



The European Commission's 'proposal on information to patients' will boost drug sales not serve patients' interests

Response to the consultation on the legal proposal on information to patients (1);
deadline: 7 April 2008

Third open letter to:

Interested parties

- Members of the Patient Information group of the Pharmaceutical Forum;
- Members of the European Parliament;
- The press

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Paris, March 2008, 31

Dear Commissioner Verheugen, Dear Commissioner Vassiliou,

When the new regulatory framework for medicinal products was adopted in 2004, the European Parliament overwhelmingly rejected the Commission's proposal to remove the ban on direct-to-consumer advertising of prescription drugs by 494 votes to 42, even under the guise of "pilot project" (a) (2).

However, already in 2005 the Commission undermined this choice notably by establishing the European Pharmaceutical Forum, whose remit is, among others, to draft proposals within the framework of public private partnerships relating to "information to patients". The pharmaceutical industry is over-represented in this group (2).

During 2007, the European Commission, particularly the DG Enterprise and Industry, held numerous consultations on "information to patients". The consultation published on 5 February 2008 was the fourth since May 2007 on this issue (3). In this consultation, the Commission proposes legal changes that would allow pharmaceutical companies to communicate directly to the public about prescription medicines.

The Commission is maintaining its project to deregulate direct-to-consumer communication by pharmaceutical companies, ignoring the results of previous consultations

Direct-to-consumer advertising of prescription drugs is banned worldwide except in two countries where it is increasingly being challenged (the USA and New Zealand) (4). This ban is one of the means of providing protection to citizens, guaranteed by the status of prescription drug.

The results of the numerous consultations on "information to patients" held by the European Commission during 2007 clearly indicate that nearly all stakeholders are vehemently opposed to direct-to-consumer communication by pharmaceutical companies (3,5,6,7).

And yet, ignoring both this overwhelming opposition and the constructive proposals from many actors on other measures to improve information to patients (8), the consultation published in February 2008 merely revisits the only option envisaged by the European Commission since 2002. Under the guise of improving “information” to patients, it intends to allow the pharmaceutical industry to promote their products to the public (a) (1).

Disregarding any logical reasoning, citizens are being asked to express their views when the results of the ongoing “impact assessment” study are not yet known (b) (3).

► **The Medicines in Europe Forum (MiEF), Health Action International (HAI) Europe, the International Society of Drug Bulletins (ISDB) and the Association Internationale de la Mutualité (AIM) are appalled by the absence of a true democratic debate and by the Commission’s refusal to consider the options prioritising the interests of patients and European citizens.**

The Commission’s proposals jeopardise European citizens’ health and the financial security of the member states’ health systems

After having claimed for months that Europe is an “information desert” which only the pharmaceutical industry is able to fill, the Commission has finally been forced to acknowledge the existence of numerous, accessible and independent sources of quality information in the various EU member states (c) (9).

The Commission’s arguments justifying the proposal, against all odds, to allow pharmaceutical companies to promote their products directly to the public remain unconvincing (1,9). It is now insisting on the need to “*harmonize the existing situation in Member States*” to provide patient-information on prescription medicines in order to promote ‘equality’ among European citizens. But, as the experience of the diabetes information model has shown, ‘equality’ should not mean going for the lowest common denominator (remember the diabetes data sheet) (d).

The European Commission and the pharmaceutical industry deny any attempt to allow direct-to-consumer advertising for prescription drugs; yet the Commission is proposing pharmaceutical companies to be able to promote their products to the public via the media: television, radio, to actively distribute printed literature, as well as audiovisual and printed material via health professionals! (1,10)

Can a television programme produced by a pharmaceutical company be a less effective form of promotion than a 30-second TV ad?

Maintaining patients’ freedom to choose. Informing patients, by meeting their needs as fully as possible, implies a relationship of trust which is at the core of the caregivers’ profession and is crucial for the day-to-day life of the patient’s entourage, the work of independent patient groups and is part of the remit of the independent drug bulletins aimed at the public (2,8).

Patient information should help users to analyse their concerns, to realistically 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.

In order to make genuinely informed choices, patients need, above all, reliable comparative data. But this crucial criterion has been arbitrarily excluded from the “quality criteria” proposed by the European Commission: “Comparisons between medicinal products should not be allowed”! (1)

Information on a single drug is inadequate and biased if it is not placed in a comparative context nor supported by systematic, unbiased evidence-based documentation research.

In order to help patients to cope with the changes in European society (ageing population and obesity, as well as the growing number of self-medication drugs), it is important to reinforce and promote the role of local caregivers in providing information and to clarify the roles of the various actors, which are becoming increasingly blurred (2).

Information provided by pharmaceutical companies = advertising. Claiming that pharmaceutical companies have “key information” to justify granting direct access to patients is hypocritical: what key information is the industry going to provide to patients that it has not already given to the authorities and health professionals? What key data are pharmaceutical companies going to give to patients that have not been included on the patient leaflet or the assessment reports that are available at any time on the Eudrapharm European database and on the websites of the member states health authorities, and constitute regulatory obligations? Countless recent examples show that pharmaceutical companies are not in the habit of divulging certain items of “key information” which they possess, such as information on the

risks associated with their drugs (remember the recent affairs with Vioxx°, Zyprexa°, Avandia°, Seroxat°, etc.) (e).

The “*lack of a clear distinction between advertising and non-promotional information*” is a stumbling block over which the Commission tripped in 2002 (1). “Information” as defined by the Commission is a definition by default: “*communication not covered by the definition of advertisement, should be regarded as information*” (f). However the quality criteria proposed by the European Commission that “*should distinguish the information that is allowed from the information that is not allowed*” were not the subject of a consensus within the Pharmaceutical Forum (11) and are insufficient where patients’ needs are concerned (8). Furthermore, during the consultation held by the Commission in June 2007, pharmaceutical companies themselves acknowledged that the boundaries between the “information” they provided and advertising were not clear (6).

The so-called safeguards on the content of the “information” to be provided do not dispel this confusion. On the contrary, the plan to allow companies to “*give information about scientific studies*” approves a dangerous marketing practice. It stimulates demand, thus favouring the commercial launch of drugs being trialled for new indications on the basis of partial results, with insufficient time to evaluate the drug’s efficacy and safety for such new indications (1).

In a fiercely competitive climate, pharmaceutical companies are under pressure to champion the drugs they market to the detriment of other preventive or curative means, making the “information” they provide promotional by nature. Their conflicts of interest are an insurmountable obstacle to objectivity.

Ineffective controls, leaving the door wide open to abuse. Controls on direct-to-consumer advertising in the USA or of direct-to-doctor advertising in Europe are a failure, and this failure underscores only their ineffectiveness. The watchdog authorities confine themselves to acknowledging the abuse at later stages, often after the initial damage has been done, and struggle to apply their sanctions (12,13).

At a time when the US Food and Drug Agency has just increased its budget by several million dollars to improve the monitoring of direct-to-consumer-advertising by pharmaceutical companies, especially on television (14), the Commission’s proposals on the “control” of “information to patients” with regard to prescription-only drugs are minimalist.

No previous (ex ante) controls are planned: only the obligation to provide information on planned activities for information received ‘passively’ by citizens (known as ‘push’); and a vague ‘monitoring’ of information sought ‘actively’ (websites, etc.) (known as ‘pull’) by a so-called national ‘co-regulation body’, which will act both as judge and defendant, since the pharmaceutical industry will be among its stakeholders (1).

Sanctions will be imposed retrospectively, once the “information” has been disseminated and the first public health damage established, and only in cases of “*repeated and severe non-compliance*”! (1)

Setting things straight: our recommendations

A rational approach consists of learning from past mistakes, in the United States and in Europe, to avoid reproducing models that damage European citizens’ health and the future of our health systems.

Learn from past experience. In countries where direct-to-consumer advertising of prescription drugs is allowed, several studies have shown that it creates patient demand, leading to over-prescription by physicians (15 to 18). It thus increases non-medically-justifiable health expenditure on drugs that expose patients to adverse effects (19 to 21). The increasingly frequent health scandals are reminders of both the legal and medical risks associated with an over-promotion of new drugs and its irrational use (22,23).

The European experience of direct-to-doctor advertising, in particular through medical sales representatives, has shown that, despite the European and national “codes of conduct” and other tools such as the French “medical sales reps’ Charter”, pharmaceutical companies fail to ‘inform’ health professionals correctly, which results in inappropriate, even dangerous, prescribing (24,25). Its extent and impact on health spending and public health is so large that the authorities in several European countries had to counter the influence of the pharmaceutical companies’ propaganda via academic detailing (26) and recommended the “*progressive promotional disarmament of pharmaceutical companies*” (24). Do we want to extend this experience to the entire European population?

Enforce existing obligations and end the confusion of roles. The European legal framework is clear (see inset on page 4). In accordance with the legal obligations on transparency adopted in 2004, one of the medicines regulatory authorities’ remits is to make available to the public standardised documents designed to be easily understandable and accessible to the public:

- package leaflets (article 21) ;

- assessment reports (article 13) ;
- and pharmacovigilance data (article 26.3).

Pharmaceutical companies have a very specific part to play in promoting rational use of medicines, one which is strictly limited to improving the quality and clarity of the package labelling and patient leaflets in compliance with the law (article 59), which they already have difficulty in implementing.

The enforcement of these obligations must be strongly encouraged by the Commission, and this applies to all the EU member states (these obligations are set out in Appendix I point 2 of reference 29).

**Articles 88 and articles 86:
Two key articles that must be upheld**

The current EU regulatory framework does not allow direct-to-consumer advertising of prescription drugs (article 88 of Directive 2001/83/EC modified by Directive 2004/27/EC).

However, according article 86 of the Directive, the ban does not apply to:

- *“information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products”;*
- *“correspondence (...) needed to answer a specific question about a particular medicinal product”;*
- *“factual, informative announcements and reference material (...) provided they include no product claims”* [Editor’s note: for example, information on the existence of a risk of counterfeit].

Pharmaceutical companies and their representative organisations benefit greatly from the opportunities offered by this framework and already go far beyond (“disease awareness” campaigns, disease mongering, etc.).

The Medicines in Europe Forum (MiEF), Health Action International (HAI) Europe, the International Society of Drug Bulletins (ISDB) and the International Association of Mutualité (AIM) stress the importance of article 88 of Directive 2001/83/EC, the only safeguard against the deregulation of direct-to-consumer communication by pharmaceutical companies.

The Commission cannot continue to overlook the economic and health consequences on health spending and their burden on the public purse of member states if direct-to-consumer communication by pharmaceutical companies is deregulated in the EU.

Prior to any legislative proposal, the Medicines in Europe Forum, HAI Europe, the ISDB and the AIM call on the European Commission to fulfil its mission of protecting public health (article 152 of the Treaty establishing the European Community) (27).

The signatories of this letter urge their representatives at the European Parliament and the Member States’ Ministers of Health to remain vigilant with regard to this issue.

► **Blindly defending the competitiveness of pharmaceutical companies must not take priority over public health.**

► **The scope of articles 86 and 88 of Directive 2001/83/EC, the only safeguards against deregulation of the industry’s direct communication with the public, must not be undermined, under any circumstances.**



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of Drug Bulletins**



Medicines in Europe Forum



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Notes

- a-** Already in 2002, an explanatory memorandum concerning the 2002 proposal to modify Directive 2001/83/EC clearly laid out the aim of this proposal in the following terms: *"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."* (ref. 28). [Editor's note: the Commission itself uses the word 'advertising'.]
- b-** This "impact assessment" study was carried out in December 2007 using questionnaires solely in English. The study's methodology is blatantly flawed: some of the respondents to previous consultations received the questionnaire, others not, with no justification being given as to the selection criteria; questions were irrelevant or even precluded a reliable answer; there is incoherence between the principal option of regulation proposed in the questionnaire (monitoring governed by health authorities) and the hypothesis chosen by the Commission ("self- or "co-regulation" by pharmaceutical companies) (ref. 3).
- c-** The paucity of the report on "current practices with regard to the provision information to patients" in Europe has been extensively criticised (refs. 6, 27), which prompted the Commission to acknowledge and list several existing initiatives in the working document made public in December 2007 (ref. 29). The initiatives mentioned are mainly those being implemented by member state health authorities, and the few examples of public-private partnerships mentioned are under the careful control of the health authorities. Reference 8 lists numerous independent quality patient information initiatives in Europe.
- d-** Announced amid great fanfare as it was supposed to serve as a "model", the diabetes data sheet sent out for consultation in May 2007 had been compiled as part of a public-private partnership, after more than two years' work by the Pharmaceutical Forum. Much criticism has been made of the mediocre quality and uselessness of this data sheet (refs 5, 30). The question arises as to the pertinence of a "one-size-fits-all" approach of this kind on a Europe-wide scale given the different health systems and cultures in the member states.
- e-** The recent pharmacovigilance drug tragedies such as the Vioxx^o affair (an anti-inflammatory drug which caused fatal cardiac accidents) or the Zyprexa^o affair (an anti-psychotic drug which was found to cause diabetes and metabolic disorders), Avandia^o (an antidiabetic drug that can cause fatal cardiac disorders), Seroxat^o (an antidepressant that carries an increased risk of suicide), etc. are a reminder that adverse effects are often minimised, even concealed by the pharmaceutical companies, for as long as possible (refs. 21,22,31,32).
- f-** The definition of advertising (Directive 2001/83/EC modified by Directive 2004/27/EC article 86(1) states that it *"shall include any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products"*.

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