



Joint Open Letter to:

John Dalli, Commissioner for Health and Consumer Policy

CC:

Paola Testori-Coggi

Martin Seychell

Nils Behrndt, Deputy Head of Cabinet

A Cautionary Message on Information to Patients

Brussels, 20 May 2011

Dear Commissioner Dalli,

We are aware that the Commission is about to release a new version of the legislative proposal on “information to patients” (amending Directive 2001/83/EC on the Community code relating to medicinal products for human use).

As a follow-up to our joint meeting on February 7th, we would like to reiterate our views on the role to be played by the pharmaceutical industry as regards to information to patients relating to prescription medicines. We hope that the contribution of AIM, HAI, ISDB and MIEF will be taken into account by the EU Commission when re-drafting the legislative proposal.

In order to effectively uphold the ban on direct-to-consumer advertising of prescription medicines in Europe, we would recommend limiting any amendments to the current EU legislation on advertising to a bare minimum.

The current EU legislation and regulations do not preclude the pharmaceutical industry from communicating or disseminating officially approved documents to the general public. However, there is an asymmetry in the implementation of the European Directive across different Member States. We propose a minor adjustment to the article 86.2 of the current directive (see Annex I). This change would clarify the legal text and enable enactment without creating considerable administrative burdens to public authorities.

Contrary to what is being portrayed in the public domain, no further changes to the legislation are needed to enable dissemination by manufacturers of information concerning:

- Correspondence requests;
- Answers to specific questions about a particular medicinal product;
- Factual, informative announcements;
- Changes in packaging; adverse-reaction warnings as part of general drug precautions; or
- Trade catalogues and price lists.

All these can be made available, provided no product claims are included, as outlined in article 86.2 of the current directive.

Useful patient information on therapeutics should be comparative, so that patients, consumers and healthcare professionals can learn about the different treatments available and what to expect from them, in order to make an informed choice. Comparative information could be generated by setting up more stringent marketing authorisation criteria at a drug regulatory level, by including ‘therapeutic advance’ as a fourth criterion, in addition to quality, safety and efficacy. This would prevent medicines with low efficacy and/or high potential for harm from entering the European market. The therapeutic advance of a new medicine should be appraised in comparison with existing treatments, and demonstrated by relevant clinical data collected from comparative clinical trials. In order to do so, disclosure of and access to all clinical trial data is a fundamental requirement.

Better access to medicines safety information can be encouraged by improving package leaflets. To improve the readability, quality, and consistency of the package leaflets, a thorough review of the guidelines governing the readability of the labelling and package leaflets is needed to achieve better enforcement of article 59 of Directive 2001/83/EC consolidated. As a start, it is essential to consider the sequence of the information and to conduct thorough consultations/testing with groups of patients/users who are representative of the population that will receive the treatment (the elderly, for instance). In addition, other key aspects need to be taken into account. The potential benefit and harm of a given treatment should be clearly presented. The inclusion of a standardised “drug facts box” could be helpful in this context. Since the Commission is already foreseeing a review of patient information leaflets, it would be prudent to await the results of that exercise and to use them to strengthen this *Information to Patients* proposal.

The EMA provides a public service as the guardian of medicines safety and it is, first and foremost, accountable to European citizens. We call on the Agency to strengthen its transparency policy and demonstrate its political will to put citizens first, and to protect public health. Taking that into account, the following documents should be publicly available and easily accessible:

- Using the Eudrapharm database and national DRAs websites:
 - o package leaflets;
 - o summary of product characteristics;
 - o labelling (outer packaging and primary packaging as well as any delivery device);
 - o European public assessment reports, as well as their summaries in user-friendly format. The latter should include information on the conditions of use of the product, list other therapeutic options available, and include information on whether the new product brings an added therapeutic value;
 - o risk management plans together with the detailed conditions to be fulfilled and their deadline, as well as their results measures;
 - o periodic safety update reports (PSURs);

- Using the EudraCT database: All clinical trials, whether conducted within the EU or in third countries, whose data will be used in an EU market authorisation application, should be included in the EU Clinical Trials Register without exception. Mandatory inclusion of research protocols and outcomes, crucial safety data and ethical considerations in a publicly accessible register increases transparency, ultimately benefiting public health.

Furthermore, the European Commission should recognise and encourage the many existing independent sources of information in European Union Member States, by ensuring that sufficient resources are in place to promote access to reliable health information.

Sincerely,

Association Internationale de la Mutualité
Health Action International Europe
Medicines in Europe Forum
International Society of Drug Bulletins

Endorsing Organisations



AIM. The '*Association Internationale de la Mutualité*' (International Association of Mutual benefit societies) brings together 38 national federations of autonomous health insurance and social protection bodies in 23 countries. Operating according to the principles of solidarity and not-for-profit orientation in Europe, they provide coverage against sickness and other social welfare risks to more than 170 million people, either by participating directly in the management of compulsory health insurance, by providing voluntary health insurance or by delivering directly health care and social services through own facilities.

More info: www.aim-mutual.org. Contact: rita.kessler@aim-mutual.org



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



ISDB. 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. Currently ISDB has 76 members in 44 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.