

“Patient information” by pharmaceutical companies comes up against almost unanimous opposition from civil society

International
and European
signatory
organisations



Joint open letter from 18 organisations

- to the Health Ministers of the Member States
- to the Permanent Representatives of the Member States (CoRePers)

To other stakeholders:

- Directors of Member State Drug Regulatory Agencies;
- Members of the European Parliament;
- European Commissioners Verheugen and Vassiliou;
- Members of the Pharmaceutical Forum patient information group;
- The press.

Brussels, 5 June 2008

Dear Health Ministers,
Dear Permanent Representatives,

Patient information is on the agenda of the Council of Ministers' of Health meeting scheduled for Tuesday 10 June 2008 (item 16) (Employment, Social policy, Health and Consumer Affairs Council).

We wish to draw your attention to this vital issue, which raises the highly controversial question of the pharmaceutical companies' role in providing “information” to patients (a) (1). The industry's attempts to attain this goal are supported to a large extent by the European Commission (Enterprise and Industry Directorate-General) (b) (2).

Overwhelming opposition from nearly all the stakeholders in the health system

The results of the many consultations on the issue of “Patient information”, held by the European Commission (Enterprise and Industry Directorate-General) over 2007 and 2008, have shown that nearly all health stakeholders are overwhelmingly opposed to allowing pharmaceutical companies to communicate directly to the public (1,3).

But, ignoring these findings, the European Commission held a new consultation in February 2008 proposing to allow pharmaceutical companies to provide information on their prescription drugs directly to the public, via all available media (3,4).

The results of this consultation are unequivocal, as is stated in the report by the Commission itself: “The great majority of the respondents had a view that the ban on direct-to-consumer advertising of prescription-only medicines should be maintained, making sure that there is a clear distinction between advertising and non-promotional information. However, it was agreed that such a distinction is not easy to establish” (5).

Even pharmaceutical companies have felt that these proposals went too far and were tantamount to advertising! (6)

The “lack of a coherent distinction between advertising and information” is a seemingly insurmountable obstacle (c). How can a television “information” programme on medicinal products produced by a pharmaceutical firm be any less effective as promotional vehicle than a 30-second ad?

“Information” biased by conflicts of interest

In a highly competitive environment that is subject to the constraints of the financial markets, the pharmaceutical companies will defend their medicinal products to the detriment of other preventive or therapeutic means, which makes the “information” they provide promotional by definition.



Their obvious conflicts of interest were underlined by the majority of respondents to the consultation: 55% of respondents were opposed to any involvement of the pharmaceutical companies in providing information on prescription drugs to the public (d).

In total, 70% of respondents (92% of the healthcare professionals, 71% of the patients, 87% of the regulatory authorities, 100% of the consumers and 100% of the payers) stated they were opposed to the companies providing information directly to the public, or “*accused that there is a lack of a coherent distinction between advertising and information*” while at the same time calling for the ban on direct advertising of prescription medicines to be maintained (e) (5).



Need for information tailored to each patient

In the light of the lessons learned from the United States (direct-to-consumer advertising) and Europe (advertising to healthcare professionals), nearly all the respondents with no commercial interests at stake are opposed to the deregulation of direct-to-public communication by the pharmaceutical companies as intended by the European Commission.



Many respondents emphasised the importance of developing a more global approach to patient information, in order to take patients’ needs fully into account (5).

According to the majority of respondents, informing patients and fulfilling their needs implies a relationship of trust, which is at the core of the healthcare professions (5).



Optimum patient information should enable patients to analyse their concerns, give them a realistic idea of the evolution of their state of health, help them to understand whether further investigations are preferable, whether there are existing treatments and what they can expect from these, and help them share or make informed choices from the available treatment options (7).

For patients to make truly informed choices, they need, above all, reliable comparative data (f). Many patient groups, consumers and healthcare professionals have highlighted that comparisons “*could be very useful for patients and help them to take more responsibility for their healthcare*” (5).



The current legislation is adequate but must be rigorously enforced

The European regulatory framework is clear (articles 86(2) and 88 of Directive 2001/83/EC modified by Directive 2004/27/EC) (g). Pharmaceutical companies are already permitted to provide information to the public on diseases. They make the most of the opportunities provided by this framework, often going beyond with disease “awareness” campaigns and even disease- mongering.



The legislation lays down a specific role for the pharmaceutical companies in promoting a better use of medicinal products, and that is to improve the quality and clarity of labelling and the package leaflet (article 59 of Directive 2001/83/EC). Patients and professionals constantly notice that the companies have difficulties in carrying out such a task.

The Commission should be strongly encouraging the application of these provisions in all the EU member states.

One major step forward would be that the pharmaceutical companies' websites systematically refer to the national regulatory authorities' websites, and to the Eudrapharm website at EU level, where the latest updates of official documents are available (h).

Conclusion

We recommend that the pharmaceutical industry should refocus its efforts on its core public health role, which is to develop new medicines to meet patients' needs, instead of becoming involved in direct-to-patient communication strategies, the goal of which is to boost sales of medicinal products.

We rely on you to take up this issue and to safeguard the European legislative framework from any hasty modification.

We draw your attention to the fact that the summary of consultation responses, as published by the Commission in May 2008, does not accurately reflect the strong opposition of the majority of stakeholders to the direct communication by pharmaceutical companies to patients about prescription drugs (5).

The risk is that European citizens would be exposed to the excessive promotion of new medicinal products, and this would lead to an increased demand for medicinal products which they do not necessarily need. The burden of the new medical risks and unwarranted health spending (notably the cost of managing adverse effects) thus created would be borne by the community, ultimately jeopardising the long-term financial viability of the Member States' health systems.

Thank you for giving your close consideration to these concerns, which are those of a wider constituency of European citizens.

**AGE- The European Older People's Platform
Association Internationale de la Mutualité (AIM)
Bureau Européen des Consommateurs (BEUC)
European AIDS Treatment Group (EATG)
European Forum of Primary Care (EFPC)
European Public Health Alliance (EPHA)
European Social Insurance Platform (ESIP)
European Union of Social Pharmacies (EUPS)
Health Action International (HAI) Europe
International Society of Drug Bulletins (ISDB)
Medicines in Europe Forum (MiEF)**

**French Council of Pharmacists
Union des syndicats de Pharmaciens
d'officine (USPO)
Breast Cancer Action Germany
IPPNW
MEZIS
Verein demokratischer Pharmazeuten
und Pharmazeutinnen (VDPP)
Social Audit**

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Notes

a- Reminder: During the adoption of the new regulatory framework for medicinal products 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" in relation to 3 diseases (diabetes, AIDS, asthma).

In 2002, an explanatory memorandum concerning the 2002 proposal to modify Directive 2001/83/EC clearly laid out the aim of this proposal: "*It is proposed that there should be public advertising of three classes of medicinal products*" (ref. 8). [Editor's note: the Commission itself used the word 'advertising'.]

b- On the adoption of the Directive on Medicinal Products 2004/27/EC, the European Parliament and the Council of Ministers asked the European Commission to present an inventory and report on the benefits and risks of the existing patient information system, paying special attention to online information (Article 88a). The European Commission's report published in April 2007 deviated from the Parliament and Council's request by confining itself to information on prescription drugs (and other treatments) and supplying a very incomplete and biased inventory of available sources of information (ref. 2,9).

c- In the June 2007 consultation held by the Commission, the pharmaceutical companies themselves acknowledged that the boundaries between the "information" they provide and advertising are not clear (ref. 10). The concept of "*non-promotional information*" proposed by the Commission implies that there is, conversely, information of a promotional nature (ref. 5).

d- The figures given in the European Commission's summary are expressed as a percentage of the total number of respondents to the overall consultation, instead of respondents who commented on the question concerned (valid votes). The number of those opposing the firms providing information directly to the public is given as 48%, whereas in fact it is 55%. Overall, the Commission's summary does not accurately reflect the very strong opposition to its proposals as evidenced in the contributions themselves (ref. 11).

e- Unsurprisingly, the remaining third of respondents, who stated they were for pharmaceutical companies providing information to the public, was made up of those with commercial interests at stake: 100% of the pharmaceutical companies, and 84% of the media and organisations involved in disseminating information to patients.

f- Data relating to a single medicinal product is incomplete and biased if it is not placed in a comparative context and if it is not based on a systematic and exhaustive literature review.

g- The current European legal framework does not allow direct-to-consumer advertising of prescription medicines (article 88 of Directive 2001/83/EC modified by Directive 2004/27/EC). However, according to article 86 of this 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*".

h- In accordance with the legal obligations on transparency adopted in 2004, one of the drug 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 of Directive 2001/83/EC);

- assessment reports (article 13 of Regulation (EC) No 726/2004);

- and pharmacovigilance data (article 26 of Regulation (EC) No 726/2004).

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References

1- HAI Europe and MiEF: "Direct-to-consumer communication by pharmaceutical companies: European Commission pushes ahead despite civil society's opposition." <http://www.prescrire.org/cahiers/dossierEuropeCommDirecteEN.php>: 2 pages.

2- AGE, AIM, Medicines in Europe Forum, EATG, EPHA, ESIP, HAI Europe, ISDB, Ordre national des pharmaciens français, UEPS, USPO "Information to patients by pharmaceutical companies: has the debate been hijacked?" Open letter from 11 organisations to members of the ENVI Commission of the European Parliament; 31 March 2008. <http://www.prescrire.org/docus/OpenLetter11.pdf>: 3 pages.

3- AIM, HAI Europe, ISDB, MiEF 3rd open letter to the European Commissioners: "The European Commission's "proposal on information to patients" will boost drug sales not serve patients' interests" <http://www.prescrire.org/cahiers/dossierEuropeMedOpenLetter3EN.php>: 6 pages.

4- 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.

5- European Commission – Enterprise and Industry Directorate-general – "Key ideas of a legal proposal on information to patients: summary of the public consultation responses".

http://ec.europa.eu/enterprise/pharmaceuticals/patients/docs/summary_publ_cons_220508.pdf: 11 pages.

6- European Federation of Pharmaceutical Industries and Associations (EFPIA) "EFPIA calls on EU institution to reform patient information rules without further delay – European industry does not support TV, radio, and print mass media for prescription medicines" Press release; Bruxelles : 7 April 2008.

7- 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/aLaUne/dossierNMinfoPatientDeclarationEn.php>: 9 pages.

8- "Explanatory memorandum" preceding the draft Directive 2001/0253 (COD) : pages 85-86 of the English version.

9- Moynihan R "EC report on drug advertising found to be "biased"" *BMJ* 2007; 23 June 2007.

10- 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.

11- List of responses "Information to Patients - Responses to the Public consultation on the key ideas of a legal proposal on information to patients" made available online on 14 May 2008: http://ec.europa.eu/enterprise/pharmaceuticals/patients/patients_responses_200805.htm.

International and European signatory organisations



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: 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@aim-mutual.org.



BEUC. BEUC's membership includes 41 well respected, independent national consumer organisations from some thirty European countries (EU, EEA and applicant countries). BEUC, the European Consumer's organisation, acts as a sort of "embassy" for these organisations in Brussels and its main task is to represent its members and defend the interests of all Europe's consumers. More info: www.beuc.org. Contact: Ilaria.Passarani@beuc.eu.



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: nicole.heine@eatg.org.



EFPC. The European Forum for Primary Care is a network of more than 100 organisations and individuals in Europe – and beyond. The aim of the Forum is to improve the health of the population by promoting strong Primary Care. In the Forum, practitioners, policy makers and researchers share experiences, views and information. More info: www.euprimarycare.org. Contact: d.aarendonk@euprimarycare.org.



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, the **Sociale Verzekeringsbank** 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 : mh_cornely@multipharma.be.



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@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@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: europedumedicament@free.fr.

National signatory organisations

FRANCE



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: IBaron@ordre.pharmacien.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.

GERMANY



BC Action Germany. Breast Cancer Action Germany project is a low-budget and non-profit activist/advocacy group directed by women who have been sensitised to the trauma of breast cancer affecting themselves and other close friends and who are committed - long-term - to erasing the disease. More info: www.bcaction.de. Contact: kemper@bcaction.de.



IPPNW. IPPNW is a federation of medical organizations helping to implement a diverse set of programs designed to build a healthier and more secure future. IPPNW affiliates in Europe are part of IPPNW's vast global network of medical professionals and concerned citizens in over 60 countries. As "Physicians in Social Responsibility", IPPNW members work, for example, to improve the health situation of migrants, access to essential medicine or to analyse the influence of the pharma-industry on the health sector. More info: www.ippnw.de. Contact : hessmann@ippnw.de.



MEZIS. MEZIS is a German initiative of independent health care providers, which aims to encourage physicians to practice medicine on the basis of rational and scientific evidence, rather than on pharmaceutical marketing. MEZIS discourages the acceptance of all gifts from industry and advises to reassure independence on all levels of medical education. MEZIS's goal is improved patient care. MEZIS is part of the international "No free lunch" network. More info: www.mezis.de. Contact: as@schaeffler.cc.



VDPP. VDPP (Verein demokratischer Pharmazeuten und Pharmazeutinnen), the Association of German Democratic Pharmacists, represents pharmacists with social responsibility. VDPP's main goals are: democratisation of the health system, responsible supply with medicine and consumer-friendly drug law. More info: www.vdpp.de. Contact: geschaeftsstelle@vdpp.de.

UNITED KINGDOM

Social Audit. For over 30 years, Social Audit has campaigned to make the drug establishment truly accountable and transparent - but still there is the risk of Pharmageddon, "*the prospect of a world in which medicines and medicine produce more ill-health than health, and when medical progress does more harm than good*". Social Audit aims to investigate and explore that risk and to identify the factors and features that describe it. More info: www.socialaudit.org.uk. Contact: charles@socialaudit.org.uk.