



## Direct-to-consumer communication by pharmaceutical companies? Europeans deserve better

### *Supporting the right choice in health information*



Earlier this year, during his hearing at the European Parliament, the new Commissioner for Health and Consumer protection, John Dalli, stated that the proposals on patient “information” needed to be reassessed. We welcome this commitment.

As of middle of March 2010, the legislative process is ongoing at the European Parliament, generating uncertainties.



The European Commission’s proposals on “*‘information’ to the general public on medicinal products subject to medical prescription*” were issued in December 2008. The directive and the regulation are based on an incomplete report that failed to fulfil the demand of the European Parliament and the Council for a report on “*the benefits and risks of information currently available to the public*”.<sup>1,2</sup> Moreover, the proposals contradict the views of the wider health community, as expressed in responses to the public consultations in 2007 and 2008, which stated that the pharmaceutical industry cannot be considered a reliable source of unbiased information due to an obvious and unavoidable conflict of interest.<sup>3,4</sup> During the Council meetings and discussions on this topic, Member States have also repeatedly echoed strong concerns.



### Should Members of the European Parliament work on such inadequate proposals?

The current Commission proposals do not meet the needs of citizens for relevant, independent and comparative health information tailored to users.<sup>5</sup>

Moreover, the proposals endanger specific Treaty rules that aim to ensure a high level of health protection. European citizens would be exposed to intensive promotion of new medicinal products, and this would lead to increased public demand for medicinal products that they may not need or that they should not take (contra-indications, drug interactions, etc.), thereby putting public health at risk.<sup>6,7</sup>

The Commission proposals pose additional hurdles for Member States to put in place efficient and affordable pharmaceutical policies. In fact, the burden of drug-induced harm and unwarranted health spending created by increased consumption of medicines (notably the cost of managing adverse drug reactions) would be borne by the State, ultimately jeopardising the long-term financial viability of the Member States’ health systems.

We therefore consider the current proposals on “*‘information’ to the general public on medicinal products subject to medical prescription*” to be of no added value to European citizens.<sup>8</sup> Their only rationale seems to be to benefit the commercial interests of pharmaceutical companies by expanding their markets and helping them to build brand loyalty.<sup>9,10</sup>

**Europeans deserve better.** Any compromise on such controversial proposals could in fact hamper improved access to relevant patient information for European citizens in future.



**National  
signatory  
organisations**



## Concrete proposals to improve access to relevant (independent and comparative) health information

The following 5 key points encapsulate our proposals:

1. make the officially approved leaflet more useful and accessible for patients by ensuring that pharmaceutical companies consistently abide by their **obligations relative to drug packaging and patient leaflets** (i.e. consultations with target patient groups) (enforcement of article 59 of Directive 2001/83/EC modified by Directive 2004/27/CE);
2. optimise **communication between patients and health professionals**: informing patients and fulfilling their needs implies a relationship of trust and interpersonal dialogue, which are the core responsibilities of the healthcare professions;
3. encourage **national agencies to become proactive and more transparent providers of information** so as to guarantee full public access to data on the efficacy and safety of medicines and other healthcare products both before and after a product is marketed;
4. **develop and reinforce existing sources of comparative, unbiased information on treatment choices**;
5. put a **rapid and permanent end to the confusion of roles between the pharmaceutical companies and other actors** in the healthcare sector: full implementation and enforcement of the European regulation on pharmaceutical promotion, including measures to ensure that article 88 of Directive 2001/83/EC, is not weakened or undermined (a).

We urge the Commissioner for Health and Consumer protection to start the reassessment of the current legislative proposals on patient “information” now, and to take into account our concrete proposals in order to ensure a better basis for the improved provision of relevant, independent and comparative information to patients.

AGE- The European Older People’s Platform  
 Association Internationale de la Mutualité (AIM)  
 Confederation of Family Organisations in the European Union (COFACE)  
 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 (EUSP)  
 Health Action International (HA) Europe  
 HOPE, the European Hospital and Healthcare Federation  
 International Society of Drug Bulletins (ISDB)  
 Medicines in Europe Forum (MIEF)

Akdä (Arzneimittelkommission der deutschen Ärzteschaft)  
 AKF (Arbeitskreis Frauengesundheit)  
 BAGP (BundesArbeitsGemeinschaft der PatientInnenstellen und –Initiativen)  
 BC Action Germany  
 Bioskop  
 Bremen Forum for Women’s Health  
 DEGAM (Deutsche Gesellschaft für Allgemeinmedizin und Familienmedizin)  
 Formindep  
 German EbM Network  
 IPPNW (Germany- Physicians for Social Responsibility)  
 MEZIS  
 Netzwerk Frauen Gesundheit Berlin  
 PSOAG (Psoriasis Selbsthilfe Arbeitsgemeinschaft)  
 Seroxat & SSRI user group  
 USPO (Union des Syndicats de Pharmaciens d’Officine)  
 VDÄÄ (Verein demokratischer Ärztinnen und Ärzte)  
 VDPP (Verein demokratischer Pharmazeuten und Pharmazeutinnen)

a- The scientific exchanges between industry and **expert patients’ organisations** in the frame of the existing “Community Advisory Boards” are excluded from article 88 which deals with advertising to the general public. The ban on DTCA should not be used as an excuse for secrecy on data towards expert patient organisations that have the acquired expertise to understand them.

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## Notes

- <sup>1</sup>- It was 'based' on an incomplete and biased inventory of available sources of information.
- <sup>2</sup>- The European Parliament overwhelmingly rejected attempts to legalize direct-to-consumer 'information' (DTCI) of prescription medicines in 2003 (by 494 votes to 42), even in the frame of a pilot project, acknowledging the impossibility of distinguishing between advertising and 'information' from pharmaceutical companies.
- <sup>3</sup>- See for example the Joint open letter by 18 organisations "Patient information. by pharmaceutical companies comes up against almost unanimous opposition from civil society" 5 June 2008: 6 pages (available at [www.isdbweb.org/pag/documents/1.pdf](http://www.isdbweb.org/pag/documents/1.pdf)).
- <sup>4</sup>- The 'impact assessment' on which the proposals are based is unrealistic: according to the assessment of the European Commission, if adopted, direct-to-consumer information on prescription medicines would cost up to 88 billions euros and save up to 329 billions euros over the forthcoming 10 years. But the estimates for "savings" are based on "awareness", "prevention", "interaction [with health professionals]" and "compliance", activities that can all better be achieved through the promotion of independent public health campaigns on specific conditions, driven by public authorities. In fact, "awareness" campaigns by the pharmaceutical industry are often "disease mongering" campaigns aimed at increasing sales for a specific drug when the market seems too narrow (Watters E "How the US exports its mental illness" [www.newscientist.com](http://www.newscientist.com) 20 January 2010).
- <sup>5</sup>- Useful patient information should be comparative to enable users to analyse their concerns, give them a realistic idea of the evolution of their health status, help them to understand when further investigations are necessary, to know what treatments exist and what they can expect from them, and to make informed choices (or participate in the choice) among the different available options.  
In a highly competitive environment, drug companies must promote their products above the use of other preventive or curative options, thus any 'information' they provide will be, by definition, of a promotional nature. This inevitable conflict of interest means that a drug company cannot be expected to provide reliable information.
- <sup>6</sup>- Kravitz et al. "Influence of patients requests for direct-to-consumer advertised antidepressants: a randomized controlled trial" *JAMA* 2005; **293**: 1995-2002; Mintzes B et al. "How does direct-to-consumer advertising (DTCA) affect prescribing? A survey in primary care environments with and without legal DTCA" *CMAJ* 2003; **169** (5): 405-412.
- <sup>7</sup>- See informative examples of misleading messages provided by pharmaceutical companies in Barbara Mintzes' presentation at the European Parliament expert meeting chaired by MEP Dr Thomas Ulmer (EPP, Germany) and MEP Carl Schlyter (Greens, Sweden) the 3 December 2010: [www.aim-mutual.org/index.php?page=17&id=200](http://www.aim-mutual.org/index.php?page=17&id=200).
- <sup>8</sup>- See the Joint AIM, ESIP, HAI Europe, ISDB, MiEF detailed analysis of the proposals "Legal proposals on "information" to patients by pharmaceutical companies: a threat to public health" March 2009 : 6 pages (available at: [www.isdbweb.org/pag/documents/En\\_LegalProposalsInfoPatient\\_JointPaper\\_March2009\\_000.pdf](http://www.isdbweb.org/pag/documents/En_LegalProposalsInfoPatient_JointPaper_March2009_000.pdf)).
- <sup>9</sup>- Benzing L "In search of the Holy Grail; the quest for brand loyalty in prescription marketing" Patient marketing group. Site internet [www.dtcperspectives.com](http://www.dtcperspectives.com) accessed 4 June 2007: 5 pages.
- <sup>10</sup>- The Directorate General for Competition's "Pharmaceutical sector enquiry" shows how far pharmaceutical companies are willing to go to delay competition. The proposals on "information to patients" are yet another tactic to delay generic competition by building brand loyalty for their own medicines.

### *International and European signatory organisations*

**AGE** - The European Older People's Platform 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.eu/en](http://www.age-platform.eu/en). Contact: [annesophie.parent@age-platform.org](mailto: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](http://www.aim-mutual.org). Contact: [rita.kessler@aim-mutual.org](mailto:rita.kessler@aim-mutual.org).

**COFACE**. Originally founded in 1958, the Confederation of Family Organisations in the European Union (COFACE) is an international not-for-profit voluntary organisation, which aims at promoting family policy, solidarity between generations and the interests of children within the European Union. COFACE advocates a policy of non-discrimination and of equal opportunities between persons and between family forms, and specifically supports policies aiming at equality between women and men. COFACE links together general and single-issue national family organisations. In 2010, it has 50 member organisations across 21 Member States of the European Union. More info: [www.coface-eu.org](http://www.coface-eu.org). Contact: [secretariat@coface-eu.org](mailto:secretariat@coface-eu.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](http://www.eatg.org). Contact: [nicole.heine@eatg.org](mailto:nicole.heine@eatg.org).

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**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](http://www.euprimarycare.org). Contact: [d.aarendonk@euprimarycare.org](mailto: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.epha.org](http://www.epha.org). Contact: [epha@epha.org](mailto: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](http://www.esip.org). Contact: [esip@esip.org](mailto: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](http://www.EuroSocialPharma.org). Contact: [mh\\_cornely@multipharma.be](mailto: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](http://www.haiweb.org). Contact: [teresa@haiweb.org](mailto:teresa@haiweb.org).

**HOPE,** the European Hospital and Healthcare Federation, is an international non-profit organisation, created in 1966. HOPE represents national public and private hospital associations and hospital owners, either federations of local and regional authorities or national health services. Today, HOPE is made up of 32 organisations coming from 26 Member States of the European Union, plus Switzerland. HOPE mission is to promote improvements in the health of citizens throughout Europe, high standard of hospital care and to foster efficiency with humanity in the organization and operation of hospital and healthcare services. More info: [www.hope.be](http://www.hope.be). Contact: [sg@hope.be](mailto:sg@hope.be).

**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, it has 80 members in 40 countries around the world. More info: [www.isdbweb.org](http://www.isdbweb.org). Contact: [jschaaber@buko-pharma.de](mailto:jschaaber@buko-pharma.de).

**MiEF.** Medicines in Europe Forum (MiEF), launched in March 2002, covers 12 European Member States. It includes more than 70 member organizations representing 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: [pierrechirac@aol.com](mailto:pierrechirac@aol.com).

### *National signatory organisations*

**Akdä.** The Drug Commission of the German Medical Association (DCGMA) (Arzneimittelkommission der deutschen Ärzteschaft) is the scientific expert committee for drug-related matters of the German Medical Association (GMA). Relying on the expertise of their 40 full members and approximately 130 associate members from all areas of medicine and pharmacy, the commission provides the medical profession with a variety of up-to-date information on rational drug therapy and drug safety. More info: [www.akdae.de](http://www.akdae.de). Contact: [sekretariat@akdae.de](mailto:sekretariat@akdae.de).

**AKF.** The Working Party for Female Health in Medicine, Psychotherapy and Society (Arbeitskreis Frauengesundheit) is a German association of committed female experts. It provides a national and international networking platform for diverse experiences and competences in female health (i.e. pathogenic beauty ideals). More info: [www.akf-info.de](http://www.akf-info.de). Contact: [buer@akf-info.de](mailto:buer@akf-info.de).

**BAGP.** Founded in 1989, the Federal Community for Patients Advice and Empowerment (BundesArbeitsGemeinschaft der PatientInnenstellen und –Initiativen) works as a lobby for all patients. BAGP aims to create a social, solid, democratic, non-hierarchical health-system; and to develop independent information and advice, patient empowerment and patient complaints procedures. More info: [www.gesundheits.de](http://www.gesundheits.de). Contact: [info@bagp.de](mailto:info@bagp.de).

**BC Action Germany.** Breast Cancer Action Germany project is a non-profit activist/advocacy group directed by women who have experienced the trauma of breast cancer, affecting themselves and other close friends, and

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who are committed - long-term - to eradicating the disease. More info: [www.bcaction.de](http://www.bcaction.de). Contact: [kemper@bcaction.de](mailto:kemper@bcaction.de).

**Bioskop.** Bioskop is a non-commercial association concerned with conditions in biomedical research and public health care. BioSkop-Journal, homepage and campaigning focus on more equitable conditions in social life, health care and terminal care. More info: [www.bioskop-forum.de](http://www.bioskop-forum.de). Contact: [info@bioskop-forum.de](mailto:info@bioskop-forum.de).

**Bremen Forum for Women's Health.** Founded in 1994, the Bremen Forum for women's health is an interdisciplinary platform for women's health issues and policies which brings together 48 member organisations. Its goals are to develop strategies for healthcare tailored to women's needs and to advise policymakers. More info: [www.frauen.bremen.de](http://www.frauen.bremen.de). Contact: [angelika.zollmann@frauen.bremen.de](mailto:angelika.zollmann@frauen.bremen.de).

**DEGAM.** The German College of General Practitioners and Family Physicians (Deutsche Gesellschaft für Allgemeinmedizin und Familienmedizin) is the scientific association of German primary care doctors. More info: [www.degam.de](http://www.degam.de). Contact: [froehlich@degam.de](mailto:froehlich@degam.de).

**Formindep** (as FORMation-INDEPendant, formation being the French translation of education) is a group of French healthcare professionals and citizens acting for independent medical information and education, free from vested interests. More info: [www.formindep.org](http://www.formindep.org). Contact: [media@formindep.org](mailto:media@formindep.org).

**German Network for Evidence Based Medicine.** Founded in Berlin in 2000, the German EbM Network's primary mission is to establish a competence and reference centre on evidence-based medicine. It provides an interdisciplinary communication platform for the basic principles of EbM that aims to promote coordination between medical research and clinical care. More info: [www.ebm-netzwerk.de/english](http://www.ebm-netzwerk.de/english). Contact: [david.klempere@soz.fh-regensburg.de](mailto:david.klempere@soz.fh-regensburg.de).

**IPPNW.** Germany- Physicians for Social Responsibility (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 in a number of areas, 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](http://www.ippnw.de). Contact: [wilmen@ippnw.de](mailto:wilmen@ippnw.de).

**MEZIS.** Part of the international "No free lunch" movement, "Mein Essen zahl ich selbst" (MEZIS) is a German initiative of independent health care providers, which encourages rational drug use and evidence based medicine. MEZIS discourages the acceptance of any gifts from industry and promotes independence on all levels of medical education. MEZIS's goals are improved patient care and the development of independent information. More info: [www.mezis.de](http://www.mezis.de). Contact: [as@schaeffler.cc](mailto:as@schaeffler.cc).

**Netzwerk Frauen Gesundheit Berlin.** The network "Women Health Care Berlin" is an organisation campaigning for better and women-specific health promotion and care. More information: [www.frauengesundheit-berlin.de](http://www.frauengesundheit-berlin.de). Contact: [godin@frauengesundheit-berlin.de](mailto:godin@frauengesundheit-berlin.de).

**PSOAG.** Psoriasis Selbsthilfe Arbeitsgemeinschaft is a German umbrella-organisation of 12 independent patient-groups. The organisation receives no funding from the pharmaceutical industry, and provides independent and critical information, committed only to the interests of patients. More info: [www.psoriasis-selbsthilfe.org](http://www.psoriasis-selbsthilfe.org). Contact: [info@Psoriasis-Selbsthilfe.org](mailto:info@Psoriasis-Selbsthilfe.org).

**Seroxat & SSRI user group.** The Seroxat & SSRI user group is a self-funding, non profit group that was formed in June 2002 to support and advise patients experiencing problems (side effects and withdrawal symptoms) with Seroxat<sup>o</sup> and other SSRI antidepressants. More info: [www.seroxatusergroup.org.uk](http://www.seroxatusergroup.org.uk). Contact: [janice@seroxatusergroup.org.uk](mailto:janice@seroxatusergroup.org.uk).

**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 actions favouring the public health mission of community pharmacists. More info: [www.uspo.fr](http://www.uspo.fr). Contact: [auge-caumon@uspo.fr](mailto:auge-caumon@uspo.fr).

**VDÄÄ.** VDÄÄ (Verein demokratischer Ärztinnen und Ärzte), the Association of Democratic Doctors aims to create a democratic, fairly financed health care system, with access to appropriate, and the best possible care for everyone living in Germany. More info: [www.vdaee.de](http://www.vdaee.de). Contact: [info@vdaee.de](mailto:info@vdaee.de).

**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, the responsible provision of medicines and consumer-friendly drug law. More info: [www.vdpp.de](http://www.vdpp.de). Contact: [vorstand@vdpp.de](mailto:vorstand@vdpp.de).