute to improved use of medicines.

The Medicines in Europe Forum, Health Action International (HAI) Europe, International Society of Drug Bulletins (ISDB), and Association Internationale de la Mutualité (AIM), as well as a large body of European citizens, are increasingly concerned by the escalating merchandizing of health, and call on European parliamentarians to protect public health interests.

The signatories of this communiqué call on the European Commission to uphold patients' interests above all else, in keeping with its mission to protect public health (article 152 of the European Treaty). Measures intended to protect the competitiveness of the European health product industry must not be allowed to undermine the health of European citizens.

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Notes:

a- In its current form, article 86 states that the ban on direct-to-consumer advertising does not concern "*information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products*". This opens the way to so-called "awareness campaigns", which are no more than surreptitious promotional campaigns for new drugs. If article 86 were to be revised, it should take into account one member state's request to integrate the notion of "*prior validation by the national authorities of information provided by the drugs industry on health disorders*" (ref 7).

b- One important measure expected to contribute to better use of drugs and to error prevention is the evaluation of information leaflets by patient panels, as provided for in the Regulation (article 59 of ref 6).

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References:
1- European Commission – Enterprise and industry directorate-general "Outcome of the public consultation on a Draft report on current practices with regard to the provision of information to patients on medicinal products" 19 October 2007: 9 pages.
2- "Consultation shows no support for DTC advertising in Europe" SCRIP October 31st 2007; n°3307: 2.
3- GAO "Prescription drugs: improvements needed in FDA's oversight of direct-to-consumer advertising". Http://www.gao.gov consulted on 6 April 2007: 52 pages.
4- KCE Centre fédéral d'expertise des soins de santé "Valeur en termes de données probantes des informations écrites de l'industrie pharmaceutique destinées aux médecins généralistes" 2007; reports 55B . www.kce.fgov.be: 178 pages.
5- Joint declaration by HAI Europe, ISDB, BEUC, AIM and Medicines in Europe Forum "Relevant health information for empowered citizens" 3 October 2006. www.prescrire.org or www.isdbweb.org: 9 pages.
6- European Directive 2001/83/CE, as modified by Directive 2004/27/CE.
Ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev1.htm.
7- Représentation permanente de la France auprès de l'Union européenne "Note des autorités françaises – Réponse à la consultation relative à « questionnaire relatif à l'avenir des produits pharmaceutiques à usage humain en Europe »" 17/10/2007. Ec.europa.eu/enterprise/pharmaceuticals/pharmacommunication/pubconsult.htm: 7 pages.