



Joint letter
to European Commissioner for Health and
Consumer Policy John Dalli
European Commission
B - 1049 Brussels
Belgium

Brussels, 11 March 2010

Subject: Request for a meeting

Dear Commissioner Dalli,

*Association Internationale de la Mutualité (AIM)*¹, *Health Action International (HAI) Europe*,² the *International Society of Drug Bulletins (ISDB)*,³ and the *Medicines in Europe Forum*⁴ congratulate you on your appointment as the new Commissioner for Health and Consumer policy, with extended responsibilities for the policies governing medicinal products and medical devices.

We welcome your commitment to “*put the interests of patients and consumers first*” and share your view that there is a need to reassess the “information” to patients’ legislative proposals, as expressed during your hearing at the European Parliament earlier this year.

In fact, the Directorate General for Enterprise & Industry’s proposals do not meet the needs of patients for relevant, independent and comparative health information tailored to users.⁵ Moreover, the proposals endanger specific Treaty rules which aim to ensure a high level of health protection. Citizens would be exposed to intensive promotion of new medicinal products, and this would lead to increased public demand in Europe for medicinal products that they may not need or should not take, putting public health at risk.^{6,7}

One of the Commission’s central responsibilities is the protection of the health of European citizens. **We urge you to deeply re-assess the “information to patients” proposals** to provide Members of the European Parliament with improved proposals. Any compromise on the current controversial proposals could in fact hamper improved access to relevant patient information for European citizens in future.

Our vision is that European citizens deserve better.

¹- **The Association Internationale de la Mutualité (AIM)** brings together national federations of mutuals providing coverage against sickness and other social welfare risks, either by participating directly in the management of compulsory health insurance, by providing voluntary health insurance or by delivering directly health and social services through own facilities.

²- **Health Action International (HAI) Europe** is an independent European network of health, consumer and development organisations working to increase access to essential medicines and improve rational use.

³- **International Society of Drug Bulletins (ISDB)**, founded in 1986, is a worldwide network of bulletins and journals on drugs and therapeutics that are financially and intellectually independent of pharmaceutical industry.

⁴- **Medicines in Europe Forum (MiEF)** was launched in March 2002. It covers 12 European Member States and 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.

⁵- 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. They can not be expected to provide reliable information.

⁶- 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.

⁷- 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 2 December 2010: www.aim-mutual.org/?page=17&id=200.

Our immediate proposals to improve European citizens' access to relevant (independent and comparative) health information

The following 11 key points encapsulate our proposals (detailed further in the annex to this letter):

- **Proposal 1: Improve the communications skills of health professionals** (undergraduate education);
- **Proposal 2: Encourage the development of independent continuing education programmes for health professionals** (training in critical appraisal skills; basics of evidence based medicine);
- **Proposal 3: Enforce the advertising ban for prescription medicines** to avoid the delivery of promotional and misleading information;
- **Proposal 4: Improve preventive health information, notably on health determinants;**
- **Proposal 5: Promote and reinforce existing sources of comparative and unbiased patient information** (raising awareness, providing financial support and encouraging independence);
- **Proposal 6: Improve the content of the Eudrapharm database content to include more scientific and comparative information** (add the summaries of the European Public Assessment Reports (EPARs) and of the Public Assessment Reports; include a section about the degree of “added therapeutic value” provided by the new product in the summaries of the European Public Assessment Reports);
- **Proposal 7: Improve the transparency of drug regulatory agencies** at national and European levels so as to guarantee full public access to data on the efficacy and safety of medicines and other healthcare products both before and after authorisation (amend the legislative proposals on pharmacovigilance toward more transparency);
- **Proposal 8: Improve content of the EudraCT database and of EPARs to ease access to drug study results**, enabling the development of reliable information;
- **Proposal 9: Improve readability, quality and accessibility of package leaflets and of other packaging elements** (ensure equal interpretation/enforcement of article 59 of Directive 2001/83/EC; through a thorough review of the corresponding guidelines which are insufficient);
- **Proposal 10: Ensure public access to statutory information at national level - "Summary of Product Characteristics" (SPC)** (ensure equal interpretation/enforcement of article 86 of Directive 2001/83/EC at Member State level);
- **Proposal 11: Promote and develop the health literacy of the public** (through independent education campaigns at national and community levels; support of direct patient reporting of adverse drug reactions).

We would be very interested in meeting you and your team to discuss the abovementioned proposals in more detail.

Thank you for taking our concerns into consideration, which represent a wider constituency of European citizens. We look forward to your early response.

AIM

HAI Europe

ISDB

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Enclosed:

- **Annex detailing each of our 11 proposals** (4 pages)

- 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).

- 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 (www.isdbweb.org/pag/documents/En_LegalProposalsInfoPatient_JointPaper_March2009_000.pdf).



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HAI Europe. Health Action International (HAI) Europe is an independent European 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, ISDB has 79 members in 40 countries around the world. More info: www.isdbweb.org. Contact : press@isdbweb.org.



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: pierrechirac@aol.com.