

“Information to patients” by pharmaceutical companies: has the debate been hijacked?

Joint open letter from 11 organisations To members of the ENVI Committee

of the European Parliament, especially the Committee coordinators;

And to stakeholders:

- Commissioner Vassiliou and Commissioner Verheugen
- Members of the Information to Patients working group of the Pharmaceutical Forum
- The Press



Brussels, 31 March 2008



Dear Member of the European Parliament,



On the adoption of Directive 2004/27/EC relating to medicinal products for human use, the European Parliament and the Council mandated the Commission to present a report on current practice with regard to information provision – particularly on the Internet – and its risks and benefits for patients and, if appropriate, to put forward proposals (Art. 88a) (a).



At the end of April 2007, the European Commission (Enterprise and Industry Directorate General) launched a consultation on its “Draft Report on current practice with regard to provision of information to patients on medicinal products”, which was presented as the Commission’s response to the above request from the European Parliament and Council of Ministers (1).



In December 2007, the Commission published a communication to the European Parliament based on this report, disregarding the responses to the consultation (2).



In this report, the inventory of the sources of information to patients on medicinal products and other treatments described is woefully incomplete, failing to mention numerous sources independent of pharmaceutical companies and European regulatory authorities (3).



Following this highly unsatisfactory inventory, the report’s conclusion is clear-cut and biased: only the pharmaceutical industry would be capable of providing patients with the information they so desperately lack.



Furthermore, the report focuses mainly on information relating to prescription drugs (and other therapies) delivered via the Internet, with the aim of proposing ways to improve its access, thus departing from the Parliament and Council’s initial request.



Ignoring the extensive criticism generated by the report (3,4), the Commission has subsequently held further consultations on the issue of “information to patients” (6).



In the consultation on the proposed changes to the legislation published in February 2008, the Commission now makes it clear that it proposes to allow pharmaceutical companies to communicate directly with consumers about prescription drugs via all the available media (7).

The current proposal is far removed from the European Parliament and Council of Ministers' 2004 request, and it amounts quite simply to deregulating direct-to-consumer advertising for prescription drugs. In fact, can we possibly imagine that a television programme produced by a pharmaceutical company could be less effective as a form of promotion than a 30-second TV ad (8)?

Permitting pharmaceutical companies to provide 'information' about their medicinal products to patients within a self- or co-regulated framework will only increase consumers' demand for unnecessary drugs and create new medical risks. This will lead to unjustified spending on health (notably the cost of managing adverse effects), the burden of which will fall collectively on Member States' taxpayers (b).

We solemnly call on Members of European Parliament to scrutinise the Commission's proposal of February 2008 very closely, and to reject this clear flouting of the mandate entrusted to the Commission in 2004.

In order to foster a true democratic debate we urge you to follow up this issue, which is likely to be addressed in a proposal from the Commission to amend the legislation, scheduled for Autumn 2008. We thank you for supporting these concerns, which are those of a vast number of European citizens.

European Older People's Platform (AGE)
Association Internationale de la Mutualité (AIM)
European AIDS Treatment Group (EATG)
European Public Health Alliance (EPHA)
European Social Insurance Platform (ESIP)
European Union of Social Pharmacies (EUSP)

French Council of Pharmacists
Health Action International (HAI) Europe
International Society of Drug Bulletins (ISDB)
Medicines in Europe Forum (MiEF)
Union des syndicats de Pharmaciens d'officine (USPO)

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Notes

a- NB: When the 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" relating to 3 diseases (diabetes, AIDS and asthma). 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. 9). [Editor's note: the Commission itself uses the word 'advertising'.]

b- In recent years, there have been countless examples of pharmaceutical companies delaying or concealing crucial information, particularly concerning adverse effects associated with their drugs.

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References

- 1- European Commission – Enterprise and Industry Directorate General "Draft report on current practice with regard to provision of information to patients on medicinal products"
http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2007/2007_04/draft_infopatients2007_04.pdf: 27 pages.
- 2- Joint Declaration by HAI Europe, the ISDB, BEUC, AIM and the Medicines in Europe Forum "Relevant health information for empowered citizens" 3 October 2006. <http://www.prescrire.org/docus/JointDeclaration.pdf> : 9 pages.
- 3- European Commission "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.
http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2007/2007_10/d-34327-summary-of-consultation-responses.pdf.
- 4- Moynihan R "EC report on drug advertising found to be "biased"" *BMJ* 2007; 23 June 2007. 5- HAI Europe and MiEF "Direct-to-consumer communication by pharmaceutical companies: European Commission pushes ahead despite civil society's opposition".
<http://www.prescrire.org/aLaUne/dossierEuropeCommDirecteEN.php>: 2 pages.
- 6- European Commission "Background information supportive to the Communication from the Commission to the European Parliament and the Council concerning the Report on Current Practice with Regard to Provision of Information to Patients on Medicinal Products, in the form of different annexes." COM (2007) 862 final; Brussels, 20.12.2007: 11 pages.
- 7- European Commission – Enterprise and Industry Directorate General "Legal proposal on information to patients" deadline for Public Consultation: 7 April 2008;
http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2008/2008_02/info_to_patients_consult_200802.pdf: 10 pages.
- 8- AIM, HAI Europe, ISDB, MiEF Joint 3rd Open Letter to EU Commissioners "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; March 2008,31 : 6 pages.
- 9- "Explanatory memorandum" preceding the proposal for Directive 2001/0253 (COD): pages 85–86.

Signatories



AGE. The European Older People's Platform (AGE) is a European network of organisations of people aged 50+ and directly represents over 25 million older people in Europe. AGE aims to voice and promote the interests of the 150 million inhabitants aged 50+ in the European Union and to raise awareness of the issues that concern them most. More info: www.age-platform.org. Contact: Anne-Sophie Parent (annesophie.parent@age-platform.org).



AIM. The Association Internationale de la Mutualité (AIM) is a grouping of autonomous health insurance and social protection bodies operating according to the principles of solidarity and non-profit-making orientation. Currently, AIM's membership consists of 41 national federations representing 29 countries. In Europe, they provide social coverage against sickness and other risks to more than 150 million people. AIM strives via its network to make an active contribution to the preservation and improvement of access to health care for everyone. More info: www.aim-mutual.org. Contact: Rita Kessler (rita.kessler@aim-mutual.org).



EATG. The European AIDS Treatment Group (EATG) is a non profit patient organisation. EATG members come from 31 European countries. One guiding principle of EATG is to reflect the diversity of people living with HIV and their advocates. More information: www.eatg.org. Contact: wim-vandevelde@usa.net.



EPHA. The European Public Health Alliance (EPHA) is the largest European Platform, representing approximately 100 not-for-profit organisations across the public health community: representations of patient groups, healthcare professionals, public sector bodies, disease-specific organisations, treatment groups, and representatives of the social society. Their memberships include representatives at international, European, national, regional and local level. EPHA's missions are to protect and promote public health in Europe and to ensure health is at the heart of European policy and legislation. More information: www.eph.org. Contact: epha@epha.org.



ESIP. The European Social Insurance Platform (ESIP) represents a strategic alliance of over 30 statutory social security organisations across Europe. ESIP's mission is to preserve high profile social security for Europe, to reinforce solidarity based social insurance systems, and to maintain European social protection quality. More info: www.esip.org. Contact: esip@esip.org.

Note: ESIP members support this position with the specific exceptions of the International Pension Centre, the Försäkringskassan and the Sociálna poisťovňa since the subject matter covered by this paper falls outside their field of competence.



EUSP. The European Union of the Social Pharmacies (EUSP) is the professional Association of the Social Economy Companies aiming to make, services, medicines and health products accessible to the patients, at affordable conditions, through a network of 2.000 city-pharmacies in Belgium, France, Italy, The Netherlands, Poland, Portugal, United-Kingdom and Switzerland. More information: www.EuroSocialPharma.org. Contact: Marc-Henry Cornely (mh_cornely@multipharma.be).



French Council of Pharmacists. The French Council of Pharmacists conducts public health missions and promotes the interests of the public and the pharmacist profession. More info: www.ordre.pharmacien.fr. Contact: Isabelle Baron (IBaron@ordre.pharmacien.fr).



HAI Europe. Health Action International (HAI) is an independent global network of health, consumer and development organisations working to increase access to essential medicines and improve rational use. More info: www.haiweb.org. Contact: Teresa Alves (teresa@haiweb.org).



ISDB. International Society of Drug Bulletins (ISDB), founded in 1986, is a world wide Network of bulletins and journals on drugs and therapeutics that are financially and intellectually independent of pharmaceutical industry. Currently, their members include 57 members in 35 countries around the world. More info: www.isdbweb.org. Contact: Maria Font (maria.font@ulss20.verona.it).



MiEF. Medicines in Europe Forum (MiEF), launched in March 2002, covers 12 European Member States. It includes more than 70 member organizations representing the four key players on the health field, i.e. patients groups, family and consumer bodies, social security systems, and health professionals. Such a grouping is unique in the history of the EU, and it certainly reflects the important stakes and expectations regarding European medicines policy. Admittedly, medicines are no simple consumer goods, and the Union represents an opportunity for European citizens when it comes to guarantees of efficacy, safety and pricing. Contact: Antoine Vial (europedumedicament@free.fr).



USPO. The "Union des Syndicats de Pharmaciens d'Officine" (community pharmacist union) includes 36 unions of French community pharmacists. One of its aims is to promote any actions favouring the public health mission of community pharmacists. More info: www.uspo.fr.