



Open letter

to interested parties:

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

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

Commissaire Markos Kyprianou
Commission européenne
200, Rue de la Loi
B-1049 Brussels (Belgium)
Fax: +32.2 / 298.87.01
markos.kiprianou@ec.europa.eu

Paris, May 3. 2007

Dear Commissioner Verheugen,
Dear Commissioner Kyprianou,

In mid-March 2007, the European Pharmaceutical Forum's working group on information to patients released two documents for public consultation: a list of 'quality criteria' for patient information, and a sample patient information sheet on diabetes.

We are concerned that the questions that accompany this consultation frame it in such a way as to prevent any real democratic debate and to predetermine the type of responses that are likely to be received. This creates yet another sham consultation process, designed to justify a long-term plan for legislative change aiming to remove the ban on direct-to-consumer advertising of prescription drugs. The Medicines in Europe Forum cannot in all conscience take part in this consultation. Nevertheless, as key stakeholders with responsibilities for medicines information policies, we would like to contribute towards an honest, balanced debate by means of this open letter. Health Action International* (HAI) Europe and the International Society of Drug Bulletins** (ISDB) support the content of this letter and shares the concerns expressed by the Medicines in Europe Forum.

Both the Pharmaceutical Forum's lack of transparency and lack of explicitly described methods remain unacceptable. The Medicines in Europe Forum, together with Health Action International (HAI) and the International Society of Drug Bulletins (ISDB), deplore the fact that since its inception the Pharmaceutical Forum has operated with an almost total lack of transparency. (1) This consultation provides additional evidence of this lack of transparency: two documents have been submitted for public consultation with no explanation on methods that were used to produce them, nor any disclosure of information on authors or their potential conflicts of interest. In fact, many of the participants of the Pharmaceutical Forum have suggested that no systematic methods were used to develop these documents, which is even more serious. Under these circumstances, the poor quality of the results is not surprising.

The proposed quality criteria are vague and far removed from patients' best interests. The proposed list of criteria is long and uses ambiguous terms that are susceptible to 'flexible' interpretation. Moreover, the title of this document is likely to create confusion between 'health information' and 'information on illnesses and drugs'.

It is important to remember that the sole purpose of patient information is to provide answers to patients' questions. The information provided should help patients to better understand their concerns and should provide them with realistic expectations of their future health status. It should help them to understand diagnoses and the likely results of different treatment options, as well as the various choices of treatments and services available. Finally, this information should help patients to cope with the suffering and to obtain help. (2)

To make an informed decision, patients need comparative information that presents the whole range of available options and, for each option, expected benefits and harm. Recent tragic examples such as Vioxx^o and more recently Zyprexa^o are potent reminders that pharmaceutical companies often minimize or even fail to disclose adverse effects.

Above all, health information should fulfil three very simple criteria. It should be:

- **Reliable:** evidence-based (with references cited to back each claim), totally transparent as regards to authors and their conflicts of interest, and up-to-date;
- **Comparative:** presenting benefits and risks for all treatment options, including, if appropriate, the option not to treat, as well as information on natural disease and symptom progression;
- **Adapted to users' needs:** understandable, adapted to patient's social, linguistic and cultural backgrounds, and easily accessible.

In a fiercely competitive marketplace, pharmaceutical manufacturers naturally have an obligation to their shareholders to realize profits from sales. They must therefore promote their own drugs rather than other preventative or treatment options. As a result, pharmaceutical companies are utterly incapable of providing the reliable comparative information needed by patients.

The diabetes 'example' is a counterexample of patient information. Those involved in health care provision, such as health professionals, consumer and patient groups that are independent of the pharmaceutical industry, health authorities and reimbursement agencies have not waited for pharmaceutical companies to take an interest in patient-'information' to produce relevant information for patients.

Many sources of high quality information are now available to the public in Europe and internationally. (2) Granted, improvements are still needed, especially when it comes to helping the public evaluate the ever-growing mass of information in order to better distinguish between useful and useless information. (a)

With the diabetes patient information 'example', the Pharmaceutical Forum asks citizens to express an opinion on a document when they do not even know how it was produced. Transparency concerning the methods used to produce patient information is an essential prerequisite if the people whose opinions are being sought are to be treated in a responsible and respectful manner.

We have however made the effort to read the document and are alarmed at the poor quality of its content. It does not answer patients' basic questions, nor does it prioritize information in terms of its importance. It does not compare existing treatment options and fails to provide any information on the amount of evidence available concerning effects of long-term use, nor does it cite references to back claims. It is pointless to give a detailed list of the changes required: the entire document needs to be rewritten if it is to provide the type of information needed to meet patients' needs. Currently, it patently fails to do.

This purported 'example' demonstrates -- as if proof were necessary -- that standardised 'information' produced at European level as part of a public-private partnership without rigorous literature search criteria or editorial methods, is of no benefit to patients.

We would like to believe that the European Commission is capable of challenging this process and will stop funding projects of this type, which are completely unsuited to the needs of European citizens.

We demand an end to the skilfully maintained confusion of roles. In recent months, a few Members of the European Parliament, claiming to defend patients' 'right to information', have been attempting to sway public opinion by creating the misleading impression that Europe is devoid of quality

health information, and that only the pharmaceutical industry is capable of remedying this situation. This has been done through a fanfare of publicity of all kinds including seminars, facilitation of workshops, conferences opportunely set-up by so-called think-tanks, etc.

The Medicines in Europe Forum, together with HAI and the ISDB, stresses once again that the 'information' provided by pharmaceutical companies is by definition promotional, and that the use of the word 'information' in this context is an abuse of the term: ultimately this is advertising. Patients' and citizens' ability to make decisions concerning their own care must be protected all the more from the influence of advertising masquerading as 'information', especially as illness increases people's vulnerability.

Information needs are complex and vary from person to person. Differences in physical and/or mental abilities, educational background and socio-economic status help to determine the type of information expected by patients and how they will use it. Providing information that meets patients' expectations as closely as possible implies a relationship of trust that is part of the day-to-day work of health professionals independent patient groups, families, and the mission of independent drug bulletins aimed at the public. (2)

Pharmaceutical manufacturers have a different and very specific role to play: the law requires them to supply properly labelled medicinal products accompanied by a patient information leaflet. Directive 2004/27/EC specifies additionally that these leaflets must be evaluated by patients. (3) This important measure was much needed. The development of safe, informative packaging and relevant patient leaflets by pharmaceutical manufacturers can contribute to improved medicine use and to prevention of medication errors. (4) There is still much room for improvement, and some companies have begun to make important progress.

Any confusion of roles between these different actors runs the risk of jeopardizing the quality of care and the freedom of each person to make choices that meet their own health needs.

May we remind you of your mission to protect public health. After an initial failure to introduce legislation removing the ban on direct-to-consumer advertising of prescription medicines in 2002, due to overwhelming rejection by the European Parliament, the European Commission and the pharmaceutical industry, actively supported by a few Members of the European Parliament (MEP's), appear to wish to reintroduce this initiative, taking advantage of the fact that more than 70% of MEP's are new. Will this little game, which consists of regularly challenging democratic choices for the benefit of a small interest group, be repeated with each new European Parliament? We sincerely hope not.

The Medicines in Europe Forum, together with HAI and the ISDB, condemns the fact that the European Commission has overstepped its remit from Parliament, which was merely to present a report in 2007 on the benefits and risks of current approaches to information provision, including information on the Internet (Directive 2004/27/EC - article 88a). **(b)** The Commission is biasing this debate by clearly supporting direct-to-consumer advertising under cover of 'public-private-partnerships' in patient information. This misrepresentation fools no one. (5,6,7) This position fails to take into account the evidence of harm from direct-to-consumer advertising, nor the ongoing efforts of health care providers to improve patient information for the benefit of public health.

The health products market is not a market like any other. Patients who are facing illness are vulnerable; they are not simply consumers. In allowing pharmaceutical firms to be competitive the Commission must not forget the key role it has to play in protecting European citizens' health (article 152 of the Treaty establishing the European Community).

We wish to draw your attention to a few simple proposals to improve citizens' access to relevant information. In practice, improved access for European citizens to relevant health information requires:

- Guaranteeing the transparency of drug regulatory agencies to ensure that the public has full access to effectiveness and safety data on drugs or health technologies both before and after market approval;
- Ensuring that pharmaceutical manufacturers fulfil their drug packaging obligations;
- Developing and strengthening sources of reliable, comparative information on treatment options in every member state;
- Allowing patients to be directly involved in reporting drugs' adverse effects and thus contribute to improved drug use;
- Ensuring that EU regulations on drug advertising are fully implemented;

- And above all, putting an end to the confusion of roles between pharmaceutical companies and other actors.

The Medicines in Europe Forum, Health Action International Europe and the International Society of Drug Bulletins call on the European Commission to fulfil its responsibilities by including these proposals in the report on patient information in Europe required by Directive 2004/27/EC, the preliminary version of which has just been made available for consultation. (b)

The Medicines in Europe Forum, HAI Europe and the ISDB thank you for acknowledging these concerns, which are shared by many European citizens who fear that healthcare is being treated as a mere commodity.



**Medicines in Europe Forum
with the exception of those who are involved
in the work of the Pharmaceutical
Forum***.**



International Society of Drug Bulletins**

- * HAI Europe provides also an individual reply to the consultation.
- ** ISDB also produced a press release 'Patient-'information' by Big Pharma: A threat to public health' (www.isdbweb.org).
- *** The members of the Medicines in Europe Forum who are involved in the work of the Pharmaceutical Forum wish, in accordance with their commitments, to present objections and proposals to the Commission during the Forum's working parties.

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a- *To do this, a number of specific tools for evaluating and measuring the quality of health information have been developed to identify quality information available (ref. 2).*

b- *We will be sending you a second open letter on the subject of the 'draft report on current practices with regard to the provision of information to patients on medicinal products' in the European Union, available for consultation until 30 June 2007.*

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- 1- Joint position of the Medicines in Europe Forum, the International Society of Drug Bulletins, Health Action International Europe "Health information: A clear division of roles is needed to protect public health" March 2007: 4 pages.
 - 2- Joint declaration by HAI Europe, the ISDB, BEUC, the AIM and the Medicines in Europe Forum "Relevant information for empowered citizens" 3 October 2006: 9 pages. Website: <http://www.isdbweb.org> accessed 30 April 2007: 8 pages.
 - 3- European Commission "Guidance concerning consultations with target patient groups for the package leaflet" May 2006: 5 pages.
 - 4- European Commission Notice to applicants "Guideline on the packaging information of medicinal products for human use authorised by the Community" March 2007 : 34 pages.
 - 5- Verheugen G "Pharmaceutical Forum: delivering better information, better access and better prices" Brussels 29 September 2006. Website <http://europa.eu> accessed 23 October 2006: 4 pages.
 - 6- Kyprianou M "Pharmaceutical Forum: delivering better information, better access and better prices" Brussels 29 September 2006. Website <http://europa.eu> accessed 23 October 2006: 5 pages.
 - 7- European Commission "Draft report on current practices with regard to provision of information to patients on medicinal products, in accordance with article 88a of Directive 2001/83/EC, as amended by Directive 2004/27/EC on the community code relating to medicinal products" 19 April 2007 : 27 pages.