



2nd Open letter

to interested parties:

- European Pharmaceutical Forum's working group on information to patients;
- Members of European Parliament;
- the Media

Commissioner Günter Verheugen
European Commission
200, Rue de la Loi
B-1049 Brussels (Belgium)
Fax: +32.2 / 299.18.27
guenter.verheugen@ec.europa.eu

Commissioner Markos Kyprianou
European Commission
200, Rue de la Loi
B-1049 Brussels (Belgium)
Fax: +32.2 / 298.84.73
markos.kyprianou@ec.europa.eu

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Dear Commissioner Verheugen,
Dear Commissioner Kyprianou,

When Directive 2004/27/EC on medicinal products for human use was adopted, the Parliament and Council asked the Commission to prepare a report in 2007 on the benefits and risks of information currently available to the public (article 88a). This was to include information that is available via the Internet, and was meant to put forward proposals for improvements in information provision, if needed. In late April 2007 the Commission (Enterprise and Industry Directorate-General) released a consultation paper entitled '*Draft report on current practices with regard to the provision of information to patients on medicinal products*', supposed to answer this request.

The report's review of sources of patient information on drugs and other treatments is so incomplete that it casts doubts on the Commission's willingness to address the issues raised by article 88a. Additionally, the report's conclusions are exclusively biased in favour of allowing drug companies to communicate directly with the public, further undermining the Commission's credibility. In short, the Commission failed to respond to the mandate set out in article 88a. The Medicines in Forum Europe (MiEF), Health Action International Europe (HAI Europe) and the International Society of Drug Bulletins (ISDB) are three organizations with strong concerns about the future of patient information in Europe. We are addressing this open letter to you in order to contribute to an honest, balanced and public debate on the issue, with a focus on public health as an overriding priority.

The report's methodology: multiplication of trickery

Despite a first legislative failure in 2002, when the European Parliament rejected by 494 votes to 42 the Commission's proposal to lift the ban on direct-to-consumer advertising for prescription-only drugs (even within the framework of a 'pilot project') the Commission still appears to be pursuing the same objective: removal of all obstacles, including regulatory barriers, to direct-to-consumer communication by pharmaceutical companies (aⁱ)(1).

The Commission has confused the issue by carrying out a number of initiatives simultaneously. With no respect for logical progression or timing, the Commission released a consultation paper on patient information containing proposals made by its Pharmaceutical Forum before releasing its report on the

ⁱ - Notes and references: page 5.

current state of patient information in the European Union. Both documents were produced in a near-total secrecy (b).

The methodology used to prepare the Commission report on patient information in Europe is described in vague terms and in just a few lines. The main body of the report is badly organised and unclear and the annexes are incomplete. No list is included of the individuals and organizations who were consulted when the report was produced and the table listing sources of information fails to indicate who supplied information within each Member State, apart from regulatory agencies. Additionally, the table entitled 'Information available on the Internet' only lists approved product information and accompanying administrative documents (c) and omits all other types of information. The text accompanying this table mentions a few other sources of information, provided by various sources in a few Member States only, without providing details on how these initiatives were financed, methods used to produce the information, nor what types of information are covered.

Despite the incomplete inventory of sources of information in Europe in this report, and the flawed methodology used to produce it, the authors come to the firm conclusion that only the pharmaceutical industry is capable of providing patients with the information they would otherwise miss.

► **MiEF, together with HAI Europe and the ISDB, consider that no proposal for legislative change should be based on a report that has been produced without any clearly defined methodology and with a near-total lack of transparency.**

An incomplete and biased report

The Parliament and Council asked for a report on the benefits and risks of current patient information, including information that is available via the Internet, which is difficult to regulate. The report focuses on information on prescription-only drugs (and other therapies) available on the Internet, and proposes means of improving access to this type of information (d,e). Thus, the Commission's report fails to fulfill the mandate entrusted by Parliament.

A poor report on current sources of information. The report provides an incomplete list of current sources of information. For example, it omits many information providers in Europe that are independent of drug companies and regulatory bodies, including the 33 ISDB member bulletins (many of which are accessible to the public), health professional organizations, patients and consumer groups, agencies that carry out pharmaco-economic evaluations, health technology assessment groups, healthcare service providers, drug reimbursement agencies, and patient health education organizations settled up by Member States. However, these sources of information are clearly mentioned, including many examples, in the Joint Declaration 'Relevant health information for empowered citizens', signed by AIM, BEUC, HAI Europe, ISDB and the MiEF. This Declaration was published in October 2006 and has been widely circulated (2). Furthermore, not all the results of the survey conducted by the Commission concerning sources of patient information in EU Member States appear to have been taken into account in the report.

In the last few months, without carrying out a proper investigation of sources of information in Europe, the Commission has unremittingly repeated the same argument, which is also that of the pharmaceutical industry: namely that Europe is a health information 'desert' and that only drug companies are capable of remedying the situation (1,3).

► **MiEF, together with HAI Europe and ISDB regret that this report is used as a further source of public opinion disinformation.**

A biased description of risks and benefits. The report provides no substantive evidence on the benefits to patients of the many existing sources of information to which they have access. The risk analysis is brief and combines issues as diverse as counterfeiting and the risks associated with uninformed choices due to a lack of comparative information on treatments (f).

Comparative information, which is indeed crucial for informed decisions, cannot be provided by pharmaceutical companies, because of inherent conflicts of interest (4). What company could possibly recommend a competitor's product over its own, or recommend discontinuing treatment with its own product?

At the end of the section on benefits and risks, the Commission highlights the paucity of the published literature on the subject. Indeed, few references accompany the report, suggesting that the authors failed to conduct an extensive literature search before editing this document.

► **MiEF, together with HAI Europe and the ISDB, condemn the shaky and undocumented nature of the Commission's analysis, and the resultant bias in its conclusions.**

Patient exploitation. The report's description of patient information needs comes down to a simple claim that patients have a 'fundamental right' to information on medicines (g). However, information needs are defined by 'quality criteria' developed by the Pharmaceutical Forum, even though the results of the consultation on these criteria were not available when the discussion paper was released (h)!

The report does not even mention that patient information must answer patients' own questions, especially when it comes to making informed choices among available options and services (2). Considering the real needs of patients would have led to propose very different solutions from those proposed by the Commission (see for example the proposals of MiEF, HAI Europe and ISDB on the next page).

► **MiEF, together with HAI Europe and ISDB, believe that if patients have a fundamental right to information, this right should be to the comparative information that forms the basis for informed treatment choices. The Commission's report disregards this key fact.**

Bypassing health professionals and regulatory bodies. Providing patients with the information they are seeking implies the need for trust, which is at the heart of the relationship between patients and health professionals, patients and their families, independent patient groups, and independent drug bulletins that produce information for the public (2). Yet the Commission's report marginalizes health professionals, mentioning them only in passing. As a result health professionals would be simple intermediaries for information provided by pharmaceutical companies (i).

One of the responsibilities of regulatory agencies is to ensure the availability and quality of patient information leaflets, assessment reports, and also information on drug safety, as required by EU transparency obligations. The Commission needs to strongly encourage regulatory agencies in all EU Member States to implement these transparency obligations. The responsibilities and mission of regulatory agencies must not be allowed to be hijacked by drug companies, as the report implies, under the pretext that companies "possess key information about their products".

To argue that companies should be allowed to communicate directly with patients because they possess key information is a sophism: what "key information" are companies going to provide to patients that they would not provide to regulatory agencies or health professionals? Companies are not known for publicly revealing "key information" they hold, such as evidence of health risks associated with their products. Recent examples such as the Vioxx^o disaster (j) or the current Zyprexa^o and Avandia^o scandals (k,l) are potent reminders that adverse effects are often minimized and sometimes even concealed by drug companies as long as they can do.

► **MiEF, HAI Europe, and ISDB condemn the fact that this report skillfully maintains the confusion of roles between the pharmaceutical industry and other actors in the healthcare sector. This confusion of roles interferes with the ability of individuals to make rational choices based on reliable comparative evidence. In other words, it undermines healthcare quality.**

Further weakening of the legislative framework. The current European legislative framework prohibits companies from advertising prescription-only medicines directly to the public. There is no prohibition of "*information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products*" (Directive 2001/83/EC article 86).

This legislative framework is clear. However, pharmaceutical companies and industry associations already exploit and sometimes abuse the possibilities available under existing regulations (4). Public-private partnerships have already led to concerns about conflicts of interest in information provision. Curiously, among listed national sources of information, the Commission's report highlights three ventures that involve public-private partnerships (annex 2). The Commission is in essence admitting that the existing legal framework is already loosely interpreted in some EU Member States (1). The risk in making these approaches into the norm, rather than the exception, is a shift towards the lowest common denominator (m).

► **MiEF, HAI Europe and ISDB stress the importance of article 88 of Directive 2001/83/EC, which is the only legislative safeguard against full introduction of direct-to-consumer advertising of prescription drugs. All three organisations condemn the Commission's attempt to undermine this prohibition.**

Concrete proposals

A report of such low quality cannot contribute to an improvement in the provision of reliable health information to EU citizens. The following changes are needed if the aim is to bring about real improvement:

- a rapid and permanent end to the confusion between the role of pharmaceutical companies and other actors in the healthcare sector;
- recognition of the many existing sources of information in European Union Member States (see reference 2) and the role of local caregivers;
- development and reinforcement, in each Member State, of the existing sources of reliable comparative information on available treatment options;
- actions to ensure that pharmaceutical companies consistently respect their obligations to provide high-quality drug packaging and patient leaflets;
- full enforcement of European regulations on pharmaceutical advertising, including measures to ensure that article 88 of Directive 2001/83/EC is not weakened or undermined;
- a guarantee of the full transparency of drug regulatory agencies, to ensure that the public has access to data on the efficacy and safety of medicines and other healthcare products, both before and after a product is marketed;
- provisions for the direct consumer reporting of adverse drug reactions, which will contribute to improvements in the use of medicines.

MiEF, HAI Europe and ISDB, reaffirm that the market for healthcare products has unique characteristics. Patients are not consumers. One of the Commission's central responsibilities is protection of the health of European citizens (article 152 of the European Treaty). Support for industrial competitiveness must not be allowed to supersede public health interests.

Increasingly frequent health scandals are ongoing reminders of the medical and legal dangers of excessive promotion of new medicines. One cannot ignore the consequences of the drug disasters not only for public health but also for healthcare costs. These include both direct costs and costs of management of adverse effects. The Commission cannot continue to ignore the economic implications of deregulation and direct-to-consumer communication by pharmaceutical companies on healthcare expenditures supported by healthcare services within Member States. Sooner or later the negative long-term consequences will become apparent to all, including the pharmaceutical industry.

MiEF, HAI Europe and ISDB thank you for your attention to these concerns, which are shared by many European citizens increasingly worried by the commercialization of healthcare.



Medicines in Europe Forum



HAI Europe*



**International Society
of Drug Bulletins**



**Association Internationale
de la Mutualité**

Contacts:

MiEF: Antoine Vial (europedumedicament@free.fr)

HAI Europe: Teresa Alves (teresa@haiweb.org)

ISDB: Maria Font (maria.font@ulss20.verona.it)

AIM: Rita Kessler (rita.kessler@aim-mutual.org)

* HAI Europe is also submitting a response to the report.

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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 5).
- b- In our first open letter we alerted you to the flawed methodology and deficiencies of documents issued by the Pharmaceutical Forum (only in English) (ref 6). In addition, on 10 May 2007, i.e. 2 working days only after the end of the consultation of the Pharmaceutical Forum, when the results of the Forum’s and Commission’s consultations were not yet available, MEP Jorgo Chatzimarkakis recommended during an oral presentation by the Pharmaceutical Forum the introduction of direct-to-public communication by pharmaceutical companies on prescription medicines, within a self-regulatory framework, despite evidence that self-regulation of pharmaceutical advertising is ineffective (ref 4).
- c- The following documents are listed: summaries of product characteristics (SPC); patient information leaflets (PIL); and European public assessment reports (EPARs).
- d- In addition to this report, the Pharmaceutical Forum conducted a ‘literature search’ on access to information by children and adolescents, the elderly, the deaf, the blind and the illiterate. The methodology of this ‘search’ is not clearly described. Online publication of the results on DG Enterprise’s website, in early May 2007, seemed intended solely to provide companies with a pretext for distributing information via the Internet, and also by any other means that might increase their audience such as: interactive television; distribution of brochures in community and hospital pharmacies by healthcare professionals (who would in effect become company representatives); telephone contacts; cassettes; pictograms; school education; etc. (ref 7).
- e- Furthermore, two pseudo-workshops were organized in November 2006, apparently to address the criticisms of some healthcare professionals. The reports generated by those workshops were of poor quality and were only published online in early May 2007 on DG Enterprise’s website; they were not circulated for consultation (refs 8,9).
- f- There is evidence of bias in the information provided by pharmaceutical companies on counterfeiting (ref 10).
- g- Drug companies have used a variety of techniques to justify their attempts to legitimize the view that patients ‘need’ information on medicines that can only be provided by pharmaceutical companies. For example, Pfizer organized a national survey of patient groups that included biased questions and went so far as to ask “whether the law prohibiting companies from mentioning the name and the characteristics of drugs in advertising to the public ‘should evolve’” (ref 11).
- h- Responses to the consultation show there is no consensus on the proposed quality criteria.
- i- The role of health professionals in providing information to patients on behalf of pharmaceutical companies already has a name: “infomediaries”, and pharmacists are already being asked to become “brochure distributors”. These brochures are for example being included in some community pharmacies’ computer programmes that are used to manage sales.
- j- After being intensely promoted to the public in the USA, Vioxx^o (rofecoxib), a non-steroidal antiinflammatory drug whose cardiovascular adverse effects had been played down, caused many deaths (ref 12).
- k- Zyprexa^o (olanzapine) is an antipsychotic drug whose serious adverse effects (diabetes and cardiotoxicity) were concealed by the company. There are currently several legal actions against the manufacturer, Eli Lilly, in the United States (ref 13).
- l- Avandia^o (rosiglitazone) is an antidiabetic drug with cardiovascular adverse effects. Patients were not adequately informed of these adverse effects, even though they had been known for several years (refs 14,15).
- m- The “information model” on diabetes released for consultation by the Pharmaceutical Forum, clearly illustrates the fact that “information” produced in a private-public partnership, without systematic literature search procedures and editorial methods, is of no use to patients (ref 6). It mentioned for example the glitazones as a therapeutic option despite concerns about their safety. Cardiovascular adverse effects of rosiglitazone (Avandia^o) have since been disclosed (ref 14,15).

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