

Patient information in Europe: many concerns

In 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.

Below are reprinted extracts from some contributions to the consultation and other reactions related to this consultation (origine specified when different from a contribution to the consultation).

Extracts from the press:

- *The Lancet*

"The direct-to-consumer advertising genie" 2007 ; 369 : 1.

- *The British Medical Journal*

Direct to consumer advertising should not come to Europe" by Ray Moynihan 2007; 19 May.

"Sweetening the pill – Can big pharma be trusted to provide independent health information to patients?" by Hannah Brown 2007; **334**: 664-666.

"Pfizer conducts survey of French patients on information provided by industry" by Barbara Mintzes 2007; **334**: 1027.

- *The Guardian*

"Coming soon: the shopping channel run by drug firms" by Sarah Boseley May 21, 2007

- *Test Achats*

Consumer organisation - Belgium
"Non aux "programmes d'accompagnement" des firmes pharmaceutiques ! Oui à une information indépendante et objective sur les médicaments"
Press release – 30/05/2007 (www.test-achats.be)

- *Bulletin national de l'ordre de l'Ordre des Pharmaciens* (Pharmacists Representative Organisation - France)

"Information des patients : l'Ordre est inquiet" 2007, May 31

- *APTEKARZ Pharmaco-Economic Society Journal* (Poland)

"Look at EU drug policy" *APTEKARZ* 2007; 15 (3) : 73.

For more information:

Submissions to the consultation available at:
http://ec.europa.eu/health/ph_overview/other_policies/pharmaceutical/results_consultation_en.htm



Medicines in Europe Forum (MIEF). We are concerned that the questions that accompany this consultation frame it in such a way

(...) as to predetermine the type of responses that are likely to be received. (...)

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 are potent reminders that pharmaceutical companies often minimize or even fail to disclose adverse effects. (...)

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. (...)

We demand an end to the skilfully maintained confusion of roles. (...) 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 [which] can contribute to improved medicine use and to prevention of medication errors.

(Extracts from a joint MIEF, HAI and ISDB Open letter sent to Commissioners Verheugen and Kiprianou May 4, 2007. Complementary briefing papers on the subject available on Prescrire's website: www.prescrire.org).



International Society of Drug Bulletins (ISDB). Why should one sit together with industry to develop

patient information? Health professionals, consumer and patient groups that are independent of the pharmaceutical companies, health authorities and funding bodies have not waited for the pharmaceutical companies to take an interest in patient information and to produce relevant information for patients. Many quality sources of information are now available to the public in Europe and worldwide. (...)

How to increase pharma companies competitiveness? By making medicines which offer real therapeutic advantage as defined in the ISDB Declaration on therapeutic advance. In contrast to pseudo-innovations such products do not need big marketing efforts.

(Extract from ISDB Press release May 3, 2007 : www.isdbweb.org)



Health Action International (HAI Europe). The Pharmaceutical Forum follows on the G-10; both advisory committees are heavily dominated by

the pharmaceutical industry and appear to have an industry-driven agenda. (...) The Parliament did not ask the Commission to examine ways to assist the industry in promoting its products to the European Public.

(...) Information needs can only be met by information providers without conflict of interests. (www.haiweb.org)



European Public Health Alliance (EPHA). EPHA consider that the

High Level Pharmaceutical Forum or results from the consultation should not replace or interfere with the standard decision making procedures in the EU. (...) As stated in the EU Health Policy Forum recommendations on health information [May 2005], EPHA would like to stress that no relaxation of the current EU legislation which prohibits the advertising of prescription only medicines should be envisaged.

(www.ephao.org)



Association Internationale de la Mutualité (AIM). AIM strongly demands that public health interests

are not mixed or even replaced by commercial interests. (...) AIM insists that "unbiased" has to be included in the list of criteria. (www.aim-mutual.org)



Insulin Dependent Diabetes Trust. General Comments about the document as a whole: (...)

there are inaccuracies and at times wrong information; (...) no information about suspected adverse effects of medications and insulin; no information to inform patients that they should have an informed choice of treatment based on independent, high quality evidence; a lack of comparative information about the various treatments to enable patients to make an informed choice based on independent evidence; a lack of information about comparative costs of treatment options.

(www.iddtinternational.org)



European Social Insurance Platform (ESIP). (...) The

Pharmaceutical Forum Patient information working group are divergent on crucial aspects (...). ESIP fully supports the ban on DTCA which was clearly reaffirmed by the European Parliament and the Council of Ministers in 2004. Weakening the ban on DTCA would open the door to a wave of marketing that will be difficult to control following international experience. (...) ESIP has some important concerns regarding the drafting procedure as well as the factual content of the proposed diabetes fact-sheet: it is to be regretted that this document has been drafted without any agreed methodology and procedure, (...)

the draft does not comply with the quality criteria discussed above (...), omissions and mistakes. ESIP has serious concerns about the added value of such factsheets. (www.esip.org)



Diabetes UK. It is difficult to see how one source of information about a condition would be valid or applicable in every nation state. (www.diabetes.org.uk)



Which? (United Kingdom). (...) Is this about improving consumers' health and use of medicines, or is it about increasing the competitiveness and market for pharmaceutical products? (...) Research has shown a high level of consumer mistrust of information supplied by the pharmaceutical industry. (...) Pharmaceutical companies' remit is to sell their medicines, not inform choice. Any funding or sponsorship they enter into will be biased by virtue of what they choose to fund (such that information provision about less potentially profitable illnesses would be unlikely) and how they choose to present such information (in a manner designed to boost sales). (...) We do not believe that there is any value in further development of this type of information package (...). (www.which.co.uk)



European Respiratory Society (ERS) and European Lung Foundation (ELF). We are concerned by the transparency of the process to produce an information package for patients and how the results of this exercise will be used in the future. (...) Any information package should be developed and agreed at a national level (...) by one or a combination of the following organisations: national health services, national regulatory agencies, centers for reference, medical societies and patient groups or charities. (...) Health information (...) should not be confused with advertising for treatment drugs. (www.ersnet.org ; www.european-lung-foundation.org)



Consumer International (CI) and the Bureau Européen des Unions de Consommateurs (BEUC). (...) Providing health related information is a primary responsibility of the Member States who are in the best position to address the specific needs of the citizens. (...) The methods and the outcomes of the working group of the High Level Pharmaceutical Forum (...) do not bring added value and are not the way to develop information for patients. Health and social policy on information to patients should be based on the rights of patients to independent information and not on the rights of pharmaceutical companies to market their products. (...) Pharmaceutical companies' role in the production of good quality information for patients and consumers should be limited to clear labelling and informative patients' leaflet. (www.beuc.org; www.consumersinternational.org)

European Federation of Neurological Associations (EFNA). There is little need for additional information to be produced at European level for most illnesses. Serious effort should be put into (...) finding ways effectively to disseminate existing high quality information.

European Cancer Patient Coalition (ECPC). ECPC considers that an important principle to be added is that the information provided considers and responds to patients' real needs (...). (www.cancerworld.org)



European Management Health Association (EMHA). We suggest that (...) the type of information destined to patients should be offered in an unbiased way. (...) EMHA stresses that EU legislation which relaxes rules on direct-to-consumer advertising should not be encouraged! (...) The relationship of a patient with a health professional is nonetheless one that will continue to remain of utmost importance. (www.emha.org)

French Government. (...) It is necessary to address all concerns regarding the methodology used to produce the fact sheet. It is also necessary to address any conflicts of interest arising from the involvement of the healthcare industry in establishing patient information on treatment options.

France insists that the following principles be complied with: no direct-to-patient promotional activities by the pharmaceutical industry for prescription- only medicines (...); information on diseases for patients should be validated ex ante. (...) All elements relating to national context, for instance, diagnosis and treatment options should be provided at the national level to ensure that national specificities and financing constraints are taken into account.



European Aids Treatment Groups (EATG). Info is not info if it concerns one product (...). If we can't trust Pharma to tell everything to drug regulatory authorities, how can we trust them to tell everything to us ? (European Parliament Intergroup on Patient Information 6/10/2006. www.guscairns.com)

Pharmaceutical Group of the European Union (PGEU). (...) Undertaking two consultations in this key area at the same time creates confusion. (...) We believe patients would expect objective AND unbiased information on medicines and health-related issues to be made available and not solely commercial/ brand information with no comparative data. (...) The existing EU legislation on medicinal products (...), in particular in the field of information to patients, helps ensure a high level of public health, and should, therefore, be maintained. We expect that the Commission's proposals resulting from this consultation will (...) prevent industry produced information from being directly communicated to the general public. (www.pgeu.org)



The Royal Pharmaceutical Society of Great Britain. (...) We would expect that the Commission's proposals

resulting from this consultation will not only respect the decisions of the European Parliament (in 2002) to prevent industry produced information to be directly communicated to the general public but also reinforce what has already been achieved with this.

APTEKARZ Pharmaco-Economic Society Journal (Poland). There is actually a big pharma's pressure in Europe on the free promotion of prescription drugs. The European Commission would like but has no courage to do so, therefore, it has started to prepare the Pharmaceutical Forum to the turn of the worst. ("Extracted from Look at EU drug policy" APTEKARZ 2007; 15 (3) : 73.)



Medicines and Healthcare products Regulatory Agency (MHRA ; United Kingdom). Much work is required to make this [diabetes information package] a truly patient-centred document (...). (www.mhra.gov.uk)



Läkemedelsverket Medical Products Agency (Sweden). Patient information should be provided on a national level. (www.lakemedelsverket.se)



Institut for Rationel Farmakoterapi (IRF) (Denmark). There is a need to focus on the already existing national evidence-based comparative information, prepared by those involved in public health care and independent of the pharmaceutical industry. (www.irf.dk)

Danish Consumer Council. (...) Today (...) the industry is focusing at the consumers, to make them aware of diseases or life conditions, for which there is a possible treatment. (...) A demand and expectation from the consumer is placed on the doctor, who is already reached by the industry's marketing. This pincer movement makes the distance to the prescription pad very short. (...) (www.fbr.dk)

European Association of Hospital Pharmacists (EAHP). Information has to be adapted to the one receiving it and to his needs. EAHP considers that there is no better source of information on patients' conditions, treatments, procedures, examinations than the patients' healthcare professionals. (...) The High Level Pharmaceutical Forum set up by the European Commission (...) does not represent the breadth of organisation working on information to patient, and is composed of members that have been appointed arbitrarily. (...) The outcome of its work cannot be considered as a reliable source of information. (www.eahp.eu)