



Press Release
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Direct-to-Consumer Communication by pharmaceutical companies: European Commission pushes ahead despite Civil Society's opposition

In 2003 the European Parliament overwhelmingly rejected attempts to legalize direct-to-consumer advertising of prescription medicines even under the guise of a "pilot project". Despite such opposition, the European Commission and the pharmaceutical industry have resumed their efforts since 2005 particularly through the Pharmaceutical Forum, a group with heavy industry representation, established by the Commission to draft proposals aimed at enhancing the competitiveness of the pharmaceutical industry (1). The attempt to disguise promotion as "information" in this process is even more alarming.

The European Commission intensified its pressure in 2007 and 2008. The Commission resorted to numerous so-called consultations to legitimize a legislative project planned long ago: to authorize the pharmaceutical industry to advertise prescription medicines directly to consumers. Very significantly, all public "consultations" were launched by the Directorate-General Enterprise & Industry, whose main objective is to support industrial competitiveness (a).

In May 2007: Consultation on the quality criteria and the draft diabetes model

The Commission and its Pharmaceutical Forum launched a "consultation" on the "quality" criteria to be met in patient-information, as well as a 'model' patient information package on diabetes. The absence of a clear methodology in the Forum's work, its lack of transparency and its flawed conclusions (built upon lack of consensus) were all widely denounced. Both the poor quality of the diabetes information sheet and the questionable output of a public private partnership were broadly exposed (2,3). Yet, the Forum continued to pursue further work disregarding the negative results of its first consultation.

In June 2007: Consultation on the "report on current practices with regard to the provision of information to patients, in particular through the Internet, and on their risks and advantages for the patients"

The Commission launched a consultation on a report containing an "inventory" of sources of information to patients about medicines and other treatments. The report was so incomplete that it cast doubts on the Commission's willingness to address the issues raised (4). Nearly all respondents clearly expressed their opposition to direct-to-consumer communication on prescription medicines by pharmaceutical companies (5).

End of June 2007: Second preliminary conclusions of the European Pharmaceutical Forum

On 26 June, the conclusions publicly announced by the Pharmaceutical Forum were based upon incomplete reviews, poor methodology and hasty findings, thus opening the way to biased proposals supporting the pharmaceutical industry. The lack of consensus resulted meant some Forum members could not endorse its conclusions (6).

July 2007: Consultation on the future of pharmaceutical products in Europe

Unwilling to wait for the results of the June consultation, the Commission slotted in information to patients onto the agenda of a third consultation round. This time, the strategic consultation was of general nature and aimed at "the future of pharmaceutical products in Europe". It emphasized a so-called need to remove "regulatory hindrances" in various sectors, among which the direct communication of pharmaceutical industry to patients. Nonetheless, the Pharmaceutical Forum had not, in its conclusions, suggested any proposal for legislative change (7).

Most remarkably, as soon as May 2007 and prior to the start of all consultations relating to a possible legislative change, the European Commission launched an impact assessment study of potential alterations to the legislation related to information to patients (8).

December 2007 – January 2008: Selective "impact assessments"

Other "impact assessments" were carried out in December 2007: these consisted of surveys, only available in English, prepared by Europe Economics, the consulting firm to which the European Commission outsourced the policy assessment. Some of the respondents to previous consultations received the questionnaire, others not, with no justification being given as to the selection criteria (9,10).

The questionnaire fell short in methodology: the close-ended questions showed a clear bias in favor of direct industry to patient "information" (b). Many queries were irrelevant or even precluding a serious answer (c). No opportunity was given for respondents to substantiate their responses, for example through the inclusion of scientific references. Open-ended questions were to be replied with limited space. For example, no more than 2,000 characters are available to explain to what extent responders' answers would be different if the regulation

procedure for controlling the effects of the proposed lift of the ban of direct industry to patient "information" was not governed by health authorities, which is the hypothesis given at the beginning, but rather "self-" or "co-regulation" by pharmaceutical companies.

February 2008: Consultation on legislative proposals related to information to patients

However, on February 5, 2008, unwilling to await the results of the unsound "impact assessment" study, and disregarding the opposition of nearly all stakeholders to direct-to-consumer communication by drug companies, the European Commission opened a consultation on legislative proposals related to information to patients. The European Commission's proposal points to only one option to improve patient information: the possibility of allowing the pharmaceutical industry to "inform" consumers directly about prescription medicines, using the Internet, TV, radio, print media, as well as pamphlets (11).

In an Open Letter to be published in early April 2008, we will outline our views on this ongoing public consultation.

Citizens' proposals deliberately ignored

The Medicines in Europe Forum, the International Society of Drug Bulletins and Health Action International Europe regret that the meetings and consultations, despite constructive inputs from many important stakeholders towards other positive means to improve patient information, have thus far amounted to one and only poor result: the corroboration of a legislative proposal devised long ago, which aims to remove the ban on direct-to-consumer advertising by pharmaceutical companies. It is regrettable that the European Commission has resorted to such non-transparent methods, precluding a true democratic debate.

The *Joint Declaration on Health Information* (published in October 2006 by HAI Europe, ISDB, BEUC, AIM and the Medicines in Europe Forum) provided well-documented and robust information on patients' needs, on already existing solutions and initiatives, and gave concrete suggestions for improving information to patients in Europe. Taking into account this Declaration, the European Commission would have been in a better position to express a more realistic view on patients' needs. Instead, the short term commercial interests of the pharmaceutical industry are once again given priority (12).

The private interests of the pharmaceutical industry cannot and should not override public interests and public health.

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a- The fact that the documents related to the information to patients portfolio have only been available for consultation in English resulted in the exclusion of a large number of European citizens from the debate: an indication of how hastily these public consultation have been launched, one after another, without any chronological reasoning and likely to create confusion in the public opinion.

b- As a preamble to each "impact" question, a sentence was included: "now assume that due to a change in European legislation, patients can obtain high quality, objective information from the pharmaceutical industry on medicines and the diseases/conditions which they treat, in addition to the information that is already available from other sources"... (ref 9). Pretending that the information provided by companies is "of high quality and objective" wrongly suggests that such information could not be of promotional nature, whereas many years of experience of monitoring of direct-to-healthcare professional "information" have shown that such "information" is just disguised promotion.

c- For instance, trying to guess the percentage of "patients whose disease could be prevented or improved thanks to a change in lifestyle or diet" or to measure the impact, on a scale from 1 to 5, "of this new initiative on life expectancy of patients with a given disease [Disease not specified, Ed.]" (ref. 9).

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